

**National Microbiology Framework Agreement  
Order Form**

<b>Authority:</b>	<b>The Secretary of State for Health and Social Care</b> of 39 Victoria St, Westminster, London SW1H 0EU acting as part of the Crown
<b>Invoice address:</b>	All invoices must be submitted by or on behalf of the Supplier quoting a valid purchase order number to [REDACTED] with a copy sent to the nominated DHSC Contract Manager and/or Finance Business Partner.
<b>Contract Manager:</b>	Name: [REDACTED] Phone: [REDACTED] E-mail: [REDACTED]
<b>Secondary Contact:</b> eg. business operational contact, project manager	Name: [REDACTED] Phone: [REDACTED] E-mail: [REDACTED]
<b>Procurement lead</b>	Name: [REDACTED] Phone: [REDACTED] E-mail: [REDACTED]
<b>Name and address for notices:</b>	Name: [REDACTED] Address: The Secretary of State for Health and Social Care of 39 Victoria St, Westminster, London SW1H 0EU
<b>Internal reference (if applicable):</b>	To be quoted on all correspondence relating to this Order Form: Contract ID# C52975

**TO**

<b>Supplier:</b>	Medicines Discovery Catapult Services Limited
<b>Contract Manager:</b>	Name: [REDACTED] Phone: [REDACTED] E-mail: [REDACTED]
<b>Secondary Contact:</b>	Name: [REDACTED] Phone: [REDACTED] E-mail: [REDACTED]
<b>Account Manager:</b>	Name: [REDACTED] Phone: [REDACTED] E-mail: [REDACTED]
<b>Name and address for notices:</b>	Name: [REDACTED] Address: [REDACTED] [REDACTED]

**Applicable terms and conditions**

The following terms and conditions are applicable to the Contract for this Order:

<b>Appendix A</b>	Call-off Terms and Conditions for the Supply of Goods and the Provision of Services	<b>Applicable to this Contract</b>
<b>Appendix B</b>	Optional Additional Call-off Terms and Conditions for Installation and Commissioning Services	<input type="checkbox"/> (only applicable if this box is checked)
<b>Appendix C</b>	Optional Additional Call-off Terms and Conditions for Maintenance Services	<input type="checkbox"/> (only applicable if this box is checked)
<b>Appendix D</b>	Optional Additional Call-off Terms and Conditions for Bespoke Research, Development and Manufacturing Requirements	<input type="checkbox"/> (only applicable if this box is checked and to the extent the applicable terms are included in Annex A (Order Specific Key Provisions))
<b>Appendix E</b>	Optional Additional Call-off Terms and Conditions for Reagent Rental	<input type="checkbox"/> (only applicable if this box is checked)
<b>Appendix F</b>	Optional Additional Call-off Terms and Conditions for Managed Equipment Services	<input type="checkbox"/> (only applicable if this box is checked)
<b>Appendix G</b>	Optional Additional Call-off Terms and Conditions for Clinical Laboratory Diagnostic Testing Services	<input checked="" type="checkbox"/> (only applicable if this box is checked and to the extent the applicable terms are included in Annex A (Order Specific Key Provisions))
<b>Appendix H</b>	<p>Further Optional Additional Call-off Terms and Conditions</p> <p>Each of the following clauses in Appendix H is only applicable to this Contract if the relevant box is checked:</p>	(only applicable if one or more boxes are checked)

	1. TUPE applies at the commencement of the provision of Services	<input type="checkbox"/>	
	2. TUPE on exit	<input type="checkbox"/>	
	3. Different levels and/or types of insurance	<input type="checkbox"/>	
	4. Induction training for Services	<input type="checkbox"/>	
	5. Further Authority obligations	<input type="checkbox"/>	
	6. Assignment of Intellectual Property Rights in deliverables, materials and outputs of the Services	<input type="checkbox"/>	
	7. Inclusion of a Change Control Process	<input type="checkbox"/>	
	8. Authority step-in rights	<input type="checkbox"/>	
	9. Guarantee	<input type="checkbox"/>	
	10. Termination for convenience	<input type="checkbox"/>	
	11. Pre-Acquisition Questionnaire	<input type="checkbox"/>	
	12. Time of the essence (Goods)	<input type="checkbox"/>	
	13. Time of the essence (Services)	<input type="checkbox"/>	
	14. Specific time periods for inspection	<input type="checkbox"/>	
	15. Specific time periods for rights and remedies under Clause 3.6 of Schedule 2 of Appendix A	<input type="checkbox"/>	
	16. Right to terminate following a specified number of material breaches	<input type="checkbox"/>	
	17. Expert Determination	<input type="checkbox"/>	
	18. Consigned Goods	<input type="checkbox"/>	
	19. Improving visibility of Sub-contract opportunities available to Small and Medium Size Enterprises and Voluntary, Community and Social Enterprises	<input type="checkbox"/>	

	20. Management Charges and Information	<input type="checkbox"/>	
	21. COVID-19 related enhanced business continuity provisions	<input type="checkbox"/>	
	22. Buffer stock requirements	<input type="checkbox"/>	
	23. Modern slavery	<input checked="" type="checkbox"/>	
The additional Order Specific Key Provisions set out at Annex A (Order Specific Key Provisions) to this Order Form shall also apply to this Contract.			<input checked="" type="checkbox"/> (only applicable if this box is checked)

1. CONTRACT DETAILS										
<b>(1.1) Commencement Date:</b> 1 <sup>st</sup> January 2022										
<b>(1.2) Services Commencement Date (if applicable):</b> 1 <sup>st</sup> January 2022										
<b>(1.3) Contract Price ((i) breakdown and (ii) payment profile):</b>  <b>Standard Price Per Test Payment Mechanism</b>  The Price Per Test (as defined in Appendix G, which forms part of Annex A to this Order Form) is: shown in the table below (exclusive of VAT).  The Price Per Test incorporates all costs associated with testing, including re-agents and consumables. <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="width: 50%; height: 20px; background-color: black;"></td> <td style="width: 50%; height: 20px; background-color: black;"></td> </tr> <tr> <td style="height: 20px;"></td> <td style="height: 20px;"></td> </tr> <tr> <td style="height: 20px;"></td> <td style="height: 20px;"></td> </tr> <tr> <td style="height: 20px;"></td> <td style="height: 20px;"></td> </tr> </table>										
Unless otherwise agreed in writing, for the purposes of calculating payment, the number of Tests per month shall be determined from the NPEx data as made available to the Authority.  The invoicing and payment profile for any Services provided where the Price Per Test payment mechanism applies is: payment monthly in arrears. Where the amount of any invoice is queried (including where the current NPEx data is incorrect or suspected of being incorrect) the Authority shall pay any undisputed amount as provided (ie monthly in arrears) and the Parties shall liaise with each other and agree a resolution to such query within fourteen (14) days of the query being raised. If the Parties are unable to agree a resolution within fourteen (14) days the query shall be resolved in accordance with the Dispute Resolution Procedure.										
<b>(1.4) Term of Contract:</b> From the Commencement Date until 31 March 2022										
<b>(1.5) Term extension options:</b> <div style="background-color: black; height: 20px; width: 100%;"></div>										

## 2. GOODS AND/OR SERVICES REQUIREMENTS

**(2.1) Description of the Goods / Services:**

The provision of Clinical Laboratory Diagnostic Testing Services as more particularly set out in the Specification and Tender Response Document attached to Appendix 1 of this Order Form.

The Supplier shall implement the Services in accordance with the implementation plan set out in Appendix G Schedule 1.

The Supplier shall provide the Services in accordance with the Test volumes required to meet the Guaranteed Daily Capacity.

The Guaranteed Daily Capacity shall be [REDACTED] (which may be amended by prior written agreement between the Parties such agreement not to be unreasonably withheld or delayed)

There is no minimum Test volume under this Contract, and the allocation of Test kit Samples for testing to each supplier is wholly at the discretion of the Authority.

The Services shall meet the KPIs set out in Section 2.4 to this Order Form.

The Authority shall provide a UKHSA appointed Clinical Lead for use by the Supplier in relation to the Services.

**(2.2) Premises and Location(s) at which the Goods / Services are to be delivered / provided:**

[REDACTED]

**(2.3) Key personnel of the Supplier to be involved in the Goods / Services:**

[REDACTED]

**(2.4) Performance standards:**

**Part A: KPIs**

The following KPIs will be used to evaluate the performance of the Supplier:

[REDACTED]			
A	[REDACTED]		
	[REDACTED]		
	[REDACTED]		
	[REDACTED]		
	[REDACTED]		
	[REDACTED]		
	[REDACTED]		
	[REDACTED]		
	[REDACTED]		
	[REDACTED]		

1. **“Turnaround Time”** means the time from sample receipt at the laboratory as per:

- a. validate app timestamp for test site and satellite channel samples; and
- b. LIMS registration time for home channel samples or validate app timestamp once implemented, to the time when the relevant result has been uploaded to NPEX upload.

2. **“Contracted Capacity”** means the Guaranteed Daily Capacity applicable to the day in question.

1. The Supplier shall provide the Authority with a daily report detailing its performance level against each of the KPIs (as these may be updated from time to time by agreement between the Parties in accordance with the provisions of paragraph 2 below).

2. The Supplier acknowledges that this Contract is one of a number of contracts that the Authority has with laboratories in respect of testing services concerning COVID-19. Each of the contracts currently has its own KPI regime. The ultimate objective of the Authority is to have a set of common, consistent and appropriate KPIs across all of its contracts in respect of COVID-19 testing. As such the Parties shall work together in good faith and use reasonable endeavours to achieve this objective, including agreeing any necessary changes or updates to the KPIs forming part of this Contract.

## **Part B: Consequences of failing to achieve a KPI target**

### **A. Daily/Weekly Review**

- 1 DHSC's relationship manager for the Supplier will be in daily contact with the laboratory. Suppliers will be sent programme KPIs (end-to-end TATs) daily either by automated message or through their relationship manager. Any deviations from the KPI targets will be queried by the relationship manager or laboratory operations team on a daily basis.





**(3.1) The following information shall be deemed Confidential Information:** As defined in the Call-Off Terms and Conditions

**(3.2) Duration that the information shall be deemed Confidential Information:** As defined in the Call-Off Terms and Conditions

**(4.1) Personal Data to be processed by the Supplier:**  
In accordance with the Data Protection Protocol at Appendix 2 to this Order Form and the data protection provisions at Clause 2 of Schedule 3 of Appendix A.

All data collected or generated in relation to test subjects pursuant to and in connection with the subject matter of this Contract ("**Medical Data**") shall be pseudonymised, such that the Supplier shall, when it receives test Samples, only ever have access to the Unique Reference Number/Barcode (URN) associated with the test Sample. All Medical Data shall be processed by the Supplier using only the URN generated for each test Sample (which the Authority is responsible for generating and correctly allocating to collected test Samples).

The Supplier shall store all Medical Data for the duration of the Contract, and upon expiry or termination of this Contract the Authority shall be entitled to request the transfer of all such Medical Data to it or a nominee (which the Supplier shall facilitate), following which (or earlier upon request by or on behalf of the Authority) the Supplier shall be entitled to delete all Medical Data. If the Authority doesn't make any such request, for all Medical Data to be transferred to it within a period of three months following expiry or termination of the Contract, the Supplier shall be entitled to delete all Medical Data, provided it has given the Authority three (3) weeks' prior written notice of

its intention to do so.

**5. LEASE / LICENSE (if applicable)**

**(5.1) The Authority is granting the following lease or licence to the Supplier:** Not applicable

**Signature:**

[Redacted Signature]

**For and on behalf of the Authority**

**Name:** [Redacted Name]

**Job title:** [Redacted Job title]  
[Redacted Job title]

**Date:**

**Signature:**

[Redacted Signature]

**For and on behalf of the Supplier**

**Name:** [Redacted Name]

**Job title:** [Redacted Job title]

**Date:**

## Order Form Appendix 1

### Statement of Requirements

This Appendix 1 sets out the Contract Specification for the Services, and sets out obligations with which both Parties shall comply and caveats and limitations to the Services to be supplied by Supplier.

#### **Specification for Services / Testing:**

The testing process entails the Supplier taking receipt of agreed shipments of completed Test kits, subject to a finite capacity to receive completed test kits in any 24 hour period of 100% of the Guaranteed Daily Capacity. [REDACTED]

- 1.1 The Supplier accessions the Samples ("**Accessioning**") so as to qualify Samples for Testing, following the steps below:
  - opening the relevant Sample delivery medium (e.g. bags, boxes or containers, which may differ between types of test kits);
  - logging into the Supplier's laboratory information system ("**LIMS**") and scanning/logging the unique reference number / barcode ("**URN**") for each Sample (which URNs shall be generated on a programme wide basis and included on all completed Test kits returned to the Supplier) and accessing NPEx (as long as the Supplier has access to this platform) to identify the time and date the Sample was collected against each individual URN (where properly recorded) (for the avoidance of doubt the Supplier will not log or record any other data associated with these Samples);
  - qualifying the Samples for Testing, recording where these are voided during the Accessioning process, and unsuitable for Testing (e.g. where no URN or Sample collection date has been recorded / provided, there are leaks or damage to the Sample, or the age of Sample makes it unsuitable for Testing etc); and
  - racking the relevant tubes (containing qualified Samples) for Testing.
- 1.2 The Supplier will then run Tests for the COVID-19 virus through the Supplier's lab on each correctly, timely and properly returned, intact and qualified Sample (not running any other tests) which has not been voided during the Accessioning process, processing them through the Supplier's lab.
- 1.3 The Supplier shall record a Void Test at any stage during this process (i.e. post Accessioning), and any generated Test results shall be recorded on the LIMS, referencing the URN associated with the qualified and tested Sample, and subsequently uploaded to the NPEx portal managed by or on behalf of the Authority (to which the Supplier shall be given access at all times), permitting the Authority or parties under its control to notify the relevant Test subjects.

#### **Anticipated Process for Provision of Services / Testing:**

- 2.1 A nominated courier delivers all completed (but not yet analysed) Test kits / Samples to the Supplier Facilities no later than 24 hours after Sample is first taken (up to the Guaranteed Daily Capacity over the relevant 24-hour period). The Supplier shall ensure that the Supplier Facilities are open to receive and log Samples on 24/7 basis.

- 2.2 The Authority shall use its reasonable endeavours to ensure that samples arrive in accordance with an agreed delivery schedule.
- 2.3 The Supplier shall be capable of Accessioning and Testing Samples of all types as notified by the Authority to the Supplier, provided such sample types have been validated as suitable for the laboratory process of the Supplier's laboratory.
- 2.4 The Supplier Accessions relevant Samples (up to the Guaranteed Daily Capacity).
- 2.5 The Supplier then runs Testing in relation to the qualified Sample (per the Specification for Services / Testing section above). The Supplier shall ensure that the Supplier Facilities operate to conduct Testing on a 24/7 basis.
- 2.6 The Supplier then reports results directly back to the Authority via Kainos/NPEX (the Supplier has no responsibility over the security of this portal once results are uploaded).
- 2.7 Subject to any required retentions of Samples requested by the Authority (which may include retention of positive Samples for sequencing and/or research/validation work), the Supplier shall aim and expects to securely and safely destroy all Samples and delivery media returned one week after Test results have been generated and reported on.
- 2.8 The Supplier shall, on request in writing from the Authority, make available positive RNA Samples or a selection of positive RNA Samples (as requested by the Authority) for collection from the Supplier Facilities within 24 hours of a positive test result when testing such Samples.
- 2.9 The Supplier has as part of the previous contract provided reflex assay testing and sequencing capability for other organisations. These are available as part of this Contract with the addition of a suitable letter of agreement executed by each of the Parties as regards service and charges.

#### **Limitations / Caveats:**

- 3.1 **Test Portal:** The Supplier is not responsible for the operation or effectiveness of any software programmes, platforms or portals (outside of the LIMs) procured by the Authority, nor for ensuring that accurate URNs are provided by the relevant Test subjects and linked to physical Test kits.
- 3.2 **Sampling:** The Supplier has no control over sampling or failure by those delivering or collecting Samples to follow instructions. For example, the Test subject or the person taking any Sample on the Test subject may not follow the prescribed procedure for taking swabs.
- 3.3 **Other Failures by Test Subject (or those Collecting their Sample):** Test subjects, or those collecting their Samples, may fail to place a cap on testing tubes or affix them properly, resulting in loss of liquid during transport (and limitations in testing capability), or contamination, complete labelling or form as required, or any other issues arise which result in the Supplier receiving incorrect or inadequate details to properly associate the Test subject with the correct URN or receive the correct date the Test was taken.
- 3.4 **Delivery Issues:** As regards the provision of the Services, the Supplier takes no responsibility for any issues arising in the transport of Samples to the Supplier

Facilities, including loss or damage to returned Samples (at any stage other than whilst in the Supplier's custody).

- 3.5 **Return / Receipt of Samples:** The Supplier has a finite Testing capacity, and has no control over the rate or regularity at/over which Samples are delivered, or ability to provide the Services, or store completed Samples above the Guaranteed Daily Capacity, but commits to use reasonable endeavours to do so.
- 3.6 The Authority or its nominated contractor(s) shall be responsible for managing levels of over-stocking and logistics flows to prevent (inter alia):
- the Supplier running out of Samples for the provision of Services (including Accessioning);
  - Samples being dated such that accurate Testing is no longer possible; and/or
  - the Supplier's capacity being stretched beyond the Guaranteed Daily Capacity due to over-supply and/or irregular supply.
- 3.7 **Repeat Testing:** Delays may also be incurred if repeat Testing is required, e.g. where Test results are equivocal, or controls fail.

#### **Storage and Accessioning**

- 4.1 Subject to the following paragraph and the remainder of the Contract, the Supplier shall use reasonable endeavours to Accession all Samples received within 24 hours of receipt. This obligation shall not apply to any additional Samples (the "**Excess Samples**") received in any 24 hour period, in excess of 100% of the Guaranteed Daily Capacity.
- 4.2 In relation to the Excess Samples, the Supplier shall use reasonable endeavours to Accession these as soon as reasonably possible. The Supplier commits to storing no more than half the Guaranteed Daily Capacity on any given day of Accessioned Samples in cold houses.
- 4.3 The Supplier shall notify the Authority as soon as reasonably practicable upon becoming aware of having received a number of Samples that it envisages it will not be able to Accession within 24 hours of receipt, or of any other material significant issues in fulfilment of the Services on a given day.
- 4.4 The Supplier shall, on request by the Authority, make some or all of the Samples held which have not yet been Accessioned immediately available for collection by the Authority from the Supplier Facilities as a single batch (to enable the Authority to re-direct such Samples to another testing supplier).

#### **Standard Operating Procedures**

- 5.1 The Supplier shall at all times provide the Services in accordance with and comply with the Standard Operating Procedures as updated by the Authority from time to time.
- 5.2 The Authority reserves the right to replace the NPEx system with an alternative system and the Supplier shall use such alternative system in place of NPEx following receipt of notice in writing from the Authority.

**Supplier Facility Provisions**

6.1 In terms of the use of the Supplier Facility:

- The Supplier Facility shall be set up and the COVID-19 Testing will be performed to the standards set out in the Standard Operating Procedures;
- The physical control of the Supplier Facility itself will remain with the Supplier (in consultation with the Authority); and
- The Supplier shall have control over the recruitment and/or deployment of such employees, contractors, secondees and volunteers as it deems necessary to carry out the Services without consulting the Authority provided that there shall be no impact to the Contract Price.

**LIMS requirements**

7.1 The standards for the LIMS required to be used are:

- MHRA Approved as Class 2 medical device per Directive 93/42/EEC if the LIMS runs an algorithm which manipulates the data, in which case the algorithm must be MHRA approved.
- CE marked if the LIMS runs an algorithm which manipulates the data.
- ISO 15189 compliant as relevant
- ISO 13485 for any Quality Management component as relevant
- ISO 14971 compliant as relevant
- ISO ISO27001:2013
- ISO2000 aligned

**Order Form Appendix 2****Data Protection Protocol**

1. The contact details of the Authority's Data Protection Officer are: [REDACTED]  
Department of Health and Social Care, 1st Floor North, 39 Victoria Street, London SW1H 0EU. [REDACTED]
2. The contact details of the Supplier's Data Protection Officer are [REDACTED]  
[REDACTED]
3. The Processor shall comply with any further written instructions with respect to processing by the Controller.
4. Any such further instructions shall be incorporated into this Appendix.

Description	Details
Identity of Controller for each Category of Personal Data	<p><b>The Authority is Controller and the Supplier is Processor</b></p> <p>The Parties acknowledge that in accordance with the Contract and for the purposes of the Data Protection Legislation, the Authority is the Controller and the Supplier is the Processor of the following Personal Data:</p> <ul style="list-style-type: none"> <li>Pseudonymised biological data which gives unique information about COVID-19 status and which results, in particular, from the analysis of the biological sample</li> </ul> <p><b>The Parties are Independent Controllers of Personal Data</b></p> <p>The Parties acknowledge that they are Independent Controllers for the purposes of the Data Protection Legislation in respect of:</p> <ul style="list-style-type: none"> <li>Business contact details of Staff,</li> <li>Business contact details of any directors, officers, employees, agents, consultants and contractors of the Authority (excluding the Staff) engaged in the performance of the Authority's duties under this Contract).</li> </ul>
Subject matter of the Processing	The Supplier processes pseudonymised biological data, identified by a unique barcode, for the performance of the Services required by this Contract.
Duration of the Processing	Biological data shall be processed for the period required to perform the Services requested and will be retained for a further 3 months in line with the Data Protection Legislation and in order to safeguard the Authority



	rights, unless the Authority requires the Supplier to destroy samples and/or data within a shorter period of time.
Nature and purposes of the Processing	The biological data shall be processed for the purposes of this Contract and in accordance with the written instructions of the Authority.
Type of Personal Data being Processed	As described above.
Categories of Data Subject	As described above.
Plan for return and destruction of the data once the Processing is complete  UNLESS requirement under union or member state law to preserve that type of data	As described above.

**Annex A****Order Specific Key Provisions****1. Introduction**

- 1.1 This Annex A includes any supplemental requirements and any other relevant details, information, provisions and terms, forming part of this Order Form, as envisaged by the Framework Agreement, the Ordering Procedure, the other parts of this Order Form, the Call-Off Term and Conditions for the Supply of Goods and the Provision of Services and/or as required by the Authority (as applicable to this Contract and to the extent not addressed elsewhere as part of this Order Form). For the avoidance of doubt, any further annexes, appendices, schedules or other documents referred to in this Annex A shall be deemed part of this Annex A and part of this Order Form including, without limitation, the appendix / schedules set out below:

<b>Appendix G</b>	<b>Call-off Terms and Conditions for Clinical Laboratory Diagnostic Testing Services (as amended / supplemented to reflect the requirements of this specific Contract)</b>
<b>Schedule 2 of these Call-off Terms and Conditions for Clinical Laboratory Diagnostic Testing Services</b>	<b>Exit Plan</b>
<b>Schedule 3 of these Call-off Terms and Conditions for Clinical Laboratory Diagnostic Testing Services</b>	<b>Approved Sub-contractors</b>

- 1.2 The Parties agree that Clause 2 of Schedule 3 of Appendix A: Information and Data Provisions shall be deleted in its entirety and replaced by the following:

**“2. Data protection***Status of the Parties*

- 2.1 The Parties shall complete a separate Data Protection Protocol for each of the Services provided by the Supplier. The Data Protection Protocol for the Services agreed as at the Commencement Date is attached at Appendix 2 to the Order Form.
- 2.2 The Parties acknowledge that for the purposes of the Data Protection Legislation, the nature of the activity carried out by each of them in relation to their respective obligations under this Contract will determine the status of each Party under the Data Protection Legislation. A Party may act as:
- 2.1.1. “Controller” (where the other Party acts as the “Processor”);
- 2.1.2. “Processor” (where the other Party acts as the “Controller”);

- 2.1.3. “Joint Controller” (where both Parties are considered to jointly control the same Personal Data);
- 2.1.4. “Independent Controller” of the Personal Data where the other Party is also “Controller” of the same Personal Data in its own right (but there is no element of joint control); or
- 2.1.5. none of the above, in the event that there is no Personal Data processed as part of an element of the Services,

and the Parties shall set out in the relevant Data Protection Protocol which scenario or scenarios are intended to apply to the relevant Services under this Contract.

*Where one Party is Controller and the other Party its Processor*

- 2.3 Where a Party is a Processor, the only Processing that it is authorised to do is listed in Data Protection Protocol by the Controller.
- 2.4 The Processor shall notify the Controller immediately if it considers that any of the Controller’s instructions infringe the Data Protection Legislation.
- 2.5 The Processor shall provide all reasonable assistance to the Controller in the preparation of any Data Protection Impact Assessment prior to commencing any Processing. Such assistance may, at the discretion of the Controller, include:
  - 2.5.1 a systematic description of the envisaged Processing operations and the purpose of the Processing;
  - 2.5.2 an assessment of the necessity and proportionality of the Processing operations in relation to the Services;
  - 2.5.3 an assessment of the risks to the rights and freedoms of Data Subjects; and
  - 2.5.4 the measures envisaged to address the risks, including safeguards, security measures and mechanisms to ensure the protection of Personal Data.
- 2.6 The Processor shall, in relation to any Personal Data processed in connection with its obligations under this Contract:
  - 2.6.1 process that Personal Data only in accordance with the Data Protection Protocol, unless the Processor is required to do otherwise by Law. If it is so required the Processor shall promptly notify the Authority before Processing the Personal Data unless prohibited by Law;
  - 2.6.2 ensure that it has in place Protective Measures, which the Controller may reasonably reject (but failure to reject shall not amount to approval by the Controller of the adequacy of the Protective Measures) having taken account of the:
    - (i) nature of the data to be protected;

- (ii) harm that might result from a Data Loss Event;
- (iii) state of technological development; and
- (iv) cost of implementing any measures;

2.6.3 ensure that:

- (i) the Processor Personnel do not process Personal Data except in accordance with this Contract (and in particular the Data Protection Protocol);
- (ii) it takes all reasonable steps to ensure the reliability and integrity of any Processor Personnel who have access to the Personal Data and ensure that they:
  - (A) are aware of and comply with the Processor's duties under this Clause and Clause 1 (Confidentiality) of this Schedule 3 of Appendix A;
  - (B) are subject to appropriate confidentiality undertakings with the Processor or any Sub-processor;
  - (C) are informed of the confidential nature of the Personal Data and do not publish, disclose or divulge any of the Personal Data to any third party unless directed in writing to do so by the Controller or as otherwise permitted by this Contract; and
  - (D) have undergone adequate training in the use, care, protection and handling of Personal Data;

2.6.4 not transfer Personal Data outside of the UK unless the prior written consent of the Controller has been obtained and the following conditions are fulfilled:

- (iii) the Controller or the Processor has provided appropriate safeguards in relation to the transfer (whether in accordance with Article 46 of the GDPR or Section 75 of the DPA 2018) as determined by the Controller;
- (iv) the Data Subject has enforceable rights and effective legal remedies;
- (v) the Processor complies with its obligations under the Data Protection Legislation by providing an adequate level of protection to any Personal Data that is transferred (or, if it is not so bound, uses its best endeavours to assist the Controller in meeting its obligations);
- (vi) the Processor complies with any reasonable instructions notified to it in advance by the Controller with respect to the Processing of the Personal Data; and
- (vii) at the written direction of the Controller, delete or return Personal Data (and any copies of it) to the Controller on termination of the

Contract unless the Processor is required by Law to retain the Personal Data.

- 2.7 Subject to Clause 2.8 of this Schedule 3 of Appendix A, the Processor shall notify the Controller promptly if it:
- 2.7.1 receives a Data Subject Request (or purported Data Subject Request);
  - 2.7.2 receives a request to rectify, block or erase any Personal Data;
  - 2.7.3 receives any other request, complaint or communication relating to either Party's obligations under the Data Protection Legislation;
  - 2.7.4 receives any communication from the Information Commissioner or any other regulatory authority in connection with Personal Data processed under this Contract;
  - 2.7.5 receives a request from any third party for disclosure of Personal Data where compliance with such request is required or purported to be required by Law; or
  - 2.7.6 becomes aware of a Data Loss Event.
- 2.8 The Processor's obligation to notify under Clause 2.7 of this Schedule Part 3 of Appendix A shall include the provision of further information to the Controller in phases, as details become available.
- 2.9 Taking into account the nature of the Processing, the Processor shall provide the Controller with reasonable assistance in relation to either Party's obligations under Data Protection Legislation and any complaint, communication or request made under Clause 2.7 of this Schedule 3 of Appendix A (and insofar as possible within the timescales reasonably required by the Controller) including by promptly providing:
- 2.9.1 the Controller with full details and copies of the complaint, communication or request;
  - 2.9.2 such assistance as is reasonably requested by the Controller to enable it to comply with a Data Subject Request within the relevant timescales set out in the Data Protection Legislation;
  - 2.9.3 the Controller, at its request, with any Personal Data it holds in relation to a Data Subject;
  - 2.9.4 assistance as requested by the Controller following any Data Loss Event; and/or
  - 2.9.5 assistance as requested by the Controller with respect to any request from the Information Commissioner's Office, or any consultation by the Controller with the Information Commissioner's Office.
- 2.10 The Processor shall maintain complete and accurate records and information to demonstrate its compliance with this Clause. This requirement does not apply where the Processor employs fewer than 250 staff, unless:

- 2.10.1 the Controller determines that the Processing is not occasional;
  - 2.10.2 the Controller determines the Processing includes special categories of data as referred to in Article 9(1) of the GDPR or Personal Data relating to criminal convictions and offences referred to in Article 10 of the GDPR; or
  - 2.10.3 the Controller determines that the Processing is likely to result in a risk to the rights and freedoms of Data Subjects.
- 2.11 The Processor shall allow for audits of its Processing activity by the Controller or the Controller's designated auditor.
- 2.12 The Parties shall designate a Data Protection Officer if required by the Data Protection Legislation.
- 2.13 Before allowing any Sub-processor to process any Personal Data related to this Agreement, the Processor must:
- 2.13.1 notify the Controller in writing of the intended Sub-processor and Processing;
  - 2.13.2 obtain the written consent of the Controller;
  - 2.13.3 enter into a written agreement with the Sub-processor which give effect to the terms set out in this Clause 2 such that they apply to the Sub-processor; and
  - 2.13.4 provide the Controller with such information regarding the Sub-processor as the Controller may reasonably require.
- 2.14 The Processor shall remain fully liable for all acts or omissions of any of its Sub-processors.
- 2.15 Either Party may, at any time on not less than 30 Business Days' notice, revise this Clause 2 by replacing it with any applicable controller to processor standard clauses or similar terms forming part of an applicable certification scheme (which shall apply when incorporated by attachment to this Contract).
- 2.16 The Parties agree to take account of any guidance issued by the Information Commissioner's Office and shall work together in good faith to promptly agree and implement any amendments necessary to this Contract to ensure that it complies with any guidance issued by the Information Commissioner's Office.

*Where the Parties are Joint Controllers of Personal Data*

- 2.17 In the event that the Parties are Joint Controllers in respect of Personal Data under this Contract, the Parties shall together in good faith to promptly agree and implement such clauses that are necessary to comply with Article 26 of the GDPR.

*Where the Parties are Independent Controllers of Personal Data*

- 2.18 With respect to Personal Data provided by one Party to another Party for which each Party acts as Controller but which is not under a Joint Controller arrangement of the Parties, each Party undertakes to comply with the

applicable Data Protection Legislation in respect of their Processing of such Personal Data as Controller.

- 2.19 Each Party shall process the Personal Data in compliance with its obligations under the Data Protection Legislation and not do anything to cause the other Party to be in breach of it.
- 2.20 Each Party will provide the other Party with all such relevant documents and information relating to its data protection policies and procedures as the other Party may reasonably require.
- 2.21 The Parties shall be responsible for their own compliance with Articles 13 and 14 of the GDPR in respect of the Processing of Personal Data for the purposes of this Contract.
- 2.22 The Parties shall only provide Personal Data to each other:
  - 2.22.1 to the extent necessary to perform the respective obligations under this Contract;
  - 2.22.2 in compliance with the Data Protection Legislation (including by ensuring all required fair Processing information has been given to affected Data Subjects); and
  - 2.22.3 where it has recorded it in the Data Protection Protocol.
- 2.23 Taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of Processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons, each Party shall, with respect to its Processing of Personal Data as Independent Controller, implement and maintain appropriate technical and organisational measures to ensure a level of security appropriate to that risk, including, as appropriate, the measures referred to in Article 32(1)(a), (b), (c) and (d) of the GDPR, and the measures shall, at a minimum, comply with the requirements of the Data Protection Legislation, including Article 32 of the GDPR.
- 2.24 A Party Processing Personal Data for the purposes of this Contract shall maintain a record of its Processing activities in accordance with Article 30 of the GDPR and shall make the record available to the other Party upon reasonable request.
- 2.25 Where a Party receives a request by any Data Subject to exercise any of their rights under the Data Protection Legislation in relation to the Personal Data provided to it by the other Party pursuant to this Contract (the party receiving the request being the “**Request Recipient**”):
  - 2.25.1 the other Party shall provide any information and/or assistance as reasonably requested by the Request Recipient to help it respond to the request or correspondence, at the cost of the Request Recipient; or
  - 2.25.2 where the request or correspondence is directed to the other Party and/or relates to the other Party's Processing of the Personal Data, the Request Recipient will:

- (i) promptly, and in any event within five (5) Business Days of receipt of the request or correspondence, inform the other party that it has received the same and shall forward such request or correspondence to the other party; and
  - (ii) provide any information and/or assistance as reasonably requested by the other party to help it respond to the request.
- 2.26 Each Party shall promptly notify the other Party upon it becoming aware of any Personal Data Breach relating to Personal Data provided by the other Party pursuant to this Contract and shall:
  - 2.26.1 do all such things as reasonably necessary to assist the other Party in mitigating the effects of the Personal Data Breach;
  - 2.26.2 implement any measures necessary to restore the security of any compromised Personal Data;
  - 2.26.3 work with the other Party to make any required notifications to the Information Commissioner's Office and affected Data Subjects in accordance with the Data Protection Legislation (including the timeframes set out therein); and
  - 2.26.4 not do anything which may damage the reputation of the other Party or that Party's relationship with the relevant Data Subjects, save as required by Law.
- 2.27 Personal Data provided by one Party to the other Party may be used exclusively to exercise rights and obligations under this Contract as specified in the Data Protection Protocol.
- 2.28 Personal Data shall not be retained or processed for longer than is necessary to perform each Party's obligations under this Contract which is specified in the Data Protection Protocol.
- 2.29 Notwithstanding the general application of the above Clauses 2.3 to 2.16 to Personal Data, where the Supplier is required to exercise its regulatory and/or legal obligations in respect of Personal Data, it shall act as an Independent Controller of Personal Data in accordance with the above Clauses 2.17 to 2.28.

*Patient Data and Data Security and Protection toolkit*

- 2.30 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).
- 2.31 Where, as a requirement of this Contract, the Supplier is Processing Personal Data relating to NHS patients and/or service users and/or has access to NHS systems as part of the Services, the Supplier shall:
  - 2.31.1 complete and publish an annual information governance assessment using the Data Security and Protection toolkit;



- 2.31.2 achieve all relevant requirements in the Data Security and Protection toolkit;
  - 2.31.3 nominate an information governance lead able to communicate with the Supplier's board of directors or equivalent governance body, who will be responsible for information governance and from whom the Supplier's board of directors or equivalent governance body will receive regular reports on information governance matters including, but not limited to, details of all incidents of data loss and breach of confidence;
  - 2.31.4 report all incidents of data loss and breach of confidence in accordance with Department of Health and Social Care and/or the NHS England and/or Health and Social Care Information Centre guidelines;
  - 2.31.5 put in place and maintain policies that describe individual personal responsibilities for handling Personal Data and apply those policies vigorously;
  - 2.31.6 put in place and maintain a policy that supports its obligations under the NHS Care Records Guarantee (being the rules which govern information held in the NHS Care Records Service, which is the electronic patient/service user record management service providing authorised healthcare professionals access to a patient's integrated electronic care record);
  - 2.31.7 put in place and maintain agreed protocols for the lawful sharing of Personal Data with other NHS organisations and (as appropriate) with non-NHS organisations in circumstances in which sharing of that data is required under this Contract;
  - 2.31.8 where appropriate, have a system in place and a policy for the recording of any telephone calls in relation to the Services, including the retention and disposal of those recordings;
  - 2.31.9 at all times comply with any information governance requirements and/or processes as may be set out in the Specification and Tender Response Document; and
  - 2.31.10 comply with any new and/or updated requirements, Guidance and/or Policies notified to the Supplier by the Authority from time to time (acting reasonably) relating to the Processing and/or protection of Personal Data.
- 2.32 Where any Personal Data is Processed by any Sub-contractor of the Supplier in connection with this Contract, the Supplier shall procure that such Sub-contractor shall comply with the relevant obligations set out in this Clause 2 of this Schedule 3 of Appendix A, as if such Sub-contractor were the Supplier.
- 2.33 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."

- 1.3 The Parties agree that the following definitions shall be added to Schedule 4 of Appendix A: Definitions and Interpretations:

<b>"Baseline Personal Security Standard (BPSS)"</b>	HMG's Baseline Personnel Security Standard available at <a href="https://www.gov.uk/government/publications/government-baselinepersonnel-security-standard">https://www.gov.uk/government/publications/government-baselinepersonnel-security-standard</a> .
<b>"Data Loss Event"</b>	means any event that results, or may result, in unauthorised access to Personal Data held by the Processor under this Contract, and/or actual or potential loss and/or destruction of Personal Data in breach of this Contract, including any Personal Data Breach;
<b>"Data Protection Impact Assessment"</b>	means an assessment by the Controller of the impact of the envisaged processing on the protection of Personal Data;
<b>"Data Subject"</b>	shall have the same meaning as set out in the GDPR;
<b>"Data Subject Request"</b>	means a request made by, or on behalf of, a Data Subject in accordance with rights granted pursuant to the Data Protection Legislation to access their Personal Data;
<b>"Personal Data Breach"</b>	shall have the same meaning as set out in the GDPR;
<b>"Processor Personnel"</b>	means any director, officer or other member of Supplier Personnel acting on behalf of the Processor and/or any Sub-processor in relation to the performance of obligations under this Contract;
<b>"Protective Measures"</b>	means appropriate technical and organisational measures which may include: pseudonymising and encrypting Personal Data, ensuring confidentiality, integrity, availability and resilience of systems and services, ensuring that availability of and access to Personal Data can be restored in a timely manner after an incident, and regularly assessing and evaluating the effectiveness of such measures adopted;
<b>"Sub-processor"</b>	means any third party appointed to Process Personal Data on behalf of the Processor relating to this Contract;
<b>"System"</b>	means the technology systems used by the Supplier to deliver the Services;

- 1.4 The Parties agree that the definition of "GDPR" shall be deleted in Schedule 4 of Appendix A (Definitions and Interpretations) and replaced with the following:

<b>“GDPR”</b>	means the General Data Protection Regulation (Regulation (EU) 2016/679) whilst it is in force in England and Wales and, after that, means the GDPR to the extent it forms part of domestic law by virtue of section 3 of the European Union (Withdrawal) Act 2018, as amended, replaced or superseded from time to time;
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1.5 The Parties agree that the provisions set out below shall supplement the provisions of the Contract, including those relating to information security (and specifically those set out in Schedule 3 of Appendix A of the Contract):

- 1.1 An information security management System (the “**Security Management System**”), including a plan, must be developed and maintained, structured by the Supplier in accordance with ISO27001:2013 or an equivalent standard agreed with the Authority, to cover the information assurance aspects throughout the life of the Contract. This will include risk management plans and other artefacts as agreed with the Authority. The Supplier shall review and update the Security Management System and plan at least annually in order to reflect on any changes in the Services and delivery methods, and ensure that any changes to the Security Management System and plan are communicated to all relevant Supplier Personnel.
- 1.2 There must be a named accountable person from the Supplier who is accountable for the provision of technical, personnel, process and physical security aspects for the Services, including but not limited to security clearances.
- 1.3 The Authority must have the ability to audit and assess security controls and risk management methodology at the Supplier’s Premises and Locations.
- 1.4 Security must be embedded in all service management including but not limited to change management, incident management, and other Service management artefacts aligned with ISO20000 or an equivalent standard agreed with the Authority.
- 1.5 Development and test environments must have assured separation from the live/production systems, and must not use live / production information without prior written Authority approval.
- 1.6 The System must be configured in line with the law, regulations and the Authority's policies, standards and guidance as amended from time to time, including malware policy, patching policy, password standard, information handling and security monitoring.
- 1.7 The System and Supplier's Premises and Locations must have auditable authorisation, authentication and access control based on least privilege, and aligned appropriate to the business requirement.
- 1.8 The System and processes must enforce separation of duties based upon the agreed risk assessment and management.
- 1.9 The System must be developed and reviewed against Good Industry Practice, including security testing of the infrastructure and applications, in line with UK Government standards and guidelines (and as a minimum those available from

the National Cyber Security Centre).

- 1.10 The Supplier must share with the Authority the outputs of any risk assessment, mitigation actions and any remaining remediation plans.
- 1.11 The Supplier shall ensure that all Supplier Personnel and Sub-contractors are provided with appropriate security education, training and awareness in light of their role, with this aspect being reviewed at least annually. Training shall include elements of physical, personnel and electronic security guidance.
- 1.12 The Supplier must provide screening controls that conform to the Baseline Personal Security Standard (BPSS) for all Supplier Personnel and Sub-contractors who have any access to the System and information with regards to the System.
- 1.13 The Supplier must have security operational awareness, detection, prevention, response and remediation processes / controls to effectively manage security incidents.
- 1.14 The Supplier must conduct vulnerability management and penetration testing of the System and address the findings of such tests or have the Authority accept in writing any findings that will not be addressed.
- 1.15 The Supplier must ensure that the System and any associated infrastructure are designed in a manner to ensure effective physical and logical separation, including:
  - 1.15.1 laboratory/ diagnostic and back office networks must not exist on the same network subnet; and
  - 1.15.2 operative and administrative activities must not be possible using the same user accounts.
- 1.16 The Supplier must adopt the Authority's preferred protective monitoring capability or provide their own which is recognised as exceeding the former.
- 1.17 The Parties agree that the inclusion in the Contract of the supplementary provisions set out in this paragraph shall be without prejudice to any other terms of the Contract, including those related to information management and security.

## Appendix G – Call-off Terms and Conditions for Clinical Laboratory Diagnostic Testing Services (as amended / supplemented to reflect the requirements of this specific Contract)

### 1 Definitions

1.1 In this Appendix G, the following words shall have the following meanings unless the context requires otherwise:

<b>“Approved Sub-contractors”</b>	the persons listed in Schedule 3 to this Appendix G;
<b>“Assets”</b>	shall have the meaning referred to at Clause <b>Error! Reference source not found.</b> of this Appendix G;
<b>“Authority Background Intellectual Property Rights”</b>	Intellectual Property Rights owned by the Authority before the Commencement Date; and/or Intellectual Property Rights created by the Authority independently of this Contract;
<b>“Authority Equipment”</b>	any equipment and consumables provided by the Authority to the Supplier to support provision of the Services;
<b>“Authority Facilities”</b>	means any premises or other facilities and/or testing infrastructure provided by the Authority at which the Supplier or Sub-contractors (as applicable) are to provide the Services (each an Authority Facility);
<b>“Created Intellectual Property”</b>	<p>any Intellectual Property Rights in any material created or adapted by Supplier (or any of its employees, agents or Sub-contractors) that relates to;</p> <ul style="list-style-type: none"> <li>• software components created to handle the Authority connections into NHS Test Digital Platform interfaces (including components created to support the Authority connections e.g. API authorisation, error-handling, data transformation);</li> <li>• software components created to expose external interfaces to the NHS Test Digital Platform Authority connections (including external interface definitions such as OpenAPI specifications, and components related to support the external interfaces such as API authorisation, error-handling, data transformation);</li> <li>• software components created to map external on-the-wire data structures to usable data objects in code, <ul style="list-style-type: none"> <li>○ including infrastructure-as-code and configuration templates where cloud managed services have been utilised to create the components scoped above;</li> </ul> </li> </ul>

- artefacts to be provided as reference implementations / source code (they are not required to be production artefacts);

<b>“Conclusive Result”</b>	means any Test result that is positive or negative;
<b>“Disabling Device”</b>	means any virus, timer, clock, counter, time lock, time bomb, Trojan horse, worm, file infector, boot sector infector or other limiting design, instruction or routine and surveillance software or routines or data gathering or collecting software or devices that could, if triggered, erase data or programming, have an adverse impact on the Services, or cause hardware, software or other resources to become inoperable or otherwise incapable of being used in the full manner for which such hardware, software or other resources were intended to be used;
<b>“Equipment”</b>	the equipment and consumables owned by Supplier and which comprises part of the Supplier Facilities or the equipment purchased by the Authority from Supplier pursuant to this Contract for use at the Facilities;
<b>“Exit Plan”</b>	means the exit plan developed in accordance with this Schedule 2 (Exit Plan). Any reference in the Contract to an “exit plan” shall be deemed a reference to this Exit Plan;
<b>“Exit Group”</b>	the group of personnel established jointly by both Parties to manage the disengagement of the Services and the implementation of the Exit Plan;
<b>“Facilities”</b>	means the Supplier Facilities and/or the Authority Facilities;
<b>“Good Scientific Practice”</b>	means the standards of behaviour and practice set out in the publication entitled ‘Good Scientific Practice’ as published by the Academy for Healthcare Science;
<b>“Guaranteed Daily Capacity”</b>	means the guaranteed number of Tests to be performed per calendar day pursuant to the Supplier's provision of the Services, such guaranteed capacity to be on the basis set out within the Order Form with the initial guaranteed daily capacity applicable from the Commencement Date of the Contract as set out in the Order Form and subject to change as agreed by the Parties, such agreement not to be unreasonably withheld or delayed;
<b>“Inconclusive Result”</b>	means a Test result that is not a Conclusive Result;
<b>“Lease”</b>	means the lease to any premises provided by and/or operated by the Supplier under this Contract;

<b>“Licence Terms”</b>	means a royalty-free, non-exclusive right for the Authority (and if applicable a New Provider) to Use, for the Term and any period as set out in the Exit Plan, the Supplier Software solely for the purposes of receiving and benefiting from the Services;
<b>“New Provider”</b>	any third party engaged by the Authority to supply any Replacement Services;
<b>“NHS Test Digital Platform”</b>	a collection of infrastructure and services and operational processes that together form the digital platform for the NHS Test programme;
<b>“Price Per Test”</b>	means the price per Test with a Conclusive Result as referred to as part of the Contract Price;
<b>“Purchase Rejection Notice”</b>	shall have the meaning as set out in paragraph <b>Error! Reference source not found.</b> of Schedule 2 of this Appendix G;
<b>“Purchase Confirmation Notice”</b>	shall have the meaning as set out in paragraph <b>Error! Reference source not found.</b> of Schedule 2 of this Appendix G;
<b>“Records”</b>	shall have the meaning as set out in Clause 12.1.1 of this Appendix G;
<b>“Replacement Services”</b>	services which are the same as or substantially similar to any or all the Services and which are purchased by or provided to the Authority following the termination or expiry of all or a part of this Contract to replace Services formerly provided by the Supplier under this Contract;
<b>“Run-Off Period”</b>	means the period of up to three (3) months (or such other period as may be set out in the Statement of Requirements forming part of the Specification and Tender Response Document for the relevant Contract) from the date of the expiry of the Term or the effective date of any earlier termination of this Contract;
<b>“Sample ID”</b>	means the machine-readable coded form of identification used by the Authority to identify individual Samples from the point of being taken from the service user through to notification of results by Supplier;
<b>“Samples”</b>	means the samples relating to the provision of Tests required to be retained by UKAS guidelines;
<b>“Specialist”</b>	means a Haematology, clinical biochemistry, immunology and microbiology (including virology and mycology) specialist expertise or other such specialist expertise forming part of the Specification and Tender Response Document;

<b>“Specialist-Reviewed Protocols”</b>	means the Specialist reviewed protocols to be followed in the follow on investigations of Tests, amendments to Test requests and in support of managing demand and ensuring appropriate Test requests as set out in the Supplier's documents as agreed from time to time with the Authority;
<b>“Specification and Tender Response Document”</b>	means the Specification and Tender Response Document set out in Order Form Appendix 1;
<b>“Standard Operating Procedures”</b>	means the procedures to be followed in the processing of Tests as set out in the Supplier's standard operating procedures documents as agreed from time to time with the Authority;
<b>"Step-in Notice"</b>	shall have the meaning as referred to at Clause 18.2 of this Appendix G;
<b>“Step-in Termination Condition”</b>	shall have the meaning as referred to at Clause 18.6 of this Appendix G;
<b>“Supplier Party”</b>	means the Supplier, each member of Supplier Personnel and all of the directors, officers, employees and workmen of Supplier or any such person who is engaged in relation to the provision of the Services or performance of Supplier's obligations under this Contract;
<b>“Supplier Test Digital Platform”</b>	a collection of infrastructure and services and operational processes that together form the Supplier's digital platform to integrate with the NHS Test Digital Platform;
<b>“Supplier's Background Intellectual Property Rights”</b>	Intellectual Property Rights owned by the Supplier before the Commencement Date; and/or Intellectual Property Rights created by the Supplier independently of this Contract;
<b>“Supplier Facilities”</b>	means the premises and testing infrastructure provided and/or operated by the Supplier at which the Supplier or Sub-contractors (as applicable) are to provide the Services, and includes the Testing Equipment;
<b>“Supplier's Software”</b>	means the software which is proprietary to or used by the Supplier including software which is or will be used by the Supplier for the purposes of providing the Services during the Term;
<b>“Testing Equipment”</b>	means the equipment used in the provision of the Services, being all that equipment supplied by Supplier;
<b>“Test Requests”</b>	means a request for one or more Test(s) placed on the NHS Test Digital Platform which will be sent by the NHS Test Digital



Platform to the Supplier Test Digital Platform for fulfilment by Supplier;

- “Tests”** means the tests referred to in the Specification and Tender Response Document and the term 'Testing' shall be construed accordingly;
- “Third Party Software”** means the software which is proprietary to any third party and supplier as part of or used in providing the Services;
- “UKAS”** means the United Kingdom Accreditation Service being national accreditation body recognised by the British government to assess the competence of organisations that provide certification, testing, inspection and calibration services (or any successor or replacement body of UKAS) or any equivalent EU certification agreed in writing in advance with the Authority;
- “Use”** means the right to load, execute, store, transmit, display, copy (for the purposes of loading, execution, storage, transmission or display), modify, adapt, enhance, reverse compile, decode, translate or otherwise utilise that software; and
- “Void Test”** means a Sample that cannot be tested because it presents a hazard or otherwise is not capable of being tested.

## **2 Provision of Services**

### **2.1 The Supplier shall:**

- 2.1.1 process any Tests as set out in the Specification and Tender Response Document in accordance with any timescales set out in the Specification and Tender Response Document;
- 2.1.2 provide all Testing Equipment and Supplier Personnel required to process the Tests and provide the Services;
- 2.1.3 provide the Supplier Facilities in accordance with the provisions of this Contract for the purposes of Testing;
- 2.1.4 provide the Services at the Facilities at such locations as may be set out in the Specification and Tender Response Document, or as otherwise agreed between the Parties in writing;
- 2.1.5 ensure that all relevant consents, authorisations, licences and accreditations required to provide the Services and the Supplier Facilities are in place at the Services Commencement Date and are maintained throughout the Term;
- 2.1.6 maintain UKAS accreditation in respect of the Facilities;

- 2.1.7 ensure that all the Facilities are fit for the purpose of providing the Services; and
- 2.1.8 ensure that it will not embarrass the Authority (meaning by its actions or omissions contrary to the spirit of this Contract that cause material adverse public comment concerning the Authority) or otherwise bring the Authority into disrepute by engaging in any act or omission which is reasonably likely to diminish the trust that the public places in the Authority, regardless of whether or not such act or omission is related to the Supplier's obligations under this Contract.

### **3 Operation of the Services**

#### **3.1 The Supplier shall provide the Services:**

- 3.1.1 in accordance with Good Scientific Practice;
- 3.1.2 in compliance with UKAS accreditation requirements;
- 3.1.3 in accordance with the Test volumes required to meet the Guaranteed Daily Capacity,
- 3.1.4 in accordance with this Contract;
- 3.1.5 to meet the KPIs; and
- 3.1.6 at the Facilities and at such locations, as may be set out in the Specification and Tender Response Document or as otherwise agreed by the Parties in writing and shall permit the Authority or its representatives to access any relevant premises (including the Facilities) for audit and quality assurance purposes.

#### **3.2 The Parties agree that no payment is due from the Authority to the Supplier for Void Tests.. For the avoidance of doubt, the Parties agree that the Authority shall only be required to pay for Tests that produce a Conclusive Result and that the Price Per Test only applies to Conclusive Results. Except where the void result is demonstrated and agreed to be the fault of the Authority, in which case the relevant sample cost shall apply provided that the Supplier has used all reasonable endeavours to avoid performing Tests which may result in a void result.**

#### **3.3 The Supplier acknowledges and accepts that:**

- 3.3.1 the Authority gives no guarantee as to the volume of Services required by it pursuant to this Contract; and
- 3.3.2 the Supplier's appointment to provide the Services is non-exclusive and the Authority shall be entitled to purchase equivalent services from other suppliers.

#### **3.4 The Supplier undertakes throughout the Term:**

- 3.4.1 to use the NHS Test Digital Platform;
- 3.4.2 to be responsible for the health and safety of all individuals (including each member of Supplier Staff, each Sub-contractor and all of the directors, officers, employees and workmen of Supplier or any such person who is engaged in relation to the provision of the Services or performance of

Supplier's obligations under this Contract) at the Facilities and to comply with applicable Authority / Health and Safety Executive instructions provided to the Supplier with respect to the Facilities;

- 3.4.3 to provide the Services on the basis of continuous improvement in respect of operational efficiency and staffing levels;
  - 3.4.4 to maintain and comply with a recognised information security management system and be actively working towards the ISO/IEC 27001 standard and/or any other standards set out in the Specification and Tender Response Document or Order Form for the Services;
  - 3.4.5 to ensure and guarantee any Sub-contractor appointed by Supplier to provide any element of the Services is UKAS accredited at the time of providing the relevant part of the Services;
  - 3.4.6 to inform the Authority promptly, giving details of the circumstances, reasons and likely duration, in the event it becomes aware of anything of whatsoever nature and whether or not the result of any act or omission on the part of the Supplier or any Supplier Party which may prevent the Supplier fulfilling its obligations in accordance with this Contract, including immediately sending to the Authority a copy of every notice or other communication of a non-routine nature relating to the provision of the Services received from or sent to any person or body concerning health and safety, environmental, and regulatory matters relating to the performance of the Services; and
  - 3.4.7 to work collaboratively with the Authority to ensure continuous improvements relating to the Services (including those used by equivalent suppliers of the Authority) are implemented throughout the Term, provided it is reasonably practical to do so.
- 3.5 The Supplier shall remove any member of the Supplier Personnel from the provision of the Services at the reasonable request of the Authority, forthwith (and without any compensation being payable), provided it is lawful to do so, if the Authority can demonstrate that any such member of the Supplier Personnel:
- 3.5.1 has not co-operated with the Authority in meeting its reasonable requests for the provision of information relating to the Services and the Facilities relevant to this Contract;
  - 3.5.2 has breached the confidentiality obligations applicable under this Contract; or
  - 3.5.3 has caused or is likely to cause the Supplier or the Authority to breach any data protection / data security requirements under this Contract; or
  - 3.5.4 has been guilty of any misconduct which, if such member of the Supplier Personnel had been an employee of the Authority, would have entitled the Authority summarily to dismiss that employee; or
  - 3.5.5 is not performing the Services demonstrating the skill and experience expected of staff which would reasonably and ordinarily be expected from a skilled, efficient and experienced staff member carrying out services that are the same or similar to the Services,

and, in each case, shall replace such individual.

3.6 The Supplier shall comply with the provisions regarding the provision of staffing information and TUPE as set out as part of any TUPE related provisions forming part of this Contract.

3.7 The Supplier has agreed to provide the Services up to the Guaranteed Daily Capacity.

**4 [not used]**

**5 [not used]**

**6 Authority obligations**

6.1 The Authority shall through the Term at its own cost:

6.1.1 purchase barcoded Test sample kits to be delivered to the Facilities by professional courier service; and ensure they are of suitable quality to be processed by the Supplier's facilities.

6.1.2 provide the Samples to the Facilities, ensuring that such Samples have the appropriate Sample ID and are transported in accordance with Good Scientific Practice relevant to the Samples for testing or as otherwise may be defined under any Law, Guidance or Good Industry Practice;

6.1.3 provide the NHS Test Digital Platform in order for the Supplier to log the receipt of Samples; input the results of a Test; and provide the validate app along with its suitable use for tracking data to the laboratory;

6.1.4 provide such co-operation in connection with the timely progression of issues and provision of information as the Supplier may reasonably require to enable the Supplier to meet its obligation under this Contract at all reasonable times in accordance with the provisions of the Specification and Tender Response Document and the other provisions of this Contract;

6.1.5 provide the Supplier with its updated requirements for demand for the Services using a rolling forecast of at least fourteen (14) calendar days;

6.1.6 where appropriate, invite the Supplier's representative to meetings with other suppliers of services similar to the Services;

6.1.7 ensure that adequate and appropriate maintenance and support services are available and in place for all systems and software used by the Authority solely to facilitate the Supplier's delivery of the Services, including the NHS Test Digital Platform; and

6.1.8 fulfil any other Authority obligations, as may be referred to as part of the Order Form and/or Specification and Tender Response Document.

**7 Tests and Testing**

7.1 The Supplier will process any Tests set out in the Authority's requirements set out in the Specification and Tender Response Document relating to the Contract in accordance with any timescales set out in this Contract. Subject to the Authority obligations being fulfilled to ensure the Supplier may in turn fulfil its obligations under the Contract., the Supplier shall provide all Testing Equipment and the Supplier Personnel required to process a Test and provide the Services.

- 7.2 The Supplier shall ensure that it (or its Sub-contractors) shall have the required Facilities to meet the Guaranteed Daily Capacity.
- 7.3 The Parties agree that:
- 7.3.1 risk in the Testing Equipment vests at all times with the Supplier or as applicable its Sub-contractors;
  - 7.3.2 the Supplier, or its Sub-contractors shall provide, the testing capacity sufficient to comply with its obligations under this Contract; and
  - 7.3.3 subject at all times to the applicable completion requirements of Tests, it is the sole responsibility of the Supplier to ensure the Facilities have the capacity to undertake the Testing process for the required number of Samples so as to ensure the Supplier meets its obligations set out in this Contract. The Authority shall incur no liability for any delays in, or results of, the Testing process of Samples by Supplier.

**8 [not used]**

**9 Additional Supplier Warranties**

- 9.1 The Supplier to warrants and undertakes that:
- 9.1.1 during the Term, the Facilities will be operated in a manner that is compliant with, and has all necessary consents in relation to standards set down by UKAS;
  - 9.1.2 the Tests shall be suitable for the purposes 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 the Specification and Tender Response Document and any standards required by Law, Guidance or Good Industry Practice;
  - 9.1.3 the Supplier Facilities are compliant with all applicable Laws, Guidance and Good Industry Practice and all relevant health and safety standards;
  - 9.1.4 it shall ensure that, the handling and storage of Samples at the Facilities is in accordance with good practice, as may be defined under any Law, Guidance and/or Good Industry Practice relevant to the Samples for testing, and in accordance with any specific requirements set out in Specification and Tender Response Document, the Standard Operating Procedures and any Specialist-Reviewed Protocols (as required in accordance with the Specification and Tender Response Document);
  - 9.1.5 it shall ensure that all materials and/or products used in the provision of Tests are kept in a state and condition necessary to enable the Supplier to comply with its obligations in accordance with this Contract;
  - 9.1.6 it has, or its Sub-contractors have, testing capacity sufficient to comply with its obligations under this Contract;
  - 9.1.7 the Testing Equipment shall be suitable for the purposes as referred to in the Specification and Tender Response Document, be of satisfactory quality, fit for its intended purpose, maintained fully in accordance with the manufacturer's specifications as applicable; and shall comply with the standards and requirements set out in this Contract;

- 9.1.8 it will work collaboratively with the Authority to devise plans and demand forecasts to help manage and ensure sufficient levels of consumables inventory are in place such that the Supplier can meet its obligations under this Contract, including managing the inventory availability of assays and the availability of the Facilities for testing purposes during the Term;
- 9.1.9 it has and shall as relevant maintain all rights, consents, authorisations, licences and accreditations required to supply the Services at the Facilities;
- 9.1.10 use of the Facilities, the Testing Equipment or of any other item or information supplied or made available by the Supplier will not infringe any third party rights, to include without limitation any Intellectual Property Rights; and
- 9.1.11 the Supplier IT systems (including the Supplier Test Digital Platform) will:
- (i) be fit for their purpose and for Supplier's requirements;
  - (ii) comply with the IT specification set out in the Specification and Tender Response document;
  - (iii) be maintained regularly in accordance with Good Industry Practice;
  - (iv) not infringe third party Intellectual Property Rights;
  - (v) not expose, subject, transfer or introduce any Disabling Device to the Authority's IT systems from time to time (including without limitation, hardware, software, firmware, middleware and memory capacity); and
  - (vi) prior to installation and during the Term have the benefit of an up to date virus checker.

## **10 Additional Authority Warranties**

- 10.1 The Authority warrants and undertakes that the NHS Test Digital Platform will:
- 10.1.1 be fit for its purpose to meet the requirements set out in this Contract;
  - 10.1.2 be maintained regularly in accordance with Good Industry Practice;
  - 10.1.3 not infringe third party Intellectual Property Rights;
  - 10.1.4 not expose, subject, transfer or introduce any Disabling Device to Supplier's IT systems from time to time (including without limitation, hardware, software, firmware, middleware and memory capacity); and
  - 10.1.5 prior to installation and during the Term have the appropriate security protections and controls in place.

## **11 Intellectual Property Rights**

- 11.1 For the avoidance of doubt, to the extent of any conflict between Clause 11 of Schedule 2 of Appendix A and this Clause 11 of this this Appendix G, this Clause 11 of this Appendix G shall prevail to the extent of such conflict.

- 11.2 All Authority Background Intellectual Property Rights provided to the Supplier by Authority pursuant to this Contract shall remain vested in and the property of Authority or licensed to the Authority, as appropriate. The Authority hereby grants to the Supplier a royalty-free, non-exclusive licence for the duration of this Contract to use such Authority Background Intellectual Property Rights, as the Authority may from time to time notify the Supplier that it may use for the sole purpose of performing its obligations under this Contract.
- 11.3 All Supplier Background Intellectual Property Rights provided to Authority by the Supplier pursuant to this Contract shall remain vested in and the property of the Supplier or licensed to the Supplier, as appropriate. The Supplier hereby grants to Authority a royalty-free, non-exclusive licence for the duration of this Contract to use such Supplier Background Intellectual Property Rights as the Supplier may from time to time notify Authority that it may use for the sole purpose of performing its obligations under this Contract.
- 11.4 All Intellectual Property Rights in any data relating to the results of the Tests performed by the Supplier under the Contract ("**Data Rights**") shall be the property of Authority. The Supplier shall not, and shall procure that its staff, personnel and Sub-contractors shall not, use or disclose any such data without prior written approval of Authority, except where it is in the public domain. The Supplier hereby assigns to Authority, with full title guarantee, all such Data Rights. This assignment shall take effect as a present assignment of future rights that will take effect immediately on the coming into existence of the Data Rights produced by the Supplier. The Supplier shall execute all documentation necessary to execute such assignment
- 11.5 The Supplier shall not infringe any Intellectual Property Rights of any third party in supplying the Services and the Supplier shall, during and after the Term, indemnify and keep indemnified and hold the Authority harmless from and against all actions, suits, claims, demands, losses, charges, damages, costs and expenses and other liabilities which Authority may suffer or incur as a result of or in connection with any breach of this Clause 11 of this Appendix G, except where any such claim arises from:
- 11.5.1 items or materials based upon designs supplied by Authority; or
- 11.5.2 the use of data supplied by Authority which is not required to be verified by the Supplier under any provision of the Contract.
- 11.6 Unless restricted from doing so, the Authority shall notify the Supplier in writing of any claim or demand brought against the Authority for infringement or alleged infringement of any Intellectual Property Rights in materials supplied or licensed by the Supplier.
- 11.7 The Supplier shall at its own expense conduct all negotiations and any litigation arising in connection with any claim for breach of Intellectual Property Rights in materials supplied or licensed by the Supplier, provided always that the Supplier:
- 11.7.1 shall consult the Authority on all substantive issues which arise during the conduct of such litigation and negotiations;
- 11.7.2 shall take due and proper account of the interests of the Authority; and
- 11.7.3 shall not settle or compromise any claim without the Authority's prior written consent (not to be unreasonably withheld or delayed).
- 11.8 The Authority shall at the request of the Supplier afford to the Supplier all reasonable assistance for the purpose of contesting any claim or demand made or action brought

against Authority or the Supplier by a third party for infringement or alleged infringement of any third party Intellectual Property Rights in connection with the performance of the Supplier's obligations under the Contract and the Supplier shall indemnify the Authority for reasonable costs and expenses (including, but not limited to, legal costs and disbursements) incurred in doing so. The Supplier shall not, however, be required to indemnify the Authority in relation to any costs and expenses incurred in relation to or arising out of a claim, demand or action which relates to the matters in Clauses 11.5.1 or 11.5.2 above.

- 11.9 The Authority shall not make any admissions which may be prejudicial to the defence or settlement of any claim, demand or action for infringement or alleged infringement of any Intellectual Property Right by Authority or the Supplier in connection with the performance of its obligations under the Contract.
- 11.10 If a claim, demand or action for infringement or alleged infringement of any Intellectual Property Right is made in connection with the Contract or, in the reasonable opinion of the Supplier, is likely to be made, the Supplier shall notify Authority and, at its own expense and subject to the consent of the Authority (not to be unreasonably withheld or delayed), use its best endeavours to:
- 11.10.1 modify any or all of the Services without reducing the performance or functionality of the same, or substitute alternative Services of equivalent performance and functionality, so as to avoid the infringement or the alleged infringement, provided that the provisions herein shall apply mutatis mutandis to such modified Services or to the substitute Services; or
  - 11.10.2 procure a licence to use and supply the Services, which are the subject of the alleged infringement, on terms which are acceptable to Authority; and
  - 11.10.3 in the event that the Supplier is unable to comply with Clauses 11.10.1 or 11.10.2 within twenty (20) calendar days of receipt of the Supplier's notification, the Authority may terminate the Contract with immediate effect by issuing a Termination Notice to the Supplier.

#### *Licences*

- 11.11 The Supplier hereby grants throughout the Term, or if applicable, shall procure the direct grant, to the Authority of a non-exclusive licence of the Supplier's Software (including any Supplier's Background Intellectual Property Rights or Intellectual Property Rights owned by a third party that are embedded in or which are an integral part of the Supplier's Software) on the Licence Terms. For the purposes of this Contract and not for use into other contracts without agreement.

## **12 Records and Samples**

- 12.1 Subject at all times to any instruction from the Authority to transfer the Records to the Authority and thereafter to destroy the Records and to any specific provisions in the Order Form, the Supplier shall during the Term and for the period of three (3) years thereafter:
- 12.1.1 maintain such clinical records relating to the provision of the Services (including the Sample ID and associated Test result, whether in hardcopy or electronic form as referred to in the Specification and Tender Response Document) ("**Records**");



- 12.1.2 store and preserve the integrity of all Samples for such duration and in such manner as the Authority may reasonably require;
- 12.1.3 on request, produce the Records and Samples for inspection by the Authority or, on receipt of reasonable notice, allow or procure for the Authority and/or its authorised representatives access to any premises where any such Records and Samples are stored for the purposes of inspecting and/or taking copies of and extracts from any such Records free of charge;
- 12.1.4 preserve the integrity of the Records and Samples in the possession or control of the Supplier or any Supplier Party and all data which is used in, or generated as a result of, providing the Services and to prevent any corruption or loss of that data; and
- 12.1.5 promptly provide the management information to the Authority as reasonably requested including the total number of Samples processed in the last 24 hours (including positive results, negative results, Inconclusive Results and the reason for Inconclusive Results, Void Tests and the reason for Void Tests) together with any other management information set out in and in accordance with the Specification and Tender Response Document.

### **13 Liability**

- 13.1 The Parties agree that for the purposes of this Contract costs associated with advising, screening, testing, treating, retreating or otherwise providing healthcare to individuals who have provided Samples shall be direct recoverable losses (to include under any relevant indemnity) by the Authority only to the extent to which such costs, expenses and/or loss of income arise or result from the Supplier's breach of contract, negligent act or omission, breach of statutory duty, and/or other liability under or in connection with this Contract.

### **14 Suspension**

- 14.1 In addition to any other rights of the Authority under this Contract, the Authority shall be entitled at any time during the Term, upon serving written notice of twenty-eight (28) calendar days to the Supplier, to suspend the provision of the Services (in full or part). The terms of any suspension pursuant to this Clause 14 shall be agreed by the Parties, with both Parties acting reasonably and in good faith.

### **15 Termination**

- 15.1 The Authority shall be entitled to terminate this Contract at any time upon serving four (4) weeks' written notice by issuing a Termination Notice to the Supplier.
- 15.2 The Authority may terminate this Contract at its convenience without payment of compensation or other damages caused to the Supplier in accordance with Clause 15.1.

### **16 Consequences of Termination**

- 16.1 On the expiry or termination of this Contract in whole for any reason whatsoever the Supplier shall:
  - 16.1.1 Continue in so far as is reasonably practical to do so, for the Run-Off Period following expiry or termination of this Contract, to undertake Tests on any Samples received from service users and the Authority shall continue to pay

the applicable Price Per Test (all in accordance with paragraph 3 of Schedule 2 (Exit Plan) of this Appendix G; and

- 16.1.2 without limitation to any of the requirements set out in any agreed Exit Plan or Schedule 2 to this Appendix G (which, for the avoidance of doubt, the Supplier must comply with), if requested by the Authority, the Supplier shall use reasonable endeavours to procure the novation (or other form of transfer as may be agreed with the Authority such as assignment) of all contracts entered into with third parties to the extent that they relate specifically to delivery of the Services to the Authority, or to such New Provider as the Authority shall nominate.

## **17 Sub-contracts**

- 17.1 In addition to Clause 28 (Assignment, novation and Sub-contracting) of Schedule 2 of Appendix A, the Supplier shall comply with the provisions of this Clause 17 of Appendix G.
- 17.2 The Authority hereby provides its consent for the Supplier to enter into Sub-contracts with the Approved Sub-contractors for their respective sub-contracted elements of the Services, as set out in Schedule 3 (Approved Sub-Contractors).

### *Matters to be included in Sub-Contracts*

- 17.3 To the extent not already required in accordance with the Appendix A, the Supplier shall, at all times, ensure that all Sub-contracts include:
- 17.3.1 provisions such that the Sub-contract shall not be rescinded, or varied in such a way as to alter or extinguish any rights granted to the Authority without the prior written consent of the Authority;
- 17.3.2 a right for the Authority to enforce the termination rights under the Sub-contract;
- 17.3.3 a requirement that either Party to the Sub-contract may release to the Authority any of those parts of the Sub-contract as are necessary to be sufficient to demonstrate compliance with the provisions of this Clause 17 of this Appendix G and that any such release shall not amount to a breach of any provision of confidentiality contained within the Sub-contract;
- 17.3.4 a term which gives the Supplier a right to terminate the Sub-contract if the Sub-contractor fails to materially comply in the performance of the Sub-contract;
- 17.3.5 provisions enabling the Supplier to terminate the Sub-contract on notice on terms no more onerous on the Supplier than those imposed on the Authority under this Contract;
- 17.3.6 a provision restricting the ability of the Sub-contractor to sub-contract all or any part of the services provided to the Supplier under the Sub-contract without first seeking the written consent of the Authority;
- 17.3.7 a term which, upon the Supplier or the Authority's request, requires the Sub-contractor to participate and attend any meetings (whether in person or remotely) with the Authority;

- 17.3.8 a term which requires the Supplier, the Authority or any other party receiving goods or services under that Sub-contract to consider and verify invoices under that Sub-contract in a timely fashion;
- 17.3.9 provisions that if the Supplier, the Authority or any other party fails to consider and verify an invoice in a timely fashion, the invoice shall be regarded as valid and undisputed, after a reasonable time has passed;
- 17.3.10 a term which requires payment of undisputed sums to be made by the Supplier to the Sub-contractor within a specified period not exceeding thirty (30) days from the Supplier's receipt of a valid invoice;
- 17.3.11 a right for the Authority to publish the Supplier's compliance with its obligation to pay undisputed invoices to its Sub-contractors within the specified payment period; and
- 17.3.12 a licence for the Authority to use any Intellectual Property Rights relevant to the Services owned or controlled by a Sub-contractor in the same terms as the licence the Authority receives in relation to Intellectual Property Rights owned or controlled by the Supplier as set out in Clause 11 (Intellectual Property Rights) of this Appendix G.

***Termination of Sub-contracts***

17.4 The Authority may require the Supplier to terminate:

- 17.4.1 a Sub-contract where:
  - (i) the acts or omissions of the relevant Sub-contractor have caused or materially contributed to the Authority having a right of termination pursuant to this Contract regardless of whether the Authority has elected to exercise that right or not; and/or
  - (ii) the relevant Sub-contractor has embarrassed the Authority (meaning by its actions or omissions contrary to the spirit of the subcontract with the Supplier that cause material adverse public comment concerning the Authority) or otherwise brought the Authority into disrepute by engaging in any act or omission which is reasonably likely to diminish the trust that the public places in the Authority, regardless of whether or not such act or omission is related to the Sub-contractor's obligations in relation to the Services or otherwise.
- 17.4.2 a Sub-contract where there is a change in control of the relevant Sub-Contractor within the meaning of sections 450 and 451 of the Corporation Tax Act 2010 (other than for an intra-group change of control), unless:
  - (i) the Authority has given its prior written consent to the particular change in control, which subsequently takes place as proposed; or
  - (ii) the Authority has not served its notice of objection within three (3) weeks of the later of the date the change in control took place or the date on which the Authority was given notice (or otherwise became aware) of the change in control.

**18 Step-In**

- 18.1 The provisions of this Clause 18 shall apply to the Contract if:
- 18.1.1 the Authority acting reasonably, considers that a breach by the Supplier of any obligation under this Contract:
    - (i) may create an immediate and serious threat to the health and safety of any service user or person; or
    - (ii) may result in a material interruption in the provision of one or more of the Services.
- 18.2 In any of the circumstances set out in Clause 18.1, the Authority acting reasonably may serve notice on the Supplier ("**Step-in Notice**") to:
- 18.2.1 require the Supplier to remedy such breach by re-executing the relevant part of the Services for no extra charge and in accordance with the Specification and Tender Response Document and the requirements of this Contract;
  - 18.2.2 require the Supplier to repay or credit to the Authority that part of the Contract Price paid by the Authority to the Supplier relating to the provision of the relevant part of the Services not provided; or
  - 18.2.3 advise the Supplier that the Authority considers there is not sufficient time, or that the Supplier will be unable to take the necessary or expedient steps to correct any event set out at Clause 18.1, and that the Authority shall take such steps as the Authority considers to be appropriate (either itself or by engaging others to take such steps) to ensure performance of the relevant Services to the standards required by this Contract (but without giving the Authority any rights with regard to the management or operation of the Facilities) and the Supplier shall provide the Authority with all reasonable assistance to enable the Authority to take such steps under this Clause 18.2.3.
- 18.3 Any costs or expenses incurred by the Supplier in taking such steps as are required by the Authority pursuant to Clause 18.2 shall be borne by the Supplier and the Supplier shall provide the Authority with all reasonable and necessary co-operation. The Supplier shall reimburse the Authority for all reasonable costs, losses, expenses or damages incurred by the Authority in taking the steps or engaging others to take the steps referred to in Clause 18.2.3, net of what the Authority would have had to pay to the Supplier for the performance of the applicable Service if the right of step-in under such sub-clause had not been exercised, and the Authority shall be entitled to deduct such amounts from any other sum or amount payable to the Supplier under the provisions of this Contract.
- 18.4 After the expiry of one (1) month after the Step-in Notice has been served, the Authority shall promptly (and in any event within 7 calendar days) either:
- 18.4.1 if the Step-in Termination Condition defined in Clause of this Appendix G is satisfied, immediately terminate this Contract by issuing a Termination Notice to the Supplier;
  - 18.4.2 if the Supplier has failed to demonstrate that it can resume the performance of the Services so as to meet the KPIs and/or the Guaranteed Daily

Capacity, immediately terminate this Contract by issuing a Termination Notice to the Supplier; or

- 18.4.3      notify the Supplier that it may resume carrying out the Services.
- 18.5      In the event that the Authority does not give notice under either Clause 18.4.1, Clause 18.4.2 or Clause 18.4.3 of this Appendix G, it shall be deemed to have given notice under Clause 18.4.3 of this Appendix G.
- 18.6      For the purposes of Clause 18.4 of this Appendix G, the step-in termination condition ("**Step-in Termination Condition**") shall be satisfied if there has been a breach by the Supplier of any obligation under this Contract which is continuing at the date falling 1 month after the Step-in Notice was served and which:
- 18.6.1      has created or is likely to create an immediate and serious threat to the health and safety of any service user or person; or
- 18.6.2      has resulted or is likely to result in a material interruption in the provision of any of the Services.

**Schedule 1**

**Implementation Plan**

The Parties shall work together to agree an implementation plan within five (5) Business Days of the Commencement Date (or such other period as the Parties agree in writing). The Supplier agrees that the implementation plan will include any commitments made by the Supplier in the implementation plan submitted to the Authority with the Supplier's tender response. The implementation plan shall include Service commencement from 1st January 2022 pending completion of the below implementation plan activities:

- Completion and sign off of the Operational Readiness Checklist
- Completion and sign off of the Validation Audit Checklist
- Development and successful test upload of the NPEx results file in line with the approved specification

## **Schedule 2**

### **Exit Plan**

#### **1 INTRODUCTION**

- 1.1 Consistent with Clause 15.9 of Schedule 2 of Appendix A, the Parties will produce an Exit Plan based on the principles set out in this Schedule 2 for the orderly transition of the Services from the Supplier to the Authority or any New Provider in the event of any expiry or earlier termination of the Contract. The Parties shall use best endeavours to agree the contents of the Exit Plan.
- 1.2 The Exit Plan shall:
- 1.2.1 address each of the issues set out in this Schedule 2 to facilitate the transition of the Services from the Supplier to the New Provider and/or the Authority and shall include measures aimed at minimising (to the Supplier's best ability) disruption in the supply of the Services and at avoiding any deterioration in the quality of delivery of the Services;
  - 1.2.2 detail how the Services will transfer to the New Provider and/or the Authority including details of the processes, documentation, data transfer, systems migration, security and the segregation of the Authority's technology components from any technology components run by the Supplier or any of its Sub-contractors (where applicable);
  - 1.2.3 provide a timetable with milestones and the associated obligations of each Party in achieving such milestones, such milestones to reflect all critical issues and dependencies for carrying out and meeting the milestone obligations in the Exit Plan; and
  - 1.2.4 set out the management structure to be put in place and employed during the Exit Plan period.
- 1.3 The Exit Plan should be updated during the Term by agreement between the Parties and include any changes to the Contract made under the relevant Contract change provisions. The Exit Plan must be applicable in whatever circumstances termination arises.
- 1.4 The information in the Exit Plan shall be accurate and complete in all material respects and the level of detail to be provided by the Supplier shall be such as would be reasonably necessary to enable a third party to undertake the Services.

#### **2 EXIT PLAN - COMMENCEMENT**

- 2.1 The Exit Plan will become effective pursuant to Clause 16 (Consequences of expiry or early termination of this Contract) of Schedule 2 of Appendix A.
- 2.2 The Parties will, from the Exit Plan becoming effective, jointly establish an Exit Group comprising staff of both Parties to manage disengagement of the Services and the Contract and to implement the provisions of the Exit Plan. Each Party is to make available sufficient resources to meet the requirements of the Exit Plan. The Exit Group will manage all the activities needed for the transfer of the Services from the Supplier to the Authority or any New Provider so that the transition is carried out as seamlessly as possible.

- 2.3 Notwithstanding anything to the contrary in the Contract, the Parties agree that during the Exit Plan period:
- 2.3.1 the Authority shall give no guarantees in relation to the volume of Services required;
- 2.3.2 the Authority shall have no obligations to pay the Contract Price or other costs to the Supplier unless the Authority places a Test Request for Tests in accordance with the Contract.

### **3 RUN-OFF PERIOD**

- 3.1 Notwithstanding that this Contract will terminate or expire at the end of the Term, the Parties recognise that Samples may continue to be sent to the Facilities. For the avoidance of doubt, for the purposes of this paragraph 3 of this Schedule 2 of this Appendix G, the end of the Term will be the date of the expiry or earlier termination of this Contract for whatever reason. The Parties agree the following in relation to Samples submitted for Testing after the end of the Term:
- 3.1.1 the Supplier and its Sub-contractors shall, for a period up to three (3) months from the end of the Term following expiry or earlier termination, continue to process and complete Tests on any Samples received and to report the Test results in accordance with The Specification and Tender Response Document, provided they are still able to do so.
- 3.1.2 such Testing of Samples and the reporting of Test results shall be in accordance with the standards and requirements set out in this Contract;
- 3.1.3 the Supplier shall, at the end of each month, submit an invoice to the Authority for any such processed Tests, such invoices to be in the form as agreed by the Parties and the basis of the Contract Price shall be calculated on the same basis as immediately prior to such termination or expiry; and
- 3.1.4 the Authority shall pay the appropriate Contract Price for all Samples tested and reported in the three (3) month period following expiry or termination but shall have no liability to meet any costs incurred by the Supplier thereafter. Payment of the Contract Price for this three (3) month period shall be made by the Authority in accordance with the relevant provisions of this Contract.

### **4 THE SUPPLIER'S CHARGES**

- 4.1 The Authority will continue to pay Contract Price for Goods and/or Services provided during the Exit Plan period, as referred to in the Exit Plan.

### **5 THE SUPPLIER'S RESPONSIBILITIES**

- 5.1 The Supplier's responsibilities are set out in the Contract in Clause 16 (Consequences of expiry or early termination of this Contract) of Schedule 2 of Appendix A and in any TUPE provisions applicable to exit.
- 5.2 The Supplier's further responsibilities shall be those set out in the Exit Plan, as well as the following:
- 5.2.1 Requests – the Supplier will, for a period equalling the longer of (1) the period covered by the Exit Plan period; or, (2) three (3) months following effective date of the termination or expiry of this Contract, comply with and/or respond to any reasonable requests made to it from by the Authority.



- 5.2.2 .
- 5.2.3 Management Procedures - both Parties must work in accordance with the management process, controls and project style defined in the current version of the Exit Plan.
- 5.2.4 Return of the Authority's Confidential Information - in accordance with Clause 16 (Consequences of expiry or early termination of this Contract) of Schedule 2 of Appendix A and in accordance with any relevant dates in the Exit Plan.
- 5.2.5 Ceasing use of any Authority Facilities and return of any Authority Equipment or other Assets or inventory owned by the Authority - in accordance any relevant processes and dates in the Exit Plan.
- 5.2.6 Avoidance of Unnecessary Costs - the Supplier is to take all reasonable steps to co-operate with the Authority and any New Provider to prevent any avoidable costs incurred by the Authority or any New Provider as a result of the Supplier's acts or omissions in respect of the Exit Plan.
- 5.2.7 Retention of Records –
- (i) The Supplier shall, subject to paragraph 5.2.10(ii) of this Schedule 2 of this Appendix G, retain all papers, files, records and vouchers (or copies thereof) relating to the provision of the Services and which the Supplier is entitled to keep pursuant to terms of this Contract for the period of six (6) years after the date of the termination or expiry of this Contract and thereafter shall not destroy them but deliver them to the Authority.
  - (ii) Notwithstanding paragraph 5.2.10(i) of this Schedule 2 of this Appendix G, if any papers, files, records or vouchers (or copies thereof) are required to be retained for a period of more than six (6) years following termination or expiry in order to comply with any relevant industry guidance or other provisions of this Contract, then the Supplier shall retain such papers, files, records or vouchers for such longer period as may be required by such guidance.

**Schedule 3**

**Approved Sub-contractors**

<b>Supplier</b>	<b>Location</b>	<b>Incorporated Name</b>	<b>Company Number</b>	<b>VAT number</b>
None				