

# PHE Public Health Microbiology Framework Agreement Order Form

(in accordance with NHS Framework Agreement for the Supply of Goods (August 2014) – Appendix A – Calloff Terms and Conditions for the Supply of Goods / Services)

# **FROM**

Participating Authority:	Public Health England (PHE), an executive agency of the Department of Health and Social Care.	
Service address:	As per PHE official purchase order(s)	
Invoice address:	PHE Accounts Payable Team Financial Accounting Services PHE Porton Down, Manor Farm Road Salisbury, Wiltshire SP4 0JG Email: payables@phe.gov.uk	
PHE Procurement Lead:	Name: Phone: E-mail:	
PHE Project Manager for Implementation Phase:	Name: Phone: E-mail:	
PHE Supplier Relationship Manager (SRM):	Name: Phone: E-mail:	
PHE Internal Reference (if applicable)	To be quoted on all correspondence relating to this Order Form: Supply of cobas® SARS-CoV-2 COVID-19 assays and related consumables, instruments and service to Public Health England.	

# TO

Roche Diagnostics Limited ("Roche") Charles Avenue Burgess Hill
West Sussex
RH15 9RY

Supplier Details:	Contact	Name: E-mail: Phone:
		Email: Phone:
		Email Phone:

# 1. CONTRACT DETAILS

(1.1) Contract Purpose: Pursuant to this Contract, Roche shall supply the cobas® SARS-CoV-2 COVID-19 assay and related consumables to PHE and, on PHE's direction from time to time, PHE-Roche partnership sites across the United Kingdom which are operated by the NHS in England, Public Health Wales, Health and Social Care Northern Ireland, the Northern Ireland Blood Transfusion Service, NHS Scotland and the Scottish National Blood Transfusion Service. This Contract shall also govern the use and service of cobas® instruments in connection with the performance of the cobas® SARS-CoV-2 COVID-19 assay by PHE Porton Down and Glasgow Royal Infirmary.

The Parties agree that, unless otherwise stated, all equipment, associated software, reagents and consumables will be supplied under the Microbiology Framework Agreement, Lot 1 Terms and Conditions for the Supply of Goods (Appendix A\_i).

- (1.2) Contract Effective Date: 16th March 2020
- (1.3) Contract Value (and breakdown if applicable): Estimated approximate value of £21,000,000 based on the assumption of tests per week for the Initial Term.
- (1.4) Contract End Date: 30 September 2020 subject to any permitted extensions as set out at 1.5 below.
- (1.5) Contract Extension Options: The Contract shall run until 30 September 2020 ("Initial Term"), with an option to extend for six further periods of 3 months each ("Extension Term").

Prior to the end of the Initial Term, Public Health England will give 60 calendar days notice in writing on whether this Contract will come to an end or be extended for a further 3 month period. Prior to the end of any Extension Term, Public Health England shall provide 30 calendar days notice in writing on whether the Contract will come to an end or be extended for a further 3 month period.

(1.6) Deliverables - Goods: Pursuant to this Contract, Roche shall deliver the goods identified in Annex 1 ("the Goods").

<ul> <li>Timing of Delivery and Delivery Volumes: For the Initial Term and any subsequent Extension Term, the Goods are subject to the allocation process agreed between Roche and PHE, specifically:</li> <li>(a) By no later than Wednesday of any given week, Roche shall provide PHE with the total number of tests available for distribution within the United Kingdom for that weekly allocation cycle, and the results of the weekly stock check from the testing sites;</li> <li>(b) By no later than 13:00 PM the following day (Thursday), PHE shall instruct Roche with the number of tests and delivery locations of the allotted Goods, by email, addressed to ; and</li> </ul>		
<ul><li>(c) Based on the email allocation received from PHE, Roche shall deliver the allocated amount to the relevant designated laboratory within 2 working days.</li><li>(d) Roche will provide with the delivery notes on dispatch of each allocated amount with unique reference numbers.</li></ul>		
(e) Roche will provide with a summary of the delivered allocated amounts on a weekly basis to allow verification of invoices.		
The Parties reserve the right to modify the above process, by written agreement of both Parties, as necessary during the Term of this Contract.		
(1.7) Deliverables – Instruments. For purposes of this Contract, PHE agrees that it shall use the existing installed instruments at the sites identified in Annex 2 Part 1, except as identified in this section 1.7 and Annex 2 Parts 2 and 3.		
(a) PHE Porton Down - Instrument Delivery Details:  (i) Pursuant to an agreement with an effective date of 30 March 2020 between Roche and PHE ("the Agreement"), Roche will be responsible for de-installing and collecting the Instruments (as defined in the Agreement) from and delivering and reinstalling them at Public Health England's Porton Down location (Public Health England, Manor Farm Rd, Porton Down, Salisbury SP4 OJG). These Instruments were released by agreement of (ii) In addition, Roche and PHE agree that Roche shall relocate a further cobas 6800 instrument from the in accordance with the terms as set out in Annex 3. This		
instrument was released by agreement of and and with prior approval from		
(iii) In addition, Roche and PHE have previously arranged for the relocation of a cobas 6800 instrument from the This instrument was released by agreement of the This instrument was released by agreement was released by agreement was released by agreement of the This instrument was released by agreement was release		
(iv) At the end of the relevant contract terms, if the instruments are to be returned to and/or Roche will be responsible for collecting the Instruments from Public Health England Porton Down and reinstating them at and/or and/or The anticipated go live dates for these instruments are identified in the separate correspondence with PHE.		
(b) ————————————————————————————————————		
(together the above shall be known and referred to as the "Relocated Instruments")		

Roche is required to have the necessary insurance provision for the above movements, or operate an adequate programme of self-insurance.

**Title:** With respect to the Relocated Instruments, full legal, beneficial and equitable title in the Relocated Instruments shall remain vested in Roche throughout the Initial Term and any subsequent Extension Term. Risk in each of the Relocated Instruments shall pass to PHE following the completion of installation, verification and validation. at the respective locations as outlined in Annex 2. Public Health England shall store and maintain the Instruments at its nominated premises in accordance with the Applicable Law and in conditions which adequately protect and preserve the Goods in accordance with the manufacturer's manual. Public Health England shall also insure the Instruments, without any charge to Roche, or operate an adequate programme of self-insurance.

Public Health England agrees to indemnify and hold Roche harmless from and against any claims, costs, expenses, and damage arising out of the abnormal or improper use, misuse, or neglect of those Relocated Instruments recommissioned at PHE Porton Down or any breach of these terms and conditions or default on the part of Public Health England. Public Health England shall have no such obligation for any fair wear and tear associated with normal and ordinary use of such Relocated Instruments recommissioned at PHE Porton Down.

# (1.8) Deliverables – Instrument Support

The parties recognize the importance of maintaining these Relocated Instruments, and others being used to address the COVID-19 crisis. Roche will ensure that the instruments listed in Annex 2 are maintained in line with the manufacturer's specification. In the event of a system fault or breakdown and the use of remote diagnostics prove unsuccessful, Roche shall use reasonable endeavours to deploy an engineer to fix the fault as soon as practicable, and will communicate with PHE to coordinate such service.

Roche agrees that it shall continue to offer, subject to agreement and payment of the relevant service cost, maintenance support for a minimum of seven (7) years:

- (a) in the case of each Relocated Instrument retained by PHE pursuant to the provisions of Section 1.9, from the original date of completion, verification and validation of such Instrument at or Roche Burgess Hill (as the case may be); and
- (b) in the case of the cobas® 8800 purchased by PHE under this Contract, from the date of completion, verification and validation of such Instrument at PHE Porton Down.

## (1.9) Contract Price:

<u>General Provisions:</u> The Contract Price shall, subject to successful delivery and installation, be comprised of the following:

# **Goods**

# (a) Goods (including Purchased Instrument):

Roche shall use its best endeavours to deliver, install and commission prior to the end of the Initial Term, and Public Health England shall pay to Roche the cost of, the high throughput Instrument, associated software and ancillary equipment as set forth in Annex 4 Part 1.

With respect to the testing kits provided under this Contract, as well as the related consumables and reagents, for the duration of this Contract, Public Health England shall pay to Roche the amounts

identified in Annex 4 Part 1. Relocated Instruments (b) PHE Porton Down – Instruments from As stated in the Agreement, PHE has agreed to reimburse Roche for certain expenses and costs related to the de-installation, transportation and re-installation of the instruments. Indicative figures are outlined in Annex 4 Part 2. In addition, with respect to those instruments, PHE agrees to pay Roche a monthly charge for use of those instruments and for any necessary technical service, as set forth in Annex 4 Part 2. (c) PHE Porton Down – Instrument from \_\_\_\_\_\_As set out below at Annex 3, PHE has agreed to reimburse Roche for certain expenses and costs related to the de-installation, transportation and re-installation of the instrument. Indicative figures are outlined in Annex 4 Part 2. At the conclusion of this Contract, Roche will further invoice Public Health England for the reasonable and documented costs of decommissioning the Instrument from Porton Down, and the return transportation, reinstatement and re-validation of the Instrument at IIII In addition, with respect to the instrument, PHE agrees to pay Roche a monthly charge for use of the Instrument and for any necessary technical service, as set forth in Annex 4 Part 2. (d) PHE Porton Down - Instrument from PHE has agreed to reimburse Roche for certain expenses and costs related to the de-installation, transportation and re-installation of the Indicative figures are outlined in Annex 4 Part 2. At the conclusion of this Contract, Roche will further invoice Public Health England for the reasonable and documented costs of decommissioning the Instrument from Porton Down, and the return transportation, reinstatement and re-validation of the In addition, with respect to the instrument, PHE agrees to pay Roche a monthly charge for use of those instruments and for any necessary technical service, as set forth in Annex 4 Part 2. (e) PHE has agreed to reimburse Roche for certain expenses and costs related to the de-installation, transportation and re-installation of the instrument from Roche to Indicative figures are outlined in Annex 4 Part 2. At the conclusion of this Contract, Roche will further invoice Public Health England for the reasonable and documented costs of decommissioning the Instrument from Porton Down, and the return transportation, reinstatement and re-validation of the Instrument at Roche. In addition, with respect to the instrument, PHE agrees to pay Roche a monthly charge for use of those instruments and for any necessary technical service, as set forth in Annex 4 Part 2. Contingent Costs – Relocated Instruments (I). Notwithstanding the obligations for PHE to reimburse Roche for the decommissioning of any Instrument from Porton Down, and the return transportation, reinstatement and re-validation of any Instrument at its original location as provided above, Public Health England may elect to retain a Relocated Instrument ("PHE Option Event") or be required to retain a Relocated Instrument as outlined in the Agreement ("Third Party Option Event"). (II). To confirm a PHE Option Event, PHE shall give Roche written notice stating its desire to either: (a) purchase the Relocated Instrument(s) from Roche for the residual value of the instrument(s) (based on a 7 year straight line depreciation); or (b) enter into a reagent rental agreement with Roche with regard to that Relocated Instrument(s). Following receipt of such notice from PHE, Roche shall provide a quotation to PHE within 10 Working Days.

- (III). On the occurrence of a Third Party Option Event, Roche shall give PHE written notice that such a Third Party Option Event has occurred ("Third Party Option Notice") requesting a confirmation in accordance with sub-paragraph (IV) below.
- (IV). PHE shall confirm within 10 Working Days of valid receipt of a Third Party Option Notice (delivered in accordance with clause 27 of Schedule 2 to the Call-off Terms and Conditions) whether it will either
  - (a) purchase the Relocated Instrument(s) from Roche for the residual value of the instrument(s) (based on a 7 year straight line depreciation); or
  - (b) enter into a reagent rental agreement with Roche with regard to such Relocated Instrument(s).
- (V). In the event that PHE fails to provide confirmation in accordance with paragraph (IV) above, PHE shall be deemed to have purchased such instruments in accordance with sub-paragraph (IV)(a) above and Roche shall raise an invoice for the amount equal to the residual value which shall be payable by PHE.
- (VI). For the avoidance of doubt, if any of the Relocated Instruments are to be returned to Roche, PHE will provide Roche with the necessary decontamination certificates 10 Working Days prior to collection.

	,
<u>Inc</u>	idental Costs
(f)	Pursuant to the separate agreement between and Roche, as amended on 3 April 2020, following the de-installation of the Instruments at Roche shall provide one additional cobas 4800 instrument and one replacement cobas 4800 instrument to be used by during the duration of this Contract. Roche shall invoice Public Health England for the reasonable and documented costs associated with transporting and installing the two 4800 instruments at and shall also invoice Public Health England for the costs of decommissioning and transporting the two 4800 instruments from after the termination of this Contract.
(g)	Send-away Reimbursement  (i) As set out in the Agreement, Roche and have separately agreed that in respect of the TV/MG testing which cannot be undertaken by for the duration of this Contract, that may send-away the and tests which are estimated to be no more than tests per week to at a fixed cost of per test for and for plus the reasonable costs for handling and processing, which are to be per sample, and transportation costs which shall be limited to per parcel. Roche has agreed to reimburse for such send-away costs. In consideration for the inconvenience and interruption, Public Health England have agreed to reimburse Roche for these send-away costs. In order to be reimbursed for these costs, Roche shall submit to Public Health England the invoices from and Public Health England will pay such charges within 30 days of receipt.
	In addition, Public Health England have agreed to reimburse Roche for any reasonable and documented costs Roche incurs to as a result of lost stock and consumables that can no longer be used by cransferred to an alternative laboratory as a result of the urgent relocation of the Instruments.
	he interest of clarity, references to reimbursement of Roche's costs in this Contract shall refer to actual, of pocket costs, and shall not include loss of profit.

VAT shall only be payable on items under this Contract in accordance with clause 9.4 of Schedule 2 of the Call-off Terms and Conditions.

Wherever this Contract contains an obligation for one party to compensate or indemnify the other for or against any costs, claims, expenses or damages, the party receiving such compensation or indemnification shall use its best efforts to minimise and mitigate the amount of such costs etc.

# (1.10) PAYMENTS:

PHE will issue 3 separate Purchase Orders ("POs") based on quotes provided by Roche.

The POs will cover:

- Capital purchase;
- Consumables and reagents;
- Any other agreed costs including but not limited to:
  - Maintenance service cover;
  - Equipment rental;
  - Relocation of instruments; and
  - Send-away reimbursement costs.

To avoid delay in payment it is important that the any invoice issued to PHE is compliant and that it includes a valid PO Number and unique order reference number issued by Roche.

If Roche have any queries regarding an outstanding payment, please contact PHE by email to:

# 2. ADDITIONAL REQUIREMENTS

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

The Parties hereby agree to work together in good faith to explore the possible development and/or operation of a SARS-CoV-2 assay utilising the cobas® omni Utility Channel on the cobas® 6800 or cobas® 8800.

The Parties acknowledge that during the term of the Contract a non-COVID-19 health-related emergency or risk to public health may emerge (a "New Public Health Risk") and in such event the Parties further acknowledge this Contract may be amended in accordance with clause 21.1 (Change Management) of Schedule 2 of the Call-off Terms and Conditions.

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

# Exceptional circumstances as a result of the Covid-19 pandemic

2.1 Without prejudice to the Parties' obligations under the Contract (including but not limited to the Supplier's obligations under the Contract to supply the Goods, including as set out within the Order Form) the Parties recognise that the circumstances created as a result of the COVID-19 pandemic are exceptional and fast-moving. As a consequence, the Parties agree that they will act reasonably and in good faith together to seek to resolve any difficulties or challenges which may impact upon the manufacture and supply

of Goods and in relation to the wider COVID-19 issues so as to ensure that public health is protected and preserved.

## 2.2 In this context:

- 2.2.1 the Supplier recognises that there may be a shortage of supply of Component Parts and accordingly, the Supplier shall take all reasonable steps to safeguard and protect all stocks of Component Parts held by it and its Group from time to time which may be required to manufacture the Goods;
- 2.2.2 the Supplier agrees to provide the Authority sufficient visibility of the Supplier's manufacturing processes and timelines for the manufacture and supply of Goods, in the form of its four week forecast, if so requested, to allow the Authority to plan an adjust order scheduling across the Authority's supply chain for products equivalent to or similar to the Goods:
- 2.2.3 the Supplier shall notify the Authority promptly of any exceptional events or circumstances which may impact upon the Supplier's ability to manufacture and supply Goods in accordance with this Contract and the Authority's requirements.

# (2.2) Variations to Call-off Terms and Conditions for the Supply of Goods:

The Parties have agreed to certain amendments to the Call-Off Terms and Conditions for Goods, as set forth in Annex 5 to this Order Form.

In the event of any conflict, inconsistency or ambiguity between the provisions of the following agreements, the order of priority for construction purposes shall be that a higher listed document shall prevail over a lower listed document, i.e. document (a) shall prevail over all other documents; document (b) shall prevail over document (c):

- (a) Agreement;
- (b) Relocation Agreement (Annex 3);
- (c) The master agreement between Roche and PHE set out in this Order Form (other than the Relocation Agreement referred to above).

Variations to Call-off Terms and Conditions for the Supply of Services: Not applicable.

3. GOODS AND/OR SERVICES REQUIREMENTS	
(3.1) Key personnel of the Supplier to be involved in the Services and delivers	erables:
(3.2) Performance standards: As set out in the Supplier's validation data at	Ref 09175431190

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

Listed at Annex 2 together with the full address and site contact information as appropriate.

## (3.4) Quality standards:

As set out in the Supplier's validation data at

Ref 09175431190

### (3.5) Contract monitoring arrangements:

As agreed by both parties in line with Schedule 8: Supplier Relationship Management of the Framework Agreement.

# (3.6) Management Information and meetings:

As agreed by both parties in line with Schedule 8: Supplier Relationship Management of the Framework Agreement.

### (3.7) Notices

For the purposes of this Contract, any contractual notice to be served, shall be sent to the persons named in this Order Form.

# 4. CONFIDENTIAL INFORMATION (if applicable)

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

All information regarding pricing and charges (Section 1.9 above), installations and existing installed base location Annexes 1-4) shall be considered Confidential.

For the avoidance of doubt, this restriction shall not prevent PHE from complying with its obligations by notifying under Contracts Finder or complying with its reporting obligations under regulation 84 of the Public Contracts Regulations 2015.

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

Duration of the Contract plus ten (10) years from termination of the Contract.

Signature: DecuSigned by:	Signature: DocuSigned by:
For and on behalf of the Authority Name:	For and on behalf of the Contractor Name:
Job Title:	Job Title:
Date: 27-May-2020	Date: 25-mai-2020

Consumables

# Annex 1 Goods

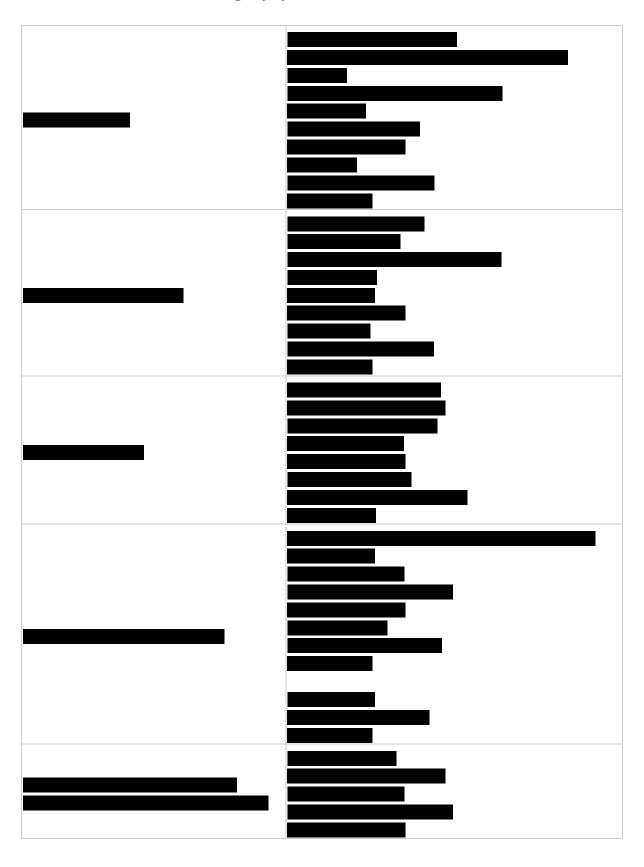
Equipment		Description
Cobas 8800		Cobas 8800 and associated software and ancillary equipment
<b>Assay Components</b>		
<b>Report Classification</b>	Mat. Number	Description
Reagent	9175431190	KIT COBAS 6800/8800 SARS-COV-2 192T
Controls	7002238190	KIT COBAS 6800/8800 BUFF NEG RMC IVD
Controls	9175440190	KIT COBAS 6800/8800 SARS-COV-2 RMC
Consumables	Mat. Number	Description
Consumables Consumables	<b>Mat. Number</b> 6997503190	<b>Description</b> KIT COBAS 6800/8800 WASH IVD
		•
Consumables	6997503190	KIT COBAS 6800/8800 WASH IVD
Consumables Consumables	6997503190 5534925001	KIT COBAS 6800/8800 WASH IVD cobas omni Pipette Tips
Consumables Consumables Consumables	6997503190 5534925001 6997546190	KIT COBAS 6800/8800 WASH IVD cobas omni Pipette Tips KIT COBAS 6800/8800 MGP IVD
Consumables Consumables Consumables Consumables	6997503190 5534925001 6997546190 6997511190	KIT COBAS 6800/8800 WASH IVD cobas omni Pipette Tips KIT COBAS 6800/8800 MGP IVD KIT COBAS 6800/8800 SPEC DIL REAGENT IVD

Solid Waste Bag With Insert Set of 20

8030073001

# Annex 2

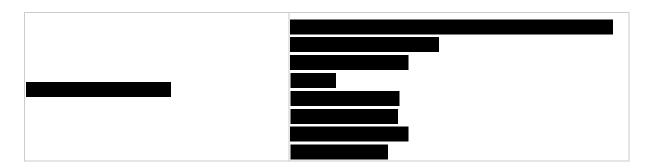
Part 1 - Existing Equipment locations and addresses





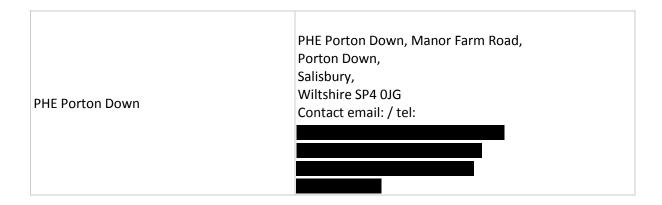


Part 2 – Relocated Instruments locations and addresses





Part 3 – Purchased Instrument location and address



# Annex 3 Relocation Agreement

1. Contract Reference	Supply of 1x Roche cobas 6800 instrument to Public Health England	
2. Effective Date	1 <sup>st</sup> May 2020	
3. Buyer	Public Health England ("PHE"), an executive agency of the Department of Health and Social Care	
	Wellington House 133-155 Waterloo Road London SE1 8UG	
4. Supplier	Roche Diagnostics Limited ("Roche") Charles Avenue Burgess Hill West Sussex RH15 9RY	
5. The Contract	has an existing contract with Roche on a reagent rental basis that includes the use of one cobas 6800 instrument  The Agreement has now been amended to permit Public Health England to obtain the cobas 6800 instrument, as described in this Contract.  Pursuant to this Contract, Roche shall supply the Instrument defined below on the terms set out in this Order Form and in accordance with the Call-off Terms And Conditions for the Supply of Goods, Annex Ai to the PHE Microbiology Framework – Lot 1, BSP 2415/ ECM 4121 between PHE and Roche as amended in accordance with Annex 5 ("the Call-Off Terms").	
6. Deliverables	Goods  Description: Roche cobas 6800 Instrument ("Instrument")  Delivery Address: Public Health England Porton Down, Manor Farm Rd, Porton Down, Salisbury SP4 0JG.  Anticipated Delivery Dates:  Delivery as soon as possible but no later than week commencing 18 May 2020 (Anticipated Go Live Week commencing 22 June 2020)  The above delivery and go-live dates are based	
		on the best information currently available and are subject to modification based on

exigent circumstances. Roche agrees to use its best efforts to meet or exceed the estimated dates.

Delivery Details: Roche will be responsible for de-installing and collecting the Instrument from and delivering and reinstalling them at Public Health England's address identified above. The risk for the Instrument shall transfer to Public Health England once the Instrument have been installed and verification and validation have been completed.

At the end of the Contract term Roche will be responsible for collecting the Instrument from Public Health England and reinstating them at Risk in the Instrument shall pass to Roche from the day Roche begins deinstallation until delivered to

Roche are required to have the necessary insurance provision for the above movements or operate an adequate programme of self-insurance.

Given the rapidly changing nature of this process and PHE's desire for installation at the earliest possible date, the parties agree that final delivery instructions will be provided as early as practicable.

**Title:** Full legal, beneficial and equitable title in the Instrument shall remain vested in Roche throughout the pendency of this Contract. Risk in the Instrument shall remain with until Roche begins to de-install the Goods and shall pass to PHE as set out above.

Public Health England shall store and maintain the Instrument at its nominated premises in accordance with the Applicable Law and in conditions which adequately protect and preserve theInstrument in accordance with the manufacturer's manual. Public Health England shall also insure the Instrument, without any charge to Roche or operate an adequate programme of self-insurance.

		Public Health England agrees to indemnify and hold Roche harmless from and against any claims, costs, expenses, and damage arising out of the abnormal or improper use, misuse, or neglect of the Instrument or any breach of these terms and conditions or default on the part of Public Health England. Public Health England shall have no such obligation for any fair wear and tear associated with normal and ordinary use of the Instrument.
	Services	The parties recognise the importance of maintaining this Instrument, and others being used to address the COVID-19 crisis pursuant to the master agreement between Roche and PHE set out in this Order Form above. Roche will ensure that the Instrument is maintained in line with the manufacturer's specification. In the event of a system fault or breakdown and the use of remote diagnostics prove unsuccessful, Roche shall use reasonable endeavours to deploy an engineer to fix the fault as soon as practicable, and will communicate with PHE to coordinate such service
7. Specification	One cobas 6800 instrument and delivery and maintenance.	
8. Term	The Term shall commence on 1 <sup>st</sup> May 2020 and the Contract shall run for a period of three months to 31st July 2020 ("Initial Term"), with an option to extend for two further periods of 3 months ("Extension Term").  Prior to the end of the Initial Term or the first Extension Term, Public Health England will give ten working days' notice on whether the Contract will come to an end or be extended for a further 3 month period.  The terms and conditions of the Contract shall apply until the collection date of the Instrument.	
9. Charges	The Charges for the Deliverables shall, following Go Live and subject to successful delivery and installation be calculated as stated in this Section 9.  In the interest of clarity, references to reimbursement of Roche's costs in this Contract shall refer to actual, out of pocket costs, and shall not include loss of profit.  Wherever this Contract contains an obligation for one party to compensate or indemnify the other for or against any costs, claims, expenses or damages, the party receiving such compensation or indemnification shall use its best efforts to minimise and mitigate the amount of such costs etc.	

	Roche will invoice Public Health England for the reasonable and documented delivery costs associated with decommissioning the Instrument from transporting them to Public Health England's site at Porton Down and installing them at Porton Down. At the conclusion of this Contract, Roche will further invoice Public Health England for the reasonable and documented costs of decommissioning the Instrument from Porton Down, and the return transportation, reinstatement and revalidation of the Instrument at
	In the event that the Redeployment Period continues for more than 6 months, have reserved the right to request a replacement cobas 6800 instrument at nil cost to On the occurrence of a new instrument being requested and a notice to such effect from Roche, Public Health England agrees that it will either  (a) purchase the Instrument from Roche for the residual value of the instrument (based on a 7 year straight line depreciation) or  (b) enter into a reagent rental agreement with Roche with regard to the Instrument.
	On receiving such notice of replacement from Roche, PHE will respond in accordance with the Third Party Option Event procedure, as set out in section 1.9 of the Order Form above.
	With respect to testing during the Term of this Contract, Public Health England shall pay to Roche the cost per test, as well as any additional expenses for servicing and instrument costs, as set out in the Order Form above.
10. Payment	All invoices must be sent, quoting a valid purchase order number (PO Number), to:
	PHE Accounts Payable Team Financial Accounting Services PHE Porton Down, Manor Farm Road Salisbury, Wiltshire SP4 OJG
	To avoid delay in payment it is important that the any invoice issued to PHE is compliant and that it includes a valid PO Number and unique order reference number issued by Roche.
	If Roche have any queries regarding an outstanding payment, please contact PHE by email to:
11. Buyer Authorised Representative	For general liaison your contact will continue to be , PHE Porton Down ).

12. Address for notices & Key Personnel	Public Health England  PHE Porton  Down.  PHE Porton Down  Manor Farm Road  Porton Down  Salisbury  SP4 0JG	Roche Diagnostics Limited - RMS - RMS  Charles Avenue Burgess Hill West Sussex RH15 9RY	
13. Email	Public Health England:		
Addresses for notices and	Roche Diagnostics:		
key personnel			
14. Procedures and Policies	PHE may require Roche to ensure that and delivery of the Deliverables has undertaken		
and Policies	Service check but does only expect to ex	_	
	circumstances and only following prior notice to Roche.		
	Roche shall ensure that no person who discloses that he/she has a conviction that is relevant to the nature of the Contract, relevant to the work of PHE, or is of a type otherwise advised by PHE (each such conviction a "Relevant Conviction"), or is found by Roche to have a Relevant Conviction (whether as a result of a police check, a Disclosure and Barring Service check or otherwise) is employed or engaged in the provision of any part of the Deliverables.		
In respect of any Confidential Information it may receive di indirectly from the other Party (" <b>Discloser</b> ") and subject to the obtained provisions of Schedule 3 of the Call-off Terms, each Party unto keep secret and strictly confidential and shall not disclose Confidential Information to any third party without the Disclose written consent. Roche understands that PHE is subject to the of Information Act 2000 and both parties hereby acknowledge at that the provisions of Schedule 3 of the Call-Off Terms are incoherein and shall apply to any such requests.		erms, each Party undertakes shall not disclose any such without the Discloser's prior HE is subject to the Freedom reby acknowledge and agree	

# Annex 4 Contract Price

# Part 1 – Equipment, tests, reagents and consumables

Equipment		Description	Unit Price Exc VAT
Cobas 8800		Cobas 8800 and associated software and ancillary equipment.	
Assay Components			
Report Classification	Mat. Number	<b>Description</b> KIT COBAS 6800/8800 SARS-COV-2	Unit Price
Reagent	9175431190	192T KIT COBAS 6800/8800 BUFF NEG	
Controls	7002238190	RMC IVD KIT COBAS 6800/8800 SARS-COV-2	
Controls	9175440190	RMC	
Consumables			
Report Classification	Mat. Number	Description	<b>Unit Price</b>
Consumables	6997503190	KIT COBAS 6800/8800 WASH IVD	
Consumables	5534925001	cobas omni Pipette Tips	
Consumables	6997546190	KIT COBAS 6800/8800 MGP IVD KIT COBAS 6800/8800 SPEC DIL	
Consumables	6997511190	REAGENT IVD	
Consumables	5534917001	cobas omni Processing Plate KIT COBAS 6800/8800 LYS REAGENT	
Consumables	6997538190	IVD	
Consumables	5534941001	cobas omni Amplification Plate	
Consumables	8030073001	Solid Waste Bag With Insert Set of 20	

# Part 2 – Relocated Instrument Costs

# **Instrument Costs**

Service cost per instrument per month Instrument rental price per month



# Annex 5

The Parties agree the following amendments to the Framework Call-Off Terms and Conditions for the Supply of Goods:

Clause 1.3	The parties hereby acknowledge and agree that the Relocated Instruments are not new equipment.
Clause 1.7	The cross-reference to Clause 1.5 shall be amended to cross-refer to Clause 1.6.
Clause 2.3	Clause 2.3 shall be deleted and replaced by the following:
	"The following details shall be shown on the outside of every package and within a delivery note which must accompany each package:
	2.3.1 a description of the Goods which shall include, without limitation, the weight of the Goods where available and any order number allocated to the Goods by the Authority and/or Supplier;
	2.3.2 the quantity in the package, where available;
	2.3.3 any special directions for storage;
	2.3.4 the expiry date of the contents, where applicable;
	2.3.5 the batch number; and
	2.3.6 the name and address of the manufacturer of the Goods and Supplier.
	In addition, all Goods that customarily bear any mark, tab, brand, label, serial numbers or other device indicating place of origin, inspection by any government or other body or standard of quality must be delivered with all the said marks, tabs, brands, labels, serial numbers or other devices intact. Without prejudice to the generality of the foregoing, the Supplier shall label all Goods supplied to the Authority, and the packaging of such Goods, to highlight environmental and safety information as required by applicable Law."
Clause 3.2	It is agreed that the ownership in the Relocated Instruments shall at all times remain with the Supplier unless and until any of the Relocated Instruments are purchased capital in accordance with terms set out in the Order Form.
Clause 9.2	In respect of the COVID19 testing, the Supplier confirms that the pricing shall remain fixed for the next 12 months.
Clause 9.2.2	The Parties agree that the entire price payable is as described in the Order Form.
Clause 9.9	A new clause 9.9 shall be inserted as follows:
	"Where the Authority is entitled to receive any sums (including, without limitation, any costs, charges or expenses) from the Supplier under this Contract, the Authority may invoice the Supplier for such sums. Such

	invoices shall be paid by the Supplier within 30 days of the date of such invoice."	
Clause 9.10	A new clause 9.10 shall be inserted as follows:	
	"If a Party fails to pay any undisputed sum properly due to the other Party under this Contract, the Party due such sum shall have the right to charge interest on the overdue amount at a rate of 4% above Bank of England base rate, accruing on a daily basis from the due date up to the date of actual payment, whether before or after judgment."	
Clause 10.1.8	Given the current pandemic, the Authority accepts that the Supplier will use its best endeavours to ensure that there are sufficient stock levels to comply with the Authority's demand. The initial weekly allocation for the United Kingdom as at the Contract Effective Date was no less than COVID-19 tests with the intent to provide more as and when possible.	
Clause 10.1.31	A new clause 10.1.31 shall be inserted as follows:	
	"it shall: (i) comply with all relevant Law and Guidance and shall use Good Industry Practice to ensure that there is no slavery or human trafficking in its supply chains; and (ii) notify the Authority immediately if it becomes aware of any actual or suspected incidents of slavery or human trafficking in its supply chains;"	
Clause 10.1.32	A new clause 10.1.32 shall be inserted as follows:	
	"it shall at all times conduct its business in a manner that is consistent with any anti-slavery Policy of the Authority that is notified to the Supplier and shall provide to the Authority any reports or other information that the Authority may request as evidence of the Supplier's compliance with this Clause 10.1.32 and/or as may be requested or otherwise required by the Authority in accordance with its anti-slavery Policy."	
Clause 12	Clause 12.1 shall be deleted and replaced by the following:	
	12.1 "The Supplier shall be liable to the Authority for, and shall indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings in respect of:  12.1.1 any injury or allegation of injury to any person, including injury resulting in death;  12.1.2 any loss of or damage to property (whether real or personal); and/or	
	12.1.3 any breach of Clause 10.1.19 and/or Clause 11 of this Schedule 2 of these Call-off Terms and Conditions; that arise or result from the Supplier's negligent acts or omissions or breach of contract in connection with the performance of this Contract including the supply of the Goods. The indemnity set out in this Clause 12.1 shall not apply to the extent that such loss, damages, costs, expenses (including	

	without limitation legal costs and expenses), claims or proceedings have been caused by any act or omission by, or on behalf of, or in accordance with the instructions of, the Authority or a PHE Authorised User of the Goods, including without limitation any use by the Authority or a PHE Authorised User of the Goods either for a purpose not authorised by the Specification or in a manner which is inconsistent with the instructions set out or referred to in the Specification. For the purposes of this Clause 12, a PHE Authorised User of the Goods is a person to whom the Goods are made available by the Authority."	
Clause 15.2	The Parties hereby agree that in the circumstances the Term may be extended as outlined in this Order Form.	
Clause 15.5.6	A new clause 15.5.6 shall be inserted as follows:	
	"15.5.6 upon the occurrence of any of the events in regulations 73(1)(a)-(c) of the Public Contracts Regulations 2015 (SI 2015/102)."	
Clause 17	Clause 17 shall be amended by the addition of the following to amend/replace the current provision as indicated:	
	17.2 [to be inserted after current provision] "and in relation to Goods imported into the United Kingdom for the purposes of the Producer Responsibility Obligations (Packaging Waste) Regulations 2007 and all applicable product and safety liability legislation in force in the United Kingdom from time to time, the Supplier shall assume all obligations for all activities performed outside the United Kingdom in relation to the Goods and the packaging, in addition to any other obligations the Supplier may have pursuant to such regulations and other legislation."	
	17.4 [to replace the current provision] "The Supplier shall ensure that all Goods that are required by Law or Guidance to bear any safety information, environmental information, any mark, tab, brand, label, serial numbers or other device indicating place of origin, inspection by any government or other body or standard of quality at the point such Goods are delivered shall comply with such requirements at the point of delivery."	
Clause 18	Clause 18 shall be deleted and replaced by following:	
	18.1 "Unless otherwise confirmed and/or agreed by the Authority in writing the Supplier shall ensure full compliance with any Guidance issued by the Department of Health in relation to the adoption of GS1 and PEPPOL standards (to include, without limitation, any supplier compliance timeline and other policy requirements published by the Department of Health in relation to the adoption of GS1 and PEPPOL standards for master data provision and exchange, barcode labelling and purchase to pay transacting).	
	18.2 Once compliance with any published timelines has been achieved by the Supplier pursuant to the Order Form, the Supplier shall, during the Term, maintain the required level of compliance relating to the Goods in	

	accordance with any such requirements and Guidance referred to as part of this Contract.
	18.3 Once product information relating to Goods is placed by the Supplier into a GS1 certified data pool, the Supplier shall, during the Term, keep such information updated with any changes to the product data relating to the Goods."
Clause 28.5	The existing clause 28.5 shall be amended to read as follows:
	"Where the Authority pays the Supplier's undisputed invoices earlier than thirty (30) days from receipt in accordance with any applicable government prompt payment targets, the Supplier shall use its reasonable endeavours to pay its relevant subcontractors within a comparable timeframe from receipt by the Supplier of such undisputed invoices from its subcontractors."
Clause 28.7	The existing clause shall be removed and replaced as follows:
	"Neither Party may at any time transfer, assign, novate, subcontract or otherwise dispose of its rights and obligations under this Contract or any part of this Contract without the prior written consent of the other party, such consent not to be unreasonably withheld or delayed".

# **Information Governance Provisions - Schedule 3**

Clause 2.1	The existing definition shall be removed and replaced as follows:	
	"The Parties each acknowledge and agree that they may need to undertake Processing of Personal Data relating to each Party's representatives (in their respective capacities as Controllers) in order to (as appropriate):	
	<ul><li>(a) administer and provide the Goods;</li><li>(b) request and receive the Goods;</li></ul>	
	(c) compile, dispatch and manage the payment of invoices relating to the Goods;	
	<ul><li>(d) manage the Contract and resolve any disputes relating to it;</li><li>(e) respond and/or raise general queries relating to the Goods; and</li><li>(f) comply with their respective regulatory obligations.</li></ul>	
	Processing of Personal Data relating to each Party's representatives for the purposes set out above shall only be done by each Party in accordance with their respective privacy policies. The Parties acknowledge that they may be required to share Personal Data with their affiliates, group companies and other relevant parties, within or outside of the country of origin, in order to carry out the activities listed above, and in doing so each Party will ensure that the sharing and use of this Personal Data complies with applicable Data Protection Legislation."	

# **Definitions – Schedule 4**

"Contracting Authority"	The existing definition shall be removed and replaced as follows:
Authority	"means any contracting authority as defined in Regulation 2 of the Public Contracts Regulations 2015 (SI 2015/102) (as amended), other than the Authority;"
"Controller"	A new definition shall be inserted as follows:
	"shall have the same meaning as set out in the General Data Protection Regulation (Regulation (EU) 2016/679);"
"Data Protection Legislation"	The existing definition shall be removed and replaced as follows:
	"means (i) the Data Protection Act 2018 to the extent that it relates to processing of personal data and privacy; (ii) the GDPR, the Law Enforcement Directive (Directive (EU) 2016/680) and any applicable national implementing Law as amended from time to time; and (iii) all applicable Law about the processing of personal data and privacy including where applicable guidance and codes of practice issued by the Information Commissioner;"
"Data Subject"	The existing definition shall be removed and replaced as follows:
	"shall have the same meaning as given to it in the Data Protection Legislation"
"Force Majeure Event"	The following text shall be included at the end of the existing definition:
	"but excluding, for the avoidance of doubt, the COVID-19 crisis and any related circumstances, events, changes or requirements;"
"Personal Data"	The existing definition shall be removed and replaced as follows:
	"shall have the same meaning as set out in the General Data Protection Regulation (Regulation (EU) 2016/679);"
"Process"	The existing definition shall be removed and replaced as follows:
	"shall have the same meaning as set out in the General Data Protection Regulation (Regulation (EU) 2016/679) and for the purposes of this Contract shall include both manual and automatic processing. "Processing" and "Processed" shall be construed accordingly;"
t	

"Sensitive Personal	The existing definition shall be removed and replaced as follows:
Data"	
	"means special categories of personal data as defined in the Data Protection Legislation;



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