Order Form

CONTRACT FOR THE SUPPLY OF GOODS RELATED TO TESTING FOR COVID-19

The Authority	**The Secretary of State for Health and Social Care acting as part of the Crown through the Department of Health and Social Care** **39 Victoria Street** **Westminster** **London** **SW1H 0EU**
The Supplier	**Hologic Ltd** **Heron House** **Oaks Business Park** **Crewe Road** **Wythenshawe** **Manchester** **M23 9HZ**
Date	**24 April 2020**
Type of Goods	**SARS-CoV-2 tests, controls, and associated consumables**

This Contract is made on the date set out above subject to the terms set out in this Order Form, the front page and all Schedules of the Call-off Terms and Conditions provided for in Appendix A i (Call-off Terms and Conditions for the Supply of Goods) and any applicable provisions of the Framework Agreement which are incorporated by reference.

BACKGROUND:

- On 11 March 2020 the World Health Organisation declared COVID-19 a pandemic;

- The UK Government response to the national emergency posed by COVID-19 includes the putting in place by it of arrangements for large-scale testing for COVID-19 on an urgent basis;
- Having made enquiries across the relevant market for the test-products it needed to acquire in order to implement a large-scale testing programme, the Authority wishes to purchase certain goods, principally newly developed reagent test and control kits and associated consumables from the Supplier to run on 'Panther' test instruments it already owns or otherwise possesses;
- The Authority has awarded this Contract to the Supplier under a negotiated procedure without prior publication as permitted by regulation 32(2)(b)(iii) of the Public Contracts Regulations 2015;
- Whereas this Contract incorporates the Call-off Terms and Conditions as set out in the document entitled "Appendix A i (Call-off Terms and Conditions for the Supply of Goods)"and this Order Form shall be taken as referring to the Framework Agreement as applicable, the Authority and the Supplier acknowledge and agree that this Contract does not constitute a call-off under the Framework Agreement. Instead, this Contract is a standalone arrangement which, for convenience only, in terms of a contracting vehicle already known to both parties in the context of an urgent requirement, substantively mirrors the terms applicable to a call-off under the Framework Agreement. Order of precedence of documents forming the Contract is as set out in Annex 2 to this Order Form (as referenced at section 2.2 of this Order Form).

AGREEMENT:

A.1 The Authority and the Supplier undertake to comply with the provisions of the Order Form and the Schedules in the performance of this Contract.

A.2 The Supplier shall supply to the Authority and the Authority shall receive and pay for, Goods on the terms of this Contract. For the avoidance of doubt, the Contract consists of the terms set out in the Order Form (including the annexes referred to within the Order Form) and the Schedules (which Schedules together comprise the Call-off Terms and Conditions) and shall incorporate by reference any necessary terms of the Framework Agreement.

FROM

Authority	The Secretary of State for Health and Social Care acting as part of the Crown through the Department of Health and Social Care 39 Victoria Street Westminster London SW1H 0EU
Invoice address	Invoices will be sent to: [redacted] Accounts Payable Department of Health & Social Care 39 Victoria Street London, SW1H 0EU
Contact	*For general liaison your contact will be:* [redacted] Innovation, Research and Life Sciences Group (IRLS) NHS England and NHS Improvement [redacted] Quarry House, Quarry Hill, Leeds, LS2 7UE For notices / commercials your contact will be: [redacted] Department of Health & Social Care, 39 Victoria Street, London, SW1H 0EU [redacted]

Order number / Contract Reference	To be quoted on all correspondence relating to this Order DHSC Hologic 240420

TO

Supplier	Hologic Ltd
For the attention of	[redacted]
Address	Hologic Ltd Heron House Oaks Business Park Crewe Road Wythenshawe Manchester M23 9HZ

1. GOODS AND/OR SERVICES REQUIREMENTS

(1.1) Goods and/or Services and deliverables required:

Subject to the receipt of regulatory approvals under the IVD Directive (98/79/EC) and to the Authority's rights under the Call Off Terms and Conditions (Annex 3: Call-off Terms and Conditions for the Supply of Goods, the supplier shall provide Aptima SARS-CoV-2 tests, controls, and associated consumables (as outlined in the below table) in agreed fixed ratios required to perform [redacted] with Hologic Panther instrument(s), as agreed with the Authority as per the agreed Roll-out Plan (Annex 1).

For the avoidance of doubt, the Supplier acknowledges that the primary purpose of the Contract is for the Authority to obtain CE Marked Goods (as specified in the Specification and within the Order Form) from the Supplier and that the initial batch of RUO Goods is principally for validation purposes. Further, whilst there is flexibility under the Order Form for the Authority, at its option, to accept a limited batch of

RUO Goods greater than that needed for validation purposes as against the volumes agreed from 1 June, the Supplier acknowledges that those volumes were fixed on the assumption that CE Marking would at that point be in place. If CE Marking isn't in place by 1 June and the Authority, having discussed with the Supplier in accordance with the mechanism provided for exceptional circumstances at Clause 2.1 of the Order Form does not wish to take any further RUO Goods from the Supplier, because at that point the Supplier will be unable to meet the Authority's requirements for CE Marked Goods, the Authority may, subject to the provisions of Clause 15.3 of the Call-off Terms and Conditions, terminate the Contract for breach as provided for within Clause 15.4.1 of the Call-off Terms and Conditions.

The Roll-out Plan is a working document. Any required changes will be agreed in writing, and made with the approval of the Parties. The Authority and the Supplier will work constructively and collaboratively on the plan for operational roll out and delivery of tests, controls and consumables.

The Panther Aptima Sars CoV-2 RUO assay will be independently validated by PHE [redacted] The Supplier will deliver the test kits required for validation to PHE [redacted] on the week commencing 4th May 2020, with the expected delivery date as the 6th May 2020, as per the agreed Roll-out Plan.

Enablement of existing Hologic Panther instruments in UK labs that have been designated by the Authority to run the SARS-CoV-2 TMA test including software upgrades and training as per the Roll-out Plan.

The Supplier will support any reasonable information request from each location as may be required to support eRequesting and interface into LIMS.

The Supplier will provide a combination of on-site, web based and document based training as will be agreed with each site based on a needs assessment that the Authority will undertake, and that is proportionate to the new test being introduced.

The full volume of tests and associated controls and consumables will be available from the start date of June 1st 2020 (or earlier date in May if tests are available sooner).

At the request of the Authority, the Supplier may ship some of the June test volumes earlier (depending on availability) ahead of the main start date. In this event the rollout can be brought forward as agreed with the Authority .

Tests and reagents will be shipped using the Supplier's existing infrastructure to the relevant labs on a standing order basis with the potential to vary the Roll-out Plan. Shipments will be weekly or every two weeks depending on volumes as agreed with

the Authority. The Authority will work on a weekly allocation, informing the Supplier of any changes to be made to deliveries and locations.

Product Code	Description	Monthly Volume Contracted	Contract Commencement		Offer Price
			Start	End	
PRD-06419: SARS-CoV-2 Assay Kit, 250- Or PRD-06495: SARS-CoV-2 RUO Assay Kit, 250-Test	Aptima SARS CoV-2 Test (250 test/kit) Or Aptima SARS CoV-2 RUO Test (250 test/kit) if available earlier.	[redacted]	01 June 2020	28 February 2021	[redacted]
903031	Tecan Tips 1000ul conductive (960 tips) (Tecan Part Number 10612513 LiHa disposable tip 1000ul with Filter)	[redacted]	01 June 2020	28 February 2021	[redacted]

PRD-06420: SARS-CoV-2 Assay Controls Or PRD-06496: SARS-CoV-2 RUO Assay Controls	Aptima SARS CoV-2 Test Control Kit Or Aptima SARS CoV-2 RUO Control Kit	[redacted]	01 June 2020	28 February 2021	[redacted]
PRD-04339	Specimen Lysis Tubes (100 tubes/bag)	[redacted]	01 June 2020	28 February 2021	[redacted]
104772-02	Multi-Tube Unit (MTU) Kit	[redacted]	01 June 2020	28 February 2021	[redacted]
902731	Panther Waste Bag Kit	[redacted]	01 June 2020	28 February 2021	[redacted]
504405	Panther Waste Bin Cover	[redacted]	01 June 2020	28 February 2021	[redacted]
303001	Panther Assay Fluids Kit	[redacted]	01 June 2020	28 February 2021	[redacted]

303000	Panther Auto Detect Kit	[redacted]	01 June 2020	28 February 2021	[redacted]
402950	Panther Advanced Cleaning Solution, 255ml	[redacted]	01 June 2020	28 February 2021	
CL0041	Replacement Caps Amp & Probe Reagent 250TK	[redacted]	01 June 2020	28 February 2021	
CL0040	Replacement Caps for TCR and selection 250 Test Kit	[redacted]	01 June 2020	28 February 2021	
501616	Replacement Caps for Enzyme 250 Test Kit	[redacted]	01 June 2020	28 February 2021	

[redacted]. Some of the June 2020 test volumes may be delivered in May 2020, depending on availability. If any of the June 2020 test shipments are brought forward ahead of June 1st date this will not increase the minimum expected purchase volumes.

Storage requirements: The TMA SARS-CoV-2 assay reagent kit is supplied in two parts, the first of which is stored at ambient conditions, the second part is stored refrigerated at 2-8 degrees centigrade. [redacted]. The Aptima Control kit is stored refrigerated at 2-8 degrees centigrade, [redacted]. The volume of the control kits is approximately [redacted] All other consumables as described above are stored at ambient conditions.

The Aptima SARS-CoV-2 TMA assay is performed on a standard Hologic Panther instrument following the required software upgrade. The Panther instrument is a

continuous random access instrument for automated processing of molecular assays. The SARS-CoV-2 TMA assay described in the Contract will be performed on Panther instruments [redacted] in diagnostic laboratories across the UK, no additional utilities or environmental changes are required. [redacted] For all product quantities, manufacturer catalogue numbers, reagents/assays/kits descriptions please refer to the table above.

Laboratories will be supplied through the current Hologic distribution network and procedures.

The Panther is a fully automated sample to result instrument.

The Panther workflow model is appended in Annex 5. The Supplier may need to modify the workflow and required consumables during the contract. Any modifications to the workflow model must be made with the Authority's prior approval, such approval not to be unreasonably withheld or delayed.

The Supplier will maintain the service as currently provided across UK installed fleet. Service will be delivered by dedicated the Supplier's engineers, training and support will be provided on site (if required) by a Hologic Commercial Solution Specialist. Hologic will diligently coordinate those activities and provide training and support to individual sites.

It is the intention of the Supplier to supply the Authority's requirement from [redacted]. If the Supplier identifies a need to supply the requirement from an alternative location in order to maintain supply, the Supplier will notify the Authority of this change stating the alternative location.

(1.2) Goods delivery date and/or Service Commencement Date:

Test delivery and roll out will be from 1st June 2020, though test supply and roll out may be brought forward if agreed in writing by both the Parties, if tests are available earlier than this date.

Should any test supply and roll out be brought forward prior to 1st June 2020, the Parties acknowledge that the provisions of the Contract will apply as though the Goods had been supplied from the Commencement Date and the Authority

acknowledges that tests supplied prior to the Commencement Date may be RUO Goods (research use only), and subject to the restrictions applicable to RUO Goods.

The roll out and delivery schedule is as per as the agreed Roll-out Plan (Annex 1) and any subsequent amendments, as per the change process outlined above.

(1.3) Price payable by Customer and payment profile:

[redacted].

[redacted]

Any extension beyond the initial 9 months of the Term up to a further 3 months will be on the basis of the prices as stated above.

All invoices must be sent quoting a valid purchase order number to [redacted]

Invoices will be sent upon shipment of tests to the Panther labs.

Within 10 Business Days of receipt of your countersigned copy of the Contract, we will send you a unique Purchase Order number (the **"PO Number"**). You must be in receipt of a valid PO Number before submitting an invoice.

To avoid delay in payment it is important that the invoice is compliant and that it includes a valid PO Number, PO item number (if applicable) and the details (name and telephone number) of your Buyer contact (i.e. Contract Manager). Non-compliant invoices will be sent back to you, which may lead to a delay in payment.

If you have a query regarding an outstanding payment please contact our Accounts Payable section by email to [redacted]

(1.4) Contract Term (including any extension period or periods):

The Term of this Contract is for a period of 9 months effective from the Commencement Date (1st June 2020) to 28th February 2021 subject to the right of the Authority to extend the Term as provided for at Clause 15.2 (as amended through Annex 2 referenced at section 2.2 of this Order Form and subject to the further provisions of Clause 15 of the Call-off Terms and Conditions. For the

avoidance of doubt, if the Authority exercises its option to extend the Term under Clause 15.2, the Term would expire on 31st May 2021.

If stock becomes available in advance of the Commencement Date, deployment may be brought forward but whilst any such pre-Commencement Date deployment will be subject to the terms of this Contract this will not impact the term dates as detailed.

2. Additional Requirements

(2.1) Supplemental requirements in addition to Call-off Terms and Conditions:

1. Exceptional circumstances as a result of the Covid-19 pandemic

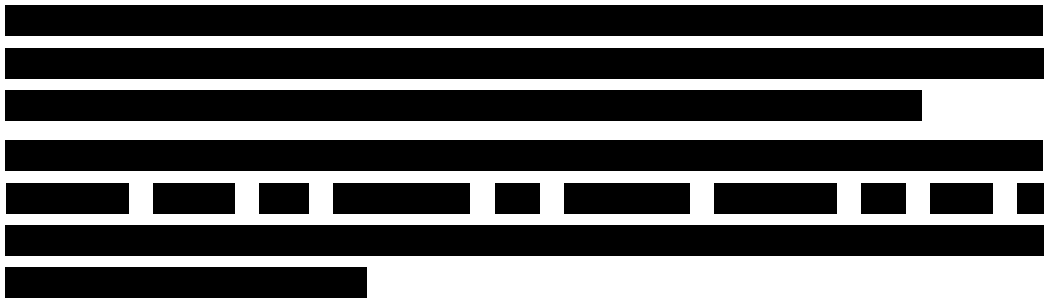
1.1 Without prejudice to the Parties' obligations under the Contract (including but not limited to the Supplier's obligations under the Contract to supply the Goods, including as set out within the Order Form and the Roll-out Plan, at the Contract Price for the Term), the Parties recognise that the circumstances created as a result of the COVID-19 pandemic are exceptional and fast-moving. As a consequence, the Parties agree that they will act reasonably and in good faith together to develop mitigating actions and seek to resolve any difficulties or challenges which may impact upon the manufacture and supply of Goods and in relation to the wider COVID-19 issues so as to ensure that public health is protected and preserved.

1.2 In this context:

1.2.1 the Supplier recognises that there may be a shortage of supply of Component Parts and accordingly, the Supplier shall take all reasonable steps to safeguard and protect all stocks of Component Parts held by it and its Group from time to time which may be required to manufacture the Goods;

1.2.2 the Supplier shall notify the Authority promptly of any exceptional events or circumstances which may impact upon the Supplier's ability to manufacture and supply Goods in accordance with this Contract and the Authority's requirements, including at the Contract Price.

1.2.3 [redacted]



2.**RUO Goods**

2.1 In respect of the RUO Goods only, the Authority acknowledges and agrees that the RUO Goods are being provided for research use only in order that the Authority's laboratories can validate the same prior to putting the Goods into clinical diagnostic use, and it is the Authority's responsibility to procure that the Authority's laboratories do so, and to limit use of the RUO Goods to research purposes specified by the Supplier in line with the Aptima SARS-CoV-2 Assay (Panther™ System) for Research Use Only Package insert (contained in Annex 4).

3.Warranty and exclusions

3.1Without prejudice and in addition to the provisions of Clause 10 of the Call Off Terms and Conditions, the Supplier warrants that:

3.1.1 the Goods will conform to the Order Form, to the Specification set out at Annex 4 to the Order Form, and other descriptions referred to in the Order Form; and

3.1.2 the Goods will be free from defects in material and workmanship

for a period of 12 months from the date of delivery to the Authority (the "Warranty Period").

3.2 The Supplier shall be under no liability under this Order Form:

3.2.1 in respect of any defect in Goods arising from fair wear and tear, neglect, failure to follow the Supplier's instructions, misuse (including, without limitation, use of unauthorised supplies, performance of improper or inadequate maintenance by the Authority or any third party, installation of software not supplied by the Supplier, improper use or connection to incompatible equipment, unauthorised modifications to Goods and external causes such as power failure) or improper alteration or repair of Goods; or

3.2.1 if the Authority fails to notify any claim in respect of any defective Goods which is based on a breach of any warranty within 45 working days after the discovery of the breach.

3.3 Where any valid claim in respect of Goods which is based on a breach of any of the warranties is notified to the Supplier, the Supplier shall either replace the affected defective Goods (or the part(s) in question) free of

charge or provide the Authority with a refund in respect of the affected Goods (at the option of the Authority which shall act reasonably).

3.4 The warranties hereunder shall apply to any replaced Goods for the unexpired term of the Warranty Period for the Goods.

3.5 The Authority shall have sole responsibility and liability (as between the Authority and the Supplier) for any conclusions drawn from results obtained from the use of the Goods. The Supplier shall have no liability for or any actions taken by it at the Authority's direction pursuant to this Order Form.

3.6 Save as expressly stated in this clause and in Clauses 10, 12 and 13 of the Call Off Terms and Conditions, and to the fullest extent permitted by applicable law, all terms, conditions, warranties and representations express or implied in relation to the Goods are hereby excluded.

(2.2) Variations to Call-off Terms and Conditions:

As contained in Annex 2 headed "Additional Requirements (2.2): Variations to Call-off Terms and Conditions

3. PERFORMANCE OF THE CONTRACT REQUIREMENTS

(3.1) Key personnel of the Supplier to be involved in the provision of Goods:

Name	Role	Email Address	Telephone Number
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

(3.2) Performance standards:

The performance and management of the Hologic UK diagnostics systems running Hologic SARS CoV-2 tests (including but not limited to Panther system uptime, Panther preventative maintenance visit completion, Panther uptime reporting, Panther system reliability) will continue to be managed via [redacted] Hologic and the organisations in which the Panthers are located in accordance with the obligations as provided for in such contracts. The existing contracts are for provision of high volume NAAT (Nucleic Acid Amplification Testing) for pathogens in multiple sample types [redacted]

Without prejudice to the warranties included in the Contract, the SARS-CoV-2 RUO tests provided will comply to the Panther Aptima SARS CoV-2 RUO assay performance specification (appended in Annex 4) and the CE-IVD SARS-CoV-2 tests will comply with the Panther Aptima SARS-CoV-2 CE-IVD test performance specification. Annex 4: Performance Specification will be amended to include the CE-IVD performance specification, when that is available through the validation process. The CE-IVD performance specification is expected around the 18th May 2020.

The design goal for the Panther Aptima SARS-CoV-2 CE-IVD test is to have substantially similar or better performance than the existing Panther Fusion SARS-CoV-2 FDA EUA assay. The performance specification for this Fusion SARS-CoV-2 FDA EUA test is included in Annex 4 as a comparator. Preliminary results indicate Panther Aptima SARS-CoV-2 assay is meeting this design goal of having substantially similar or better performance than the Panther Fusion SARS-CoV-2 assay. Preliminary testing also shows no cross reactivity to closely related or common respiratory pathogens.

(3.3) Location(s) at which the Services are to be provided:

UK Panther labs as per phased implementation as agreed with the Authority, in line with the agreed Roll-out plan (Annex 1).

(3.4) Quality standards:

STANDARD / CERTIFICATION NOTE: Standards referencing or relating to EC Medical Devices Directive 93/42/EC **and IVD Directive (98/79/EC)** will not apply to RUO Goods.
Hold BS, EN, ISO 9000 or equivalent.
Comply to IEC 60601-1:1990 (BS 5724-1:1989) Medical Electrical Equipment: General Requirements for Safety
Comply to EC Medical Devices Directive 93/42/EC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993) as amended (OJ L 331,7.12.1998) (will not apply to the RUO Goods)
Conform to IVD Directive (98/79/EC) (of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998) (will not apply to the RUO Goods)
Comply with COSHH (Control of Substances Hazardous to Health) Regulations 2002. Safety data sheets in English **MUST** be available.
Subscribe to the practices and principles of MHRA (Medicines and Healthcare products Regulatory Agency) DB2006 (02) for reporting adverse incidents related to in vitro medical devices. Comply with any additional and relevant, regulations for electrical, mechanical and biological safety. Enables the laboratory to comply with the ISO 15189 (2012) standard

UK Standards for Microbiology Investigations

Good Laboratory Practice when Performing Molecular Amplification Assays (Dec 2013, under review)

(3.5) Contract monitoring arrangements:

Contract Management and Monitoring arrangements will be as provided for within the Call-off Terms and Conditions.

(3.6) Management Information and meetings

Management Information and meetings will be as provided for within the Call-off Terms and Conditions.

4. CONFIDENTIAL INFORMATION

(4.1) The following information shall be deemed Confidential Information:

1. [redacted]

(4.2) Duration that the information shall be deemed Confidential Information:

- Items 1-3 in (4.1) to remain confidential through the duration of the Contract.
- [redacted]

[redacted]

Signed by the authorised representative of THE AUTHORITY

Name:	[redacted]	Signature:	[redacted]
Position:	[redacted]	Date:	24th April 2020

Signed by the authorised representative of THE SUPPLIER

Name:	[redacted]	Signature:	[redacted]
Position:	[redacted]	Date:	April 24th 2020

Annexes

Annex 1: Roll-out Plan

Appended in the document titled **"***DHSC Hologic 240420 – FINAL – Annex 1 Roll-out Plan.***"**

Annex 2: Additional Requirements (2.2): Variations to Call-off Terms and Conditions

Appended in the document titled **"***DHSC Hologic 240420 – FINAL – Annex 2 Additional Requirements (2.2) Variations to the Call-off Terms and Conditions***."**

Annex 3: Call-off Terms and Conditions for the Supply of Goods

Appended in the document titled **"***DHSC Hologic 240420 – FINAL – Annex 3 Call Off Terms and Conditions for the Supply of Goods."*

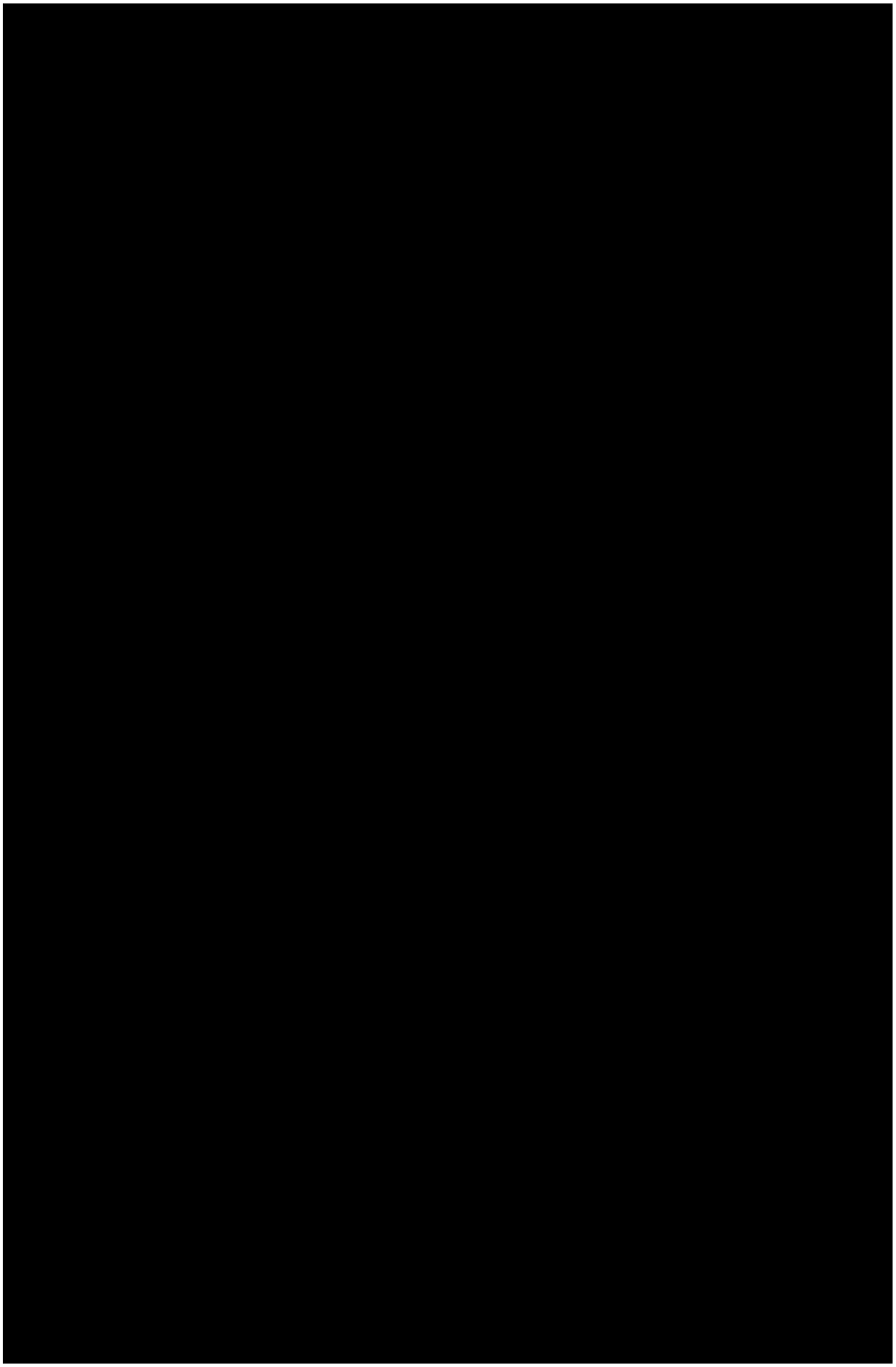
Annex 4: Performance Specification

Appended in the documents titled **"***DHSC Hologic 240420 – FINAL – Annex 4 Panther Aptima SARS CoV-2 RUO assay performance specification***"** and **"***DHSC Hologic 240420 – FINAL – Annex 4 Panther Fusion SARS-CoV-2 FDA EUA assay performance specification.***"**

This Annex will also contain the Panther Aptima SARS-CoV-2 CE-IVD test performance specification when this is available post validation.

Annex 5: Workflow Model

Appended in the document titled **"***DHSC Hologic 240420 – FINAL – Annex 5 Workflow Model***."**



ANNEX 2 TO CONTRACT FOR THE SUPPLY GOODS RELATED TO TESTING FOR COVID-19

ADDITIONAL REQUIREMENTS (2.2 – Variations to Call-off Terms and Conditions)

SCHEDULE 1 of the Call-off Terms and Conditions

Clause 5 Order of Precedence shall be replaced with the following:

5.1 Subject always to Clause 1.10 of Schedule 4 of these Call-off Terms and Conditions, should there be a conflict between any other parts of this Contract the order of priority for construction purposes shall be:

5.1.1 the Order Form;

5.1.2 the provisions on the front page of these Call-off Terms and Conditions for the Supply of Goods;

5.1.3 Schedule 1 of these Call-off Terms and Conditions: Key Provisions;

5.1.4 Schedule 2 of these Call-off Terms and Conditions: General Terms and Conditions;

5.1.5 Schedule 3 of these Call-off Terms and Conditions: Information Governance Provisions;

5.1.6 Schedule 4 of these Call-off Terms and Conditions: Definitions and Interpretations; and

5.1.7 the applicable provisions of the Framework Agreement.

SCHEDULE 2 of the Call-off Terms and Conditions

All references to “Tender Response Document” within the Call-off Terms and Conditions shall be deleted.

Clause 1.7 (Supply of Goods) shall be amended by the replacement of the cross-reference with the correct cross-reference to Clause 1.6.

Clause 2.3 shall be deleted and replaced by the following:

2.3 “The following details shall be shown on the outside of every package and within a delivery note which must accompany each package:

2.3.1 a description of the Goods which shall include, without limitation, the weight of the Goods where available and any order number allocated to the Goods by the Authority and/or Supplier;

2.3.2 the quantity in the package, where available;

2.3.3 any special directions for storage;

2.3.4 the expiry date of the contents, where applicable;

2.3.5 the batch number; and

2.3.6 the name and address of the manufacturer of the Goods and Supplier.

In addition, all Goods that customarily bear any mark, tab, brand, label, serial numbers or other device indicating place of origin, inspection by any government or other body or standard of quality must be delivered with all the said marks, tabs, brands, labels, serial numbers or other devices intact. Without prejudice to the generality of the foregoing, the Supplier shall label all Goods supplied to the Authority, and the packaging of such Goods, to highlight environmental and safety information as required by applicable Law."

Clause 9 (Price and Payment) shall be amended by the addition of the following:

"9.9 Where the Authority is entitled to receive any sums (including, without limitation, any costs, charges or expenses) from the Supplier under this Contract, the Authority may invoice the Supplier for such sums. Such invoices shall be paid by the Supplier within 30 days of the date of such invoice.

9.10 If a Party fails to pay any undisputed sum properly due to the other Party under this Contract, the Party due such sum shall have the right to charge interest on the overdue amount at a rate of 4% above Bank of England base rate, accruing on a daily basis from the due date up to the date of actual payment, whether before or after judgment."

Clause 10 (Warranties) shall be amended by the addition of the following and/or varied or deleted as applicable, as follows:

10.1.1 *[deleted and replaced with the words]* Not used.

10.1.2 *[deleted and replaced with the words]* Not used.

10.1.4 *[deleted and replaced with the words]* Not used.

10.1.5 *[deleted and replaced with the words]* Not used.

10.1.6 *[deleted and replaced with the words]* Not used.

10.1.9 *[deleted and replaced with the words]* Not used.

10.1.11 *[the following words to be deleted]* "…, including without limitation patient information leaflets,"

10.1.14 *[deleted and replaced with the words]* Not used.

10.1.15 *[to be inserted after current provision]* "and for the avoidance of doubt, unless otherwise set out in the Order Form, any such changes or substitute goods, if accepted, shall not lead to an increase in the Charges;"

10.1.16 *[deleted and replaced with the words]* Not used.

10.1.21 *[to be inserted after the word 'promptly']* "(and in any event within one (1) Business Day;"

10.1.30 *[deleted and replaced with the words]* Not used.

10.1.31 it shall: (i) comply with all relevant Law and Guidance and shall use Good Industry Practice to ensure that there is no slavery or human trafficking in its supply chains; and (ii) notify the Authority immediately if it becomes aware of any actual or suspected incidents of slavery or human trafficking in its supply chains;

10.1.32 it shall at all times conduct its business in a manner that is consistent with any anti-slavery Policy of the Authority that is notified to the Supplier and shall provide to the Authority any reports or other information that the Authority may request as evidence of the Supplier's compliance with this Clause 10.1.32 and/or as may be requested or otherwise required by the Authority in accordance with its anti-slavery Policy.

10.5 *[deleted and replaced with the words]* Not used.

10.6 *[deleted and replaced with the words]* Not used.

Clause 13 (Limitation of liability) shall be amended as follows:

Clause 13.2 shall be deleted and replaced by the following:

13.2 Subject to Clauses 12.2, 13.1 and 13.5 of this Schedule 2 of these Call-off Terms and Conditions, the total liability of each Party to the other under or in connection with this Contract whether arising in contract, tort, negligence, breach of statutory duty or otherwise shall be limited to one hundred percent (100%) of the total Contract Price paid or payable by the Authority to the Supplier for the Goods.

Clause 13.5 shall be deleted and replaced with the words "Not used."

Clause 15 (Term and Termination) shall be amended by the addition of the following to replace the current provision:

15.2 The Authority shall be entitled to extend the Term by three (3) months at its sole option by giving the Supplier written notice no less than three (3) months prior to expiry of the Term.

Clause 17 (Packaging, etc) shall be amended by the addition of the following to amend/replace the current provision as indicated:

17.2 *[to be inserted after current provision]* "and in relation to Goods imported into the United Kingdom for the purposes of the Producer Responsibility Obligations (Packaging Waste) Regulations 2007 and all applicable product and safety liability legislation in force in the United Kingdom from time to time, the Supplier shall assume all obligations for all activities performed outside the United Kingdom in relation to the Goods and the packaging, in addition to any other obligations the Supplier may have pursuant to such regulations and other legislation."

17,4 *[to replace the current provision] "*The Supplier shall ensure that all Goods that are required by Law or Guidance to bear any safety information, environmental information, any mark, tab, brand, label, serial numbers or other device indicating place of origin, inspection by any government or other body or standard of quality at the point such Goods are delivered shall comply with such requirements at the point of delivery."

Clause 18 (Coding requirements) shall be deleted and replaced by following:

18.1 Unless otherwise confirmed and/or agreed by the Authority in writing the Supplier shall ensure full compliance with any Guidance issued by the Department of Health in relation to the adoption of GS1 and PEPPOL standards (to include, without limitation, any supplier compliance timeline and other policy requirements published by the Department of Health in relation to the adoption of GS1 and PEPPOL standards for master data provision and exchange, barcode labelling and purchase to pay transacting).

18.2 Once compliance with any published timelines has been achieved by the Supplier pursuant to the Order Form, the Supplier shall, during the Term, maintain the required level of compliance relating to the Goods in accordance with any such requirements and Guidance referred to as part of this Contract.

18.3 Once product information relating to Goods is placed by the Supplier into a GS1 certified data pool, the Supplier shall, during the Term, keep such information updated with any changes to the product data relating to the Goods.

Clause 28 (Assignment, novation and subcontracting) shall be amended by deleting the following:

28.5 "…use its reasonable endeavours to…"

SCHEDULE 3 of the Call-off Terms and Conditions

Clause 2 shall be deleted, and replaced with the following:

"**2 <u>Data Protection</u>**

2.1 The Parties each acknowledge and agree that they may need to undertake Processing of Personal Data relating to each Party's representatives (in their respective capacities as Controllers) in order to (as appropriate):

(a) administer and provide the Goods;

(b) request and receive the Goods;

(c) compile, dispatch and manage the payment of invoices relating to the Goods;

(d) manage the Contract and resolve any disputes relating to it;

(e) respond and/or raise general queries relating to the Goods; and

(f) comply with their respective regulatory obligations.

2.2 Processing of Personal Data relating to each Party's representatives for the purposes set out in Clause 2.1 of this Schedule 3 of these Call-off Terms and Conditions shall only be done by each Party in accordance with their respective privacy policies. The Parties acknowledge that they may be required to share Personal Data with their affiliates, group companies and other relevant parties, within or outside of the country of origin, in order to carry out the activities listed in Clause 2.1 of this Schedule 3 of these Call-off Terms and Conditions, and in doing so each Party will ensure that the sharing and use of this Personal Data complies with applicable Data Protection Laws."

SCHEDULE 4 of the Call-off Terms and Conditions

Clause 1.1 of Schedule 4 of the Call-off Terms and Conditions shall be deleted, and replaced with the following:

"1.1 In this Contract the following words shall have the following meanings unless the context requires otherwise:

"Authority"	means the authority named on the Order Form;
"Authority's Obligations"	means the Authority's further obligations, if any, referred to in the Specification and/or the Order Form;
"Business Continuity Event"	means any event or issue that could impact on the operations of the Supplier and its ability to supply the Goods including an influenza pandemic and any Force Majeure Event;
"Business Continuity Plan"	means the Supplier's business continuity plan which includes its plans for continuity of the supply of the Goods during a Business Continuity Event;

"Business Day"	means any day other than Saturday, Sunday, Christmas Day, Good Friday or a statutory bank holiday in England and Wales;
"Call-off Terms and Conditions"	means these Call-off Terms and Conditions for the Supply of Goods (comprising of the front page of the document and the Schedules);
"CE Marked"	means the marking of the Goods as CE-IVD under the IVD Directive (98/79/EC) and "CE Marking" shall bear the same meaning;
"Codes of Practice"	shall have the meaning given to the term in Clause 1.2 of Schedule 3 of these Call-off Terms and Conditions;
"Commencement Date"	means the date of the Order Form;
"Component Parts"	means the raw materials or any other constituent element of the Goods;
"Confidential Information"	means information, data and material of any nature, which either Party may receive or obtain in connection with the conclusion and/or operation of the Contract including any procurement process which is: (a) Personal Data or Sensitive Personal Data including without limitation which relates to any patient or other service user or his or her treatment or clinical or care history; (b) designated as confidential by either party or that ought reasonably to be considered as confidential (however it is conveyed or on whatever media it is stored); and/or (c) Policies and such other documents which the Supplier may obtain or have access to through the Authority's intranet;

"Contract"	means the Order Form, the provisions on the front page and all Schedules of these Call-off Terms and Conditions, the Specification and the applicable provisions of the Framework Agreement;
"Contracting Authority"	means any contracting authority as defined in Regulation 2 of the Public Contracts Regulations 2015 (SI 2015/102) (as amended), other than the Authority;
"Contract Manager"	means for the Authority and for the Supplier the individuals specified in the Order Form or as otherwise agreed between the Parties in writing or such other person notified by a Party to the other Party from time to time in accordance with Clause 8.1 of Schedule 2 of these Call-off Terms and Conditions;

"Contract Price"	means the price exclusive of VAT that is payable to the Supplier by the Authority under the Contract for the full and proper performance by the Supplier of its obligations under the Contract calculated in accordance with the provisions of the Framework Agreement and as confirmed in the Order Form;
"Controller"	shall have the same meaning as set out in the General Data Protection Regulation (Regulation (EU) 2016/679);
COVID-19	means the coronavirus 2019;
"Data Protection Laws"	means (i) the Data Protection Act 2018 to the extent that it relates to processing of personal data and privacy; (ii) the General Data Protection Regulation (Regulation (EU) 2016/679), the Law Enforcement Directive (Directive (EU) 2016/680) and any applicable national implementing Law as amended from time to time; and (iii) all applicable Law about the processing of personal data and privacy;
"Defective Goods"	has the meaning given under Clause 4.6 of Schedule 2 of these Call-off Terms and Conditions;
"Dispute Resolution Procedure"	means the process for resolving disputes as set out in Clause 22 of Schedule 2 of these Call-off Terms and Conditions;
"DOTAS"	means the Disclosure of Tax Avoidance Schemes rules which require a promoter of tax schemes to tell HM Revenue and Customs of any specified notifiable arrangements or proposals and to provide prescribed information on those arrangements or proposals within set time limits as contained in Part 7 of the Finance Act 2004 and in secondary legislation made under vires contained in Part 7 of the Finance Act 2004 and as extended to National Insurance Contributions by the National Insurance Contributions (Application of Part 7 of the Finance Act 2004) Regulations 2012, SI 2012/1868 made under s.132A Social Security Administration Act 1992;
"Electronic Trading System(s)"	means such electronic data interchange system and/or world wide web application and/or other application with such message standards and protocols as the Authority may specify from time to time;
"Environmental Regulations"	shall have the meaning given to the term in Clause 1.2 of Schedule 3 of these Call-off Terms and Conditions;

"eProcurement Guidance"	means the NHS eProcurement Strategy available via: http://www.gov.uk/government/collections/nhs-procurement together with any further Guidance issued by the Department of Health in connection with it;
"Equality Legislation"	means any and all legislation, applicable guidance and statutory codes of practice relating to equality, diversity, non-discrimination and human rights as may be in force in England and Wales from time to time including, but not limited to, the Equality Act 2010, the Part-time Workers (Prevention of Less Favourable Treatment) Regulations 2000 and the Fixed-term Employees (Prevention of Less Favourable Treatment) Regulations 2002 (SI 2002/2034) and the Human Rights Act 1998;
"FOIA"	shall have the meaning given to the term in Clause 1.2 of Schedule 3 of these Call-off Terms and Conditions;

"Force Majeure Event"	means any event beyond the reasonable control of the Party in question to include, without limitation: (a) war including civil war (whether declared or undeclared), riot, civil commotion or armed conflict materially affecting either Party's ability to perform its obligations under this Contract; (b) acts of terrorism; (c) flood, storm or other natural disasters; (d) fire; (e) unavailability of public utilities and/or access to transport networks to the extent no diligent supplier could reasonably have planned for such unavailability as part of its business continuity planning; (f) government requisition or impoundment including without limitation where such measures are effected under the United States of America Defense Production Act to the extent such requisition or impoundment does not result from any failure by the Supplier to comply with any relevant regulations, laws or procedures (including such laws or regulations relating to the payment of any duties or taxes) and subject to the Supplier having used all reasonable legal means to resist such requisition or impoundment; (g) compliance with any local law or governmental order, rule, regulation or direction that could not have been reasonably foreseen; (h) industrial action which affects the ability of the Supplier to supply the Goods, but which is not confined to the workforce of the Supplier or the workforce of any subcontractor of the Supplier; and (i) pandemic (excluding COVID-19 and any related circumstances, events, changes or requirements but this exclusion shall only apply to the extent that the same (1) is, or ought to have been, known to the Party in question as at the Commencement Date; and (2) is within the reasonable control of the Party in question, taking into account the circumstances set out in section 2.1 of the Order Form).
"Framework Agreement"	means the Framework Agreement referred to in the Order Form;
"Fraud"	means any offence under any law in respect of fraud in relation to this Contract or defrauding or attempting to defraud or conspiring to defraud the government, parliament or any Contracting Authority;

"General Anti-Abuse Rule"	means (a) the legislation in Part 5 of the Finance Act 2013; and (b) any future legislation introduced into parliament to counteract tax advantages arising from abusive arrangements to avoid national insurance contributions;
"Good Industry Practice"	means the exercise of that degree of skill, diligence, prudence, risk management, quality management and foresight which would reasonably and ordinarily be expected from a skilled and experienced supplier engaged in the manufacture and/or supply of goods similar to the Goods under the same or similar circumstances as those applicable to this Contract, including in accordance with any codes of practice published by relevant trade associations;
"Goods"	means all goods, materials or items that the Supplier is required to supply to the Authority under this Contract (including, without limitation, as stated in the Order Form which sets out the requirements of the Authority and the Supplier's response to these requirements) and shall include parts of such Goods which have been repaired or replaced by or on behalf of the Supplier;
"Group"	means entities (other than the Supplier) within its corporate structure;
"Guidance"	means any applicable guidance, direction or determination and any policies, advice or industry alerts which apply to the Goods, to the extent that the same are published and publicly available or the existence or contents of them have been notified to the Supplier by the Authority and/or have been published and/or notified to the Supplier by the Department of Health, Monitor, NHS England, the Medicines and Healthcare Products Regulatory Agency, the European Medicine Agency the European Commission, the Care Quality Commission and/or any other regulator or competent body;
"Halifax Abuse Principle"	means the principle explained in the CJEU Case C-255/02 Halifax and others;
"Intellectual Property Rights"	means all patents, copyright, design rights, registered designs, trade marks, know-how, database rights, confidential formulae and any other intellectual property rights and the rights to apply for patents and trade marks and registered designs;
"Key Provisions"	means the key provisions set out in Schedule 1 of these Call-off Terms and Conditions and/or as part of the Order Form;
"KPI"	means the key performance indicators as set out in the Specification and/or the Order Form, if any;

"Law"	means: (a) any applicable statute or proclamation or any delegated or subordinate legislation or regulation; (b) any applicable European Union directive, regulation, decision or law; (c) any enforceable community right within the meaning of section 2(1) European Communities Act 1972; (d) any applicable judgment of a relevant court of law which is a binding precedent in England and Wales; (e) requirements set by any regulatory body; and (f) any applicable code of practice, in each case as applicable in England and Wales; and (g) any relevant collective agreement and/or international law provisions (to include, without limitation, as referred to in (a) to (f) above;
"Mediation Notice"	has the meaning given under Clause 22.5.1 of Schedule 2 of these Call-off Terms and Conditions;
"NHS"	means the National Health Service;
"Occasion of Tax Non-Compliance"	means: (a) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 is found on or after 1 April 2013 to be incorrect as a result of: (i) a Relevant Tax Authority successfully challenging the Supplier under the General Anti-Abuse Rule or the Halifax Abuse Principle or under any tax rules or legislation that have an effect equivalent or similar to the General Anti-Abuse Rule or the Halifax Abuse Principle; (ii) the failure of an avoidance scheme which the Supplier was involved in, and which was, or should have been, notified to a Relevant Tax Authority under the DOTAS or any equivalent or similar regime; and/or (b) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 gives rise, on or after 1 April 2013, to a criminal conviction in any jurisdiction for tax related offences which is not spent at the Effective Date or to a civil penalty for fraud or evasion;
"Order Form"	means the order form for the Goods, including its Annexes issued by the Authority and incorporated within the Contract;
"Party"	means the Authority or the Supplier as appropriate and Parties means both the Authority and the Supplier;

“Personal Data”	shall have the same meaning as set out in the General Data Protection Regulation (Regulation (EU) 2016/679);
“Policies”	means the policies, rules and procedures of the Authority as notified to the Supplier from time to time;
“Processing”	shall have the same meaning as set out in the General Data Protection Regulation (Regulation (EU) 2016/679);
“Product Information”	means information concerning the Goods as may be reasonably requested by the Authority and supplied by the Supplier to the Authority in accordance with Clause 20 of Schedule 2 of these Call-off Terms and Conditions for inclusion in the Authority's product catalogue from time to time;
“Rejected Goods”	has the meaning given under Clause 4.2 of Schedule 2 of these Call-off Terms and Conditions;
“Relevant Tax Authority”	means HM Revenue and Customs, or, if applicable, a tax authority in the jurisdiction in which the Supplier is established;
“Remedial Proposal”	has the meaning given under Clause 15.3 of Schedule 2 of these Call-off Terms and Conditions;
“Requirement to Recall”	has the meaning given under 4.9 of Schedule 2 of these Call-off Terms and Conditions;
“Roll-out Plan”	means the document as referred to within and annexed at Annex 1 of the Order Form as at the date that the Contract is signed which sets out the plan agreed between the Parties for roll out and delivery of the Goods to the required sites as updated from time to time by agreement of both Parties during the Term as further provided for in the Order Form;
“RUO”	means, as referred to in respect of the Goods (including for the avoidance of doubt references to “RUO Goods”, “RUO tests” and “RUO products”, that initial supply of Goods which are designated for research use only in order that the Authority’s laboratories can validate the same prior to putting the Goods into clinical diagnostic use and which term shall also include the same Goods which are FDA EUA marked [US Food and Drug Administration Emergency Use Authorization] but not those Goods which are CE Marked;
“Schedule”	means the relevant part of the Call-off Terms and Conditions as per the headings within that document;
“Sensitive Personal Data”	means special categories of personal data as defined in the Data Protection Laws;

“Specification”	means the specification of requirements set out and/or referred to in the Order Form and as amended and/or updated in accordance with this Contract;
“Staff”	means all persons employed or engaged by the Supplier to perform its obligations under this Contract including any subcontractors and person employed or engaged by such subcontractors;
“Supplier”	means the supplier named on the Order Form;
“Term”	means the term as referred to in the Key Provisions and more particularly provided for within the Order Form;
“Third Party Body”	has the meaning given under Clause 8.5 of Schedule 2 of these Call-off Terms and Conditions; and
“VAT”	means value added tax chargeable under the Value Added Tax Act 1994 or any similar, replacement or extra tax.

Clause 1.4 of Schedule 4 of the Call-off Terms and Conditions shall be amended by the addition of references to “Annex”.

Appendix A i

Call-off Terms and Conditions for the Supply of Goods

Where an Order Form is issued by the Authority that refers to the Framework Agreement, the Contract is made between the Authority and the Supplier on the date of that Order Form. The Contract is subject to the terms set out in the schedules of these Call-off Terms and Conditions listed below ("**Schedules**").

The Authority and the Supplier undertake to comply with the provisions of the Schedules in the performance of the Contract.

The Supplier shall supply to the Authority, and the Authority shall receive and pay for, the Goods on the terms of the Contract.

For the avoidance of doubt, any actions or work undertaken by the Supplier prior to the receipt of an Order Form covering the relevant Goods shall be undertaken at the Supplier's risk and expense and the Supplier shall only be entitled to invoice for Goods covered by a valid Order Form.

The Definitions in Schedule 4 of these Call-off Terms and Conditions apply to the use of all capitalised terms in the Contract.

Schedules

Schedule 1 of these Call-off Terms and Conditions	Key Provisions
Schedule 2 of these Call-off Terms and Conditions	General Terms and Conditions
Schedule 3 of these Call-off Terms and Conditions	Information Governance Provisions
Schedule 4 of these Call-off Terms and Conditions	Definitions and Interpretations

Schedule 1 of these Call-off Terms and Conditions

Key Provisions

1 Application of the Key Provisions

1.1 The standard Key Provisions at Clauses 1 to 6 of this Schedule 1 of these Call-off Terms and Conditions shall apply to this Contract.

1.2 Extra Key Provisions shall only apply to this Contract where such provisions are set out as part of the Order Form.

1 Term

1.1 This Contract commences on the Commencement Date.

1.2 The Term of this Contract shall be as set out in the Order Form.

1.3 The Term may be extended in accordance with Clause 15.2 of Schedule 2 of these Call-off Terms and Conditions provided that the duration of this Contract shall be no longer than any maximum duration applicable to the Contract if such maximum duration is set out in the Framework Agreement (including any options to extend).

2 Contract Managers

2.1 The Contract Managers at the commencement of this Contract shall be as set out in the Order Form or as otherwise agreed between the Parties in writing.

3 Names and addresses for notices

3.1 Unless otherwise agreed by the Parties in writing, notices served under this Contract are to be delivered to such persons at such addresses as referred to in the Order Form.

4 Management levels for dispute resolution

4.1 Unless otherwise agreed by the Parties in writing, the management levels at which a dispute will be dealt with are as follows:

Level	**Authority representative**	**Supplier representative**
1	Contract Manager	Contract Manager
2	Assistant Director or equivalent	Assistant Director or equivalent
3	Director or equivalent	Director or equivalent

5 Order of precedence

5.1 Subject always to Clause 1.10 of Schedule 4 of these Call-off Terms and Conditions, should there be a conflict between any other parts of this Contract the order of priority for construction purposes shall be:

5.1.1 the Order Form;

5.1.2 the applicable provisions of the Framework Agreement other than the Specification and Tender Response Document;

5.1.3 the provisions on the front page of these Call-off Terms and Conditions for the Supply of Goods;

5.1.4 Schedule 1 of these Call-off Terms and Conditions: Key Provisions;

5.1.5 the Specification and Tender Response Document (but only in respect of the requirements);

5.1.6 Schedule 2 of these Call-off Terms and Conditions : General Terms and Conditions;

5.1.7 Schedule 3 of these Call-off Terms and Conditions: Information Governance Provisions; and

5.1.8 Schedule 4 of these Call-off Terms and Conditions: Definitions and Interpretations.

Schedule 2 of these Call-off Terms and Conditions

General Terms and Conditions

Contents

1 Supply of Goods

1.1 The Supplier shall supply the Goods ordered by the Authority under this Contract:

1.1.1 promptly and in any event within any time limits as may be set out in this Contract;

1.1.2 in accordance with all other provisions of this Contract;

1.1.3 using reasonable skill and care in their delivery;

1.1.4 using reasonable skill and care in their installation, associated works and training to the extent that such installation, works or training is a requirement of this Contract;

1.1.5 in accordance with the provisions of the Framework Agreement as applicable and/or the provisions of the Order Form;

1.1.6 in accordance with the Law and with Guidance;

1.1.7 in accordance with Good Industry Practice;

1.1.8 in accordance with the Policies; and

1.1.9 in a professional and courteous manner.

In complying with its obligations under this Contract, the Supplier shall, and shall procure that all Staff shall, act in accordance with the NHS values as set out in the NHS Constitution from time to time.

1.2 The Supplier shall comply fully with its obligations set out in the Specification and Tender Response Document and/or the Order Form (to include, without limitation, the KPIs and all obligations in relation to the quality, performance characteristics, supply, delivery and installation and training in relation to use of the Goods).

1.3 Unless otherwise agreed by the Parties in writing, the Goods shall be new, consistent with any sample, and shall comply with any applicable specification set out in this Contract (to include, without limitation, the requirements set out in the Specification and Tender Response Document and the Supplier's response to such requirements) and any applicable manufacturers' specifications.

1.4 The Supplier shall ensure that all relevant consents, authorisations, licences and accreditations required to supply the Goods are in place prior to the delivery of any Goods to the Authority.

1.5 If there are any incidents that in any way relate to or involve the use of the Goods by the Authority, the Supplier shall cooperate fully with the Authority in relation to the Authority's application of the Policies on reporting and responding to all incidents, including serious incidents requiring investigation, and shall respond promptly to any reasonable and proportionate queries, questions and/or requests for information that the Authority may have in this context in relation to the Goods.

1.6 If there are any quality, performance and/or safety related reports, notices, alerts or other communications issued by the Supplier or any regulatory or other body in relation to the Goods, the Supplier shall promptly provide the Authority with a copy of any such reports, notices, alerts or other communications.

1.7 Upon receipt of any such reports, notices, alerts or other communications pursuant to Clause 1.5 of this Schedule 2 of these Call-off Terms and Conditions, the Authority shall be entitled to request further information from the Supplier and/or a meeting with the Supplier, and the Supplier shall cooperate fully with any such request.

2 Delivery

2.1 The Supplier shall deliver the Goods in accordance with any delivery timescales, delivery dates and delivery instructions (to include, without limitation, as to delivery location and delivery times) set out in the Specification and Tender Response Document, the Order Form or as otherwise agreed with the Authority in writing.

2.2 Delivery shall be completed when the Goods have been unloaded at the location specified by the Authority and such delivery has been received by a duly authorised agent, employee or location representative of the Authority. The Authority shall procure that such duly authorised agent, employee or location representative of the Authority is at the delivery location at the agreed delivery date and times in order to accept such delivery. Any arrangement by which the Goods are collected by the Authority in return for a discount on the Contract Price shall be agreed by the Parties in writing (where due to an emergency such arrangements cannot be committed to writing prior to collection, the Parties shall confirm such arrangements in writing as soon as possible following collection). Where the Authority collects the Goods, collection is deemed delivery for the purposes of the Contract.

2.3 The Supplier shall ensure that a delivery note shall accompany each delivery of the Goods. Such delivery note shall contain the information specified in the Specification and Tender Response Document or as otherwise agreed with the Authority in writing. Where such information requirements as to the content of delivery notes are not specified or separately agreed, such delivery notes shall, as a minimum, contain the Authority's order number, the name and address of the Authority, a description and quantity of the Goods, and shall show separately any extra agreed charges for containers and/or any other item not included in the Contract Price or, where no charge is made, whether the containers are required to be returned.

2.4 Part deliveries and/or deliveries outside of the agreed delivery times/dates may be refused unless the Authority has previously agreed in writing to accept such deliveries. Where delivery of the Goods is refused by the Authority in accordance with this Clause 2.4 of this Schedule 2 of these Call-off Terms and Conditions, the Supplier shall be responsible for all risks, costs and expenses associated with the re-delivery of the Goods in accordance with the agreed delivery times/dates. Where the Authority accepts delivery more than five (5) days before the agreed delivery date, the Authority shall be entitled to charge the Supplier for the costs of insurance and storage of the Goods until the agreed date for delivery.

2.5 Unless otherwise set out in the Specification and Tender Response Document or agreed with the Authority in writing, the Supplier shall be responsible for carriage, insurance, transport, all relevant licences, all related costs, and all other costs associated with the delivery of the Goods to the delivery location and unloading of the Goods at that location. Without limitation to the foregoing provision of this Clause 2.5 of this Schedule 2 of these Call-off Terms and Conditions, unless otherwise stated in the Specification and Tender Response Document or agreed with the Authority in writing, the Supplier shall be responsible for obtaining all export and import licences for the Goods and shall be responsible for any delays to the delivery time due to such licences not being available when required. In the case of any Goods supplied from outside the United Kingdom, the Supplier shall ensure that accurate information is provided to the Authority as to the country of origin of the Goods and shall be liable to the Authority for any extra duties or taxes for which the Authority may be accountable should the country of origin prove to be different from that set out in the Specification and Tender Response Document.

2.6 All third party carriers engaged to deliver the Goods shall at no time be an agent of the Authority and accordingly the Supplier shall be liable to the Authority for the acts and omissions of all third party carriers engaged to deliver the Goods to the Authority.

3 Passing of risk and ownership

3.1 Risk in the Goods shall pass to the Authority when the Goods are delivered as specified in this Contract or, in the case of Goods which require installation by the Supplier, when that installation process is complete.

3.2 Ownership of the Goods shall pass to the Authority on the earlier of:

3.2.1 full payment for such Goods; or

3.2.2 where the goods are consumables or are non-recoverable (e.g. used in clinical procedures), at the point such Goods are taken into use. For the avoidance of doubt, where ownership passes in accordance with this Clause 3.2.2 of this Schedule 2 of these Call-off Terms and Conditions, then the full Contract Price for such Goods shall be recoverable by the

Supplier from the Authority as a debt if there is non-payment of a valid undisputed invoice issued by the Supplier to the Authority in relation to such Goods.

3.3 All tools, equipment and materials of the Supplier required in the performance of the Supplier's obligations under this Contract shall be and remain at the sole risk of the Supplier, whether or not they are situated at a delivery location.

4 Inspection, rejection, return and recall

4.1 As relevant and proportionate to the Goods in question and subject to reasonable written notice, the Supplier shall permit any person authorised by the Authority, to inspect work being undertaken in relation to the Goods and/or the storage facilities used in the storage of the Goods at all reasonable times at the Supplier's premises or at the premises of any subcontractor or agent of the Supplier in order to confirm that the Goods are being manufactured and/or stored in accordance with Good Industry Practice and in compliance the requirements of this Contract and/or that stock holding and quality assurance processes are in accordance with the requirements of this Contract.

4.2 Without prejudice to the provisions of Clause 4.6 of this Schedule 2 of these Call-off Terms and Conditions and subject to Clause 4.7 of this Schedule 2 of these Call-off Terms and Conditions, the Authority shall visually inspect the Goods within a reasonable time following delivery (or such other period as may be set out as part of the requirements in the Specification and Tender Response Document, if any) and may by written notice reject any Goods found to be damaged or otherwise not in accordance with the requirements of this Contract ("**Rejected Goods**"). The whole of any delivery may be rejected if a reasonable sample of the Goods taken indiscriminately from that delivery is found not to conform in all material respects to the requirements of the Contract.

4.3 Without prejudice to the provisions of Clause 4.5 of this Schedule 2 of these Call-off Terms and Conditions, upon the rejection of any Goods in accordance with Clauses 4.2 and/or 4.6 of this Schedule 2 of these Call-off Terms and Conditions, the Supplier shall at the Authority's written request:

4.3.1 collect the Rejected Goods at the Supplier's risk and expense within ten (10) Business Days of issue of written notice from the Authority rejecting the Goods; and

4.3.2 without extra charge, promptly (and in any event within twenty (20) Business Days or such other time agreed by the Parties in writing acting reasonably) supply replacements for the Rejected Goods to the Authority subject to the Authority not cancelling its purchase obligations in accordance with Clause 4.5 of this Schedule 2 of these Call-off Terms and Conditions.

If the Supplier requests and the Authority accepts that the Rejected Goods should be disposed of by the Authority rather than returned to the Supplier, the Authority reserves the right to charge the Supplier for the costs associated with the disposal of the Rejected Goods and the Supplier shall promptly pay any such costs.

4.4 Risk and title in respect of any Rejected Goods shall pass to the Supplier on the earlier of: (a) collection by the Supplier in accordance with Clause 4.3 of this Schedule 2 of these Call-off Terms and Conditions; or (b) immediately following the expiry of ten (10) Business Days from the Authority issuing written notification rejecting the Goods. If Rejected Goods are not collected within ten (10) Business Days of the Authority issuing written notification rejecting the Goods, the Authority may return the Rejected Goods at the Supplier's risk and expense and charge the Supplier for the cost of storage from the expiry of ten (10) Business Days from the date of notification of rejection.

4.5 Where the Authority rejects any Goods in accordance with Clauses 4.2 and/or 4.6 of this Schedule 2 of these Call-off Terms and Conditions and the Authority no longer requires replacement Goods, the Authority may by written notice cancel its purchase obligations in relation to such quantity of Rejected Goods. Should the Authority have paid for such Rejected Goods the Supplier shall refund such payment to the Authority within thirty (30) days of the Authority cancelling such purchase obligations and informing the Supplier that the Authority does not require replacements for such Rejected Goods.

4.6 Without prejudice to any other provisions of this Contract or any other warranties or guarantees applicable to the Goods supplied and subject to Clause 4.7 of this Schedule 2 of these Call-off Terms and Conditions, if at any time following the date of the delivery of any Goods, all or any part of such Goods are found to be defective or otherwise not in accordance with the requirements of this Contract ("**Defective Goods**"), the Supplier shall, at the Authority's discretion:

4.6.1 upon written request and without charge, promptly (and in any event within twenty (20) Business Days or such other time agreed by the Parties in writing acting reasonably) remedy the deficiency by repairing such Defective Goods; or

4.6.2 upon written notice of rejection from the Authority, treat such Defective Goods as Rejected Goods in accordance with Clauses 4.2 to 4.5 of this Schedule 2 of these Call-off Terms and Conditions.

4.7 The Supplier shall be relieved of its liabilities under Clauses 4.2 to 4.5 (inclusive) and/or Clause 4.6 of this Schedule 2 of these Call-off Terms and Conditions to the extent only that the Goods are damaged, there are defects in the Goods and/or the Goods fail to comply with the requirements of this Contract due, in each case, to any acts or omissions of the Authority.

4.8 The Authority's rights and remedies under Clause 4.6 of this Schedule 2 of these Call-off Terms and Conditions shall cease within a reasonable period of time from the date on which the Authority discovers or might reasonably be expected to discover that the Goods are Defective Goods or within such other period as may be set out as part of the requirements in the Specification and Tender Response Document, if any. For the avoidance of doubt, Goods not used before their expiry date shall in no event be considered Defective Goods following the date of expiry provided that at the point such Goods were delivered to the Authority they met any shelf life requirements set out in the Specification and Tender Response Document.

4.9 Where the Supplier is required by Law, Guidance, and/or Good Industry Practice to order a product recall ("**Requirement to Recall**") in respect of the Goods, the Supplier shall:

4.9.1 promptly (taking into consideration the potential impact of the continued use of the Goods on patients, service users and the Authority as well as compliance by the Supplier with any regulatory requirements) notify the Authority in writing of the recall together with the circumstances giving rise to the recall;

4.9.2 from the date of the Requirement to Recall treat the Goods the subject of such recall as Defective Goods in accordance with Clause 4.6 of this Schedule 2 of these Call-off Terms and Conditions;

4.9.3 consult with the Authority as to the most efficient method of executing the recall of the Goods and use its reasonable endeavours to minimise the impact on the Authority of the recall; and

4.9.4 indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings suffered or incurred by the Authority as a result of such Requirement to Recall.

5 Staff

5.1 The Supplier will employ sufficient Staff to ensure that it complies with its obligations under this Contract. This will include, but not be limited to, the Supplier providing a sufficient reserve of trained and competent Staff during Staff holidays or absence.

5.2 The Supplier shall ensure that all Staff are aware of, and at all times comply with, the Policies.

5.3 The Supplier shall employ only such persons as are careful, skilled and experienced in the duties required of them, and will ensure that every such person is properly and sufficiently trained and instructed and shall maintain throughout the Term all

appropriate licences and registrations with any relevant bodies (at the Supplier's expense) and has the qualifications to carry out their duties.

5.4 The Supplier shall comply with the Authority's staff vetting procedures and other staff protocols, as may be relevant to this Contract and which are notified to the Supplier by the Authority in writing.

6 Business continuity

6.1 Throughout the Term, the Supplier will ensure its Business Continuity Plan provides for continuity during a Business Continuity Event. The Supplier confirms and agrees such Business Continuity Plan details and will continue to detail robust arrangements that are reasonable and proportionate to:

6.1.1 the criticality of this Contract to the Authority; and

6.1.2 the size and scope of the Supplier's business operations,

regarding continuity of the supply of Goods during and following a Business Continuity Event.

6.2 The Supplier shall test its Business Continuity Plan at reasonable intervals, and in any event no less than once every twelve (12) months or such other period as may be agreed between the Parties taking into account the criticality of this Contract to the Authority and the size and scope of the Supplier's business operations. The Supplier shall promptly provide to the Authority, at the Authority's written request, copies of its Business Continuity Plan, reasonable and proportionate documentary evidence that the Supplier tests its Business Continuity Plan in accordance with the requirements of this Clause 6.2 of this Schedule 2 of these Call-off Terms and Conditions and reasonable and proportionate information regarding the outcome of such tests. The Supplier shall provide to the Authority a copy of any updated or revised Business Continuity Plan within fourteen (14) Business Days of any material update or revision to the Business Continuity Plan.

6.3 Should a Business Continuity Event occur at any time, the Supplier shall implement and comply with its Business Continuity Plan and provide regular written reports to the Authority on such implementation.

6.4 During and following a Business Continuity Event, the Supplier shall use reasonable endeavours to continue to supply the Goods in accordance with this Contract.

7 The Authority's obligations

7.1 Subject to the Supplier supplying the Goods in accordance with this Contract, the Authority will pay the Supplier for the Goods in accordance with Clause 9 of this Schedule 2 of these Call-off Terms and Conditions.

7.2 The Authority shall, as appropriate, provide copies of or give the Supplier access to such of the Policies that are relevant to the supply and delivery of the Goods.

7.3 The Authority shall comply with the Authority's Obligations.

8 Contract management

8.1 Each Party shall appoint and retain a Contract Manager who shall be the primary point of contact for the other Party in relation to matters arising from this Contract. Should the Contract Manager be replaced, the Party replacing the Contract Manager shall promptly inform the other Party in writing of the name and contact details for the new Contract Manager. Any Contract Manager appointed shall be of sufficient seniority and experience to be able to make decisions on the day to day operation of the Contract. The Supplier confirms and agrees that it will be expected to work closely and cooperate fully with the Authority's Contract Manager.

8.2 Each Party shall ensure that its representatives (to include, without limitation, its Contract Manager) shall attend review meetings on a regular basis to review the performance of the Supplier under this Contract and to discuss matters arising generally under this Contract. Each Party shall ensure that those attending such meetings have the authority to make decisions regarding the day to day operation of the Contract. Review meetings shall take place at the frequency specified in the Specification and Tender Response Document. Should the Specification and Tender Response Document not state the frequency, then the first such meeting shall take place on a date to be agreed on or around the end of the first month after the Commencement Date. Subsequent meetings shall take place at monthly intervals or as may otherwise be agreed in writing between the Parties.

8.3 Two weeks prior to each review meeting (or at such time and frequency as may be specified in the Specification and Tender Response Document) the Supplier shall provide a written contract management report to the Authority regarding the supply of the Goods and the operation of this Contract. Unless otherwise agreed by the Parties in writing, such contract management report shall contain:

8.3.1 details of the performance of the Supplier when assessed in accordance with the KPIs since the last such performance report;

8.3.2 details of any complaints by the Authority in relation to the supply of Goods, their nature and the way in which the Supplier has responded to such complaints since the last review meeting written report;

8.3.3 the information specified in the Specification and Tender Response Document;

8.3.4 a status report in relation to the implementation of any current Remedial Proposals by either Party; and

8.3.5 such other information as reasonably required by the Authority.

8.4 Unless specified otherwise in the Specification and Tender Response Document, the Authority shall take minutes of each review meeting and shall circulate draft minutes to the Supplier within a reasonable time following such review meeting. The Supplier shall inform the Authority in writing of any suggested amendments to the minutes within five (5) Business Days of receipt of the draft minutes. If the Supplier does not respond to the Authority within such five (5) Business Days the minutes will be deemed to be approved. Where there are any differences in interpretation of the minutes, the Parties will use their reasonable endeavours to reach agreement. If agreement cannot be reached the matter shall be referred to, and resolved in accordance with, the dispute resolution process set out in Clause 5 of the Key Provisions and Clause 22.3 of this Schedule 2 of these Call-off Terms and Conditions.

8.5 The Supplier shall provide such management information as the Authority may request from time to time within seven (7) Business Days of the date of the request. The Supplier shall supply the management information to the Authority in such form as may be specified by the Authority and, where requested to do so, the Supplier shall also provide such management information to another Contracting Authority, whose role it is to: (a) analyse such management information in accordance with UK government policy (to include, without limitation, for the purposes of analysing public sector expenditure and planning future procurement activities); or (b) manage the Framework Agreement with the Supplier ("**Third Party Body"**). The Supplier confirms and agrees that the Authority may itself provide the Third Party Body with management information relating to the Goods purchased, any payments made under this Contract and any other information relevant to the operation of this Contract.

8.6 Upon receipt of management information supplied by the Supplier to the Authority and/or the Third Party Body, or by the Authority to the Third Party Body, the Parties hereby consent to the Third Party Body and the Authority:

8.6.1 storing and analysing the management information and producing statistics; and

8.6.2 sharing the management information, or any statistics produced using the management information with any other Contracting Authority.

8.7 If the Third Party Body and/or the Authority shares the management information or any other information provided under Clause 8.6 of this Schedule 2 of these Call-off Terms and Conditions, any Contracting Authority receiving the management information shall, where such management information is subject to obligations of confidence under this Contract and such management information is provided direct by the Authority to such Contracting Authority, be informed of the confidential nature

of that information by the Authority and shall be requested by the Authority not to disclose it to any body that is not a Contracting Authority (unless required to do so by Law).

8.8 The Authority may make changes to the type of management information which the Supplier is required to supply and shall give the Supplier at least one (1) month's written notice of any changes.

9 Price and payment

9.1 The Contract Price shall be calculated in accordance with the provisions of the Framework Agreement, as confirmed in the Order Form.

9.2 Unless otherwise stated in the Framework Agreement and/or the Order Form, the Contract Price:

9.2.1 shall remain fixed during the Term; and

9.2.2 is the entire price payable by the Authority to the Supplier in respect of the provision of the Goods and includes, without limitation:

(i) packaging, packing materials, addressing, labelling, loading, delivery to and unloading at the delivery location, all appropriate tax (excluding VAT) and duty, any installation costs and associated works, the costs of all associated documentation and information supplied or made accessible to the Authority in any media, and any training in relation to the use, storage, handling or operation of the Goods;

(ii) any royalties, licence fees or similar expenses in respect of the making, use or exercise by the Supplier of any Intellectual Property Rights for the purposes of performing this Contract, and any licence rights granted to the Authority in accordance with Clause 11 of this Schedule 2 of these Call-off Terms and Conditions; and

(iii) costs and expenses in relation to supplies and materials used by the Supplier or any third party in the manufacture of the Goods, and any other costs incurred by the Supplier in association with the manufacture, supply or installation of the Goods.

9.3 Unless stated otherwise in the Framework Agreement and/or the Order Form:

9.3.1 where the Framework Agreement and/or the Order Form confirms that the payment profile for this Contract is monthly in arrears, the Supplier shall invoice the Authority, within fourteen (14) days of the end of each calendar month, the Contract Price in respect of the Goods supplied in compliance with this Contract in the preceding calendar month; or

9.3.2 where Clause 9.3.1 of this Schedule 2 of these Call-off Terms and Conditions does not apply, the Supplier shall invoice the Authority for Goods at any time following completion of the supply of the Goods in compliance with this Contract.

Each invoice shall contain such information and be addressed to such individual as the Authority may inform the Supplier from time to time.

9.4 The Contract Price is exclusive of VAT, which, if properly chargeable, the Authority shall pay at the prevailing rate subject to receipt from the Supplier of a valid and accurate VAT invoice. Such VAT invoices shall show the VAT calculations as a separate line item.

9.5 Where the Contract Price is or may become subject to any pricing requirements of any voluntary and/or statutory pricing regulation schemes, the Parties shall comply with such requirements as required by Law from time to time and specifically as required by the statutory pricing regulation scheme (and any future regulation) or to the extent applicable to the Supplier from time to time as an industry member of a voluntary scheme, including any reductions in price by reason of the application of such schemes.

9.6 The Authority shall pay each undisputed invoice received in accordance with Clause 9.3 of this Schedule 2 of these Call-off Terms and Conditions within thirty (30) days of receipt of such invoice at the latest. However, the Authority shall use its reasonable endeavours to pay such undisputed invoices sooner in accordance with any applicable government prompt payment targets.

9.7 Where the Authority raises a query with respect to an invoice the Parties shall liaise with each other and agree a resolution to such query within thirty (30) days of the query being raised. If the Parties are unable to agree a resolution within thirty (30) days the query shall be referred to dispute resolution in accordance with Clause 22 of this Schedule 2 of these Call-off Terms and Conditions.

9.8 The Authority reserves the right to deduct any monies due to the Supplier from the Authority from any monies due to the Authority from the Supplier under this Contract.

10 Warranties

10.1 The Supplier warrants and undertakes that:

10.1.1 it shall comply with the Framework Agreement;

10.1.2 the Goods shall be suitable for the purposes and/or treatments as referred to in the Specification and Tender Response Document, be of satisfactory quality, fit for their intended purpose and shall comply with the standards and requirements set out in this Contract;

10.1.3 unless otherwise confirmed by the Authority in writing (to include, without limitation, as part of the Specification and Tender Response Document), it will ensure that the Goods comply with requirements five (5) to eight (8), as set out at Annex 1 of the Cabinet Office Procurement Policy Note - Implementing Article 6 of the Energy Efficiency Directive (Action Note 07/14 3rd June 2014), to the extent such requirements apply to the relevant Goods;

10.1.4 it shall ensure that prior to actual delivery to the Authority the Goods are manufactured, stored and/or distributed using reasonable skill and care and in accordance with Good Industry Practice;

10.1.5 without prejudice to the generality of the warranty at 10.1.4 of this Schedule 2 of these Call-off Terms and Conditions, it shall ensure that, the Goods are manufactured, stored and/or distributed in accordance with good manufacturing practice and/or good distribution practice, as may be defined under any Law and/or Guidance relevant to the Goods, and in accordance with any specific instructions of the manufacturer of the Goods;

10.1.6 it shall ensure that all facilities used in the manufacture, storage and distribution of the Goods are kept in a state and condition necessary to enable the Supplier to comply with its obligations in accordance with this Contract;

10.1.7 it has, or the manufacturer of the Goods has, manufacturing and warehousing capacity sufficient to comply with its obligations under this Contract;

10.1.8 it will ensure sufficient stock levels to comply with its obligations under this Contract;

10.1.9 it shall ensure that the transport and delivery of the Goods mean that they are delivered in good and useable condition;

10.1.10 where the Goods are required to be stored at a certain temperature, it shall provide, or shall procure the provision of, complete and accurate temperature records for each delivery of the Goods during the period of transport and/or storage of the Goods from the point of manufacture to the point of delivery to the Authority;

10.1.11 where there is any instruction information, including without limitation patient information leaflets, that accompany the Goods, it shall provide a sufficient number of copies to the Authority and provide updated copies should the instruction information change at any time during the Term;

10.1.12 all Goods delivered to the Authority shall comply with any shelf life requirements set out in the Specification and Tender Response Document;

10.1.13 it has and shall maintain a properly documented system of quality controls covering all aspects of its obligations under this Contract and/or under Law and/or Guidance and shall at all times comply with such quality controls;

10.1.14 it shall not make any significant changes to its system of quality controls in relation to the Goods without notifying the Authority in writing at least twenty one (21) days in advance of such change (such notice to include the details of the consequences which follow such change being implemented);

10.1.15 it shall not make any significant changes to the Goods without the prior written consent of the Authority, such consent not to be unreasonably withheld or delayed;

10.1.16 any equipment it uses in the manufacture, delivery, or installation of the Goods shall comply with all relevant Law and Guidance, be fit for its intended purpose and maintained fully in accordance with the manufacturer's specification;

10.1.17 where any act of the Supplier requires the notification to and/or approval by any regulatory or other competent body in accordance with any Law and Guidance, the Supplier shall comply fully with such notification and/or approval requirements;

10.1.18 it has and shall as relevant maintain all rights, consents, authorisations, licences and accreditations required to supply the Goods;

10.1.19 receipt of the Goods by or on behalf of the Authority and use of the Goods or of any other item or information supplied, or made available, to the Authority will not infringe any third party rights, to include without limitation any Intellectual Property Rights;

10.1.20 it will comply with all Law, Guidance and Policies in so far as is relevant to the supply of the Goods;

10.1.21 it will promptly notify the Authority of any health and safety hazard which has arisen, or the Supplier is aware may arise, in connection with the Goods and take such steps as are reasonably necessary to ensure the health and safety of persons likely to be affected by such hazards;

10.1.22 it will promptly respond to all requests for information regarding this Contract and the Goods at the frequency and in the format that the Authority may reasonably require;

10.1.23 all information included within the Supplier's responses in the Specification and Tender Response Document and all accompanying materials is accurate;

10.1.24 it has the right and authority to enter into this Contract and that it has the capability and capacity to fulfil its obligations under this Contract;

10.1.25 it is a properly constituted entity and it is fully empowered by the terms of its constitutional documents to enter into and to carry out its obligations under this Contract and the documents referred to in this Contract;

10.1.26 all necessary actions to authorise the execution of and performance of its obligations under this Contract have been taken before such execution;

10.1.27 there are no pending or threatened actions or proceedings before any court or administrative agency which would materially adversely affect the financial condition, business or operations of the Supplier;

10.1.28 there are no material agreements existing to which the Supplier is a party which prevent the Supplier from entering into or complying with this Contract;

10.1.29 it has and will continue to have the capacity, funding and cash flow to meet all its obligations under this Contract; and

10.1.30 it has satisfied itself as to the nature and extent of the risks assumed by it under this Contract and has gathered all information necessary to perform its obligations under this Contract and all other obligations assumed by it.

10.2 Where the sale, manufacture, assembly, importation, storage, distribution, supply, delivery, or installation of the Goods under this Contract relates to medical devices and/or medicinal products (both as defined under any relevant Law and Guidance), the Supplier warrants and undertakes that it will comply with any such Law and Guidance relating to such activities in relation to such medical devices and/or medicinal products. In particular, but without limitation, the Supplier warrants that:

10.2.1 at the point such Goods are supplied to the Authority, all such Goods which are medical devices shall have valid CE marking as required by Law and Guidance and that all relevant marking, authorisation, registration, approval and documentation requirements as required under Law and Guidance relating to the sale, manufacture, assembly, importation, storage, distribution, supply, delivery, or installation of such Goods shall have been complied with. Without limitation to the foregoing provisions of this Clause 10.2 of this Schedule 2 of these Call-off Terms and Conditions, the Supplier shall, upon written request from the Authority, make available to the Authority evidence of the grant of such valid CE marking, and evidence

of any other authorisations, registrations, approvals or documentation required;

10.2.2 at the point such Goods are supplied to the Authority, all such Goods which are medicinal products shall have a valid marketing authorisation as required by Law and Guidance in order to supply the Goods to the Authority and that all relevant authorisation, labelling, registration, approval and documentation requirements as required under Law and Guidance relating to the sale, manufacture, assembly, importation, storage, distribution, supply or delivery of such Goods shall have been complied with. Without limitation to the foregoing provisions of this Clause 10.2 of this Schedule 2 of these Call-off Terms and Conditions, the Supplier shall, upon written request from the Authority, make available to the Authority evidence of the grant of any required valid marketing authorisation, and evidence of any other authorisations, labelling, registrations, approvals or documentation required; and

10.2.3 it shall maintain, and no later than any due date when it would otherwise expire, obtain a renewal of, any authorisation, registration or approval (including without limitation CE marking and/or marketing authorisation) required in relation to the Goods in accordance with Law and Guidance until such time as the Goods expire or the Authority notifies the Supplier in writing that it has used or disposed of all units of the Goods supplied under this Contract.

10.3 If the Supplier is in breach of Clause 10.2 of this Schedule 2 of these Call-off Terms and Conditions, then, without prejudice to any other right or remedy of the Authority, the Authority shall be entitled to reject and/or return the Goods and the Supplier shall, subject to Clause 13.2 of this Schedule 2 of these Call-off Terms and Conditions, indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings suffered or incurred by the Authority as a result of such breach.

10.4 The Supplier agrees to use reasonable endeavours to assign to the Authority upon request the benefit of any warranty, guarantee or similar right which it has against any third party manufacturer or supplier of the Goods in full or part.

10.5 The Supplier warrants that all information, data and other records and documents required by the Authority as set out in the Specification and Tender Response Document shall be submitted to the Authority in the format and in accordance with any timescales set out in the Specification and Tender Response Document.

10.6 The Supplier warrants and undertakes to the Authority that it shall comply with any eProcurement Guidance as it may apply to the Supplier and shall carry out all reasonable acts required of the Supplier to enable the Authority to comply with such eProcurement Guidance.

10.7 The Supplier warrants and undertakes to the Authority that, as at the Commencement Date, it has notified the Authority in writing of any Occasions of Tax Non-Compliance or any litigation that it is involved in that is in connection with any Occasions of Tax Non-Compliance. If, at any point during the Term, an Occasion of Tax Non-Compliance occurs, the Supplier shall:

10.7.1 notify the Authority in writing of such fact within five (5) Business Days of its occurrence; and

10.7.2 promptly provide to the Authority:

(i) details of the steps which the Supplier is taking to address the Occasion of Tax Non-Compliance and to prevent the same from recurring, together with any mitigating factors that it considers relevant; and

(ii) such other information in relation to the Occasion of Tax Non-Compliance as the Authority may reasonably require.

10.8 The Supplier further warrants and undertakes to the Authority that it will inform the Authority in writing immediately upon becoming aware that any of the warranties set out in Clause 10 of this Schedule 2 of these Call-off Terms and Conditions have been breached or there is a risk that any warranties may be breached.

10.9 Any warranties provided under this Contract are both independent and cumulative and may be enforced independently or collectively at the sole discretion of the enforcing Party.

11 Intellectual property

11.1 Unless specified otherwise in the Specification and Tender Response Document, the Supplier hereby grants to the Authority, for the life of the use of Goods by the Authority, an irrevocable, royalty-free, non-exclusive licence of any Intellectual Property Rights required for the purposes of receiving and using, and to the extent necessary to receive and use, the Goods (to include any associated technical or other documentation and information supplied or made accessible to the Authority in any media) in accordance with this Contract.

12 Indemnity

12.1 The Supplier shall be liable to the Authority for, and shall indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings in respect of:

12.1.1 any injury or allegation of injury to any person, including injury resulting in death;

12.1.2 any loss of or damage to property (whether real or personal); and/or

12.1.3 any breach of Clause 10.1.19 and/or Clause 11 of this Schedule 2 of these Call-off Terms and Conditions;

that arise or result from the Supplier's negligent acts or omissions or breach of contract in connection with the performance of this Contract including the supply of the Goods, except to the extent that such loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings have been caused by any act or omission by, or on behalf of, or in accordance with the instructions of, the Authority.

12.2 Liability under Clauses 12.1.1 and 12.1.3 of this Schedule 2 of these Call-off Terms and Conditions and Clause 2.5 of Schedule 3 of these Call-off Terms and Conditions shall be unlimited. Liability under Clauses 4.9.4, 10.3 and 12.1.2 of this Schedule 2 of these Call-off Terms and Conditions shall be subject to the limitation of liability set out in Clause 13 of this Schedule 2 of these Call-off Terms and Conditions.

12.3 In relation to all third party claims against the Authority, which are the subject of any indemnity given by the Supplier under this Contract, the Authority shall use its reasonable endeavours, upon a written request from the Supplier, to transfer the conduct of such claims to the Supplier unless restricted from doing so. Such restrictions may include, without limitation, any restrictions:

12.3.1 relating to any legal, regulatory, governance, information governance, or confidentiality obligations on the Authority; and/or

12.3.2 relating to the Authority's membership of any indemnity and/or risk pooling arrangements.

Such transfer shall be subject to the Parties agreeing appropriate terms for such conduct of the third party claim by the Supplier (to include, without limitation, the right of the Authority to be informed and consulted on the ongoing conduct of the claim following such transfer and any reasonable cooperation required by the Supplier from the Authority).

13 Limitation of liability

13.1 Nothing in this Contract shall exclude or restrict the liability of either Party:

13.1.1 for death or personal injury resulting from its negligence;

13.1.2 for fraud or fraudulent misrepresentation; or

13.1.3 in any other circumstances where liability may not be limited or excluded under any applicable law.

13.2 Subject to Clauses 12.2, 13.1, 13.3 and 13.5 of this Schedule 2 of these Call-off Terms and Conditions, the total liability of each Party to the other under or in connection with this Contract whether arising in contract, tort, negligence, breach of statutory duty or otherwise shall be limited in aggregate to the greater of: (a) five

million GBP (£5,000,000); or (b) one hundred and twenty five percent (125%) of the total Contract Price paid or payable by the Authority to the Supplier for the Goods.

13.3 There shall be no right to claim losses, damages and/or other costs and expenses under or in connection with this Contract whether arising in contract (to include, without limitation, under any relevant indemnity), tort, negligence, breach of statutory duty or otherwise to the extent that any losses, damages and/or other costs and expenses claimed are in respect of loss of production, loss of business opportunity or are in respect of indirect loss of any nature suffered or alleged. For the avoidance of doubt, without limitation, the Parties agree that for the purposes of this Contract the following costs, expenses and/or loss of income shall be direct recoverable losses (to include under any relevant indemnity) provided such costs, expenses and/or loss of income are properly evidenced by the claiming Party:

13.3.1 extra costs incurred purchasing replacement or alternative goods;

13.3.2 costs incurred in relation to any product recall;

13.3.3 costs associated with advising, screening, testing, treating, retreating or otherwise providing healthcare to patients;

13.3.4 the costs of extra management time; and/or

13.3.5 loss of income due to an inability to provide health care services,

in each case to the extent to which such costs, expenses and/or loss of income arise or result from the other Party's breach of contract, negligent act or omission, breach of statutory duty, and/or other liability under or in connection with this Contract.

13.4 Each Party shall at all times take all reasonable steps to minimise and mitigate any loss for which that Party is entitled to bring a claim against the other pursuant to this Contract.

13.5 If the total Contract Price paid or payable by the Authority to the Supplier over the Term:

13.5.1 is less than or equal to one million pounds (£1,000,000), then the figure of five million pounds (£5,000,000) at Clause 13.2 of this Schedule 2 of these Call-off Terms and Conditions shall be replaced with one million pounds (£1,000,000);

13.5.2 is less than or equal to three million pounds (£3,000,000) but greater than one million pounds (£1,000,000), then the figure of five million pounds (£5,000,000) at Clause 13.2 of this Schedule 2 of these Call-off Terms and Conditions shall be replaced with three million pounds (£3,000,000);

13.5.3 is equal to, exceeds or will exceed ten million pounds (£10,000,000), but is less than fifty million pounds (£50,000,000), then the figure of five million pounds (£5,000,000) at Clause 13.2 of this Schedule 2 of these Call-off Terms and Conditions shall be replaced with ten million pounds (£10,000,000) and the figure of one hundred and twenty five percent (125%) at Clause 13.2 of this Schedule 2 of these Call-off Terms and Conditions shall be deemed to have been deleted and replaced with one hundred and fifteen percent (115%); and

13.5.4 is equal to, exceeds or will exceed fifty million pounds (£50,000,000), then the figure of five million pounds (£5,000,000) at Clause 13.2 of this Schedule 2 of these Call-off Terms and Conditions shall be replaced with fifty million pounds (£50,000,000) and the figure of one hundred and twenty five percent (125%) at Clause 13.2 of this Schedule 2 of these Call-off Terms and Conditions shall be deemed to have been deleted and replaced with one hundred and five percent (105%).

13.6 Clause 13 of this Schedule 2 of these Call-off Terms and Conditions shall survive the expiry of or earlier termination of this Contract for any reason.

14 Insurance

14.1 Subject to Clauses 14.2 and 14.3 of this Schedule 2 of these Call-off Terms and Conditions and unless otherwise confirmed in writing by the Authority, as a minimum level of protection, the Supplier shall put in place and/or maintain in force at its own cost with a reputable commercial insurer, insurance arrangements in respect of employer's liability, public liability and product liability in accordance with Good Industry Practice with the minimum cover per claim of the greater of five million pounds (£5,000,000) or any sum as required by Law unless otherwise agreed with the Authority in writing. These requirements shall not apply to the extent that the Supplier is a member and maintains membership of each of the indemnity schemes run by the NHS Litigation Authority.

14.2 Without limitation to any insurance arrangements as required by Law, the Supplier shall put in place and/or maintain the different types and/or levels of indemnity arrangements specified in the Framework Agreement, if any.

14.3 Provided that the Supplier maintains all indemnity arrangements required by Law, the Supplier may self insure in order to meet other relevant requirements referred to at Clauses 14.1 and 14.2 of this Schedule 2 of these Call-off Terms and Conditions on condition that such self insurance arrangements offer the appropriate levels of protection and are approved by the Authority in writing prior to the Commencement Date.

14.4 The amount of any indemnity cover and/or self insurance arrangements shall not relieve the Supplier of any liabilities under this Contract. It shall be the responsibility of the Supplier to determine the amount of indemnity and/or self insurance cover that will be adequate to enable it to satisfy its potential liabilities under this Contract. Accordingly, the Supplier shall be liable to make good any deficiency if the proceeds

of any indemnity cover and/or self insurance arrangement is insufficient to cover the settlement of any claim.

14.5 The Supplier warrants that it shall not take any action or fail to take any reasonable action or (in so far as it is reasonable and within its power) permit or allow others to take or fail to take any action, as a result of which its insurance cover may be rendered void, voidable, unenforceable, or be suspended or impaired in whole or in part, or which may otherwise render any sum paid out under such insurances repayable in whole or in part.

14.6 The Supplier shall from time to time and in any event within five (5) Business Days of written demand provide documentary evidence to the Authority that insurance arrangements taken out by the Supplier pursuant to Clause 14 of this Schedule 2 of these Call-off Terms and Conditions and/or the provisions of the Framework Agreement are fully maintained and that any premiums on them and/or contributions in respect of them (if any) are fully paid.

14.7 Upon the expiry or earlier termination of this Contract, the Supplier shall ensure that any ongoing liability it has or may have arising out of this Contract shall continue to be the subject of appropriate indemnity arrangements for the period of twenty one (21) years from termination or expiry of this Contract or until such earlier date as that liability may reasonably be considered to have ceased to exist.

15 Term and termination

15.1 This Contract shall commence on the Commencement Date and unless terminated earlier in accordance with the terms of this Contract or the general law, shall continue until the end of the Term.

15.2 The Authority:

15.2.1 subject to Clause 15.2.2 of this Schedule 2 of these Call-off Terms and Conditions, shall be entitled to extend the Term on one or more occasions by giving the Supplier written notice no less than three (3) months prior to the date on which this Contract would otherwise have expired, provided that the duration of this Contract shall be no longer than the total term specified in the Key Provisions; or

15.2.2 where the Term or any extension of the Term expires at a date the same as or after expiry of the Framework Agreement (including any extensions of the Framework Agreement in accordance with its terms), shall only be entitled to extend the Term with the prior written agreement of the Supplier, such agreement not to be unreasonably withheld or delayed.

15.3 In the case of a breach of any of the terms of this Contract by either Party that is capable of remedy (including, without limitation any breach of any KPI and any failure to pay any sums due under this Contract), the non-breaching Party shall, without prejudice to its other rights and remedies under this Contract, issue notice of the breach and allow the Party in breach the opportunity to remedy such breach in the

first instance via a remedial proposal put forward by the Party in breach ("**Remedial Proposal**") before exercising any right to terminate this Contract in accordance with Clause 15.4.1(ii) of this Schedule 2 of these Call-off Terms and Conditions. Such Remedial Proposal must be agreed with the non-breaching Party (such agreement not to be unreasonably withheld or delayed) and must be implemented by the Party in breach in accordance with the timescales referred to in the agreed Remedial Proposal. Once agreed, any changes to a Remedial Proposal must be approved by the Parties in writing. Any failure by the Party in breach to:

15.3.1 put forward and agree a Remedial Proposal with the non-breaching Party in relation to the relevant default or breach within a period of ten (10) Business Days (or such other period as the non-breaching Party may agree in writing) from written notification of the relevant default or breach from the non-breaching Party;

15.3.2 comply with such Remedial Proposal (including, without limitation, as to its timescales for implementation, which shall be thirty (30) days unless otherwise agreed between the Parties); and/or

15.3.3 remedy the default or breach notwithstanding the implementation of such Remedial Proposal in accordance with the agreed timescales for implementation,

shall be deemed, for the purposes of Clause 15.4.1(ii) of this Schedule 2 of these Call-off Terms and Conditions, a material breach of this Contract by the Party in breach not remedied in accordance with an agreed Remedial Proposal.

15.4 Either Party may terminate this Contract forthwith by notice in writing to the other Party if such other Party:

15.4.1 commits a material breach of any of the terms of this Contract which is:

(i) not capable of remedy; or

(ii) in the case of a breach capable of remedy, which is not remedied in accordance with a Remedial Proposal; or

15.4.2 has been served with at least two (2) previous breach notices as a result of any material breaches which are capable of remedy within any twelve (12) month rolling period whether or not the Party in breach has remedied the breach in accordance with a Remedial Proposal. The twelve (12) months rolling period is the twelve (12) months immediately preceding the date of the third breach notice.

15.5 The Authority may terminate this Contract forthwith by notice in writing to the Supplier if:

15.5.1 the Supplier, or any third party guaranteeing the obligations of the Supplier under this Contract, ceases or threatens to cease carrying on its business; suspends making payments on any of its debts or announces an intention to do so; is, or is deemed for the purposes of any Law to be, unable to pay its debts as they fall due or insolvent; enters into or proposes any composition, assignment or arrangement with its creditors generally; takes any step or suffers any step to be taken in relation to its winding-up, dissolution, administration (whether out of court or otherwise) or reorganisation (by way of voluntary arrangement, scheme of arrangement or otherwise) otherwise than as part of, and exclusively for the purpose of, a bona fide reconstruction or amalgamation; has a liquidator, trustee in bankruptcy, judicial custodian, compulsory manager, receiver, administrative receiver, administrator or similar officer appointed (in each case, whether out of court or otherwise) in respect of it or any of its assets; has any security over any of its assets enforced; or any analogous procedure or step is taken in any jurisdiction;

15.5.2 the Supplier undergoes a change of control within the meaning of sections 450 and 451 of the Corporation Tax Act 2010 (other than for an intra-group change of control) without the prior written consent of the Authority and the Authority shall be entitled to withhold such consent if, in the reasonable opinion of the Authority, the proposed change of control will have a material impact on the performance of this Contract or the reputation of the Authority;

15.5.3 the Supplier purports to assign, subcontract, novate, create a trust in or otherwise transfer or dispose of this Contract in breach of Clause 28.1 of this Schedule 2 of these Call-off Terms and Conditions;

15.5.4 pursuant to and in accordance with any termination rights set out in any Key Provisions and Clauses 15.6, 23.8; 25.2; 25.4 and 29.2 of this Schedule 2 of these Call-off Terms and Conditions; or

15.5.5 the warranty given by the Supplier pursuant to Clause 10.7 of this Schedule 2 of these Call-off Terms and Conditions is materially untrue, the Supplier commits a material breach of its obligation to notify the Authority of any Occasion of Tax Non-Compliance as required by Clause 10.7 of this Schedule 2 of these Call-off Terms and Conditions, or the Supplier fails to provide details of proposed mitigating factors as required by Clause 10.7 of this Schedule 2 of these Call-off Terms and Conditions that in the reasonable opinion of the Authority are acceptable.

15.6 If the Authority, acting reasonably, has good cause to believe that there has been a material deterioration in the financial circumstances of the Supplier and/or any third party guaranteeing the obligations of the Supplier under this Contract and/or any

material subcontractor of the Supplier when compared to any information provided to and/or assessed by the Authority as part of any procurement process or other due diligence leading to the award of this Contract to the Supplier or the entering into a subcontract by the Supplier, the following process shall apply:

15.6.1 the Authority may (but shall not be obliged to) give notice to the Supplier requesting adequate financial or other security and/or assurances for due performance of its material obligations under this Contract on such reasonable and proportionate terms as the Authority may require within a reasonable time period as specified in such notice;

15.6.2 a failure or refusal by the Supplier to provide the financial or other security and/or assurances requested in accordance with Clause 15.6 of this Schedule 2 of these Call-off Terms and Conditions in accordance with any reasonable timescales specified in any such notice issued by the Authority shall be deemed a breach of this Contract by the Supplier and shall be referred to and resolved in accordance with the Dispute Resolution Procedure; and

15.6.3 a failure to resolve such breach in accordance with such Dispute Resolution Procedure by the end of the escalation stage of such process (as set out in Clause 22.3 of this Schedule 2 of these Call-off Terms and Conditions) shall entitle, but shall not compel, the Authority to terminate this Contract in accordance with Clause 15.4.1(i) of this Schedule 2 of these Call-off Terms and Conditions.

In order that the Authority may act reasonably in exercising its discretion in accordance with Clause 15.6 of this Schedule 2 of these Call-off Terms and Conditions, the Supplier shall provide the Authority with such reasonable and proportionate up-to-date financial or other information relating to the Supplier or any relevant third party entity upon request.

15.7 If the Authority novates this Contract to any body that is not a Contracting Authority, from the effective date of such novation, the rights of the Authority to terminate this Contract in accordance with Clause 15.5.1 to Clause 15.5.3 of this Schedule 2 of these Call-off Terms and Conditions shall be deemed mutual termination rights and the Supplier may terminate this Contract forthwith by notice in writing to the entity assuming the position of the Authority if any of the circumstances referred to in such Clauses apply to the entity assuming the position of the Authority.

16 Consequences of expiry or earlier termination of this Contract

16.1 Upon expiry or earlier termination of this Contract, the Authority agrees to pay the Supplier for the Goods which have been supplied by the Supplier and accepted by the Authority in accordance with this Contract prior to expiry or earlier termination of this Contract.

16.2 The Supplier shall cooperate fully with the Authority or, as the case may be, any replacement supplier during any re-procurement and handover period prior to and following the expiry or earlier termination of this Contract. This cooperation shall extend to providing access to all information relevant to the operation of this Contract, as reasonably required by the Authority to achieve a fair and transparent re-procurement and/or an effective transition without disruption to routine operational requirements.

16.3 The expiry or earlier termination of this Contract for whatever reason shall not affect any rights or obligations of either Party which accrued prior to such expiry or earlier termination.

16.4 The expiry or earlier termination of this Contract shall not affect any obligations which expressly or by implication are intended to come into or continue in force on or after such expiry or earlier termination.

16.5 The expiry or earlier termination of the Framework Agreement shall not affect this Contract. For the avoidance of doubt, any obligations set out in the Framework Agreement that form part of this Contract shall continue to apply for the purposes of this Contract notwithstanding any termination of the Framework Agreement.

17 Packaging, identification and end of use

17.1 The Supplier shall comply with all obligations imposed on it by Law relevant to the Goods in relation to packaging, identification, and obligations following end of use by the Authority.

17.2 Unless otherwise specified in the Specification and Tender Response Document or otherwise agreed with the Authority in writing, the Goods shall be securely packed in trade packages of a type normally used by the Supplier for commercial deliveries of the same or similar goods either in retail or in bulk quantities within the United Kingdom.

17.3 Unless otherwise (a) specified in the Specification and Tender Response Document; (b) agreed with the Authority in writing; or (c) required to comply with any regulatory requirements, the following details shall be shown on the outside of every package:

17.3.1 a description of the Goods which shall include, without limitation, the weight of the Goods where available and any order number allocated to the Goods by the Authority and/or the Supplier;

17.3.2 the quantity in the package where available;

17.3.3 any special directions for storage;

17.3.4 the expiry date of the contents where applicable;

17.3.5 the batch number; and

17.3.6 the name and address of the manufacturer of the Goods and the Supplier.

17.4 All Goods that customarily bear any mark, tab, brand, label, serial numbers or other device indicating place of origin, inspection by any government or other body or standard of quality must be delivered with all the said marks, tabs, brands, labels, serial numbers or other devices intact. Without prejudice to the generality of the foregoing, the Supplier shall label all Goods supplied to the Authority, and the packaging of such Goods, to highlight environmental and safety information as required by applicable Law.

17.5 Unless otherwise set out in the Specification and Tender Response Document or agreed with the Authority in writing, the Supplier shall collect without charge any returnable containers (including pallets) within twenty one (21) days of the date of the relevant delivery. Empty containers not so removed may be returned by the Authority at the Supplier's expense or otherwise disposed of at the Authority's discretion. The Supplier shall credit the Authority in full for any containers for which the Authority has been charged upon their collection or return.

18 Coding requirements

18.1 Unless otherwise confirmed and/or agreed by the Authority in writing and subject to Clause 18.2 of this Schedule 2 of these Call-off Terms and Conditions, the Supplier shall ensure comprehensive product information relating to each category of the Goods shall be placed by the Supplier into a GS1 certified data pool within the following timescales:

18.1.1 prior to or on the Commencement Date, in relation to all categories of Goods to be provided as part of the Contract as at the Commencement Date; or

18.1.2 where further categories of Goods are to be supplied in accordance with Clause 21 of this Schedule 2 of these Call-off Terms and Conditions, prior to or on the date of implementation of any such variation.

18.2 Where it is not practical for whatever reason for the Supplier to comply with its obligations under Clause 18.1 of this Schedule 2 of these Call-off Terms and Conditions within the timescales stated and the Authority requires compliance with such coding requirements, the Supplier shall provide an implementation plan and timetable that sets out how the Supplier shall achieve such compliance by an alternative timescale. This implementation plan and timetable must be submitted by the Supplier for agreement by the Authority prior to the first delivery of the relevant Goods under the Contract (such agreement not to be unreasonably withheld or delayed). Any failure by the Parties to agree such a timetable and plan shall be referred to and resolved in accordance with the Dispute Resolution Procedure. Once a timetable and plan have been agreed by the Authority, the Supplier shall comply with such timetable and plan as a condition of this Contract.

18.3 Once product information relating to Goods is placed by the Supplier into a GS1 certified data pool, the Supplier shall, during the Term, keep such information updated with any changes to the product data relating to the Goods.

19 Sustainable development

19.1 The Supplier shall comply in all material respects with applicable environmental and social Law requirements in force from time to time in relation to the Goods. Where the provisions of any such Law are implemented by the use of voluntary agreements, the Supplier shall comply with such agreements as if they were incorporated into English law subject to those voluntary agreements being cited in the Specification and Tender Response Document. Without prejudice to the generality of the foregoing, the Supplier shall:

19.1.1 comply with all Policies and/or procedures and requirements set out in the Specification and Tender Response Document in relation to any stated environmental and social requirements, characteristics and impacts of the Goods and the Supplier's supply chain;

19.1.2 maintain relevant policy statements documenting the Supplier's significant social and environmental aspects as relevant to the Goods being supplied and as proportionate to the nature and scale of the Supplier's business operations; and

19.1.3 maintain plans and procedures that support the commitments made as part of the Supplier's significant social and environmental policies, as referred to at Clause 19.1.2 of this Schedule 2 of these Call-off Terms and Conditions.

19.2 The Supplier shall meet reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of Clause 19 of this Schedule 2 of these Call-off Terms and Conditions.

20 Electronic product information

20.1 Where requested by the Authority, the Supplier shall provide the Authority the Product Information in such manner and upon such media as agreed between the Supplier and the Authority from time to time for the sole use by the Authority.

20.2 The Supplier warrants that the Product Information is complete and accurate as at the date upon which it is delivered to the Authority and that the Product Information shall not contain any data or statement which gives rise to any liability on the part of the Authority following publication of the same in accordance with Clause 20 of this Schedule 2 of these Call-off Terms and Conditions.

20.3 If the Product Information ceases to be complete and accurate, the Supplier shall promptly notify the Authority in writing of any modification or addition to or any inaccuracy or omission in the Product Information.

20.4 The Supplier grants the Authority a perpetual, non-exclusive, royalty free licence to use and exploit the Product Information and any Intellectual Property Rights in the Product Information for the purpose of illustrating the range of goods and services (including, without limitation, the Goods) available pursuant to the Authority's contracts from time to time. Subject to Clause 20.5 of this Schedule 2 of these Call-

off Terms and Conditions, no obligation to illustrate or advertise the Product Information is imposed on the Authority, as a consequence of the licence conferred by this Clause 20.4 of this Schedule 2 of these Call-off Terms and Conditions.

20.5 The Authority may reproduce for its sole use the Product Information provided by the Supplier in the Authority's product catalogue from time to time which may be made available on any NHS communications networks in electronic format and/or made available on the Authority's external website and/or made available on other digital media from time to time.

20.6 Before any publication of the Product Information (electronic or otherwise) is made by the Authority, the Authority will submit a copy of the relevant sections of the Authority's product catalogue to the Supplier for approval, such approval not to be unreasonably withheld or delayed. For the avoidance of doubt the Supplier shall have no right to compel the Authority to exhibit the Product Information in any product catalogue as a result of the approval given by it pursuant to this Clause 20.6 of this Schedule 2 of these Call-off Terms and Conditions or otherwise under the terms of this Contract.

20.7 If requested in writing by the Authority, and to the extent not already agreed as part of the Specification and Tender Response Document, the Supplier and the Authority shall discuss and seek to agree in good faith arrangements to use any Electronic Trading System.

21 Change management

21.1 The Supplier acknowledges to the Authority that the Authority's requirements for the Goods may change during the Term and the Supplier shall not unreasonably withhold or delay its consent to any reasonable variation or addition to the Specification and Tender Response Document, as may be requested by the Authority from time to time.

21.2 Any change to the Goods or other variation to this Contract shall only be binding once it has been agreed in writing and signed by an authorised representative of both Parties.

22 Dispute resolution

22.1 During any dispute, including a dispute as to the validity of this Contract, it is agreed that the Supplier shall continue its performance of the provisions of the Contract (unless the Authority requests in writing that the Supplier does not do so).

22.2 In the case of a dispute arising out of or in connection with this Contract the Supplier and the Authority shall make every reasonable effort to communicate and cooperate with each other with a view to resolving the dispute and follow the procedure set out in Clause 22.3 of this Schedule 2 of these Call-off Terms and Conditions before commencing court proceedings.

22.3 If any dispute arises out of the Contract either Party may serve a notice on the other Party to commence formal resolution of the dispute. Level 1 of the management levels of the dispute as set out in Clause 5 of the Key Provisions will commence on the date of service of the dispute notice. Respective representatives, as set out in

Clause 5 of the Key Provisions, shall have five (5) Business Days at each level to resolve the dispute before escalating the matter to the next level as appropriate.

22.4 If the procedure set out in Clause 22.3 of this Schedule 2 of these Call-off Terms and Conditions above fails to resolve such dispute the Parties will attempt to settle it by mediation either: (a) with the Centre for Effective Dispute Resolution ("**CEDR**"); or (b) if agreed in writing by the Parties, with any other alternative mediation organisation, using the respective model procedures of CEDR or such other mediation organisation.

22.5 To initiate mediation a Party shall:

22.5.1 give notice in writing ("**Mediation Notice**") to the other Party requesting mediation of the dispute; and

22.5.2 send a copy of the Mediation Notice to CEDR or an equivalent mediation organisation as agreed by the Parties asking them to nominate a mediator if the Parties are not able to agree such appointment by negotiation.

22.6 Neither Party may issue a Mediation Notice until the process set out in Clause 22.3 of this Schedule 2 of these Call-off Terms and Conditions has been exhausted.

22.7 The mediation shall commence within twenty eight (28) days of the Mediation Notice being served. Neither Party will terminate such mediation until each Party has made its opening presentation and the mediator has met each Party separately for at least one hour or one Party has failed to participate in the mediation process. Neither Party will commence legal proceedings against the other until thirty (30) days after such mediation of the dispute in question has failed to resolve the dispute. The Authority and the Supplier will cooperate with any person appointed as mediator providing them with such information and other assistance as they shall require and will pay their costs, as they shall determine or in the absence of such determination such costs will be shared equally.

22.8 Nothing in this Contract shall prevent:

22.8.1 the Authority taking action in any court in relation to any death or personal injury arising or allegedly arising in connection with supply of the Goods; or

22.8.2 either Party seeking from any court any interim or provisional relief that may be necessary to protect the rights or property of that Party or that relates to the safety of patients or the security of Confidential Information, pending resolution of the relevant dispute in accordance with the CEDR or other mediation organisation procedure.

22.9 Clause 22 of this Schedule 2 of these Call-off Terms and Conditions shall survive the expiry of or earlier termination of this Contract for any reason.

23 Force majeure

23.1 Subject to Clause 23.2 of this Schedule 2 of these Call-off Terms and Conditions neither Party shall be liable to the other for any failure to perform all or any of its obligations under this Contract nor liable to the other Party for any loss or damage arising out of the failure to perform its obligations to the extent only that such performance is rendered impossible by a Force Majeure Event.

23.2 The Supplier shall only be entitled to rely on a Force Majeure Event and the relief set out in Clause 23 of this Schedule 2 of these Call-off Terms and Conditions and will not be considered to be in default or liable for breach of any obligations under this Contract if:

23.2.1 the Supplier has fulfilled its obligations pursuant to Clause 6 of this Schedule 2 of these Call-off Terms and Conditions;

23.2.2 the Force Majeure Event does not arise directly or indirectly as a result of any wilful or negligent act or default of the Supplier; and

23.2.3 the Supplier has complied with the procedural requirements set out in Clause 23 of this Schedule 2 of these Call-off Terms and Conditions.

23.3 Where a Party is (or claims to be) affected by a Force Majeure Event it shall use reasonable endeavours to mitigate the consequences of such a Force Majeure Event upon the performance of its obligations under this Contract and to resume the performance of its obligations affected by the Force Majeure Event as soon as practicable.

23.4 Where the Force Majeure Event affects the Supplier's ability to perform part of its obligations under the Contract the Supplier shall fulfil all such contractual obligations that are not so affected and shall not be relieved from its liability to do so.

23.5 If either Party is prevented or delayed in the performance of its obligations under this Contract by a Force Majeure Event, that Party shall as soon as reasonably practicable serve notice in writing on the other Party specifying the nature and extent of the circumstances giving rise to its failure to perform or any anticipated delay in performance of its obligations.

23.6 Subject to service of such notice, the Party affected by such circumstances shall have no liability for its failure to perform or for any delay in performance of its obligations affected by the Force Majeure Event only for so long as such circumstances continue and for such time after they cease as is necessary for that Party, using its best endeavours, to recommence its affected operations in order for it to perform its obligations.

23.7 The Party claiming relief shall notify the other in writing as soon as the consequences of the Force Majeure Event have ceased and of when performance of its affected obligations can be resumed.

23.8 If the Supplier is prevented from performance of its obligations as a result of a Force Majeure Event, the Authority may at any time if the Force Majeure Event subsists for thirty (30) days or more, terminate this Contract on service of written notice on the Supplier.

23.9 Following such termination in accordance with Clause 23.8 of this Schedule 2 of these Call-off Terms and Conditions and subject to Clause 23.10 of this Schedule 2 of these Call-off Terms and Conditions, neither Party shall have any liability to the other.

23.10 Any rights and liabilities of either Party which have accrued prior to such termination in accordance with Clause 23.8 of this Schedule 2 of these Call-off Terms and Conditions shall continue in full force and effect unless otherwise specified in this Contract.

24 Records retention and right of audit

24.1 Subject to any statutory requirement and Clause 24.2 of this Schedule 2 of these Call-off Terms and Conditions, the Supplier shall keep secure and maintain for the Term and six (6) years afterwards, or such longer period as may be agreed between the Parties, full and accurate records of all matters relating to this Contract.

24.2 Where any records could be relevant to a claim for personal injury such records shall be kept secure and maintained for a period of twenty one (21) years from the date of expiry or earlier termination of this Contract.

24.3 The Authority shall have the right to audit the Supplier's compliance with this Contract. The Supplier shall permit or procure permission for the Authority or its authorised representative during normal business hours having given advance written notice of no less than five (5) Business Days, access to any premises and facilities, books and records reasonably required to audit the Supplier's compliance with its obligations under this Contract.

24.4 Should the Supplier subcontract any of its obligations under this Contract, the Authority shall have the right to audit and inspect such third party. The Supplier shall procure permission for the Authority or its authorised representative during normal business hours no more than once in any twelve (12) months, having given advance written notice of no less than five (5) Business Days, access to any premises and facilities, books and records used in the performance of the Supplier's obligations under this Contract that are subcontracted to such third party. The Supplier shall cooperate with such audit and inspection and accompany the Authority or its authorised representative if requested.

24.5 The Supplier shall grant to the Authority or its authorised representative, such access to those records as they may reasonably require in order to check the Supplier's compliance with this Contract for the purposes of:

24.5.1 the examination and certification of the Authority's accounts; or

24.5.2 any examination pursuant to section 6(1) of the National Audit Act 1983 of the economic efficiency and effectiveness with which the Authority has used its resources.

24.6 The Comptroller and Auditor General may examine such documents as they may reasonably require which are owned, held or otherwise within the control of the Supplier and may require the Supplier to provide such oral and/or written explanations as they consider necessary. Clause 24 of this Schedule 2 of these Call-off Terms and Conditions does not constitute a requirement or agreement for the examination, certification or inspection of the accounts of the Supplier under sections 6(3)(d) and 6(5) of the National Audit Act 1983.

24.7 The Supplier shall provide reasonable cooperation to the Authority, its representatives and any regulatory body in relation to any audit, review, investigation or enquiry carried out in relation to the subject matter of this Contract.

24.8 The Supplier shall provide all reasonable information as may be reasonably requested by the Authority to evidence the Supplier's compliance with the requirements of this Contract.

25 Conflicts of interest and the prevention of fraud

25.1 The Supplier shall take appropriate steps to ensure that neither the Supplier nor any Staff are placed in a position where, in the reasonable opinion of the Authority, there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interests of the Supplier and the duties owed to the Authority under the provisions of this Contract. The Supplier will disclose to the Authority full particulars of any such conflict of interest which may arise.

25.2 The Authority reserves the right to terminate this Contract immediately by notice in writing and/or to take such other steps it deems necessary where, in the reasonable opinion of the Authority, there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interests of the Supplier and the duties owed to the Authority under the provisions of this Contract. The actions of the Authority pursuant to this Clause 25.2 of this Schedule 2 of these Call-off Terms and Conditions shall not prejudice or affect any right of action or remedy which shall have accrued or shall subsequently accrue to the Authority.

25.3 The Supplier shall take all reasonable steps to prevent Fraud by Staff and the Supplier (including its owners, members and directors). The Supplier shall notify the

Authority immediately if it has reason to suspect that any Fraud has occurred or is occurring or is likely to occur.

25.4 If the Supplier or its Staff commits Fraud the Authority may terminate this Contract and recover from the Supplier the amount of any direct loss suffered by the Authority resulting from the termination.

26 Equality and human rights

26.1 The Supplier shall:

26.1.1 ensure that (a) it does not, whether as employer or as supplier of the Goods, and any associated services engage in any act or omission that would contravene the Equality Legislation, and (b) it complies with all its obligations as an employer or supplier of the Goods and any associated services as set out in the Equality Legislation and take reasonable endeavours to ensure its Staff do not unlawfully discriminate within the meaning of the Equality Legislation;

26.1.2 in the management of its affairs and the development of its equality and diversity policies, cooperate with the Authority in light of the Authority's obligations to comply with its statutory equality duties whether under the Equality Act 2010 or otherwise. The Supplier shall take such reasonable and proportionate steps as the Authority considers appropriate to promote equality and diversity, including race equality, equality of opportunity for disabled people, gender equality, and equality relating to religion and belief, sexual orientation and age; and

26.1.3 the Supplier shall impose on all its subcontractors and suppliers, obligations substantially similar to those imposed on the Supplier by Clause 26 of this Schedule 2 of these Call-off Terms and Conditions.

26.2 The Supplier shall meet reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of Clause 26 of this Schedule 2 of these Call-off Terms and Conditions.

27 Notice

27.1 Any notice required to be given by either Party under this Contract shall be in writing quoting the date of the Contract and shall be delivered by hand or sent by prepaid first class recorded delivery or by email to the person referred to in the Order Form or such other person as one Party may inform the other Party in writing from time to time or to a director of the relevant Party at the head office, main UK office or registered office of such Party.

27.2 A notice shall be treated as having been received:

27.2.1 if delivered by hand within normal business hours when so delivered or, if delivered by hand outside normal business hours, at the next start of normal business hours; or

27.2.2 if sent by first class recorded delivery mail on a normal Business Day, at 9.00 am on the second Business Day subsequent to the day of posting, or, if the notice was not posted on a Business Day, at 9.00 am on the third Business Day subsequent to the day of posting; or

27.2.3 if sent by email, if sent within normal business hours when so sent or, if sent outside normal business hours, at the next start of normal business hours provided the sender has either received an electronic confirmation of delivery or has telephoned the recipient to inform the recipient that the email has been sent.

28 Assignment, novation and subcontracting

28.1 The Supplier shall not, except where Clause 28.2 of this Schedule 2 of these Call-off Terms and Conditions applies, assign, subcontract, novate, create a trust in, or in any other way dispose of the whole or any part of this Contract without the prior consent in writing of the Authority, such consent not to be unreasonably withheld or delayed. If the Supplier subcontracts any of its obligations under this Contract, every act or omission of the subcontractor shall for the purposes of this Contract be deemed to be the act or omission of the Supplier and the Supplier shall be liable to the Authority as if such act or omission had been committed or omitted by the Supplier itself.

28.2 Notwithstanding Clause 28.1 of this Schedule 2 of these Call-off Terms and Conditions, the Supplier may assign to a third party ("**Assignee**") the right to receive payment of any sums due and owing to the Supplier under this Contract for which an invoice has been issued. Any assignment under this Clause 28.2 of this Schedule 2 of these Call-off Terms and Conditions shall be subject to:

28.2.1 the deduction of any sums in respect of which the Authority exercises its right of recovery under Clause 9.8 of this Schedule 2 of these Call-off Terms and Conditions;

28.2.2 all related rights of the Authority in relation to the recovery of sums due but unpaid;

28.2.3 the Authority receiving notification of the assignment and the date upon which the assignment becomes effective together with the Assignee's contact information and bank account details to which the Authority shall make payment;

28.2.4 the provisions of Clause 9 of this Schedule 2 of these Call-off Terms and Conditions continuing to apply in all other respects after the assignment

which shall not be amended without the prior written approval of the Authority; and

28.2.5 payment to the Assignee being full and complete satisfaction of the Authority's obligation to pay the relevant sums in accordance with this Contract.

28.3 Any authority given by the Authority for the Supplier to subcontract any of its obligations under this Contract shall not impose any duty on the Authority to enquire as to the competency of any authorised subcontractor. The Supplier shall ensure that any authorised subcontractor has the appropriate capability and capacity to perform the relevant obligations and that the obligations carried out by such subcontractor are fully in accordance with this Contract.

28.4 Where the Supplier enters into a subcontract in respect of any of its obligations under this Contract relating to the manufacture, supply, delivery or installation of or training in relation to the Goods, the Supplier shall include provisions in each such subcontract, unless otherwise agreed with the Authority in writing, which:

28.4.1 contain at least equivalent obligations as set out in this Contract in relation to such manufacture, supply, delivery or installation of or training in relation to the Goods to the extent relevant to such subcontracting;

28.4.2 contain at least equivalent obligations as set out in this Contract in respect of confidentiality, information security, data protection, Intellectual Property Rights, compliance with Law and Guidance and record keeping;

28.4.3 contain a prohibition on the subcontractor subcontracting, assigning or novating any of its rights or obligations under such subcontract without the prior written approval of the Authority (such approval not to be unreasonably withheld or delayed);

28.4.4 contain a right for the Authority to take an assignment or novation of the subcontract (or part of it) upon expiry or earlier termination of this Contract; and

28.4.5 require payment to be made of all sums due to the subcontractor from the Supplier within a specified period not exceeding thirty (30) days from receipt by the Supplier of a valid invoice.

28.5 Where the Authority pays the Supplier's undisputed invoices earlier than thirty (30) days from receipt in accordance with any applicable government prompt payment targets, the Supplier shall use its reasonable endeavours to pay its relevant subcontractors within a comparable timeframe from receipt by the Supplier of such undisputed invoices from its subcontractors.

28.6 The Authority shall upon written request have the right to review any subcontract entered into by the Supplier in respect of the provision of the Goods and the Supplier shall provide a certified copy of any subcontract within five (5) Business Days of the date of a written request from the Authority. For the avoidance of doubt, the Supplier shall have the right to redact any confidential pricing information in relation to such copies of subcontracts.

28.7 The Authority may at any time transfer, assign, novate, subcontract or otherwise dispose of its rights and obligations under this Contract or any part of this Contract and the Supplier warrants that it will carry out all such reasonable further acts required to effect such transfer, assignment, novation, subcontracting or disposal. If the Authority novates this Contract to any body that is not a Contracting Authority, from the effective date of such novation, the party assuming the position of the Authority shall not further transfer, assign, novate, subcontract or otherwise dispose of its rights and obligations under this Contract or any part of this Contract without the prior written consent of the Supplier, such consent not to be unreasonably withheld or delayed by the Supplier.

29 Prohibited Acts

29.1 The Supplier warrants and represents that:

29.1.1 it has not committed any offence under the Bribery Act 2010 or done any of the following ("**Prohibited Acts**"):

(i) offered, given or agreed to give any officer or employee of the Authority any gift or consideration of any kind as an inducement or reward for doing or not doing or for having done or not having done any act in relation to the obtaining or performance of this or any other agreement with the Authority or for showing or not showing favour or disfavour to any person in relation to this or any other agreement with the Authority; or

(ii) in connection with this Contract paid or agreed to pay any commission other than a payment, particulars of which (including the terms and conditions of the agreement for its payment) have been disclosed in writing to the Authority; and

29.1.2 it has in place adequate procedures to prevent bribery and corruption, as contemplated by section 7 of the Bribery Act 2010.

29.2 If the Supplier or its Staff (or anyone acting on its or their behalf) has done or does any of the Prohibited Acts or has committed or commits any offence under the Bribery Act 2010 with or without the knowledge of the Supplier in relation to this or any other agreement with the Authority:

29.2.1 the Authority shall be entitled:

(i) to terminate this Contract and recover from the Supplier the amount of any loss resulting from the termination;

(ii) to recover from the Supplier the amount or value of any gift, consideration or commission concerned; and

(iii) to recover from the Supplier any other loss or expense sustained in consequence of the carrying out of the Prohibited Act or the commission of the offence under the Bribery Act 2010;

29.2.2 any termination under Clause 29.2.1 of this Schedule 2 of these Call-off Terms and Conditions shall be without prejudice to any right or remedy that has already accrued, or subsequently accrues, to the Authority; and

29.2.3 notwithstanding Clause 22 of this Schedule 2 of these Call-off Terms and Conditions, any dispute relating to:

(i) the interpretation of Clause 29 of this Schedule 2 of these Call-off Terms and Conditions; or

(ii) the amount or value of any gift, consideration or commission,

shall be determined by the Authority, acting reasonably, and the decision shall be final and conclusive.

30 General

30.1 Each of the Parties is independent of the other and nothing contained in this Contract shall be construed to imply that there is any relationship between the Parties of partnership or of principal/agent or of employer/employee nor are the Parties hereby engaging in a joint venture and accordingly neither of the Parties shall have any right or authority to act on behalf of the other nor to bind the other by agreement or otherwise, unless expressly permitted by the terms of this Contract.

30.2 Failure or delay by either Party to exercise an option or right conferred by this Contract shall not of itself constitute a waiver of such option or right.

30.3 The delay or failure by either Party to insist upon the strict performance of any provision, term or condition of this Contract or to exercise any right or remedy consequent upon such breach shall not constitute a waiver of any such breach or any subsequent breach of such provision, term or condition.

30.4 Any provision of this Contract which is held to be invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining provisions of this

Contract and any such invalidity or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provisions in any other jurisdiction.

30.5 Each Party acknowledges and agrees that it has not relied on any representation, warranty or undertaking (whether written or oral) in relation to the subject matter of this Contract and therefore irrevocably and unconditionally waives any rights it may have to claim damages against the other Party for any misrepresentation or undertaking (whether made carelessly or not) or for breach of any warranty unless the representation, undertaking or warranty relied upon is set out in this Contract or unless such representation, undertaking or warranty was made fraudulently.

30.6 Each Party shall bear its own expenses in relation to the preparation and execution of this Contract including all costs, legal fees and other expenses so incurred.

30.7 The rights and remedies provided in this Contract are cumulative and not exclusive of any rights or remedies provided by general law, or by any other contract or document. In this Clause 30.7 of this Schedule 2 of these Call-off Terms and Conditions, right includes any power, privilege, remedy, or proprietary or security interest.

30.8 A person who is not a party to this Contract shall have no right to enforce any terms of it which confer a benefit on such person. No such person shall be entitled to object to or be required to consent to any amendment to the provisions of this Contract.

30.9 This Contract, any variation in writing signed by an authorised representative of each Party and any document referred to (explicitly or by implication) in this Contract or any variation to this Contract, contain the entire understanding between the Supplier and the Authority relating to the supply of the Goods to the exclusion of all previous agreements, confirmations and understandings and there are no promises, terms, conditions or obligations whether oral or written, express or implied other than those contained or referred to in this Contract. Nothing in this Contract seeks to exclude either Party's liability for Fraud.

30.10 This Contract, and any dispute or claim arising out of or in connection with it or its subject matter (including any non-contractual claims), shall be governed by, and construed in accordance with, the laws of England and Wales.

30.11 Subject to Clause 22 of this Schedule 2 of these Call-off Terms and Conditions, the Parties irrevocably agree that the courts of England and Wales shall have non-exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this Contract or its subject matter.

30.12 All written and oral communications and all written material referred to under this Contract shall be in English.

Schedule 3 of these Call-off Terms and Conditions

Information Governance Provisions

1 Confidentiality

1.1 In respect of any Confidential Information it may receive directly or indirectly from the other Party ("**Discloser**") and subject always to the remainder of Clause 1 of this Schedule 3 of these Call-off Terms and Conditions, each Party ("**Recipient**") undertakes to keep secret and strictly confidential and shall not disclose any such Confidential Information to any third party without the Discloser's prior written consent provided that:

1.1.1 the Recipient shall not be prevented from using any general knowledge, experience or skills which were in its possession prior to the Commencement Date;

1.1.2 the provisions of Clause 1 of this Schedule 3 of these Call-off Terms and Conditions shall not apply to any Confidential Information:

(i) which is in or enters the public domain other than by breach of this Contract or other act or omissions of the Recipient;

(ii) which is obtained from a third party who is lawfully authorised to disclose such information without any obligation of confidentiality;

(iii) which is authorised for disclosure by the prior written consent of the Discloser;

(iv) which the Recipient can demonstrate was in its possession without any obligation of confidentiality prior to receipt of the Confidential Information from the Discloser; or

(v) which the Recipient is required to disclose purely to the extent to comply with the requirements of any relevant stock exchange.

1.2 Nothing in Clause 1 of this Schedule 3 of these Call-off Terms and Conditions shall prevent the Recipient from disclosing Confidential Information where it is required to do so by judicial, administrative, governmental or regulatory process in connection with any action, suit, proceedings or claim or otherwise by applicable Law, including the Freedom of Information Act 2000 ("**FOIA**"), Codes of Practice on Access to Government Information, on the Discharge of Public Authorities' Functions or on the Management of Records ("**Codes of Practice**") or the Environmental Information Regulations 2004 ("**Environmental Regulations**").

1.3 The Authority may disclose the Supplier's Confidential Information:

1.3.1 on a confidential basis, to any Contracting Authority (the Parties agree that all Contracting Authorities receiving such Confidential Information shall be entitled to further disclose the Confidential Information to other Contracting Authorities on the basis that the information is confidential and is not to be disclosed to a third party which is not part of any Contracting Authority);

1.3.2 on a confidential basis, to any consultant, contractor or other person engaged by the Authority and/or the Contracting Authority receiving such information;

1.3.3 to any relevant party for the purpose of the examination and certification of the Authority's accounts;

1.3.4 to any relevant party for any examination pursuant to section 6(1) of the National Audit Act 1983 of the economy, efficiency and effectiveness with which the Authority has used its resources;

1.3.5 to Parliament and Parliamentary Committees or if required by any Parliamentary reporting requirements; or

1.3.6 on a confidential basis, to a proposed successor body in connection with any proposed or actual, assignment, novation or other disposal of rights, obligations, liabilities or property in connection with this Contract;

and for the purposes of this Contract, references to disclosure "on a confidential basis" shall mean the Authority making clear the confidential nature of such information and that it must not be further disclosed except in accordance with Law or this Clause 1.3 of this Schedule 3 of these Call-off Terms and Conditions.

1.4 The Supplier may only disclose the Authority's Confidential Information, and any other information provided to the Supplier by the Authority in relation to this Contract, to the Supplier's Staff or professional advisors who are directly involved in the performance of or advising on the Supplier's obligations under this Contract. The Supplier shall ensure that such Staff or professional advisors are aware of and shall comply with the obligations in Clause 1 of this Schedule 3 of these Call-off Terms and Conditions as to confidentiality and that all information, including Confidential Information, is held securely, protected against unauthorised use or loss and, at the Authority's written discretion, destroyed securely or returned to the Authority when it is no longer required. The Supplier shall not, and shall ensure that the Staff do not, use any of the Authority's Confidential Information received otherwise than for the purposes of performing the Supplier's obligations in this Contract.

1.5 For the avoidance of doubt, save as required by Law or as otherwise set out in this Schedule 3 of these Call-off Terms and Conditions, the Supplier shall not, without the prior written consent of the Authority (such consent not to be unreasonably withheld or delayed), announce that it has entered into this Contract and/or that it has been

appointed as a Supplier to the Authority and/or make any other announcements about this Contract.

1.6 Clause 1 of this Schedule 3 of these Call-off Terms and Conditions shall remain in force:

1.6.1 without limit in time in respect of Confidential Information which comprises Personal Data, Sensitive Personal Data or which relates to national security; and

1.6.2 for all other Confidential Information for a period of three (3) years after the expiry or earlier termination of this Contract unless otherwise agreed in writing by the Parties.

2 Data protection

2.1 The Parties acknowledge their respective duties under Data Protection Legislation and shall give each other all reasonable assistance as appropriate or necessary to enable each other to comply with those duties.

2.2 Where the Supplier is Processing Personal Data under or in connection with this Contract, the Supplier must, in particular, but without limitation:

2.2.1 only Process such Personal Data as is necessary to perform its obligations under this Contract, and only in accordance with any instructions given by the Authority under this Contract;

2.2.2 put in place appropriate technical and organisational measures against any unauthorised or unlawful Processing of that Personal Data, and against the accidental loss or destruction of or damage to such Personal Data having regard to the specific requirements of Clause 2 of this Schedule 3 of these Call-off Terms and Conditions, the state of technical development and the level of harm that may be suffered by a Data Subject whose Personal Data is affected by unauthorised or unlawful Processing or by its loss, damage or destruction;

2.2.3 take reasonable steps to ensure the reliability of Staff who will have access to Personal Data, and ensure that those Staff are aware of and trained in the policies and procedures identified in Clause 2 of this Schedule 3 of these Call-off Terms and Conditions; and

2.2.4 not cause or allow Personal Data to be transferred outside the European Economic Area without the prior consent of the Authority.

2.3 The Supplier and the Authority shall ensure that Personal Data is safeguarded at all times in accordance with the Law, and this obligation will include (if transferred electronically) only transferring Personal Data (a) if essential, having regard to the

purpose for which the transfer is conducted; and (b) that is encrypted in accordance with any international data encryption standards for healthcare, and as otherwise required by those standards applicable to the Authority under any Law and Guidance (this includes, data transferred over wireless or wired networks, held on laptops, CDs, memory sticks and tapes).

2.4 Where any Personal Data is Processed by any subcontractor of the Supplier in connection with this Contract, the Supplier shall procure that such subcontractor shall comply with the relevant obligations set out in Clause 2 of this Schedule 3 of these Call-off Terms and Conditions, as if such subcontractor were the Supplier.

2.5 The Supplier shall indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings whatsoever or howsoever arising from the Supplier's unlawful or unauthorised Processing, destruction and/or damage to Personal Data in connection with this Contract.

3 Freedom of Information and Transparency

3.1 The Parties acknowledge the duties of Contracting Authorities under the FOIA, Codes of Practice and Environmental Regulations and shall give each other all reasonable assistance as appropriate or necessary to enable compliance with those duties.

3.2 The Supplier shall assist and cooperate with the Authority to enable it to comply with its disclosure obligations under the FOIA, Codes of Practice and Environmental Regulations. The Supplier agrees:

3.2.1 that this Contract and any recorded information held by the Supplier on the Authority's behalf for the purposes of this Contract are subject to the obligations and commitments of the Authority under the FOIA, Codes of Practice and Environmental Regulations;

3.2.2 that the decision on whether any exemption to the general obligations of public access to information applies to any request for information received under the FOIA, Codes of Practice and Environmental Regulations is a decision solely for the Authority;

3.2.3 that where the Supplier receives a request for information under the FOIA, Codes of Practice and Environmental Regulations and the Supplier itself is subject to the FOIA, Codes of Practice and Environmental Regulations it will liaise with the Authority as to the contents of any response before a response to a request is issued and will promptly (and in any event within two (2) Business Days) provide a copy of the request and any response to the Authority;

3.2.4 that where the Supplier receives a request for information under the FOIA, Codes of Practice and Environmental Regulations and the Supplier is not itself subject to the FOIA, Codes of Practice and Environmental Regulations, it will not respond to that request (unless directed to do so by the Authority) and will promptly (and in any event within two (2) Business Days) transfer the request to the Authority;

3.2.5 that the Authority, acting in accordance with the Codes of Practice issued and revised from time to time under both section 45 of FOIA, and regulation 16 of the Environmental Regulations, may disclose information concerning the Supplier and this Contract; and

3.2.6 to assist the Authority in responding to a request for information, by processing information or environmental information (as the same are defined in FOIA and the Environmental Regulations) in accordance with a records management system that complies with all applicable records management recommendations and codes of conduct issued under section 46 of FOIA, and providing copies of all information requested by the Authority within five (5) Business Days of that request and without charge.

3.3 The Parties acknowledge that, except for any information which is exempt from disclosure in accordance with the provisions of the FOIA, Codes of Practice and Environmental Regulations, the content of this Contract is not Confidential Information.

3.4 Notwithstanding any other term of this Contract, the Supplier consents to the publication of this Contract in its entirety (including variations), subject only to the redaction of information that is exempt from disclosure in accordance with the provisions of the FOIA, Codes of Practice and Environmental Regulations.

3.5 In preparing a copy of this Contract for publication under Clause 3.4 of this Schedule 3 of these Call-off Terms and Conditions, the Authority may consult with the Supplier to inform decision making regarding any redactions but the final decision in relation to the redaction of information will be at the Authority's absolute discretion.

3.6 The Supplier shall assist and cooperate with the Authority to enable the Authority to publish this Contract.

3.7 Where any information is held by any subcontractor of the Supplier in connection with this Contract, the Supplier shall procure that such subcontractor shall comply with the relevant obligations set out in Clause 3 of this Schedule 3 of these Call-off Terms and Conditions, as if such subcontractor were the Supplier.

4 Information Security

4.1 Without limitation to any other information governance requirements set out in this Schedule 3 of these Call-off Terms and Conditions, the Supplier shall:

4.1.1 notify the Authority forthwith of any information security breaches or near misses (including without limitation any potential or actual breaches of confidentiality or actual information security breaches) in line with the Authority's information governance Policies; and

4.1.2 fully cooperate with any audits or investigations relating to information security and any privacy impact assessments undertaken by the Authority and shall provide full information as may be reasonably requested by the Authority in relation to such audits, investigations and assessments.

Schedule 4 of these Call-off Terms and Conditions

Definitions and Interpretations

1 Definitions

1.1 In this Contract the following words shall have the following meanings unless the context requires otherwise:

"Authority"	means the authority named on the Order Form;
"Authority's Obligations"	means the Authority's further obligations, if any, referred to in the Specification and Tender Response Document and/or the Order Form;
"Business Continuity Event"	means any event or issue that could impact on the operations of the Supplier and its ability to supply the Goods including an influenza pandemic and any Force Majeure Event;
"Business Continuity Plan"	means the Supplier's business continuity plan which includes its plans for continuity of the supply of the Goods during a Business Continuity Event;
"Business Day"	means any day other than Saturday, Sunday, Christmas Day, Good Friday or a statutory bank holiday in England and Wales;
"Call-off Terms and Conditions"	means these Call-off Terms and Conditions for the Supply of Goods;
"Codes of Practice"	shall have the meaning given to the term in Clause 1.2 of Schedule 3 of these Call-off Terms and Conditions;
"Commencement Date"	means the date of the Order Form;
"Confidential Information"	means information, data and material of any nature, which either Party may receive or obtain in connection with the conclusion and/or operation of the Contract including any procurement process which is: (a) Personal Data or Sensitive Personal Data including without limitation which relates to any patient or other service user or his or her treatment or clinical or care history; (b) designated as confidential by either party or that ought reasonably to be considered as confidential (however it is conveyed or on whatever media it is stored); and/or (c) Policies and such other documents which the Supplier may obtain or have access to through the Authority's intranet;

"Contract"	means the Order Form, the provisions on the front page and all Schedules of these Call-off Terms and Conditions, the Specification and Tender Response Document and the applicable provisions of the Framework Agreement;
"Contracting Authority"	means any contracting authority as defined in Regulation 3 of the Public Contracts Regulations 2006 (SI 2006/5) (as amended), other than the Authority;
"Contract Manager"	means for the Authority and for the Supplier the individuals specified in the Order Form or as otherwise agreed between the Parties in writing or such other person notified by a Party to the other Party from time to time in accordance with Clause 8.1 of Schedule 2 of these Call-off Terms and Conditions;
"Contract Price"	means the price exclusive of VAT that is payable to the Supplier by the Authority under the Contract for the full and proper performance by the Supplier of its obligations under the Contract calculated in accordance with the provisions of the Framework Agreement and as confirmed in the Order Form;
"Data Protection Legislation"	means the Data Protection Act 1998 and any other Law relating to the protection of personal data and the privacy of individuals, including where applicable guidance and codes of practice issued by the Information Commissioner;
"Data Subject"	shall have the same meaning as set out in the Data Protection Act 1998;
"Defective Goods"	has the meaning given under Clause 4.6 of Schedule 2 of these Call-off Terms and Conditions;
"Dispute Resolution Procedure"	means the process for resolving disputes as set out in Clause 22 of Schedule 2 of these Call-off Terms and Conditions;
"DOTAS"	means the Disclosure of Tax Avoidance Schemes rules which require a promoter of tax schemes to tell HM Revenue and Customs of any specified notifiable arrangements or proposals and to provide prescribed information on those arrangements or proposals within set time limits as contained in Part 7 of the Finance Act 2004 and in secondary legislation made under vires contained in Part 7 of the Finance Act 2004 and as extended to National Insurance Contributions by the National Insurance Contributions (Application of Part 7 of the Finance Act 2004) Regulations 2012, SI 2012/1868 made under s.132A Social Security Administration Act 1992;
"Electronic Trading System(s)"	means such electronic data interchange system and/or world wide web application and/or other application with such message standards and protocols as the Authority may specify from time to time;

"Environmental Regulations"	shall have the meaning given to the term in Clause 1.2 of Schedule 3 of these Call-off Terms and Conditions;
"eProcurement Guidance"	means the NHS eProcurement Strategy available via: http://www.gov.uk/government/collections/nhs-procurement together with any further Guidance issued by the Department of Health in connection with it;
"Equality Legislation"	means any and all legislation, applicable guidance and statutory codes of practice relating to equality, diversity, non-discrimination and human rights as may be in force in England and Wales from time to time including, but not limited to, the Equality Act 2010, the Part-time Workers (Prevention of Less Favourable Treatment) Regulations 2000 and the Fixed-term Employees (Prevention of Less Favourable Treatment) Regulations 2002 (SI 2002/2034) and the Human Rights Act 1998;
"FOIA"	shall have the meaning given to the term in Clause 1.2 of Schedule 3 of these Call-off Terms and Conditions;
"Force Majeure Event"	means any event beyond the reasonable control of the Party in question to include, without limitation: (a) war including civil war (whether declared or undeclared), riot, civil commotion or armed conflict materially affecting either Party's ability to perform its obligations under this Contract; (b) acts of terrorism; (c) flood, storm or other natural disasters; (d) fire; (e) unavailability of public utilities and/or access to transport networks to the extent no diligent supplier could reasonably have planned for such unavailability as part of its business continuity planning; (f) government requisition or impoundment to the extent such requisition or impoundment does not result from any failure by the Supplier to comply with any relevant regulations, laws or procedures (including such laws or regulations relating to the payment of any duties or taxes) and subject to the Supplier having used all reasonable legal means to resist such requisition or impoundment; (g) compliance with any local law or governmental order, rule, regulation or direction that could not have been reasonably foreseen; (h) industrial action which affects the ability of the Supplier to supply the Goods, but which is not confined to the workforce of the Supplier or the workforce of any subcontractor of the

	Supplier; and (i) a failure in the Supplier's and/or Authority's supply chain to the extent that such failure is due to any event suffered by a member of such supply chain, which would also qualify as a Force Majeure Event in accordance with this definition had it been suffered by one of the Parties;
"Framework Agreement"	means the Framework Agreement referred to in the Order Form;
"Fraud"	means any offence under any law in respect of fraud in relation to this Contract or defrauding or attempting to defraud or conspiring to defraud the government, parliament or any Contracting Authority;
"General Anti-Abuse Rule"	means (a) the legislation in Part 5 of the Finance Act 2013; and (b) any future legislation introduced into parliament to counteract tax advantages arising from abusive arrangements to avoid national insurance contributions;
"Good Industry Practice"	means the exercise of that degree of skill, diligence, prudence, risk management, quality management and foresight which would reasonably and ordinarily be expected from a skilled and experienced supplier engaged in the manufacture and/or supply of goods similar to the Goods under the same or similar circumstances as those applicable to this Contract, including in accordance with any codes of practice published by relevant trade associations;
"Goods"	means all goods, materials or items that the Supplier is required to supply to the Authority under this Contract;
"Guidance"	means any applicable guidance, direction or determination and any policies, advice or industry alerts which apply to the Goods, to the extent that the same are published and publicly available or the existence or contents of them have been notified to the Supplier by the Authority and/or have been published and/or notified to the Supplier by the Department of Health, Monitor, NHS England, the Medicines and Healthcare Products Regulatory Agency, the European Medicine Agency the European Commission, the Care Quality Commission and/or any other regulator or competent body;
"Halifax Abuse Principle"	means the principle explained in the CJEU Case C-255/02 Halifax and others;
"Intellectual Property Rights"	means all patents, copyright, design rights, registered designs, trade marks, know-how, database rights, confidential formulae and any other intellectual property rights and the rights to apply

	for patents and trade marks and registered designs;
"Key Provisions"	means the key provisions set out in Schedule 1 of these Call-off Terms and Conditions and/or as part of the Order Form;
"KPI"	means the key performance indicators as set out in the Specification and Tender Response Document and/or the Order Form, if any;
"Law"	means: (a) any applicable statute or proclamation or any delegated or subordinate legislation or regulation; (b) any applicable European Union directive, regulation, decision or law; (c) any enforceable community right within the meaning of section 2(1) European Communities Act 1972; (d) any applicable judgment of a relevant court of law which is a binding precedent in England and Wales; (e) requirements set by any regulatory body; and (f) any applicable code of practice, in each case as applicable in England and Wales;
"Mediation Notice"	has the meaning given under Clause 22.5.1 of Schedule 2 of these Call-off Terms and Conditions;
"NHS"	means the National Health Service;
"Occasion of Tax Non-Compliance"	means: (a) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 is found on or after 1 April 2013 to be incorrect as a result of: (i) a Relevant Tax Authority successfully challenging the Supplier under the General Anti-Abuse Rule or the Halifax Abuse Principle or under any tax rules or legislation that have an effect equivalent or similar to the General Anti-Abuse Rule or the Halifax Abuse Principle; (ii) the failure of an avoidance scheme which the Supplier was involved in, and which was, or should have been, notified to a Relevant Tax Authority under the DOTAS or any equivalent or similar regime; and/or (b) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 gives rise, on or after 1 April 2013, to a criminal conviction in any jurisdiction for tax related offences which is not spent at the Effective Date or to a civil penalty for fraud or evasion;
"Order Form"	means the order form for the Goods issued by the Authority in

	accordance with the Framework Agreement;
"Party"	means the Authority or the Supplier as appropriate and Parties means both the Authority and the Supplier;
"Personal Data"	means personal data as defined in the Data Protection Act 1998;
"Policies"	means the policies, rules and procedures of the Authority as notified to the Supplier from time to time;
"Process"	has the meaning given to it under the Data Protection Legislation and, for the purposes of this Contract, it shall include both manual and automatic processing. Processing and Processed shall be construed accordingly;
"Product Information"	means information concerning the Goods as may be reasonably requested by the Authority and supplied by the Supplier to the Authority in accordance with Clause 20 of Schedule 2 of these Call-off Terms and Conditions for inclusion in the Authority's product catalogue from time to time;
"Rejected Goods"	has the meaning given under Clause 4.2 of Schedule 2 of these Call-off Terms and Conditions;
"Relevant Tax Authority"	means HM Revenue and Customs, or, if applicable, a tax authority in the jurisdiction in which the Supplier is established;
"Remedial Proposal"	has the meaning given under Clause 15.3 of Schedule 2 of these Call-off Terms and Conditions;
"Requirement to Recall"	has the meaning given under 4.9 of Schedule 2 of these Call-off Terms and Conditions;
"Sensitive Personal Data"	means sensitive personal data as defined in the Data Protection Act 1998;
"Specification and Tender Response Document"	means the Specification and Tender Response Document set out in the Framework Agreement as supplemented by any further information set out and/or referred to in the Order Form and as amended and/or updated in accordance with this Contract;
"Staff"	means all persons employed or engaged by the Supplier to perform its obligations under this Contract including any subcontractors and person employed or engaged by such subcontractors;
"Supplier"	means the supplier named on the Order Form;
"Term"	means the term as referred to in the Key Provisions;

"Third Party Body"	has the meaning given under Clause 8.5 of Schedule 2 of these Call-off Terms and Conditions; and
"VAT"	means value added tax chargeable under the Value Added Tax Act 1994 or any similar, replacement or extra tax.

1.2 References to any statute or order shall include any statutory extension, modification or re-enactment, and any order, regulation, bye-law or other subordinate legislation.

1.3 References to any legal entity shall include any body that takes over responsibility for the functions of such entity.

1.4 References in this Contract to a "Schedule", "Appendix", "Paragraph" or to a "Clause" are to schedules, appendices, paragraphs and clauses of this Contract.

1.5 References in this Contract to a day or to the calculation of time frames are references to a calendar day unless expressly specified as a Business Day.

1.6 Unless set out in the Contract as a chargeable item and subject to Clause 30.6 of Schedule 2 of these Call-off Terms and Conditions, the Supplier shall bear the cost of complying with its obligations under this Contract.

1.7 The headings are for convenience only and shall not affect the interpretation of this Contract.

1.8 Words denoting the singular shall include the plural and vice versa.

1.9 Where a term of this Contract provides for a list of one or more items following the word "including" or "includes" then such list is not to be interpreted as an exhaustive list. Any such list shall not be treated as excluding any item that might have been included in such list having regard to the context of the contractual term in question. General words are not to be given a restrictive meaning where they are followed by examples intended to be included within the general words.

1.10 Where there is a conflict between the Supplier's responses to the requirements set out in the Specification and Tender Response Document and any other part of this Contract, such other part of this Contract shall prevail.

1.11 Where a document is required under this Contract, the Parties may agree in writing that this shall be in electronic format only.

Aptima SARS-CoV-2 Assay (Panther™ System)

For Research Use Only.

Not for use in diagnostic procedures.

CONTENTS

General Information

Intended Use

The Aptima SARS-CoV-2 assay is a nucleic acid amplification test intended for the qualitative detection of RNA from SARS-CoV-2 isolated and purified from nasopharyngeal (NP), nasal and oropharyngeal (OP) swab specimens.

The Aptima SARS-CoV-2 Assay on the Panther and Panther Fusion system is intended for use by laboratory personnel specifically instructed and trained in the operation of the Panther and Panther Fusion system.

Summary and Explanation of the Test

Coronaviruses are a large family of viruses which may cause illness in animals or humans. In humans, several coronaviruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The most recently discovered coronavirus, SARS-CoV-2, causes the associated coronavirus disease COVID-19. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019.[1]

The most common symptoms of COVID-19 are fever, tiredness, and dry cough. Some patients may have aches and pains, nasal congestion, runny nose, sore throat, or diarrhea. These symptoms are usually mild and begin gradually. Some people become infected but don't develop any symptoms and don't feel unwell. The disease can spread through respiratory droplets produced when an infected person coughs or sneezes. These droplets land on objects and surfaces around the person. Other people may acquire SARS-CoV-2 by touching these objects or surfaces, then touching their eyes, nose, or mouth.

The virus that causes COVID-19 is infecting people and spreading easily from person to person. On March 11, 2020, the COVID-19 outbreak was characterized as a pandemic by the World Health Organization (WHO).[3,4]

Principles of the Procedure

The Aptima SARS-CoV-2 assay combines the technologies of target capture, Transcription Mediated Amplification (TMA), and Dual Kinetic Assay (DKA).

Specimens are collected and transferred into their respective specimen transport tubes. The transport solutions in these tubes release the RNA target and protect them from degradation during storage. When the Aptima SARS-CoV-2 assay is performed in the laboratory, the target RNA molecules are isolated from specimens by use of capture oligomers via target capture that utilizes magnetic microparticles. The capture oligomers contain sequences complementary to specific regions of the target molecules as well as a string of deoxyadenosine residues. A separate capture oligomer is used for each target. During the hybridization step, the sequence specific regions of the capture oligomers bind to specific regions of the target molecules. The capture oligomer:target complex is then captured out of solution by decreasing the temperature of the reaction to room temperature. This temperature reduction allows hybridization to occur between the deoxyadenosine region on the capture oligomer and the poly-deoxythymidine molecules that are covalently attached to the magnetic particles. The microparticles, including the captured target molecules bound to them, are pulled to the side of the reaction vessel using

magnets and the supernatant is aspirated. The particles are washed to remove residual specimen matrix that may contain amplification reaction inhibitors. After the target capture steps are completed, the specimens are ready for amplification.

Target amplification assays are based on the ability of complementary oligonucleotide primers to specifically anneal and allow enzymatic amplification of the target nucleic acid strands. The Aptima SARS-CoV-2 assay replicates specific regions of the RNA from SARS-CoV-2 virus. Detection of the RNA amplification product sequences (amplicon) is achieved using nucleic acid hybridization. Single-stranded chemiluminescent nucleic acid probes, which are unique and complementary to a region of each target amplicon and Internal Control (IC) amplicon, are labeled with different acridinium ester (AE) molecules. The AE labeled probes combine with amplicon to form stable hybrids. The Selection Reagent differentiates hybridized from unhybridized probe, eliminating the generation of signal from unhybridized probe. During the detection step, light emitted from the labeled hybrids is measured as photon signals in a luminometer, and are reported as Relative Light Units (RLU). In DKA, differences in the kinetic profiles of the labeled probes allow for the differentiation of signal; kinetic profiles are derived from measurements of photon output during the detection read time. The chemiluminescent detection reaction for the IC signal has very rapid kinetics and has the “flasher” kinetic type. The chemiluminescent detection reaction for the SARS-CoV-2 signal is relatively slower and has the “glower” kinetic type. Assay results are determined by a cut-off based on the total RLU and the kinetic curve type.

Warnings and Precautions

A. For research use only. Carefully read this entire package insert and the *Panther/Panther Fusion System Operator’s Manual*.

B. Only personnel adequately trained on the use of this assay and in handling potentially infectious materials should perform these procedures. If a spill occurs, immediately disinfect using appropriate site procedures.

C. Handle all specimens as if infectious using safe laboratory procedures. Refer to Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019-nCoV. https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html.

D. Specimens may be infectious. Use Universal Precautions when performing this assay. Proper handling and disposal methods should be established by the laboratory director. Only personnel adequately trained in handling infectious materials should be permitted to perform this diagnostic procedure.[5]

E. If infection with SARS-CoV-2 is suspected based on current clinical screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions.

F. Use only supplied or specified disposable laboratory ware.

G. Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of being infected with SARS-CoV-2 as outlined in CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019 Novel Coronavirus (2019-nCoV).

H. Wear disposable, powderless gloves, protective eye wear, and laboratory coats when handling specimens and reagents. Wash hands thoroughly after handling specimens and reagents.

I. Dispose of all material that has come into contact with specimens and reagents in accordance with applicable national, international, and regional regulations.

J. Expiration dates listed on the Panther Specimen Lysis Tubes and Multitest Collection Kit pertain to the transfer of sample into the tube and not to testing of the sample. Specimens collected/transferred any time prior to these expiration dates are valid for testing provided they are transported and stored in accordance with the appropriate package insert, even if these expiration dates have passed.

K. Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen. Specimen stability under shipping conditions other than those recommended has not been evaluated.

L. Avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of virus or other organisms. Ensure that specimen containers do not come in contact with one another, and discard used materials without passing them over any open containers. Change gloves if they come in contact with specimens.

M. Do not use the reagents and controls after the expiration date.

N. Store assay components at the recommended storage condition. See *Reagent Storage and Handling Requirements (*page 5), and *Panther System Test Procedure* (page 10) for more information.

O. Do not combine any assay reagents or fluids. Do not top off reagents or fluids; the Panther system verifies reagent levels.

P. Avoid microbial and ribonuclease contamination of reagents.

Q. Quality control requirements must be performed in conformance with local, state, and/or federal regulations or accreditation requirements and your laboratory's standard quality control procedures.

R. Do not use material that may contain Guanidinium thiocyanate or any guanidine-containing materials on the instrument. Highly reactive and/or toxic compounds may form if combined with sodium hypochlorite.

S. A reagent in this kit is labeled with risk and safety symbols.

Note: *For information on any hazard and precautionary statements that may be associated with reagents, refer to the Safety Data Sheet Library at www.hologicsds.com.*

Selection Reagent
BORIC ACID 1-5%
WARNING
H315 - Causes skin irritation
H319 - Causes serious eye irritation
P264 - Wash face, hands and any exposed skin thoroughly after handling
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313 - If eye irritation persists: Get medical advice/attention
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P332 + P313 - If skin irritation occurs: Get medical advice/attention
P362 - Take off contaminated clothing and wash before reuse

Reagent Storage and Handling Requirements

A. The following reagents are stable when stored at 2°C to 8°C (refrigerated):
   Aptima SARS-CoV-2 Amplification Reagent
   Aptima SARS-CoV-2 Enzyme Reagent
   Aptima SARS-CoV-2 Probe Reagent
   Aptima SARS-CoV-2 Internal Control
   Aptima SARS-CoV-2 Positive Control
   Aptima SARS-CoV-2 Negative Control

B. The following reagents are stable when stored at 2°C to 30°C:
   Aptima SARS-CoV-2 Amplification Reconstitution Solution
   Aptima SARS-CoV-2 Enzyme Reconstitution Solution
   Aptima SARS-CoV-2 Probe Reconstitution Solution
   Aptima SARS-CoV-2 Selection Reagent

C. The following reagents are stable when stored at 15°C to 30°C (room temperature):
   Aptima SARS-CoV-2 Target Capture Reagent
   Aptima Wash Solution
   Aptima Buffer for Deactivation Fluid
   Aptima Oil Reagent

D. Working Target Capture Reagent (wTCR) is stable for 30 days when stored at 15°C to 30°C. Do not refrigerate.

E. After reconstitution, the Enzyme Reagent, Amplification Reagent, and Probe Reagent are stable for 30 days when stored at 2°C to 8°C.

F. Discard any unused reconstituted reagents and wTCR after 30 days or after the Master Lot expiration date, whichever comes first.

G. Controls are stable until the date indicated on the vials.

H. Reagents stored on-board the Panther System have 72 hours of on-board stability.

I. The Probe Reagent and Reconstituted Probe Reagent are photosensitive. Store the reagents protected from light. The specified reconstituted stability is based on 12 hours exposure of the Reconstituted Probe Reagent to two 60W fluorescent bulbs, at a distance of 17 inches (43 cm), and temperature less than 30°C. Light exposure of the Reconstituted Probe Reagent should be limited accordingly.

J. Upon warming to room temperature, some control tubes may appear cloudy or contain precipitates. Cloudiness or precipitation associated with controls does not affect control performance. The controls may be used whether they are clear or cloudy/precipitated. If clear controls are desired, solubilization may be expedited by incubating them at the upper end of the room temperature range (15°C to 30°C).

K. Do not freeze the reagents.

Specimen Collection and Storage

Specimens - Clinical material collected from patient placed in an appropriate transport system. For the Aptima SARS-CoV-2 assay, this includes NP, nasal and OP swab specimens in viral transport medium (VTM/UTM), saline, Liquid Amies, or specimen transport medium (STM).

Samples - Represents a more generic term to describe any material for testing on the Panther System including specimens, specimens transferred into a Panther Specimen Lysis Tube and controls.

Note: *Handle all specimens as if they contain potentially infectious agents. Use Universal Precautions.*

Note: *Take care to avoid cross-contamination during specimen handling steps. For example, discard used material without passing over open tubes.*

A. Swab Specimen collection

Collect NP swab, nasal swab, and OP swab specimens according to standard technique using a polyester-, rayon-, or nylon-tipped swab. Immediately place the swab specimen into 3mL of VTM or UTM. Swab specimens may alternatively be added to saline, Liquid Amies or STM. The Aptima Multitest Swab Specimen Collection Kit may be used for the collection of OP and nasal swab samples.

The following types of VTM/UTM were verified for use.

- Remel MicroTest M4, M4RT, M5 or M6 formulations
- Copan Universal Transport Medium
- BD Universal Viral Transport Medium

B. Specimen processing

1. Prior to testing on the Panther system, transfer specimen* to a Panther Specimen Lysis Tube, except for specimens collected in the Multitest Tube which requires no additional processing.
   - Transfer 500 µL of the collected specimen to a Panther Specimen Lysis Tube.

     ***Note:** When testing frozen specimen, allow specimen to reach room temperature prior to processing.*
2. Storing specimens before testing

a. After collection, specimens collected in VTM/UTM, saline, or Liquid Amies can be stored at 2°C to 8°C up to 96 hours before transferred to the Panther Specimen Lysis Tube. Remaining specimen volumes can be stored at ≤-70°C.

b. Specimens in the Panther Specimen Lysis Tube or Multitest Tube may be stored under one of the following conditions:

- 15°C to 30°C up to 6 days or
- 2°C to 8°C up to 3 months.

Note: *It is recommended that specimens transferred to the Panther Specimen Lysis Tube and specimens in the Multitest Tube are stored capped and upright in a rack.*

C. Samples on board the Panther system may be archived for additional testing at a later time.

D. Storing samples after testing

1. Samples that have been assayed should be stored upright in the rack under one of the following conditions:
   - 15°C to 30°C up to 6 days or
   - 2°C to 8°C up to 3 months.
2. The samples should be covered with a new, clean plastic film or foil barrier.
3. If assayed samples need to be frozen or shipped, remove the penetrable cap and place a new non-penetrable cap on the specimen tubes. If samples need to be shipped for testing at another facility, recommended temperatures must be maintained. Prior to uncapping previously tested and recapped samples, specimen transport tubes must be centrifuged for 5 minutes at 420 Relative Centrifugal Force (RCF) to bring all of the liquid down to the bottom of the tube. Avoid splashing and cross-contamination.

Specimen Transport

Maintain specimen storage conditions as described in the *Specimen Collection and Storage section on* page 6.

Note: *Specimens must be shipped in accordance with applicable national, international, and regional transportation regulations.*

Panther System

Reagents for the Aptima SARS-CoV-2 assay are listed below for the Panther System. Reagent Identification Symbols are also listed next to the reagent name.

Reagents and Materials Provided

Aptima SARS-CoV-2 Assay Kit PRD-06495

250 tests (2 boxes and 1 Controls kit (Cat. No. PRD-06496)

Aptima SARS-CoV-2 Refrigerated Box (Box 1 of 2)
(store at 2°C to 8°C upon receipt)

Symbol	Component	Quantity 250 test kit
A	**Aptima SARS-CoV-2 Amplification Reagent** *Non-infectious nucleic acids dried in buffered solution containing < 5% bulking agent.*	1 vial
E	**Aptima SARS-CoV-2 Enzyme Reagent** *Reverse transcriptase and RNA polymerase dried in HEPES buffered solution containing < 10% bulking reagent.*	1 vial
P	**Aptima SARS-CoV-2 Probe Reagent** *Non-infectious chemiluminescent DNA probes dried in succinate buffered solution containing < 5% detergent.*	1 vial
IC	**Aptima SARS-CoV-2 Internal Control**	1 vial

Aptima SARS-CoV-2 Room Temperature Box (Box 2 of 2)
(store at 15°C to 30°C upon receipt)

Symbol	Component	Quantity 250 test kit
AR	**Aptima SARS-CoV-2 Amplification Reconstitution Solution** *Aqueous solution containing preservatives.*	1 x 27.7 mL
ER	**Aptima SARS-CoV-2 Enzyme Reconstitution Solution** *HEPES buffered solution containing a surfactant and glycerol.*	1 x 11.1 mL
PR	**Aptima SARS-CoV-2 Probe Reconstitution Solution** *Succinate buffered solution containing < 5% detergent.*	1 x 35.4 mL
S	**Aptima SARS-CoV-2 Selection Reagent** *600 mM borate buffered solution containing surfactant.*	1 x 108 mL
TCR	**Aptima SARS-CoV-2 Target Capture Reagent** *Buffered salt solution containing solid phase and capture oligomers.*	1 x 54 mL
	Reconstitution Collars	3
	Master Lot Barcode Sheet	1 sheet

Aptima SARS-CoV-2 Controls Kit
(store at 2°C to 8°C upon receipt)

Symbol	Component	Quantity
PC	**Aptima SARS-CoV-2 Positive Control** *Non-infectious nucleic acid in a buffered solution containing < 5% detergent.*	5 x 1.7 mL
NC	**Aptima SARS-CoV-2 Negative Control** *A buffered solution containing < 5% detergent.*	5 x 1.7 mL

Materials Required and Available Separately

Note: *Materials available from Hologic have catalog numbers listed, unless otherwise specified.*

	Cat. No.
Panther System	303095
Aptima Assay Fluids Kit *(Aptima Wash Solution, Aptima Buffer for Deactivation Fluid, and Aptima Oil Reagent)*	303014 (1000 tests)
Aptima Auto Detect Kit	303013 (1000 tests)
Multi-tube units (MTUs)	104772-02
Panther Waste Bag Kit	902731
Panther Waste Bin Cover	504405
Or Panther Run Kit *contains MTUs, waste bags, waste bin covers, assay fluids, and auto detects*	303096 (5000 tests)
Tips, 1000 µL conductive, liquid sensing	10612513 (Tecan)
Aptima Multitest Swab Specimen Collection Kit	PRD-03546
Panther Specimen Lysis Tubes, 100 per bag	PRD-04339
Bleach, 5% to 7% (0.7M to 1.0M) sodium hypochlorite solution	—
Disposable gloves	—
SysCheck calibration standard	301078
Aptima penetrable caps	105668
Replacement non-penetrable caps	103036A
Replacement Caps for the 250-test kits	—
Amplification and Probe reagent reconstitution solutions	*CL0041 (100 caps)*
Enzyme Reagent reconstitution solution	*501616 (100 caps)*
TCR and Selection reagent	*CL0040 (100 caps)*

Optional Materials

	Cat. No.
Hologic Bleach Enhancer for Cleaning *for routine cleaning of surfaces and equipment*	302101
Tube rocker	—

Panther System Test Procedure

Note: *Refer to the Panther/Panther System Operator's Manual for additional procedural information.*

A. Work Area Preparation

Clean work surfaces where reagents and samples will be prepared. Wipe down work surfaces with 2.5% to 3.5% (0.35M to 0.5M) sodium hypochlorite solution. Allow the sodium hypochlorite solution to contact surfaces for at least 1 minute and then follow with a water rinse. Do not allow the sodium hypochlorite solution to dry. Cover the bench surface on which the reagents and samples will be prepared with clean, plastic-backed absorbent laboratory bench covers.

B. Reagent Reconstitution/Preparation of a New Kit

Note: *Reagent reconstitution should be performed prior to beginning any work on the Panther System.*

1. To reconstitute Amplification, Enzyme, and Probe Reagents, combine the bottles of lyophilized reagent with the reconstitution solution. If refrigerated, allow the reconstitution solutions to reach room temperature before use.
   a. Pair each reconstitution solution with its lyophilized reagent. Ensure that the reconstitution solution and reagent have matching label colors before attaching the reconstitution collar.
   b. Check the lot numbers on the Master Lot Barcode Sheet to ensure that the appropriate reagents are paired.
   c. Open the lyophilized reagent vial and firmly insert the notched end of the reconstitution collar into the vial opening (Figure , Step 1).
   d. Open the matching reconstitution solution, and set the cap on a clean, covered work surface.
   e. While holding the reconstitution solution bottle on the bench, firmly insert the other end of the reconstitution collar into the bottle opening (Figure , Step 2).
   f. Slowly invert the assembled bottles. Allow the solution to drain from the bottle into the glass vial (Figure , Step 3).
   g. Thoroughly mix the solution in the glass vial by swirling (Figure , Step 4).
   h. Wait for the lyophilized reagent to go into solution, then invert the assembled bottles again, tilting at a 45° angle to minimize foaming (Figure , Step 5). Allow all of the liquid to drain back into the plastic bottle.
   i. Remove the reconstitution collar and glass vial (Figure , Step 6).

j. Recap the plastic bottle. Record operator initials and reconstitution date on the label (Figure , Step 7).

k. Discard the reconstitution collar and glass vial (Figure , Step 8).

Option: Additional mixing of the Amplification, Enzyme, and Probe Reagents using a tube rocker is allowed. The reagents may be mixed by placing the recapped plastic bottle on a tube rocker set to 20 RPM (or equivalent) for a minimum of 5 minutes.

Warning: *Avoid creating foam when reconstituting reagents. Foam compromises the level-sensing in the Panther System.*

Warning: *Adequate mixing of the reagents is necessary to achieve expected assay results.*

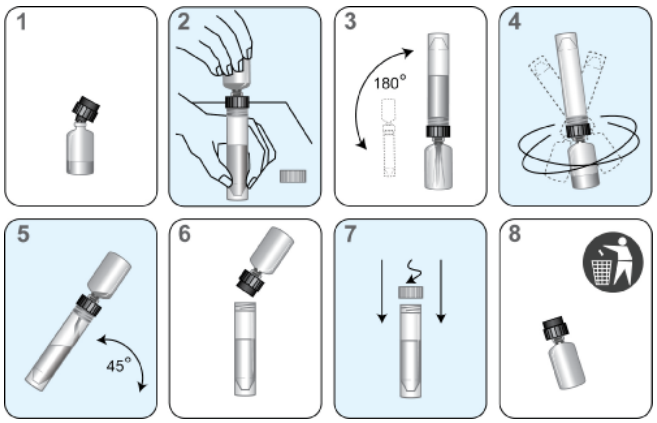


Figure 1. Panther System Reconstitution Process

2. Prepare Working Target Capture Reagent (wTCR)
   a. Pair the appropriate bottles of TCR and IC.
   b. Check the reagent lot numbers on the Master Lot Barcode Sheet to make sure that the appropriate reagents in the kit are paired.
   c. Open the bottle of TCR, and set the cap on a clean, covered work surface.
   d. Open the IC bottle and pour the entire contents into the bottle of TCR. Expect a small amount of liquid to remain in the IC bottle.
   e. Cap the bottle of TCR and gently swirl the solution to mix the contents. Avoid creating foam during this step.
   f. Record operator initials and the current date on the label.
   g. Discard the IC bottle and cap.
3. Prepare Selection Reagent
   a. Check the lot number on the reagent bottle to make sure it matches the lot number on the Master Lot Barcode Sheet.
   b. Record operator initials and the current date on the label.

Note: *Thoroughly mix by gently inverting all reagents prior to loading on the system. Avoid creating foam during inversion of reagents.*

C. Reagent Preparation for Previously Reconstituted Reagents

1. Previously reconstituted Amplification, Enzyme, and Probe Reagents must reach room temperature (15°C to 30°C) prior to the start of the assay.

   Option: The reagents may be brought to room temperature by placing the reconstituted Amplification, Enzyme, and Probe Reagents on a tube rocker set to 20 RPM (or equivalent) for a minimum of 25 minutes.

2. If reconstituted Probe Reagent contains precipitate that does not return to solution at room temperature, heat the capped bottle at a temperature that does not exceed 62°C for 1 to 2 minutes. After this heat step, the Probe Reagent may be used even if residual precipitate remains. Mix Probe Reagent by inversion, being careful not to induce foam, prior to loading onto the system.
3. Thoroughly mix each reagent by gently inverting prior to loading on the system. Avoid creating foam during inversion of reagents. This step is not required if reagents are loaded onto the system directly after mixing on the tube rocker.
4. Do not top off reagent bottles. The Panther System will recognize and reject bottles that have been topped off.
5. *Adequate mixing of the reagents is necessary to achieve expected assay results.*

D. Specimen Handling

Note: *Prepare specimens per the Specimen Processing instructions in the Specimen Collection and Storage section before loading specimens onto the Panther system.*

1. **Do not vortex samples.**
2. Inspect sample tubes before loading into the rack. If a sample tube contains bubbles or has a lower volume than is typically observed, gently tap the bottom of the tube to bring contents to the bottom.

Note: *To avoid a processing error, ensure adequate specimen volume is added to the Panther Specimen Lysis Tube. When 500 µL of collected specimen is added to the Panther Specimen Lysis Tube, there is sufficient volume to perform 3 nucleic acid extractions.*

E. System Preparation

1. Set up the system according to the instructions in the *Panther/Panther Fusion System Operator's Manual* and *Procedural Notes*. Make sure that the appropriately sized reagent racks and TCR adapters are used.
2. Load samples.

Procedural Notes

A. Controls

1. To work properly with the Aptima Assay software for the Panther System, one pair of controls is required. The Aptima SARS-CoV-2 positive and negative controls can be loaded in any rack position or in any Sample Bay Lane on the Panther System. Patient specimen pipetting will begin when one of the following two conditions has been met:
   a. A pair of controls is currently being processed by the system.
   b. Valid results for the controls are registered on the system.
2. Once the control tubes have been pipetted and are processing for a specific reagent kit, patient specimens can be run with the associated kit up to 24 hours unless:
   a. Controls results are invalid.
   b. The associated assay reagent kit is removed from the system.
   c. The associated assay reagent kit has exceeded stability limits.
3. Each Aptima control tube can be tested once. Attempts to pipette more than once from the tube can lead to processing errors.
4. Patient specimen pipetting begins when one of the following two conditions is met:
   a. Valid results for the controls are registered on the system.
   b. A pair of controls is currently in process on the system.

B. Temperature

Room temperature is defined as 15°C to 30°C.

C. Glove Powder

As in any reagent system, excess powder on some gloves may cause contamination of opened tubes. Powderless gloves are recommended.

D. Lab Contamination Monitoring Protocol for the Panther System

There are many laboratory-specific factors that may contribute to contamination, including testing volume, workflow, disease prevalence and various other laboratory activities. These factors should be taken into consideration when contamination monitoring frequency is being established. Intervals for contamination monitoring should be established based on each laboratory's practices and procedures.

To monitor for laboratory contamination, the following procedure may be performed using the Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens:

1. Label swab transport tubes with numbers corresponding to the areas to be tested.
2. Remove the specimen collection swab (blue shaft swab with green printing) from its packaging, wet the swab in the specimen transport medium (STM), and swab the designated area using a circular motion.
3. Immediately insert the swab into transport tube.
4. Carefully break the swab shaft at the score line; use care to avoid splashing of the contents.
5. Recap the swab transport tube tightly.
6. Repeat Steps 2 to 5 for each area to be swabbed.

E. If the results are positive , see *Interpretation of Results*. For additional Panther System-specific contamination monitoring information, contact Hologic Technical Support.

Quality Control

A run or specimen result may be invalidated by the Panther System if problems occur while performing the assay. Specimens with invalid results must be retested.

Negative and Positive Controls

To generate valid results, a set of assay controls must be tested. One replicate of the negative assay control and positive assay control must be tested each time a new kit lot is loaded on the Panther system or when the current set of valid controls have expired.

The Panther system is configured to require assay controls run at an administrator-specified interval of up to 30 days. Software on the Panther system alerts the operator when assay controls are required and does not start new tests until the assay controls are loaded and have started processing.

During processing, criteria for acceptance of the assay controls are automatically verified by the Panther system. To generate valid results, the assay controls must pass a series of validity checks performed by the Panther system.

If the assay controls pass all validity checks, they are considered valid for the administrator-specified time interval. When the time interval has passed, the assay controls are expired by the Panther system which requires a new set of assay controls be tested prior to starting any new samples.

If any one of the assay controls fails the validity checks, the Panther system automatically invalidates the affected samples and requires a new set of assay controls be tested prior to starting any new samples.

Internal Control

An internal control is added to each sample with the wTCR. During processing, the internal control acceptance criteria are automatically verified by the Panther system software. Detection of the internal control is not required for samples that are positive for SARS-CoV-2. The internal control must be detected in all samples that are negative for SARS-CoV-2 targets; samples that fail to meet that criteria will be reported as Invalid. Each sample with an Invalid result must be retested.

The Panther system is designed to accurately verify processes when procedures are performed following the instructions provided in this package insert and the *Panther/Panther Fusion System Operator's Manual.*

Interpretation of Results

The Panther system automatically determines the test results for samples and controls. A test result may be negative, positive, or invalid.

Table1 shows the possible results reported in a valid run with result interpretations.

Table 1: Result Interpretation

SARS-CoV-2 Result	IC Result	Interpretation
Neg	Valid	SARS-CoV-2 not detected.
POS	Valid	SARS-CoV-2 detected.
Invalid	Invalid	Invalid. There was an error in the generation of the result; retest sample.

Note: Detection of internal control is not required for samples that are positive for SARS-CoV-2.

Limitations

A. Use of this assay is limited to personnel who are trained in the procedure. Failure to follow these instructions may result in erroneous results.

B. Reliable results are dependent on adequate specimen collection, transport, storage, and processing.

C. Avoid contamination by adhering to good laboratory practices and to the procedures specified in this package insert.

D. For Research Use Only. Not for use in diagnostic procedures.

E. A positive result indicates the detection of nucleic acid from the relevant virus. Nucleic acid may persist even after the virus is no longer viable.

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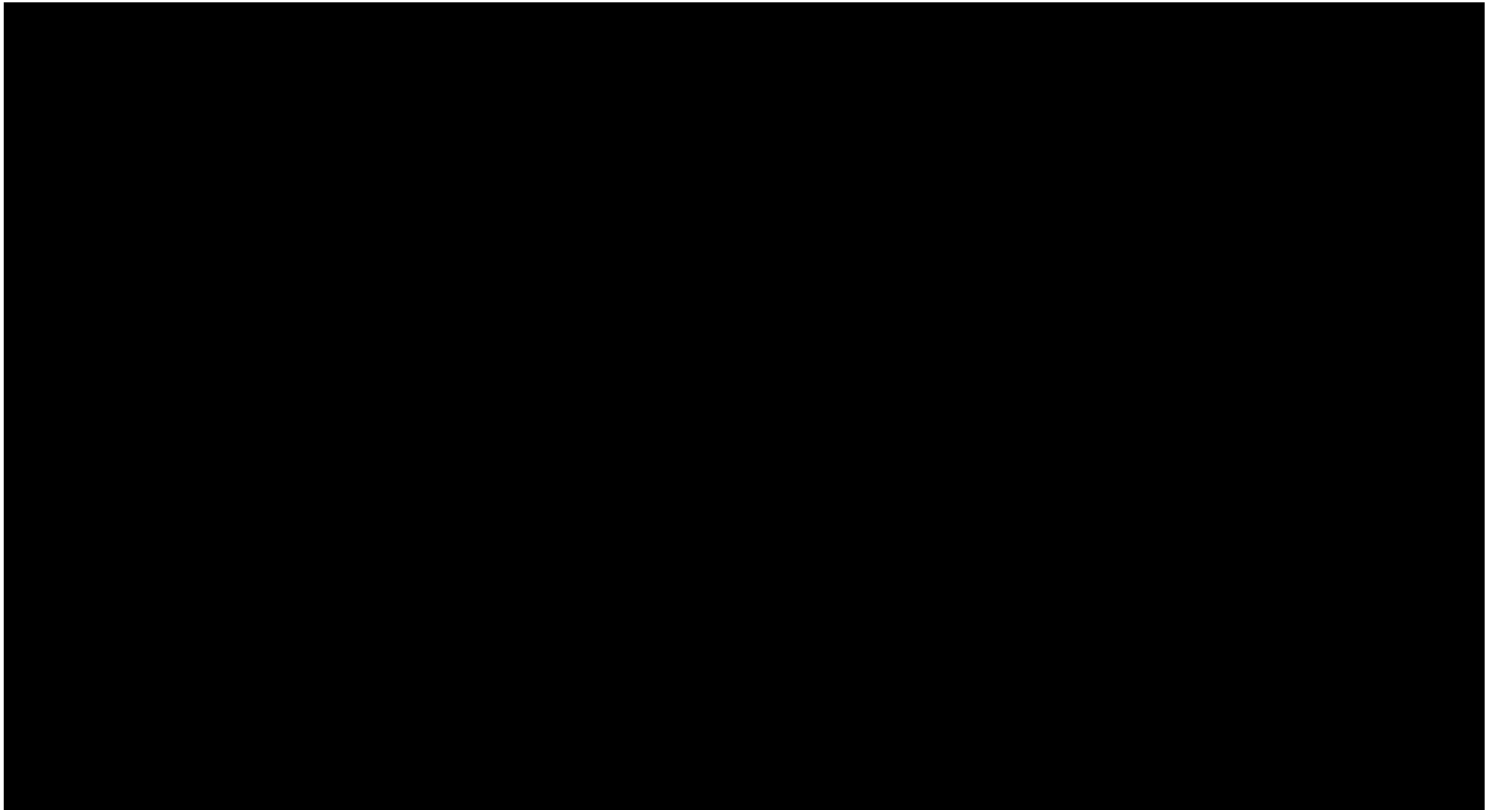
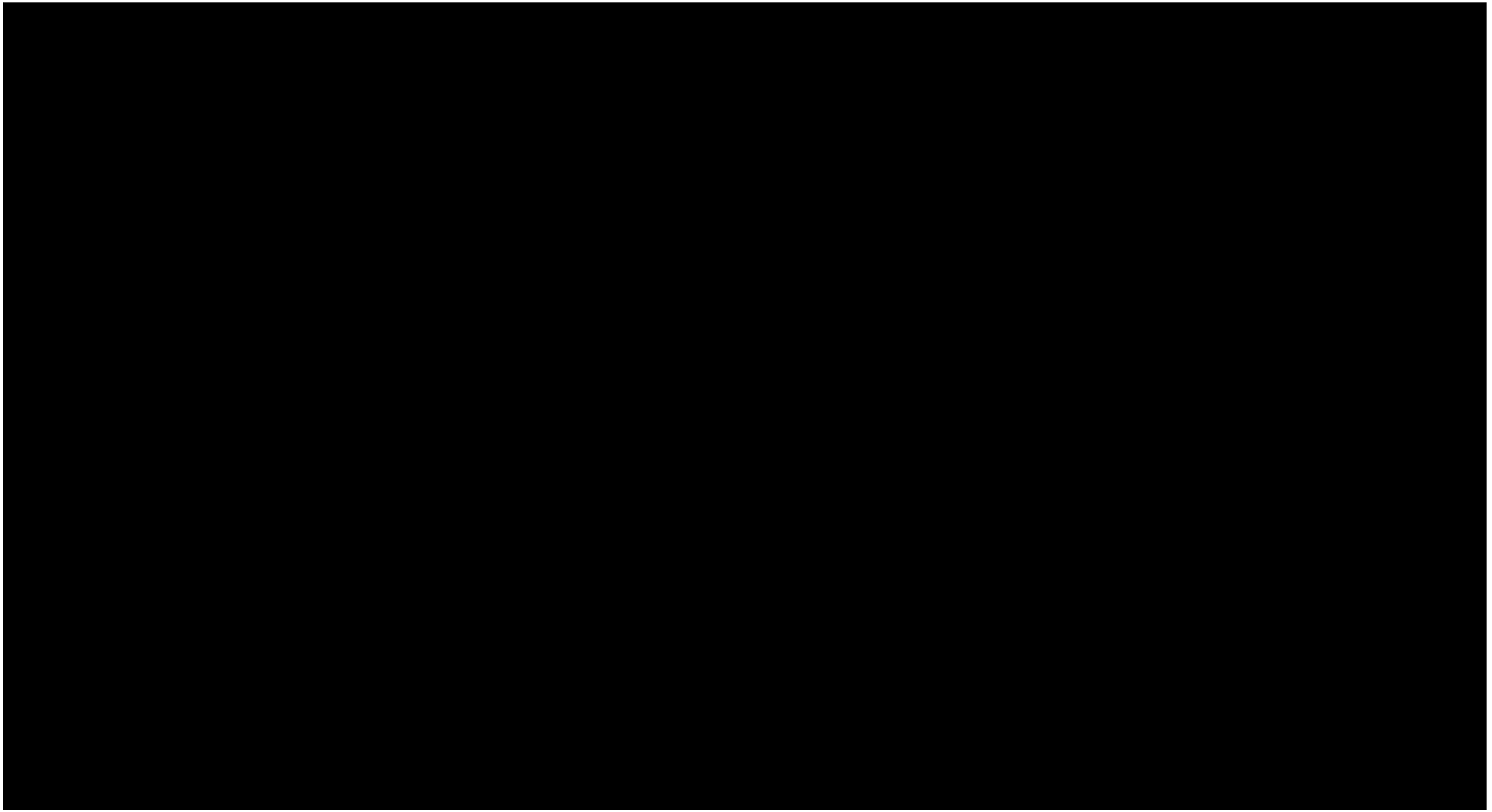
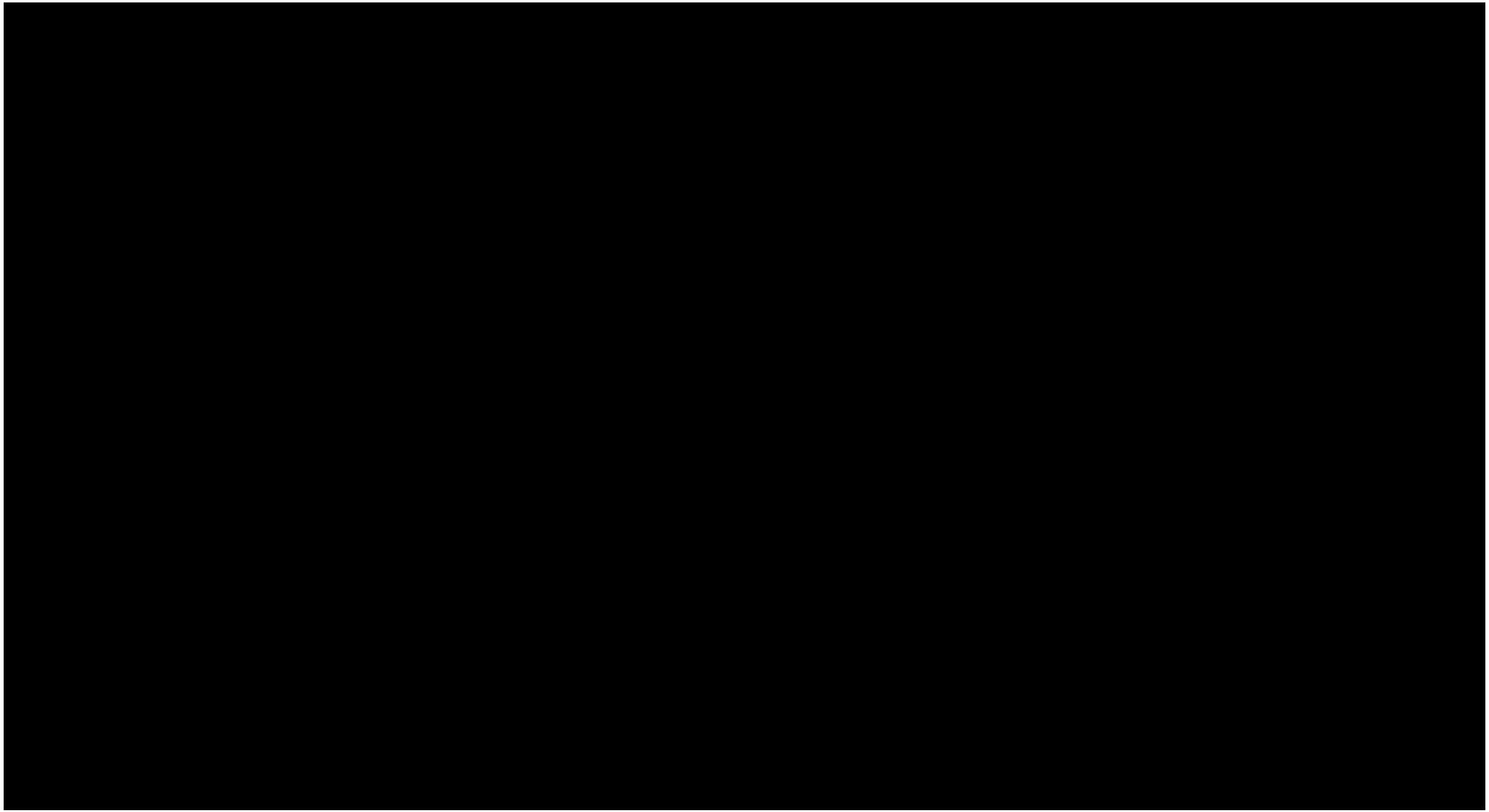
2020-04





Assay In development, Not for Sale



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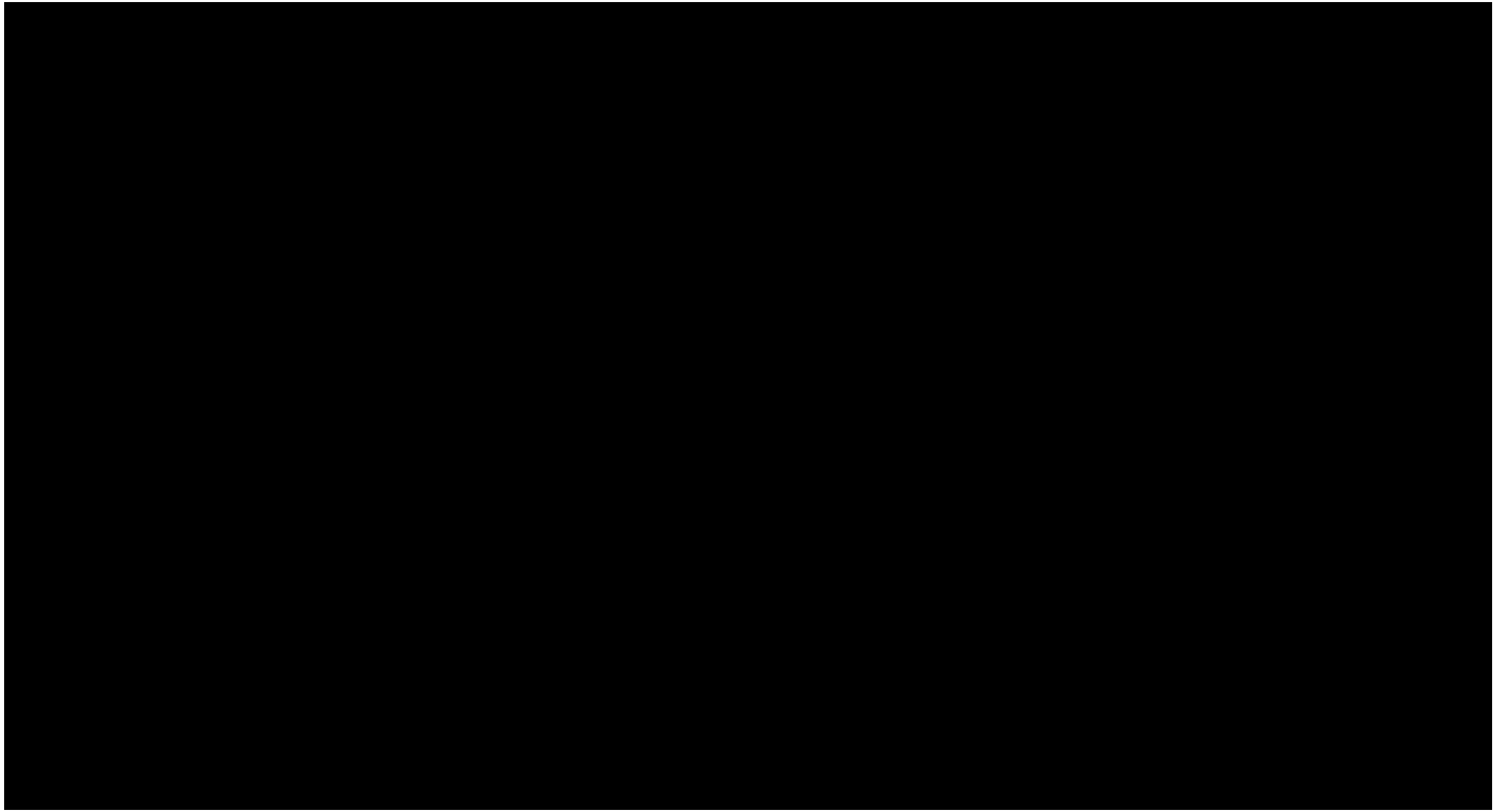

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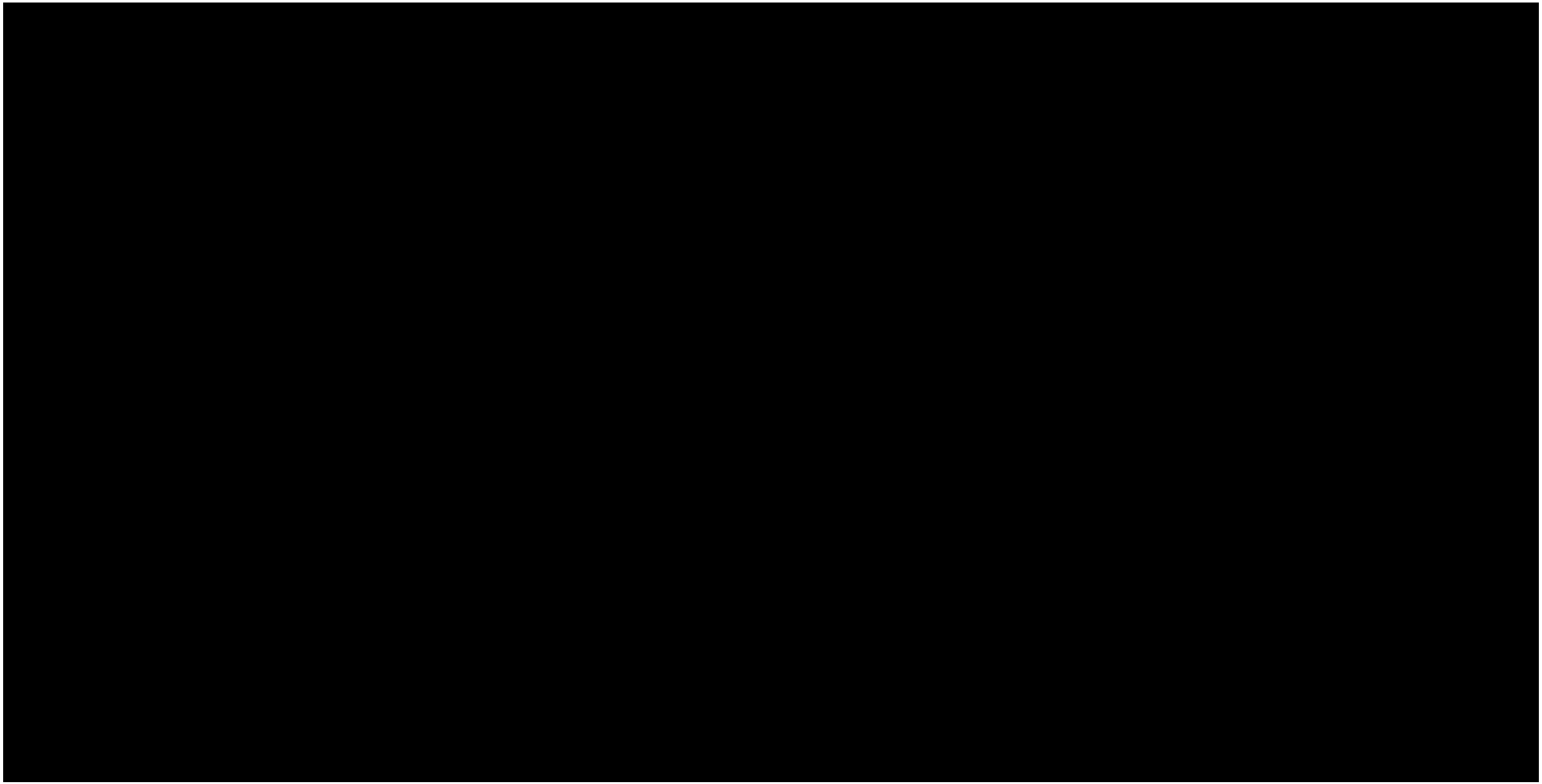
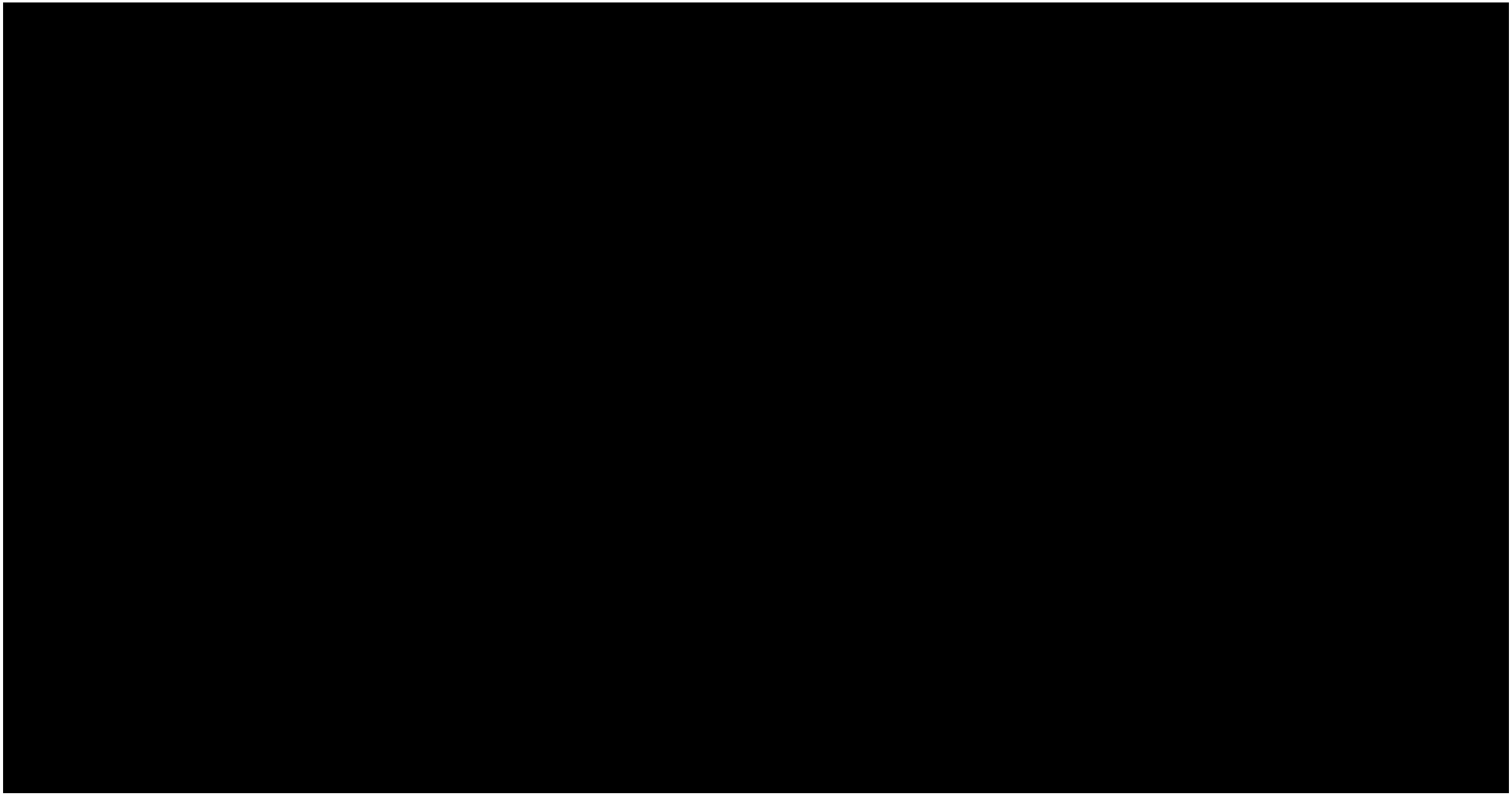


Assay In development, Not for Sale



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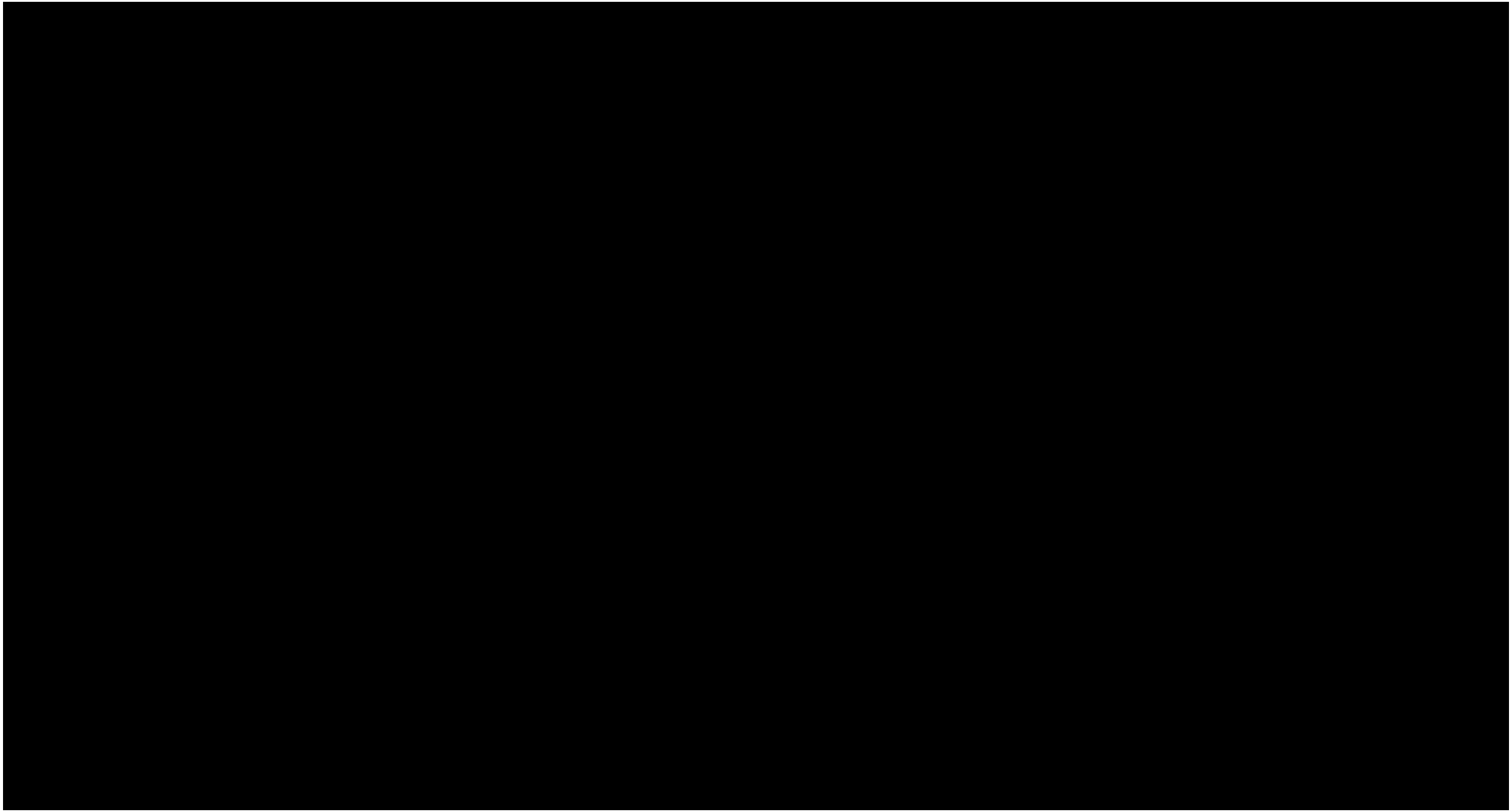

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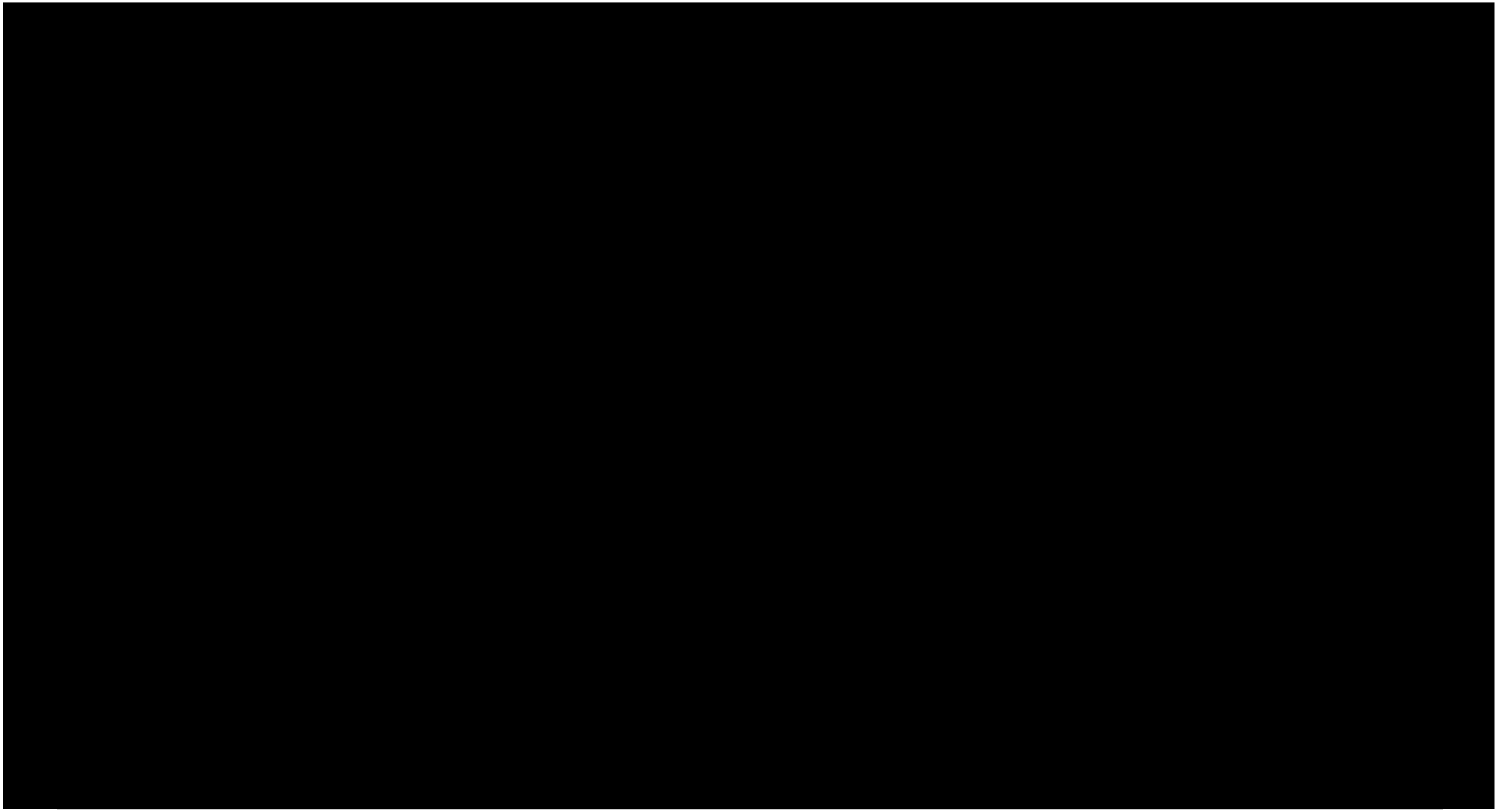

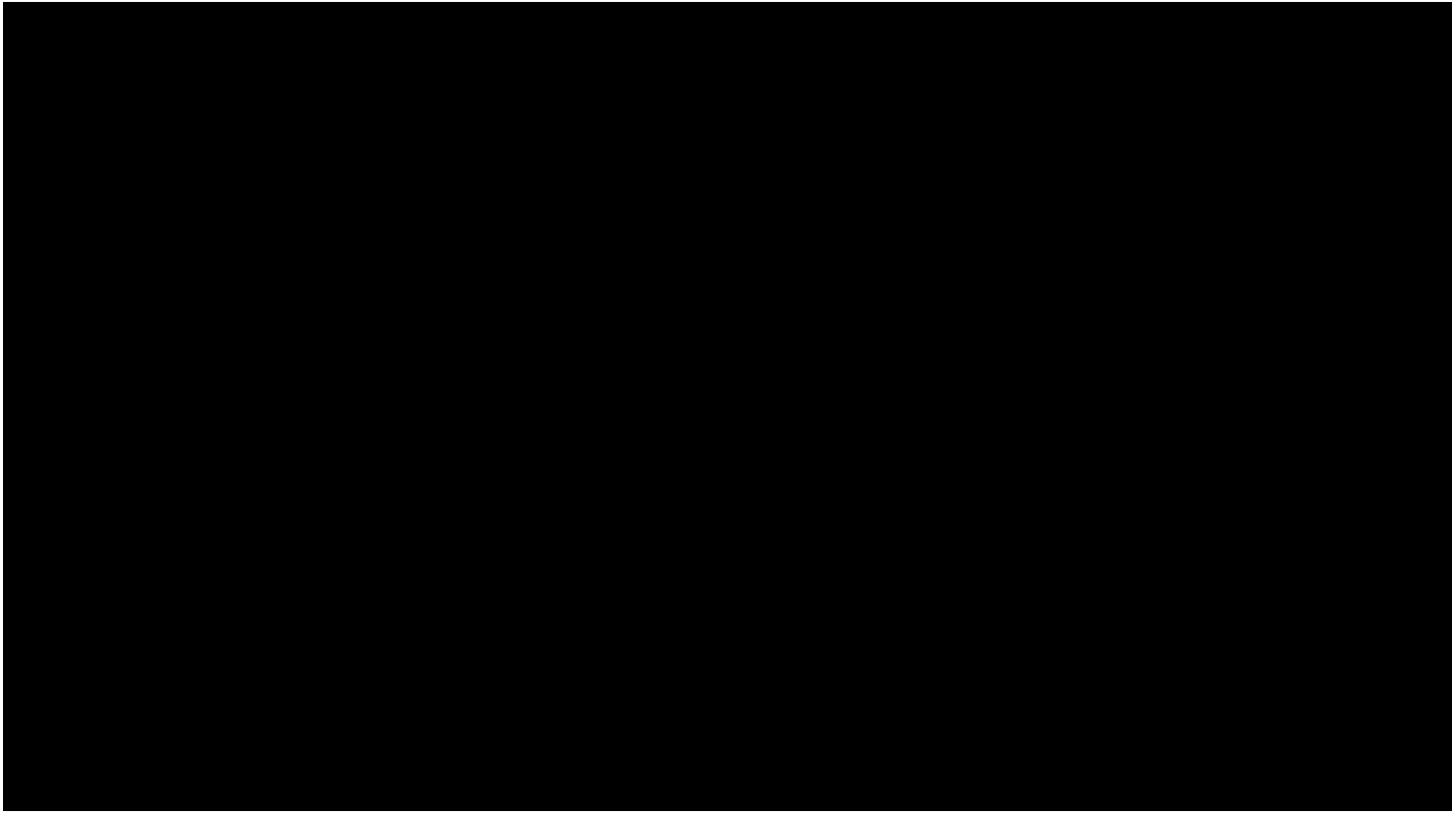

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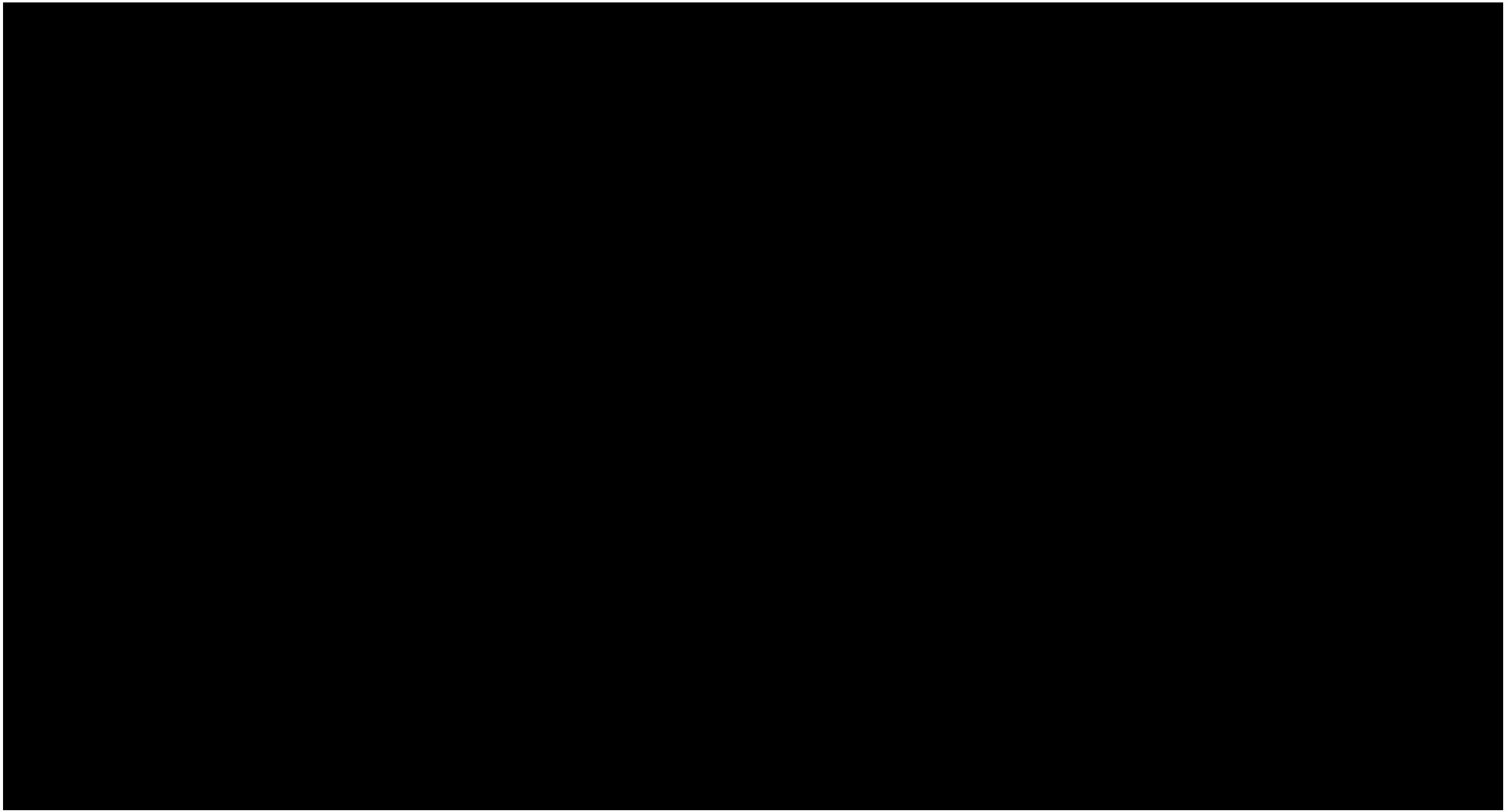

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