Appendix 1

National Microbiology Framework Agreement
Order Form

FROM

Authority:	**The Secretary of State for Health and Social Care acting as part of the Crown through the UK Health Security Agency** of 10 South Colonnade, London E14 4PU
Invoice address:	All invoices must be submitted by or on behalf of the Supplier quoting a valid purchase order number to: payables@ukhsa.gov.uk
Contract Manager:	Name: [redacted] Phone: [redacted] E-mail: [redacted]
Secondary Contact: e.g. business operational contact, project manager	Name: [redacted] Phone: [redacted] E-mail: [redacted]
Procurement lead	Name: [redacted] Phone: [redacted] E-mail: [redacted]
Name and address for notices:	Name: [redacted] Address: UK Health Security Agency of 10 South Colonnade, London E14 4PU Email: [redacted] with cc to [redacted]
Internal reference (if applicable):	To be quoted on all correspondence relating to this Order Form: Atamis Project C235942

TO

Supplier:	Serosep UK Limited of 2-3 Baird Close, Crawley, West Sussex, England, RH10 9SY. Companies House Registration Number: 08096199
Contract Manager:	Name: [redacted] Phone: [redacted] E-mail: [redacted]
Secondary Contact:	Name: [redacted] Phone: [redacted] E-mail: [redacted]

Account Manager:	Name: [redacted] Phone: [redacted] E-mail: [redacted]
Name and address for notices:	Name: Serosep UK Address: 2-3 Baird Close Crawley, West Sussex RH10 9SY, UK

Applicable terms and conditions

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

Appendix A	Call-off Terms and Conditions for the Supply of Goods and the Provision of Services	**Applicable to this Contract**
Appendix B	Optional Additional Call-off Terms and Conditions for Installation and Commissioning Services	☒ **(only applicable if this box is checked)**
Appendix C	Optional Additional Call-off Terms and Conditions for Maintenance Services	☒ **(only applicable if this box is checked)**
Appendix D	Optional Additional Call-off Terms and Conditions for Bespoke Research, Development and Manufacturing Requirements	☐ **(only applicable if this box is checked and to the extent the applicable terms are included in Annex A (Order Specific Key Provisions))**
Appendix E	Optional Additional Call-off Terms and Conditions for Reagent Rental	☐ **(only applicable if this box is checked)**
Appendix F	Optional Additional Call-off Terms and Conditions for Managed Equipment Services	☐ **(only applicable if this box is checked)**
Appendix G	Optional Additional Call-off Terms and Conditions for Clinical Laboratory Diagnostic Testing Services	☐ **(only applicable if this box is checked and to the extent the applicable terms are included in Annex A (Order Specific Key Provisions))**
Appendix H	Further Optional Additional Call-off Terms and Conditions Each of the following clauses in Appendix H is only applicable to this Contract if the relevant box is checked: 1. TUPE applies at the commencement of the provision of Services ☐	**(only applicable if one or more boxes are checked)**

	2. TUPE on exit	☐	
	3. Different levels and/or types of insurance	☐	
	4. Induction training for Services	☒	
	5. Further Authority obligations	☐	
	6. Assignment of Intellectual Property Rights in deliverables, materials and outputs of the Services	☒	
	7. Inclusion of a Change Control Process	☒	
	8. Authority step-in rights	☐	
	9. Guarantee[1]	☐	
	10. Termination for convenience	☒	
	11. Pre-Acquisition Questionnaire	☐	
	12. Time of the essence (Goods)	☐	
	13. Time of the essence (Services)	☐	
	14. Specific time periods for inspection	☐	
	15. Specific time periods for rights and remedies under Clause 3.6 of Schedule 2 of Appendix A	☐	
	16. Right to terminate following a specified number of material breaches	☒	
	17. Expert Determination	☐	
	18. Consigned Goods	☐	
	19. Improving visibility of Sub-contract opportunities available to Small and Medium Size Enterprises and Voluntary, Community and Social Enterprises	☐	
	20. Management Charges and Information	☒	
	21. COVID-19 related enhanced business continuity provisions	☒	
	22. Buffer stock requirements	☒	
	23. Modern slavery	☒	
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.			☒ **(only applicable if this box is checked)**

- Transfer of title in the equipment to UKHSA.

1. CONTRACT DETAILS

(1.1) Commencement Date:
The date of the last signature on this Order Form.

(1.2) Services Commencement Date (if applicable):
In accordance with the Supplier's Implementation Plan (C226058_Serosep_Q16_Implementation Plan for UKHSA_V2) outlined in the Supplier's Tender Response.

(1.3) Contract Price ((i) breakdown and (ii) payment profile):

Breakdown

The Charges are outlined below:

Tab & Header	Price
System	
Hardware	[redacted]
Validation & Training	[redacted]
Calibration, Servicing and Planned Preventative Maintenance Plan (CSPPM)	[redacted]
Service Desk, Technical Support and Reactive Maintenance Plan (SDTSRMP) - Package	[redacted]
Service Desk, Technical Support and Reactive Maintenance Plan (SDTSRMP) - Non-Package	[redacted]
Assays 1	
Total Assay Bid Price	[redacted]
Delivery Tab	
Total Delivery Bid Price	[redacted]
Exit Plan Pricing	
Total Exit Plan Bid Price	[redacted]
Complete Bid Price	**£15,035,772.00**

The Charges shall be fixed from the date of the Tender submission to the end of year 1, from this point any annual increase shall be no more than CPIH.

All Charges must include all delivery, installation, configuration or any other costs incurred for the goods to be fit for use, and to deliver the identification of the essential Pathogens list (Table 1 Essential Targets, Enteric Tender Specification).

Payment Profile

The following payment profiles shall apply for the duration of this Call-Off Contract:

Description	Payment Profile
System/Equipment	Upon successful delivery, installation and validation of the Systems in each of the UKHSA labs.
Materials and Material delivery charges	Monthly against consumed Materials and deliveries, with invoices raised for each of the individual sites.
Calibration, Servicing and Planned Preventative Maintenance	Align with schedule of activity. E.g. if calibration, servicing or planned preventative maintenance is required quarterly payment shall be made quarterly.
Service Desk, Technical Support and Reactive Maintenance	Quarterly
Exit Costs	As agreed in the Final Exit Plan

(1.4) Term of Contract:

The initial term of the Contract shall be five (5) years from the final Contract signature date.

(1.5) Term extension options:

The Contract can be extended for a further three (3) years after the initial term.

2. GOODS AND/OR SERVICES REQUIREMENTS

(2.1) Description of the Goods / Services:

Please see Annex B to this Call-Off Order Form

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

The Supplier shall supply the total molecular enteric pathogen detection system to the following four UKHSA laboratories:

UKHSA Birmingham,
University Hospitals Birmingham NHS Foundation Trust,
Heartlands Hospital,
Bordesley Green East,
Birmingham
B9 5SS
Site Representative: [redacted]
Representative Email: [redacted]

UKHSA Bristol
Pathology building
Southmead Hospital
Bristol
BS10 5NB
Site Representative: [redacted]
Representative Email: [redacted]

UKHSA Cambridge

Level 6, Box 236
Addenbrooke's Hospital
Hills Road
Cambridge
CB2 0QW
Site Representative: [redacted]
Representative Email: [redacted]

UKHSA Manchester
Clinical Sciences Building
Manchester Royal Infirmary
Oxford Road
Manchester
M13 9WL
Site Representative: [redacted]
Representative Email: [redacted]

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

Not applicable.

(2.4) Performance standards:

Please see Annex B to this Call-Off Order Form

(2.5) Quality standards:

Please see Annex B to this Call-Off Order Form

(2.6) Contract monitoring arrangements:

Contract Management meetings shall be conducted on the following basis:

During the delivery of the Implementation Plan meetings will be held weekly for the duration of the Implementation Plan. The Authority reserves the right to continue to require weekly reviews if Milestones are missed. Topics for the Implementation Plan progress meetings are:

Implementation Plan Reviews

- compliance with the Implementation Plan and any risks or issues with meeting them with mitigations;
- manufacturing/delivery progress for the System to each site including lead times, delivery slots, receiving protocols;
- progress on installation activities – outcome from previous site visits and planning for installation for each site;
- digital integration activities – progress on interfacing with site Laboratory Information Management Systems (LIMS) and any issues/risks and their mitigations;
- assay verification activities – progress, issues (what, why, how, plans to resolve), risks of failure and mitigations, linking with site staff;
- training activities – progress, risks and issues, sign off of individuals, quick guide creation;
- any other risks or issues regarding deliver; and
- KPI compliance.

When all Milestones in the Implementation Plan have been fully delivered, the Contract Management meetings shall shift to be being held monthly in the first instance, with a view to these being held quarterly from six (6) months post the completion of the Implementation Plan. Due to the criticality of this capability to the Authority's operations the Supplier shall supply a report on a monthly basis the **"Management Information Report"** which shall be sent to both the Operation and Commercial Contract Managers, within five (5) business days of the conclusion of the previous month. The format of the Management Information Report shall be created and agreed jointly by the Supplier and Authority representatives. The Management Information Report shall include but not be limited to:

- a general update on delivery and the services;
- KPI compliance – KPI official reporting times are as described in Annex C (KPI's), including any remediation regimes;
- risks and issues, and mitigations thereof;
- servicing and maintenance scheduling – ensuring that all scheduling is agreed and any risks to these timings are discussed and mitigated. All incidents of downtime shall be reported, including a description of the root cause of the downtime, how the downtime is being/was resolved and any steps that are being/were taken to minimise the risk of such downtimes occurring again.
- trend analysis with system issues – errors, down-time, run failures (including those caused by operator error);
- confirmation and evidence of contractually required stock holdings in UK mainland;
- quality – "Quality Events" reporting, including corrective and preventative actions. MHRA field safety notices. Authority providing TrackWise incident reports; and
- change control – any changes or variations to the contract to be discussed and follow the Contract change management system.

(2.7) Management information and meetings:

Please see section 2.6 above for detail.

3. CONFIDENTIAL INFORMATION (if applicable)

(3.1) The following information shall be deemed Confidential Information:
Not used.

(3.2) Duration that the information shall be deemed Confidential Information:
Not used.

4. DATA PROCESSING (if applicable)

(4.1) Personal Data to be processed by the Supplier:

Not applicable.

5. LEASE / LICENSE (if applicable)
(5.1) The Authority is granting the following lease or licence to the Supplier: Not applicable.

For and on behalf of the Authority	For and on behalf of the Supplier
[redacted]	[redacted]
Date Signed: 19/02/2024	Date Signed: 19/02/2024

Hardware													
Product	Name/Description	Product Code/ Catalogue No.	Description	Manufacturer Name	Manufacturer Product Code	Warranty Period	Dimensions for each section of complete system (HxWxD mm)	Lead Time/ Notice required	Operational Lifetime	Number of Sections Units to fulfil all 4 sites requirements	Price for single Section/Unit	Total Number of Units multiplied by Price	Bid price for full compliment of systems See guidance Tab for "Equipment/Platform proposed " (£)
Capital purchase of Equipment /Platform - Section/Unit 1	EntericBio Workstation	5070000450	Liquid Handler Solution for EntericBIo Assay Use	Eppendorf	5070000450	12 Months	650mm x 980mm x 620mm	Equipment Available Now upto 30 days from a delivery and set up perspective	8 Years	10	[redacted]	[redacted]	[redacted]
Capital purchase of Equipment /Platform - Section/Unit 2	EntericBio Heatstation	QB04 SEROSEP	Heating Block for use with EntericBio Assay Use	Grant	QB04 SEROSEP	12 Months	100mm x 200mm x 380mm	Equipment Available Now upto 30 days from a delivery and set up	8 Years	10	[redacted]	[redacted]	

								perspecti ve				
Capital purchase of Equipment /Platform - Section/Unit 3	**Eppendorf Centrifuge**	**5427000666**	**Centrifuge with plate inserts for use with EntericBio PCR Strips**	**Eppendorf**	**5427000666**	**12 Months**	**250mm x 330mm x 420mm**	**Equipment Available Now upto 30 days from a delivery and set up perspective**	**8 Years**	**10**	[redacted]	[redacted]
Capital purchase of Equipment /Platform - Section/Unit 4	**Eppendorf Mixmate**	**5353000030**	**Mixer for sue with Entericbio Assay Plates**	**Eppendorf**	**5353000030**	**12 Months**	**130mm x 170mm x 230mm**	**Equipment Available Now upto 30 days from a delivery and set up perspective**	**8 Years**	**10**	[redacted]	[redacted]
Capital purchase of Equipment /Platform - Section/Unit 5	**Roche Lightcycler 480 II**	05015278001	Real Type PCR Instrument	Roche Diagnostics	05015278001	12 Months	500mm x 570mm x 590mm	Equipment Available Now upto 30 days from a delivery and set up	8 Years	10	[redacted]	[redacted]

								perspecti ve					

Validation & Training		
Product	**Price for product to be completed for all 4 sites**	**Total for section**
Validation	[redacted]	[redacted]
Training	[redacted]	

Calibration, Servicing and Planned Preventative Maintenance Plan (CSPPM)									
Product	**Product Code/ Catalogue No.**	**Description**	**Manufacturer Name**	**Manufacturer Product Code**	**Warranty Period**	**Lead Time/ Notice required**	**Years 1-5 bid price See guidance Tab for "Equipment/Platform proposed "**	**Years 6-8 bid price See guidance Tab for "Equipment/Platform proposed "**	**Total bid price, years 1-8 See guidance Tab for "Equipment/Platform proposed "**

Calibration, Servicing and Planned Preventative Maintenance Plan (CSPPM) Servicing/ Maintenance/ Calibration /Software Updates (full complement of units at all sites)	SERCON	Comprehensive	Serosep UK	SERCON	12 Months	30 days	[redacted]	[redacted]	[redacted]

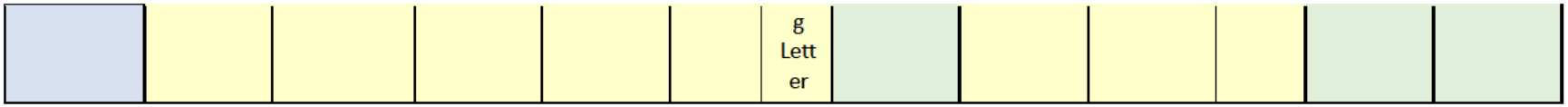
Service Desk, Technical Support and Reactive Maintenance Plan (SDTSRMP)				
Package Pricing				
Product	**Single callout price See guidance Tab for "Equipment/Platform proposed"**	**5-year initial term bid price See guidance Tab for "Equipment/Platform proposed"**	**3-year extension bid price See guidance Tab for "Equipment/Platform proposed"**	**Total bid price, years 1-8 See guidance Tab for "Equipment/Platform proposed"**

Reactive Maintenance callout charges (full complement of units at all sites, including service desk availability)	N/A	[redacted]	[redacted]	[redacted]

Service Desk, Technical Support and Reactive Maintenance Plan (SDTSRMP)												
Non-Package Pricing												
Product	**Single callouts price See guidance Tab for "Equipment/Platform proposed"**	**Year 1 - based on 4 callouts across all 4 sites**	**Year 2 - based on 4 callouts across all 4 sites**	**Year 3 - based on 4 callouts across all 4 sites**	**Year 4 - based on 4 callouts across all 4 sites**	**Year 5 - based on 4 callouts across all 4 sites**	**5-year initial term bid price See guidance Tab for "Equipment/Platform proposed"**	**Year 6 - based on 4 callouts across all 4 sites**	**Year 7 - based on 4 callouts across all 4 sites**	**Year 8 - based on 4 callouts across all 4 sites**	**3-year extension term bid price See guidance Tab for "Equipment/Platform proposed"**	**Total bid price, years 1-8 See guidance Tab for "Equipment/Platform proposed"**
Reactive Maintenance callout charges (full complement of units	N/A	N/A	N/A	N/A	N/A	N/A	[redacted]	N/A	N/A	N/A	[redacted]	[redacted]

at all sites, including service desk availability)												

Optional based upon answer to Question 19, bidder response sheet												
Out of Hours Service Desk and Technical Support												
Product	Single call-out price See guidance Tab for "Equipment/Platform proposed "	Year 1 - based on 4 call-outs across all 4 sites	Year 2 - based on 4 call-outs across all 4 sites	Year 3 - based on 4 call-outs across all 4 sites	Year 4 - based on 4 call-outs across all 4 sites	Year 5 - based on 4 call-outs across all 4 sites	5-year initial term bid price See guidance Tab for "Equipment/Platform proposed "	Year 6 - based on 4 call-outs across all 4 sites	Year 7 - based on 4 call-outs across all 4 sites	Year 8 - based on 4 call-outs across all 4 sites	3-year extension term bid price See guidance Tab for "Equipment/Platform proposed "	Total bid price, years 1-8 See guidance Tab for "Equipment/Platform proposed "
Reactive Maintenance out of hours callout charges	SEE Question 19 Response and Covering Letter	SEE Question 19 Response and Covering Letter	SEE Question 19 Response and Covering Letter	SEE Question 19 Response and Covering Letter	SEE Question 19 Response and Covering Letter	SEE Question 19 Response and Covering	[redacted]	SEE Question 19 Response and Covering Letter	SEE Question 19 Response and Covering Letter	SEE Question 19 Response and Covering Letter	[redacted]	[redacted]



Product	Assay Kit 1	Assay Kit 2	Assay Kit 3	Assay Kit 4	Total cost per assay kit	Total Assay Bid Price
Assay Type Name	Bacteria (excluding C.diff) & Parasites	C.difficile only	Viruses			£13,989,072.00
Product Name	EntericBio Dx Assay	EntericBio C.difficile Assay	EntericBio Viral Panel 3 Assay			
Components	EntericBio Dx Assay (Assay strips A-C, Positive Control, Reconsitution Fluid), SPS Buffer, Workstation Tip, EntericBio Floq Swab, Transfer Frame for PCR Strips	EntericBio C.diff Assay (Assay Strip, Positive Control, Reconsitution Fluid), SPS Buffer, Workstation Tip, EntericBio, Floq Swab, Transfer Frame for PCR Strips	EntericBio Viral Panel 3 Assay (Assay strips A-B, Positive Control, Reconsitution Fluid), SPS Buffer, Workstation Tip, EntericBio, Floq Swab, Transfer Frame for PCR Strips			
Product Code/ Catalogue No.	EBGPDX	EBCDA	EBVP3			
Tests Per Pack	240	240	120			
Pack Dimensions (HxWxD mm)						
Shelf Life (months)	24	24	24			
Storage Temperature (°C)	2-8C	2-8C	2-8C			
Targets Identified	Campylobacter, Salmonella, Shigella/EIEC, VTEC (Stx1,Stx2) ,Yersinia, Vibrio ,Giardia, Cryptosporidium, E.histolytica	C.difficile TcdB (Toxin B gene) only	Norovirus G1, Norovirus G2, Rotavirus, Adenovirus, Astrovirus, Sapovirus			
Number of tests per year	118252	59616	37274			
Number of kits required	493	249	311			

Single kit price Y1	[redacted]	[redacted]	[redacted]			
Full price Assay 1/year 1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	
Number of tests per year	121800	61405	38392			
Number of kits required	508	256	320			
Single kit price Y2	[redacted]	[redacted]	[redacted]			
Full price Assay 2/year 2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	
Number of tests per year	125454	63247	39544			
Number of kits required	523	264	330			
Single kit price Y3	[redacted]	[redacted]	[redacted]			
Full price Assay 3/year 3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	
Number of tests per year	129217	65144	40730			
Number of kits required	539	272	340			
Single kit price Y4	[redacted]	[redacted]	[redacted]			
Full price Assay 4/year 4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	
Number of tests per year	133094	67099	41952			
Number of kits required	555	280	350			
Single kit price Y5	[redacted]	[redacted]	[redacted]			
Full price Assay 5/year 5	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	
Number of tests per year	137087	69112	43210			
Number of kits required	572	288	361			
Single kit price Y6	[redacted]	[redacted]	[redacted]			
Full price Assay 6/year 6	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	
Number of tests per year	141199	71185	44507			
Number of kits required	588	297	371			
Single kit price Y7	[redacted]	[redacted]	[redacted]			
Full price Assay 7/year 7	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	
Number of tests per year	145435	73320	45842			
Number of kits required	606	306	383			

Single kit price Y8		[redacted]				[redacted]				[redacted]		
Full price Assay 8/year 8		[redacted]				[redacted]				[redacted]		

Price for 96 deliveries per year								Total Delivery Bid Price
Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Price for single delivery charge per year							
Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Bidder Proposal Description								Total Delivery Bid Price
Single Monthly Delivery to Each Site, however in some sites with adequate storage and space, we propose as part of mutual KPI/Carbon reduction initiatives that a quarterly drop at most sites would be viable and remove considerable road miles from the delivery reducing carbon cost.								
Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Exit Plan Pricing				
Activity	**Description**	**Timeframe**	**Price (£)**	**Total Exit Plan Bid Price**
Equipment uplift and orderly wind down at all sites	**Removal of instrumentation, archival of data and ongoing access required for legacy testing**	**2 Months**	[redacted]	[redacted]

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.

1.2 Clause 2.8 of Schedule 2 of Appendix A (Call off Terms and Conditions) shall be amended to read as follows:

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

2.8.1 full payment for such Goods; or

2.8.2 where the goods are consumables or are non-recoverable (e.g., used in clinical procedures), at the point such Goods are taken into use. For the avoidance of doubt, where ownership passes in accordance with this Clause 2.8.2 of this Schedule 2 of these Call-off Terms and Conditions, then the full Contract Price for such Goods shall be recoverable by the Supplier from the Authority as a debt if there is non-payment of a valid undisputed invoice issued by the Supplier to the Authority in relation to such Goods; or

2.8.3 where the Order From states that the transfer of title is accepted by the Authority once it is confirmed that the Goods have been manufactured.

1.3 the Authority discharges its duties as a Category 1 Responder to incidents and emergencies on behalf of the Secretary of State for Health. Although primarily intended for testing of enteric samples, the Authority reserves the right to utilise these Systems for other non-enteric testing purposes as appropriate and required and the Supplier accepts this shall not impact upon the warranty supplied with the System and the Parties shall discuss and agree any impact on the servicing and maintenance regime.

1.4 The following Additional Definitions shall apply to this Call-Off Contract:

"Basic Operator"	means the Authority staff at each site who are trained by the Supplier to have a good standard of overall knowledge for practical use of the System and Assay(s) in accordance with the IFU(s);
"Commercial Contract Manager"	means the UKHSA Commercial Contract Manager responsible for the commercial management of this contract;
"Contract Management"	means the process of managing the "Contract", deliverables, deadlines, and contract terms and conditions;

"Hazard Group 3"	means the biological agents that can cause severe human disease and may be a serious hazard to employees; it may spread to the community, but there is usually effective prophylaxis or treatment available;
"IFU"	means the Instructions for Use; Information provided by the manufacturer to inform the device user of the product's proper use and of any precautions to be taken;
"Implementation Plan"	means the document which outlines the "Supplier" steps to accomplish the goal of installing the "Systems", validating the assays, and training the staff that the provided "Systems" are ready for clinical use;
"LIMS"	means the Laboratory Information Management System; the system in each laboratory that manages and tracks samples and the associated patient data, test requests and test results;
"Management Information Report"	means information agreed by the parties that is to be supplied to the Authority as stipulated in Section 2.6 of the Contract Order Form";
"Materials"	means all reagents, consumables and plasticware required in the IFU;
"Material Sub-Contractor"	means a party to a Sub-contract, for provision of any key part of the Contract, other than the Supplier;
"Milestones"	means all significant events/activities to be completed by a specified time or date in the Order Form, Implementation Plan, Exit Plan, or any other plan incorporated into the provision of the "Contract";
"Operation Contract Manager"	means the UKHSA Operational Contract Manager responsible for the operational management of this contract;
"Quality Event"	means any incident that requires a quality report of any kind, including corrective and/or preventative measures;
"Supplier's Tender Response"	means the Supplier's response to the Call for Competition Procedure in relation to this Contract as outlined in Annex D including the product specification submitted by the Supplier and the Supplier's responses to clarification questions;
"System"	means a CE/UKCA marked, sample to result, Authority LIMS interfaced and integrated, total molecular enteric pathogen detection System that is suitable for use in ISO15189 accredited laboratories. This includes equipment, instrumentation, reagents, consumables, plasticware and service and maintenance; for sample inactivation / initial sample processing, extraction, test set-up, molecular amplification and detection, and result interpretation;
"Super User"	means the four members of Authority staff per site who are trained by the Supplier to have the most detailed and intimate knowledge of the System, and who are best placed to understand the practical use of the System and Assay(s) in accordance with all aspects of the IFU(s), System errors and troubleshooting, and responsibilities for downstream Basic Operator training; and
"TrackWise"	means the Authority system for tracking issues with delivery.

Annex B

Enteric Tender Specification

1. Introduction

1.1. The UKHSA mission is to prepare for, prevent and respond to health threats, save lives, and protect livelihoods. We are a centre of scientific and operational excellence in health protection. Our reach is local, national, and global as we collaborate and share learning across the NHS and wider health and care system and with partners to improve health security worldwide.

1.2. The threats we protect against range in type, scale, and intensity, covering infectious disease – from pathogens with pandemic potential to everyday infections such as measles – and environmental threats including radiation, chemical, nuclear and extreme weather events. Through our scientific and operational expertise, we aim to protect every person, community, business and public service from infectious diseases and environmental hazards, helping to create a safe and prosperous society.

1.3. At UKHSA, our aim is that the country can thrive, unlimited by the impacts of health security threats.

1.4. We support this by delivering rapid and highly effective responses to all health threats, and by preventing or reducing their harmful impacts as much as possible. With this in mind, UKHSA is seeking to modernise its methods for testing for Enteric Pathogens by implementing molecular Enteric Systems at four of its regional laboratories.

1.5. UKHSA is seeking to procure an automated enteric molecular diagnostic capability to provide front line clinical and public health diagnostics for enteric infections. Enteric services are currently undertaken by UKHSA laboratories hosted within NHS settings at large teaching hospital trusts at Birmingham, Bristol, Cambridge, and Manchester, and are contracted to deliver clinical enteric pathogen investigations as part of their overall services It should be noted that UKHSA's Reference Laboratories may also utilise the outcome of this tender in future strategic planning.

1.6. This Specification seeks out the Authority's requirements for both the Equipment, and the Services being sought for this Tender.

2. Overview and Authority Locations

2.1. The Supplier shall provide a CE/UKCA marked, sample to result, Authority LIMS interfaced and integrated, total molecular enteric pathogen detection System that is suitable for use in ISO15189 accredited laboratories. This includes all equipment, instrumentation, the Materials and service and maintenance; for sample inactivation / initial sample processing, extraction, test set-up, molecular amplification and detection, and result interpretation.

2.2. The Supplier shall supply the total molecular enteric pathogen detection System, services and Materials to the following four UKHSA laboratories:

UKHSA Birmingham,
University Hospitals Birmingham NHS Foundation Trust,
Heartlands Hospital,
Bordesley Green East,

Birmingham
B9 5SS

UKHSA Bristol
Pathology building
Southmead Hospital
Bristol
BS10 5NB

UKHSA Cambridge
Level 6, Box 236
Addenbrooke's Hospital
Hills Road
Cambridge
CB2 0QQ

UKHSA Manchester
Clinical Sciences Building
Manchester Royal Infirmary
Oxford Road
Manchester
M13 9WL

3. Pathogen Requirements

3.1. The System shall, as a minimum, be capable of testing for the Essential Pathogen Targets set out in Table 1 below.

Target organism
Norovirus I
Norovirus II
Rotavirus
Adenovirus (including serotypes 40 and 41)
Sapovirus
Astrovirus
***Salmonella* spp.**
***Shigella* spp. / EIEC**
***Campylobacter* spp.**
EHEC stx1
EHEC stx2
***C. difficile* A/B**
***Cryptosporidium* spp.**
Giardia duodenalis
***Yersinia* spp**
***Vibrio* spp.**

Table 1 Essential Targets

3.2. The System shall be capable of testing for the following Desirable Pathogens as set out in Table 2 below:

Desired Target organism List
Helicobacter pylori
Salmonella (speciated)
Shigella (speciated)
Campylobacter (speciated)
C.diff toxin A only
C.diff toxin B only
Entamoeba histolytica
Cyclospora cayentanensis
EAEC
ETEC
EPEC
Microsporidium
Strongyloides
Isospora
Aeromonas
C. difficile binary toxin
Dientamoeba fragilis
Enterovirus

Table 2- Desirable Pathogen Targets[2]

4. System Throughput Requirements

4.1. The System shall be capable of processing a minimum of the following SAMPLE volumes, for each of the Authority sites over an eight (8) hour working day:

Site	Minimum Daily SAMPLE Throughput for Lifetime of Contract
Birmingham	250
Bristol	450
Cambridge	350
Manchester	450

[2] This table will be populated based upon the winning Bidders bid.

Table 3 – Minimum System Daily SAMPLE Throughput Requirements Per Site

4.2 The System shall be capable of processing a minimum of the following TEST volumes, for each of the Authority sites over an eight (8) hour working day:

Minimum Daily TEST Throughput for Lifetime of Contract							
Site	**Supplier Panel Type**						
	Bacteria only (excluding C.diff)	**Parasites only**	***C.difficile* only**	**Viruses only**	**All essential targets**	**Bacteria (excluding C.diff) and Parasites**	**Bacteria and *C.difficile***
Birmingham	99	99	57	28	121	99	113
Bristol	222	222	84	29	250	222	243
Cambridge	162	162	70	26	186	162	180
Manchester	216	216	142	138	286	216	252

Table 4 – Minimum System Daily TEST Throughput Requirements Per Site

IMPORTANT- Table 3 AND 4 Assumptions and Information:

A. *The tables display year 8, and therefore minimum, sample and test number values which assume a year on year annual increase in sample and test number requirement of three per cent (3%) at all sites.*

B. *Sample and test number values are based on the assumption that the Authority sites all process enteric samples Monday to Friday (~260 days per year).*

C. *The values include potential for a 25% surge in sample and test numbers on any given day.*

D. *As per normal for laboratory testing platforms, platform capacity should not exceed ~70% for routine use. The minimum required sample number values in Table XX account for this additionally required capacity, plus capacity for other desirable target assays that may be utilised in the future, e.g. H. pylori.*

E. *The Authority currently processes samples for C. difficile on ~75% of the samples also processed for bacterial targets. This has been taken into account in Table 4.*

F. *The Authority currently processes samples for essential parasites on 100% of the samples also processed for bacterial targets. This has been taken into account in Table 4.]*[3]

4.3 The System shall be capable of a turn-around time on the System for fifty (50) samples for *C. difficile* testing, from LIMS sample receipt to reported result, of <5 hours.

5. System Installation Requirements

5.1 The Supplier shall ensure that all staff taking part in the System installation and validation have been appropriately trained with documented records of training and competence.

[3] To be deleted as part of contract placement as only being provided as context during the tender.

5.2 During System installation and validation, the Parties shall establish and maintain a mutually beneficial relationship as per the requirements of ISO:9001 (Principles of Quality Management), which shall include the Supplier providing analytical performance characteristics to the Authority to confirm the performance characteristics of the Equipment and Systems, prior to installation acceptance by the Authority.

5.3 System installation and validation must comply with relevant accreditation and safety requirements including, but not limited to:

5.3.1 ISO 15189 (2022); and
5.3.2 Good Manufacturing Practice (GMP) as regulated by the MHRA.

5.4 The Supplier shall provide the Authority with a Certificate of Installation.

6. Hardware Requirements

6.1. The System shall comply with all the following requirements:
- 6.1.1. be operable as a bench top system;
- 6.1.2. for the Birmingham site, the extraction/workstation equipment shall fit onto benching that is 3350mm in width, 900mm in depth (safe overhang is acceptable), and shall fit through a door frame width of 900mm;
- 6.1.3. for the Bristol site, the extraction/workstation equipment shall fit onto benching that is 3500mm in width, 748mm in depth (safe overhang is acceptable), and shall fit through a door frame width of 900mm;
- 6.1.4. for the Cambridge site, the extraction/workstation equipment shall fit onto benching that is 2000mm in width, 750mm in depth (safe overhang is acceptable), and shall fit through a door frame width of 750mm;
- 6.1.5. for the Manchester site, the extraction/workstation equipment shall fit onto benching that is 4055mm in width, 748mm in depth (safe overhang is acceptable), and shall fit through a door frame width of 900mm;
- 6.1.6. the System has been designed to minimise the carbon footprint of the System;
- 6.1.7. includes a handheld or fixed barcode scanner which records and tracks the laboratory sample number throughout the process from sample receipt to result;
- 6.1.8. includes an uninterrupted power supply unit(s) that must be maintained and replaced as necessary by the Supplier;
- 6.1.9. automatically matches results to the sample request in the LIMS;
- 6.1.10. includes automated result interpretation analysis software, and no manual interpretation of results is required by the user;
- 6.1.11. has a visual and/or audible alarm for run failure;
- 6.1.12. At the point of installation in each laboratory, the System shall be supplied with the following documentation as a minimum:
- 6.1.13. printed and electronic System installation instructions;
- 6.1.14. printed and electronic System operating instructions;
- 6.1.15. printed and electronic Assay(s) IFU;
- 6.1.16. printed and electronic User maintenance instructions;
- 6.1.17. electronic training materials;
- 6.1.18. any relevant printed and electronic certification for the systems; and
- 6.1.19. electronic Material Safety Data Sheets (MSDS).

6.2. The Supplier shall ensure that the Authority is supplied with any updated versions of the above documents during the Contract term.

7. Additional System Requirements

7.1. The System shall also be capable of the following:
7.2. The System shall also be capable of the following:

7.2.1. notifying the user that solid and liquid waste receptacles are full and/or nearing the full point;The EntericBio system does not produce liquid waste in a receptacle. No liquid waste connection is required and no connection to fluids to enable equipment functionality. The only solid waste receptacle is a waste box for tips on the deck of the liquid handling workstation and although there is no notification that this is full, it is in full view of the operator and so would be easily identifiable if it was full or nearing the full point. The system is aware of how many tips have been used and audio and visual alarms prompt users to replenish the tip box.

7.2.2. having quality management software which performs post PCR data trending analysis, e.g., trend analysis of test results and IQC results; FastFinder is an efficient automated results analysis tool used on the EntericBio platform, however the software does not offer any trend analysis with regards test results and IQC results. The QC tracking function on FastFinder is an optional feature used to monitor overall trends in Positive Control performance. i.e the positive controls performance is the only result that can be trended on the software which is done in the QC module.

7.2.3. having onboard traceability for all reagents and their associated sample numbers, and recognise and not allow expired kits or reagents to be used for testing;All kit lot numbers are added to the FastFinder software by the user, this lot number is then linked to specific runs. The user enters the expiry date, once the expiry date is passed the software will create a flag to alert the user (the customer can choose to proceed and ignore flag i.e it does not lock out that kit). The SPS lot number is not recorded. Samples can be traced back to a specific lot number using the archive function in the software.

7.2.4. having individual logins for Users;Yes, each site will have their own database. Users can then be added to the database and will login by using their own unique login credentials.The LightCycler480 PC is password protected at Windows account level, with the Operator account being restricted to ensure standard users are unable to alter critical functions of the unit. LightCycler480 software database access is further password protected and database is fully traceable, ensuring no results (raw run files) may be moved or deleted from the system. No PID is stored on LC480 software (only sample accession numbers required).FastFinder software provides a full audit trail of user currently logged into system, and this information is maintained and clearly displayed in both LIMS output and generated PDF results reports. FastFinder accounts are configured to maintain integrity of system by restricting user functionality, preventing any intentional / accidental alteration of settings. No PID is stored on FastFinder (only sample accession numbers required).

7.2.5. testing for C. difficile as an individual target;Yes Serosep have a standalone C. difficile assay for EntericBio. The throughput is 46 patient samples per run and the workflow is the same as for all other EntericBio assays. Following sample preparation, the samples can be used to run all assays so a sample that is used to set up a reaction well in the Dx assay

could then be used for setting up a C. difficile reaction or vice versa, reducing the costs and time taken for a following reflex run.

7.2.6. having the scope for assays to be extended in the future, to include additional targets without loss of any of the essential targets listed in the organism table; Yes Serosep confirms that any new developments will not impact the essential targets listed. The EntericBio solution offered can also be used for CPE molecular screening - the assay we offer covers 6 targets in 2 wells and is validated for stool, rectal swabs and colonial isolates and targets OXA-48 like, NDM,KPC,VIM,IMP and GES targets - volumes needed to be tested would impinge on the indicated 9am to 5pm routine hours but if this assay was of interest, Serosep UK would be happy to open discussion on further equipment.

7.2.7. providing an extracted eluate that is suitable for Whole Genome Sequencing; Serosep highlight the fact that we don't use a formal extraction process and so there is not a concentrated eluate available. The SPS will be available for further testing, however at this point, no WGS platforms have validated this approach. We would be willing to work with UKHSA labs in any future investigation work that may be undertaken in this area.

7.2.8. allowing the option for the System to continue operating independently without operator intervention beyond the manned routine laboratory hours (approximately 9am-5pm); In its current iteration, the Serosep EntericBio system is modular and the final stage of the process is to load the PCR reaction wells on to the Light Cycler 480 II. This automated amplification step is 60 minutes and needs no operator intervention and so could be running beyond the manned routine laboratory hours. The wells are not reused or needed for further downstream steps and so would be discarded the following morning.

7.2.9. enabling the testing menu to be expanded beyond the list of essential and desirable targets to include alternative IVD assays or Laboratory Developed Tests;; Yes Serosep confirm that the lightcycler is not locked down and so alternative IVD assays or Laboratory Developed Tests could be run on the EntericBio equipment as long as they did not compete Serosep offered assays including those offered from our distribution partners. Extra testing has not been accounted for in the throughput figures provided. The EntericBio workstation and heatstation are designed for EntericBio proprietary workflow.

7.2.10. receiving remote software support for investigating and resolving errors and breakdowns; Yes Serosep UK confirm that remote software support is available. Support can remotely log into each customer database and investigate results and queries. Users can email support with the name of the run and/ or specific sample they are querying. From there, the support team can access the database to review the queried file, and revert back to the customer with guidance. However, we may require the customer to send us additional information such as logs etc in order to help with troubleshooting as we cannot remotely access the customers instrument PCs. Technical Support is offered 7 days per week to the customer site, and in cases of urgent requirement for a Service Engineer, we have a UK-based Field

Engineer Team and back up instruments available to ensure uptime remains as high as possible.

8. Software and Digital Requirements

8.1. The System shall have the following functionality and capabilities:

- 8.1.1. be capable of using rules to 'mask' any result(s) from being transferred from the proposed System to the LIMS, while still transferring other target results as required;
- 8.1.2. archive data and reports onboard the proposed System and/or export onto encrypted removable media or external software;
- 8.1.3. be able to operate independently in the event of LIMS / interface / middleware failure;
- 8.1.4. allow result data and reports to be viewed and printed manually;
- 8.1.5. have the capability for generic laboratory user lab login/password;
- 8.1.6. have the facility to allow the User or Supplier to delete all or part of the onboard sample result data (if stored on the system) in a secure manner to maintain patient confidentiality and avoid sensitive data being removed from site due to repairs or disposal of equipment;
- 8.1.7. if a sample number is amended, have an audit trail of the change;
- 8.1.8. include all required software and licence(s) to the Authority as part of the solution;
- 8.1.9. be compatible with the following sample barcode specifications, as a minimum:
  - 8.1.9.1. 1 dimensional linear barcodes;
  - 8.1.9.2. code 128 barcodes; and
  - 8.1.9.3. 7 to 16 character barcodes (number and letter and special character combinations).

8.2. The System shall, as a minimum, be compatible with the following Laboratory Information Management Systems (LIMS):

- 8.2.1. Windows 10 and any future versions;
- 8.2.2. Clinisys, Winpath, v7.2;
- 8.2.3. Epic Systems Corporation, Beaker Module of Epic EPR, version Epic Nov 2022;
- 8.2.4. Epic Systems Corporation, Beaker Module of Epic EPR, version Epic May 2023;
- 8.2.5. Dedalus Unix Telepath v2.1; and
- 8.2.6. Magentus Evolution (forthcoming LIMS in Birmingham).

8.3. The Supplier shall provide the Authority with an interface specification for the System.

8.4. The System shall be interfaceable with at least one of the following interfacing methods to enable seamless communication between the System and the Authority LIMS:

- 8.4.1. Health Level Seven (HL7) Data Transfer and Sharing Standards;
- 8.4.2. File Transfer Protocol Secure (FTPS);
- 8.4.3. American Society for Testing and Materials Standards (ASTMS); or
- 8.4.4. Comma Separate Value (CSV) File.

8.5. The Supplier shall work collaboratively with the Authority and the Authority's LIMS providers to ensure the full and successful integration of the System with the Authority's LIMS and other digital infrastructure as appropriate.

8.6. The System shall not have a 'Cloud Connection'[4] as the only or primary interface solution.

8.7. The System shall be fully functional without the specific requirement by the Supplier for remote access only.

8.8. If the System shall require third party remote connection to an NHS network at any of the Authority sites, the Supplier shall need to obtain or show existing evidence of a HSCN Connection Agreement.

9. Quality and Technical Requirements

9.1. The Supplier shall comply with the following regulatory and quality requirements:

9.1.1.1. operate as an ISO9001 certified company, or is not certified as an ISO9001 certified company but operates an equivalent quality management system;

9.1.1.2. the System shall be suitable for use in ISO15189 accredited laboratories;

9.1.1.3. the assay(s) offered by the Supplier for this requirement shall not be RUO; and

9.1.1.4. the assay(s) offered by the Supplier for this requirement must adhere to the relevant IVD/MD regulations both now and for the duration of the contract. In the case of in vitro medical devices (IVDs) / medical devices (MDs), The Medical Devices Regulations 2002 (SI 2002 No 618, as amended) must be adhered to. Note that from 1st July 2030 all IVDs placed on the UK market must be UKCA mark certified. Any future updates to these regulations will be complied with by the supplier for the assay(s) under contract, for the duration of the contract.

9.2. The Supplier's assays shall comply with the following technical requirements:

9.2.1.1. for samples that are identified as confirmed or suspected Hazard Group 3 risk, the IFU(s) shall include a validated sample inactivation protocol, e.g., guanidine-thiocyanate (e.g., eNAT) medium, heat, other chemical, or other appropriate method;

9.2.1.2. be suitable for use with UK commercially available CE/UKCA marked third party quality control material;

9.2.1.3. be suitable for use with UK commercially available CE/UKCA marked 17043 accredited, External Quality Assessment organiser scheme(s); and

9.2.1.4. include target positive, negative and process/extraction controls for each essential organism set out in Table 1.

9.3. As part of the Supplier's post-market surveillance plans, the Supplier is advised to perform regular in silico analysis of the proposed assays to ensure primer and probe sequences will continue to detect circulating strains, genotypes etc., taking into account possible mutations as they appear which may affect assay performance. If any concerns regarding assay performance are identified or suspected, these shall be reported to the Authority and the appropriate regulator.

9.4. The Supplier shall provide information to the Authority about metrological traceability to a reference material or reference procedure of the higher metrological order available. The Supplier shall ensure that all reagents are subject to analysis and provide 'Certificate of Analysis' details as requested by the Authority.

[4] A connection between the Authority's IT infrastructure and private cloud computing services.

9.5. The Supplier shall support the Authority, as required, in the reporting of any risks, incidents or issues in accordance with the Authority's Clinical Governance procedures.

10. Health and Safety Requirements

10.1. The Supplier shall, as a minimum:

10.1.1. notify the Authority Representative of any Health and Safety issues which arise with the System, detailing the issues and proposed mitigations;

10.1.2. ensure that the Systems comply with relevant current and future UK Health and Safety guidelines;

10.1.3. supply a certificate of Health and Safety conformity (electronic), Material Safety and Data Sheets for all relevant Materials (electronic), and a recommended protocol for the biological decontamination of the equipment (printed and electronic) at the point of installation in each laboratory; and

10.1.4. identify any biological, chemical, noise, electrical, physical, or any other risks to operator safety in the preparation of samples and operation of the System. The Supplier shall also describe the mitigation actions.

11. Training Requirements

11.1. Authority staff shall be trained by the Supplier to in line with the Super User and Basic Operator training requirements set out below and any further training the Supplier believe is relevant. The Supplier shall provide ongoing refresher training to the Authority as required but no more than once per annum, per site.

11.2. Where any software, hardware or other updates are made to the System over the Contract term, the Supplier shall, when preparing to deploy the change, engage with the Authority Representatives to agree whether it is necessary to provide further appropriate training or not. Where training is required, the Supplier shall provide this to the Authority staff as part of its ongoing obligations under the Contract.

Super User Training

11.3. The Supplier shall have a Super User Training Plan relating to the System. As a minimum, the training plan will include:

11.3.1. practical use of the System and Assay(s) in accordance with all aspects of the IFU(s);

11.3.2. health and safety considerations;

11.3.3. start up and shut down procedures;

11.3.4. maintenance of the System;

11.3.5. QC procedures;

11.3.6. error and trouble-shooting procedures;

11.3.7. super user responsibilities for downstream training; and

11.3.8. structured training plan produced by the Supplier for any future downstream Basic Operator Training that the Authority may need to perform.

11.4. Following delivery and installation of the System, the Supplier shall provide full Super User training in compliance with the training plan, for a minimum of four members of staff per laboratory site. The training must be to a standard that allows full familiarity and usability of the instrument.

11.5. Super User training shall be delivered on-site at each of the Authority laboratories.

11.6. The Supplier shall provide Super Users with certification upon completion of the training.

Basic Operator Training

11.7. The Supplier shall have a Basic Operator training plan relating to the System which will provide a good standard of overall knowledge for practical use of the System and Assay(s) in accordance with the IFU(s).

11.8. Basic Operator training shall take place on-site at the Authority laboratories and be provided by the Supplier (future downstream Basic Operator Training may also be performed by Authority Super Users, as and when required).

11.9. The Supplier shall provide Basic Operators with certification upon completion of the training.

12. Supply of Goods

12.1. If stated in the Supplier's IFU(s), the Supplier shall provide all the following as a minimum:

12.1.1. all essential equipment and hardware as per the IFU(s), including but not limited to: extraction platforms, workstations, PCR equipment, heat blocks, plate sealers, plate/micro centrifuges, vortex mixers, plate coolers and other peripheral laboratory equipment.
12.1.2. any PC/laptop equipment; and
12.1.3. all essential reagents as per the IFU.

12.2. If stated in the Supplier's IFU(s), the Supplier shall be capable of supplying the following as a minimum:
12.2.1. extraction kits;
12.2.2. buffers;
12.2.3. PCR plates / tube strips / frames;
12.2.4. plate seals;
12.2.5. pipette tips;
12.2.6. test / microcentrifuge / reaction tubes and lids; and
12.2.7. any specialist collection tubes / devices.

12.3. If stated in the Supplier's IFU(s) that any of the following Materials are required, the Supplier shall not be required to provide:
12.3.1. pipettes and single use pastettes;
12.3.2. standard laboratory inoculating loops / cotton swabs; and
12.3.3. gloves.

13. Materials

Table 5: Materials for throughput estimate

Tests Per Year (starting point TPY-1 is 2022/23 Actual numbers, 3% per year is adeed from this point)														
Panel Category Names	**Laboratory**													
Type 1	**Birmingham**	**Bristol**	**Cambridge**	**Manchester**	22/23 TPY-1	23/24 TPY0	24/25 TPY1	25/26 TPY2	26/27 TPY3	27/28 TPY4	28/29 TPY5	29/30 TPY6	30/31 TPY7	31/32 TPY8
Bacteria (excluding C.diff) & Parasites	15856	35342	25818	34448	111464	114808	118252	121800	125454	129217	133094	137087	141199	145435
C.difficile only	9032	13418	11184	22560	56194	57880	59616	61405	63247	65144	67099	69112	71185	73320
Viruses	4490	4617	4091	21936	35134	36188	37274	38392	39544	40730	41952	43210	44507	45842
Type 2	**Birmingham**	**Bristol**	**Cambridge**	**Manchester**	22/23 TPY-1	23/24 TPY0	24/25 TPY1	25/26 TPY2	26/27 TPY3	27/28 TPY4	28/29 TPY5	29/30 TPY6	30/31 TPY7	31/32 TPY8
Bacteria & C.difficile	18114	38696	28614	40088	125512	129277	133156	137150	141265	145503	149868	154364	158995	163765
Parasites	15856	35342	25818	34448	111464	114808	118252	121800	125454	129217	133094	137087	141199	145435
Viruses2	4490	4617	4091	21936	35134	36188	37274	38392	39544	40730	41952	43210	44507	45842
Type 3	**Birmingham**	**Bristol**	**Cambridge**	**Manchester**	22/23 TPY-1	23/24 TPY0	24/25 TPY1	25/26 TPY2	26/27 TPY3	27/28 TPY4	28/29 TPY5	29/30 TPY6	30/31 TPY7	31/32 TPY8

Bacteria (excluding C.diff)	15856	35342	25818	34448	111464	114808	118252	121800	125454	129217	133094	137087	141199	145435
C.difficile only	9032	13418	11184	22560	56194	57880	59616	61405	63247	65144	67099	69112	71185	73320
Parasites2	15856	35342	25818	34448	111464	114808	118252	121800	125454	129217	133094	137087	141199	145435
Viruses3	4490	4617	4091	21936	35134	36188	37274	38392	39544	40730	41952	43210	44507	45842
Type 4	**Birmingham**	**Bristol**	**Cambridge**	**Manchester**	22/23 TPY -1	23/24 TPY 0	24/25 TPY 1	25/26 TPY 2	26/27 TPY 3	27/28 TPY 4	28/29 TPY 5	29/30 TPY 6	30/31 TPY 7	31/32 TPY 8
All Targets	19237	39851	29637	45572	134297	138326	142476	146750	151152	155687	160358	165168	170123	175227

13.1. Ordering of the requisite Materials to support the Authority's operations shall be undertaken on a demand basis with the Authority not committed to purchase any specific minimum volume of the Materials. The Supplier shall be capable of meeting the volumes set out in Table 5 above. The Authority anticipates that it may require an annual increase in provision of three percent (3%) year on year.

13.2. The Supplier shall maintain a minimum of a six (6) weeks supply of Materials at the levels set out in Table 2 on the UK Mainland.

13.3. For the reagents required to test the essential targets in Table 2, the Supplier shall always maintain a minimum of two different lot numbers in warehouse stock at any one time.

13.4. The Supplier shall make available from the Supplier's website, or other accessible portal, electronic certificates of analysis for each batch of reagents.

13.5. Where an order is received by the Supplier, by midday on a weekday (excluding bank holiday weekdays), the Supplier shall be able to dispatch goods the following day with delivery being completed within forty-eight (48) hours of dispatch.

13.6. The Supplier shall be able to support an increase of twenty-five per cent (25%) of Materials set out in Table 2 for a period of at least six (6) weeks to support the Authority with managing public health incidents.

13.7. All Materials supplied under the Contract shall be clearly labelled with the following information as a minimum:

13.7.1. product name;
13.7.2. product code;
13.7.3. lot number;
13.7.4. Classification, Labelling and Packaging (CLP) regulations, where applicable
13.7.5. storage requirements, where applicable; and
13.7.6. expiry date, where applicable

13.8. The Supplier shall provide printed or electronic delivery notes for each delivery including the following information as a minimum:

13.8.1. Supplier contact details;
13.8.2. order reference;
13.8.3. order and/or shipment date;
13.8.4. Authority delivery address;
13.8.5. product name;
13.8.6. product code;
13.8.7. lot number;
13.8.8. expiry date (where applicable);
13.8.9. quantity ordered;
13.8.10. quantity delivered; and
13.8.11. quantity still to follow (if applicable).

13.9. All reagents, consumables, etc.) delivered by the Supplier to the Authority shall have a minimum of six (6) months shelf life before expiry. Where out of date Materials or Materials with an expiry date less than six (6) months from the date of receipt are supplied, the process set out in the Payment procedure of the Call Off Order Form shall apply.

13.10. The Supplier shall inform the Authority and Site Authority Representative where there are any supply chain issues that affect current or may affect future order fulfilment. The Supplier will inform the Site Authority Representative of any delays to individual orders.

14. Warranty

14.1. The System warranty shall begin at each site when the System and assay(s) have been successfully verified for routine laboratory use, in agreement with the Authority.

14.2. The System shall have a minimum of a one (1) year warranty.

15. Servicing, Maintenance and Calibration Requirements

Servicing and Maintenance

15.1. The Supplier shall provide all servicing, maintenance, calibration (where necessary), service and maintenance equipment/tools and spare parts (including replacements) for all Systems, for the duration of the Contract.

15.2. The Supplier shall comply with the Calibration, Servicing and Planned Preventative Maintenance Plan (CSPPM) Plan which sets out the details of the calibration, planned preventative maintenance and servicing activities, as well as the nature and timing of those activities.

15.3. The Supplier shall supply and install all relevant hardware and software updates as necessary and as they become available, to maintain the performance of the Systems for the Contract duration.

15.4. All PPM shall be undertaken in accordance with the manufacturer's recommendations, with a minimum of one PPM visit per annum.

15.5. At least one month in advance of required PPM, the Supplier shall liaise with the Authority (local laboratory) to schedule PPM; agreeing exact engineer arrival date and time, a brief summary of the PPM activities to be performed while on site and the anticipated downtime duration and impact on System operation during the PPM visit. The Supplier shall minimise service disruption as much as is reasonably possible. PPM shall not significantly impact on the Authority's ability to meet daily sample throughput requirements.

15.6. Following any service and maintenance visit, the Supplier shall verify and provide visit report evidence to the Site Authority Representative that the System is fully operational and safe to use before leaving site, which has been countersigned by the Authority (Site Authority Representative or local laboratory senior staff). Site Authority Representative or local laboratory senior staff must be notified of any equipment that is not fully operational and/or requires further remedial action.

15.7. During PPM or RSM visits, the Supplier shall not amend any system User settings without the prior written consent of the Authority Representative.

15.8. As part of the quarterly Supplier performance review meeting process, the Supplier shall report back to the Authority on any unscheduled downtime that has occurred in the period; including a description of the root cause of the downtime, how

the downtime is being/was resolved and any steps that are being/were taken to minimise the risk of such downtimes occurring again.

15.9. The Supplier shall provide the Authority with technical advice, guidance and recommendations on the System to support the Authority in the Authority's obligation to minimise clinical risk and to ensure satisfactory System performance.

16. Calibration

16.1. If the System requires calibration as part of installation or service and maintenance the Supplier shall undertake calibration in line with the manufacturers guidelines. An electronic or printed calibration certificate / document shall be issued which shows evidence of traceability to the relevant standard (ISO 17025:2017). Pre and post calibration results shall also be supplied.

17. Service Support Helpdesk, Technical Support and Reactive Maintenance

17.1. The Supplier shall provide a Service Support Helpdesk, Technical Support and Reactive Maintenance for the Systems, for the duration of the Contract.

17.2. The Supplier shall comply with the Service Support Helpdesk, Technical Support and Reactive Maintenance Plan (SSHTSRMP) which sets out the details of how the aforementioned activities shall be delivered and the service levels associated with them. The Supplier shall provide, as a minimum:

17.2.1. manned telephone and/or manned email support, by operators that speak fluent English, which operates Monday to Friday, 0900hrs until 1700hrs, which, within two hours of the Authority logging an incident shall provide a response to the Authority with a plan for remediation;

17.2.2. remote (telephone and email) and onsite engineer support which operates Monday to Friday, 0900hrs until 1700hrs;

17.2.3. out of hours telephone and/or email support which when the Authority uses to log an incident, the Supplier shall, within two hours at the start of the next business day, provide a response to the Authority with a plan for remediation;

17.2.4. from the point that it is determined that onsite support is required, the Supplier's engineer shall arrive onsite within 24hrs.

17.3. The Supplier shall hold a stock of spare parts on the UK mainland which have a lead time for supply of greater than two (2) business days, to ensure a minimisation of any System Downtime.

18. Social value

18.1. The Supplier shall supply a Social Value plan and highlight a minimum of one (1) measurable KPI from this and then implement that plan.

Appendix 2 to Annex B (Specification)

Implementation Plan

1. Implementation Plan

1.1. The Implementation Plan is based on key requirements for the delivery, installation, verification, training and sign off on the molecular platform provided for the detection of enteric pathogens. It shall also include milestones for ensuring the delivery of required Materials is in place and accurate.

1.2. The Implementation Plan shall address all of the following as a minimum:

1.2.1. a list of essential and suggested mobilisation activities;
1.2.2. a suggested assay verification process;
1.2.3. how you will support the verification process;
1.2.4. a detail project plan, as a minimum addressing the Milestones;
1.2.5. dependencies upon the Authority;
1.2.6. Authority vs Supplier responsibilities; and
1.2.7. project risks and mitigations determined by the Supplier.

2. Milestones

2.1. The System shall not be deemed as fit for use by the Authority until such time as the Milestones set out in the Implementation Plan below are fully completed. The Longstop Date shall be tied to Milestone 05 for this contract and shall be 31/03/2024.

2.2. The Parties may agree further changes and/or development to the Implementation Plan by agreement pursuant to the Change Control Procedure.

2.3. For the avoidance of doubt, unless and until any changes to the Implementation Plan are agreed via the Change Control Procedure, all Milestones and Milestone Dates shall remain as set out in the Implementation Plan as at the date of the Agreement.

2.4. Once any changes to the Implementation Plans are agreed by via the Change Control Procedure, the updated Implementation Plan shall be deemed incorporated into the Agreement from the date the Change is agreed.

Serial	Milestone Description	Milestone Date	Acceptance Criteria
M01	Site survey by Supplier at each laboratory to ascertain, for example, ease of system delivery, appropriate siting of system in the lab, installation requirements, etc.	Within 10 working days of Contract Award	Site survey report supplied to Operational Contract Manager and approved
M02	Supplier to deliver fully completed Implementation Plan, approved by UKHSA.	Within 5 working days of final site survey	Acceptance by UKHSA as part of contracting process
M03	Delivery and installation of the System hardware to each UKHSA site	Post completion of final implementation plan; minimum 2 sites within 25 working days, and the remaining 2 sites within a further 20 working days	Operational Contract Manager acceptance of completed installation
M04	Super User Training at each UKHSA site for 4 staff per site	Within 10 working days of System installation at each site	Operational Contract Manager acceptance of completed training

M05	Basic Operator Training	Within 15 working days of System installation at each site	Operational Contract Manager acceptance of completed training
M06	Verification of all assays, of installed equipment to each UKHSA site	To be agreed as part of M02	Joint acceptance and sign-off of assays
M07	Interface build and System integration by Supplier, Authority and LIMS provider	To be agreed as part of M02	Testing and sign-off of interface and system integration

Appendix 2 to Annex B (Specification)

1. Business Continuity and Disaster Recovery (BCDR)

1.1. The Supplier shall draft and be responsible for compliance with a BCDR Plan which shall enable the Supplier, and any Material Sub-Contractors, to support the Authority at all times in accordance with the requirements of the Contract.

1.2. The BCDR Plan shall detail how the Supplier, and any Material Sub-Contractors, shall enable the Authority to deliver and maintain uninterrupted Clinical Services throughout the Term. The Supplier shall be responsible for procuring the compliance and input from any Material Sub-Contractors with respect to the BCDR Plan. The BCDR Plan shall include as a minimum:

1.2.1. management of Risk Alerts;
1.2.2. management of product recalls;
1.2.3. manufacturing and delivery supply chain of all primary and third-party Materials;
1.2.4. service modules provided by primary and third parties (i.e., Material Sub-Contractors);
1.2.5. absences of supplier personnel who are supporting the Agreement;
1.2.6. possibility of the reagents and consumables to be manufactured at more than one facility (geographically separated or with separate mains water, gas, and electricity supplies);
1.2.7. IT hardware or software (primary and third party) provided within the Agreement; and
1.2.8. Documentation of any continuities that require resource from a partner.

1.3. In all the above events the Suppliers plan shall ensure that the Authority's service operation is not disrupted nor impacted for any longer than three (3) calendar days.

Appendix 3 to Annex B (Specification)

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 Appendix 2 to Annex B (Specification) 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 Appendix 2 to Annex B (Specification) 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 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

1.2.3 set out the management structure to be put in place and employed during the Exit Plan period.

1.2.4 Set out the management for disposal of the equipment at this time. The outgoing equipment shall be disposed of in line with UKHSA guidelines taking account for the possibilities of re-use and/or re-sale of the system as a whole or any viable parts.

1.3 The Exit Plan should be updated during the Term by agreement between the Parties, reflect any issues, 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 the Call-Off Terms and Conditions.

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 THE SUPPLIER'S CHARGES

3.1 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.

4 THE SUPPLIER'S RESPONSIBILITIES

4.1 The Supplier's responsibilities are set out in the Contract in Clause 16 (Consequences of expiry or early termination of this Contract) of the Call-Off Terms and Conditions and in any TUPE provisions applicable to exit (including any such Authority specific TUPE related extra Key Provisions forming part of the Order Form).

4.2 The Supplier's further responsibilities shall be those set out in the Exit Plan, as well as the following:

4.2.1 Decontamination- the Supplier will decontaminate the System at each site prior to removal from location.

4.2.2 Disposal- the Supplier shall uninstall and remove each of the Systems from each location and dispose of them in a safe and environmentally friendly manner.

4.2.3 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.

4.2.4 Staff - the Supplier will continue to meet all its staff related obligations set out in the Contract and comply particularly with any relevant TUPE provisions in respect of transferring employees. During period covered by the Exit Plan, the Supplier shall not remove or replace any member of Staff that is designated as key to the provision of the Services as set out in the Specification and Tender Response Document, the Order Form or as otherwise agreed between the Parties in writing.

4.2.5 Documentation and Records - the Supplier shall provide the Authority or any New Provider with all records, configuration, databases details, the technical infrastructure, and operating procedures through which the Supplier provides the Services, service delivery reports and management information requested by the Authority following written notice.

4.2.6 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.

4.2.7 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.

4.2.8 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.

4.2.9 Retention of Records –

(i) The Supplier shall, subject to paragraph 5.2.10(ii) of the Call-Off Terms and Conditions, 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 the Call-Off Terms and Conditions, 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.

Annex C

KPIs

1. This Annex C sets out the KPIs which shall be used to measure the Supplier's performance of the Services and the consequences where any KPI targets are not achieved.

2. The Parties acknowledge and agree that:

    a. the KPIs are subject to review as laid out in section 2.6 (Contract monitoring arrangements) and have potential change during the Term in accordance with the Change Control Procedure and, once agreed following such process, for the purposes of this Contract shall be the "**KPIs**"; and

    b. the detail contained in Part A below shall be used for the purposes of informing any changes to the KPIs.

3. The Supplier's compliance with the KPIs for purposes of Part B of this Schedule shall be on the basis of its performance over the period set out in the column of the Table entitled "Assessment Frequency" ("**Service Period**").

4. The KPIs shall be measured and reported with effect from the Commencement Date.

5. Reporting of the KPIs shall be via a report in a form agreed by the Parties from time to time.

6. Where a KPI is multi-tiered, failure to meet the target for any single part will result in the deduction for that KPI being applied.

Part A: KPIs

KPI	Description	Target	Assessment Frequency	Deduction
A	The Supplier shall comply with all milestones in the agreed plans including the Implementation Plan, Business Continuity and Disaster Recovery Plan and Exit Plan (Appendix B – Specification to this document), and Calibration, Servicing and Planned Preventative Maintenance Plan (CSPPM) by the agreed dates.	100% of milestones are completed by the allocated dates in the respective plans. Where ongoing CSPPM activities are concerned these will be assessed monthly from the end of the Implementation Period. Should there be no activity scheduled in any given month the score will be 100%	During the Mobilisation Period meetings will be held weekly from months one (1) to five (5) and the last at the end of month six (6).	5% of monthly payment
B	The Supplier shall ensure that all orders for Materials are delivered within 48 hrs of ordering in accordance with Paragraph 13.5 of the Specification.	87.5% of Materials delivered by the end of the next working day following the order when placed before 1600hrs	Monthly	5% of monthly payment
C	**Service Support Helpdesk and Technical Support Regime**		Monthly	5% of monthly payment
	UK based technical support centre with manned telephone and/or manned email support which operates Monday to Friday, 0900 until 1700, which, within two hours will result in a response to the Authority representative who raised the issue with a plan for support.	90%		
	Out of hours telephone and/or email support which, within two hours at the start of the next business day, will result in a response to the Authority representative	90%		

	who raised the issue with a plan for support.			
	If deemed necessary, an engineer onsite within 24hrs of initial call.	90%		
D	Social Value	In accordance with the Supplier's Social Plan (C226058_Serosep_Q26_Social Value Theme 3 response) outlined in the Supplier's Tender Response.	Monthly	2% of monthly payment

Part B: KPI Monitoring and the consequences of failing to achieve a KPI

1 For the purposes of this Part B, any reference to a KPI shall include a KPI as set out in Part A.

2 The Supplier shall comply with the reporting regime set out in Paragraphs 5 to 9 below **("Reporting Regime")**.

3 The KPIs shall be subject to the remedial regime set out in Paragraphs 10 to 16 below ("**Remedial Regime**").

4 The KPIs shall be subject to the incentive regime set out in Paragraphs 17 to 22 below ("**Incentive Regime**").

REPORTING REGIME

5 The Supplier shall provide the Authority with a monthly report detailing its performance level against each of the KPIs.

6 The ultimate objective of the Authority is to have a resilient Enteric Pathogen testing service for Public Health and Clinical purposes. As such the Parties shall work together to achieve this objective, including agreeing any necessary changes or updates to the KPIs forming part of this Contract drawing upon the Change Control Process where necessary.

7 The Authority's relationship manager for the Supplier shall be in regular contact with the Supplier.

8 The performance of the Services against the KPI targets shall be reviewed by the Parties as set out in 2.6 of the Call-Off Order Form as part of a contract review meeting.

9 It shall not be a KPI failure to the extent that the Supplier is prevented from complying with any of its obligations due to any failure by the Authority to comply with the Authority's obligations in this Contract.

REMEDIAL REGIME

10 All failures of KPIs shall be treated as having equal status and meaning for purposes of the Remedial Regime. A KPI failure ("**KPI Failure**") is defined as a failure to meet a KPI during any one Service Period. Where a KPI Failure arises, the Supplier shall be required to following the remedial process set out in Paragraphs 11 to 15 below.

11 Following the Supplier becoming aware that the performance target for any KPI has not been met in a Service Period, it shall immediately notify the Authority. The Supplier shall then undertake a root cause analysis ("**RCA**") to determine the cause of the KPI failure. Once the Supplier has identified the root cause of the KPI failure the Supplier shall notify the Authority of the cause, and shall within five (5) Business Days of such notification submit to the UKHSA a plan outlining how the Supplier shall rectify the issue to ensure it does not re-occur and the steps it will put into action (as soon as reasonably practicable) to achieve the target (the **"Draft Remedy Plan"**).

12 The Authority shall either approve the Draft Remedy Plan within three (3) Business Days of its receipt pursuant to Paragraph 11, or it shall inform the Supplier of its rejection of the Draft Remedy Plan, including reasons as to why it cannot accept the Draft Remedy Plan. Where the Authority rejects the Draft Remedy Plan, the Supplier

shall address all such concerns in a revised Draft Remedy Plan ("**Revised Draft Remedy Plan**"), which it shall submit to the Authority within five (5) Business Days of its receipt of the Authority's rejection. If approval or rejection of the Draft Remedy Plan is not provided by the Authority in accordance with this paragraph, the Supplier shall contact the Authority's Contract Manager to request such approval or rejection from the Authority. If the Authority's Contract Manager fails to respond, the Draft Remedy Plan shall be deemed agreed.

13 Once agreed the Draft Remedy Plan is agreed by the Authority, it shall become the **"Remedy Plan"** and the Supplier shall immediately start implementation of the actions set out in the Remedy Plan.

14 If, despite the measures taken under Paragraph 9, a Remedy Plan cannot be agreed (following both Parties acting reasonably), then the Supplier shall be entitled to implement its Revised Remedy Plan and shall have one full Service Period after implementation of such plan ("**Trial Remedial Period**") to demonstrate to the Authority that the Revised Draft Remedy Plan is effective. The effectiveness of the Revised Draft Remedy Plan shall be evidenced by the non-reoccurrence during the Trial Remedial Period of the KPI Failure. In the event the Revised Draft Remedy Plan prevents the reoccurrence of the KPI Failure during the Trial Remedial Period, the Revised Draft Remedy Plan shall be deemed the Remedy Plan.

15 If, despite the Parties' agreement of a Remedy Plan, or the implementation of a Revised Draft Remedy Plan during a Trial Remedial Period in accordance with Paragraph 14, the Supplier (as the case may be):

a. fails to implement the relevant Remedy Plan at all;

b. fails to implement the relevant Remedy Plan in accordance with its terms; or

c. fails to demonstrate by the end of the Trial Remedial Period that the Revised Draft Remedy Plan is effective in accordance with Paragraph 14;

then the UKHSA:

(i) at its sole option, may instruct the Supplier to take further corrective actions to address the relevant issues or enter into further discussions with the Supplier in respect of how the issues or circumstances leading to the KPI Failure might be addressed; or

(ii) may serve notice to terminate this Contract for breach not capable of remedy in accordance with Clause 15.4 of Schedule 2 (General Terms and Conditions).

16 If, despite the agreement of a Remedy Plan and the proper implementation of the Remedy Plan by the Supplier, the Remedy Plan proves to be ineffective in curing the

KPI Failure in the subsequent full Service Period, the Parties shall seek to agree a new Remedy Plan in accordance with Paragraphs 10 to 15 above.

INCENTIVE REGIME

17 The Authority shall be entitled to make Deductions where a KPI failure occurs against any of the KPIs set out in Part A.

18 The Authority shall be entitled to apply the relevant Applicable Deduction in respect of the KPI failed as set out in the final column of the KPI Table set out in Part A.

Applying Temporary Deductions

19 Where a KPI Failure occurs the first failure shall trigger a **"Temporary Deduction".** In the event the Authority has the right to apply a Temporary Deduction in respect of a KPI, the Authority shall, in the Contract Month in which the right to apply the Temporary Deduction is identified, deduct from the Monthly Payment for such Contract Month (or any subsequent Contract Month) the amount of the Temporary Deduction.

20 The Authority shall consider, when deciding whether to apply a Temporary Deduction, any Draft Remedial Plans proposed by the Contractor in accordance with paragraph 11 and, when notifying the Supplier of its acceptance of rejection of the Draft Remedial Plan in accordance with paragraph 12, notify the Contractor, in writing, whether:

20.1 a Temporary Deduction shall be applied; or

20.2 whether a Temporary Deduction shall not be applied;

21 if no Draft Remedial Plan is submitted by the Supplier in accordance with Paragraph 11, or where the Authority rejects the Draft Remedial Plan, and following such failure to submit or notification of rejection (as the case may be), the Temporary Deduction shall immediately become a Permanent Deduction and the Authority shall permanently retain all of such Permanent Deduction.

Applying Permanent Deductions

22 Where there are multiple KPI Failures in a single Service Period (whether of the same KPI or multiple KPIs) or persistent failures of a singular KPI across more than 2 service periods in any six service periods, or the Supplier fails to comply with the Remedial Regime as set out in Paragraph 21 the Authority shall have the right to apply a Permanent Deduction.

Annex D: Supplier's Tender Submission

The following documents comprised the Supplier's Tender Submission. A copy of these documents shall be kept by both the Supplier and Contracting Body respectively for record keeping and audit purposes.

Annex B Enteric Tender Specifications shall take precedence in the event of any conflict with the Supplier's Tender Response.

Description	**File Name**
Financial standing document	C226058_Serosep_20231110-Bidder Financial Standing Document
Molecular Enteric Tender Pricing Form	C226058_Serosep_Serosep UK Final Response Molecular Enteric Tender Pricing Form - v4
Bidder response	C226058_Serosep_Bidder Response Document
Implementation Plan	C226058_Serosep_Q16_Implementation Plan for UKHSA_V2
Exit Plan	C226058_Serosep_Q13_Exit Plan
Business Continuity and Disaster Recovery Plan	C226058_Serosep_Q21_Business Continuity Plan - Redacted
Social Value Plan	C226058_Serosep_Q26_Social Value Theme 3 response
Calibration, Servicing and Planned Preventative Maintenance (CSPPM) plan	C226058_Serosep_Q17_CSPPM Plan
Service Desk, Technical Support and Reactive Maintenance Plan (SDTSRMP) plan	C226058_Serosep_Q18_SDTSRMP
PDAG technical information pro-forma	C226058_Serosep_PDAG Technical Information Proforma_Enteric Assays V2.0_RG
Viral Panel	C226058_Serosep_VP3 STED - EBVP3 Rev 04 - Signed.pdf C226058_Serosep_TechnicalSupportingDoc_RD012 SVR 01.pdf C226058_Serosep_TechnicalSupportingDoc_Post-Market Surveillance Report EntericBio Viral Panel (EBVP) Assay FINAL Signed.pdf

DX Panel	C226058_Serosep_TechnicalSupportingDoc_RD024_PMSR_2022 Rev 01 Dx PMS Report Apr 2022 - Mar 2023 signed.pdf C226058_Serosep_TechnicalSupportingDoc_RD023 SVR [1].pdf C226058_Serosep_DX STED - EBGPDx Rev 07 Signed.pdf
C diff Panel	C226058_Serosep_TechnicalSupportingDoc_RD007 SVR [1].pdf C226058_Serosep_TechnicalSupportingDoc_Post-Market Surveillance Report for Serosep Ltd. Product EntericBio C. Diff (EBCD2-v2) Assay_signed.pdf C226058_Serosep_TechnicalSupportingDoc_Post Market Surveillance Plan for EntericBio Clostridioides difficile Assays 3-year review.pdf C226058_Serosep_C diff STED - EBCDA v2 Rev 08_signed.pdf
Raw data	C226058_Serosep_TechnicalSupportingDoc_Clinical Performance_RAWDATA_FF (002)_KN
Current IFU for all assays	C226058_Serosep_TechnicalSupportingDoc_EntericBio Dx Instructions for Use_.pdf C226058_Serosep_TechnicalSupportingDoc_EntericBio C. difficile Instructions for Use.pd C226058_Serosep_TechnicalSupportingDoc _EntericBio Viral Panel 3 IFU.pdf
Material Safety Data Sheets	C226058_Serosep_TechnicalSupportingDoc_MSDS 95 EBSPSA_EBSPSA-v2_2021_07 V55.0.1(EU).pdf C226058_Serosep_TechnicalSupportingDoc_MSDS 99 EBCDA-v2 V55.0.1(EU).pdf C226058_Serosep_TechnicalSupportingDoc_MSDS 147 EBGPDx_EBBGPDx-US_EBGPDx-ROC V55.0.1(EU).pdf C226058_Serosep_TechnicalSupportingDoc_MSDS 159 EB VP3 V55.0.1(EU).pdf
Post market surveillance plan for variants and mutations	C226058_Serosep_TechnicalSupportingDoc_REG SOP 02 (Rev 05) Vigilance.pdf C226058_Serosep_TechnicalSupportingDoc_REG SOP 01 Post Market Surveillance-Rev_04 (1).pdf
Cover Letter	C226058_Serosep_Supporting Covering Letter

Supporting documents related to each question Supplier's Bidder Response Document	C226058_Serosep_Q2_EntericBio Dx Instructions for Use_ C226058_Serosep_Q2_EntericBio C. difficile Instructions for Use C226058_Serosep_Q2_EntericBio Viral Panel 3 Instructions for Use_FINAL C226058_Serosep_Q2_Generic EB Flyer_Uk details C226058_Serosep_Q3_UKHSA Throughput Requirements Workflows C226058_Serosep_Q4_UK-QMS-Certificate2023 (ISO9001) C226058_Serosep_Q4_SER SOP 05 FORM 01 (rev 01) EntericBio Heatstation QBD4 SEROSEP IQOQ C226058_Serosep_Q4_SER SOP 06 FORM 01 REV 01 - IQOQ Centrifuge 5430 UK_IRE C226058_Serosep_Q4_SER SOP 02 FORM 01 IQOQ Record Form for EntericBio Workstation REV 03 C226058_Serosep_Q4_SER SOP 03 FORM 01 REV 01 - IQOQ Record Form Eppendorf Mixmate (UK_Ire) C226058_Serosep_Q4_SER SOP 04 FORM 01 REV 02 - IQOQ Record Form for Roche LightCycler 480 C226058_Serosep_Q5_Centrifuge 5430R IFU C226058_Serosep_Q5_Heatstation IFU C226058_Serosep_Q5_Lightcycler480II IFU C226058_Serosep_Q5_Mixmate IFU C226058_Serosep_Q5_Workstation IFU C226058_Serosep_Q6_EBRT APP 09 (01) Configuation of FastFinder network folder C226058_Serosep_Q6_FastFinder Standard HL7 integration 1.0 C226058_Serosep_Q6_UgenTec hosted solutions - Hosting whitepaper_v1.5 C226058_Serosep_Q7_EntericBio Viral Panel 3 Instructions for Use_FINAL C226058_Serosep_Q7_EntericBio C. difficile Instructions for Use C226058_Serosep_Q7_EntericBio Dx Instructions for Use_ C226058_Serosep_Q7_UK-QMS-Certificate2023 (ISO9001) C226058_Serosep_Q7_ISO13485-Cert-12042021 C226058_Serosep_Q8_EntericBio Dx Instructions for Use_ C226058_Serosep_Q8_EntericBio Viral Panel 3 Instructions for Use_FINAL C226058_Serosep_Q8_EntericBio C. difficile Instructions for Use C226058_Serosep_Q9_EBRT APP 02 (04) Training Manual for end Users of EntericBio assays - with software PDF C226058_Serosep_Q9_Serosep EntericBio example training certificate C226058_Serosep_Q9_TS F11 (03) EntericBio Training Checklist_Sample Tracking and FF Software C226058_Serosep_Q10_EntericBio Viral Panel 3 Instructions for Use

	C226058_Serosep_Q10_EntericBio Dx Instructions for Use C226058_Serosep_Q10_EntericBio C. difficile Instructions for Use C226058_Serosep_Q10_Table of Materials and Reagents for throughput estimate C226058_Serosep_Q12_EntericBio Viral Panel 1 Instructions for Use C226058_Serosep_Q12_EntericBio Viral Panel 3 Instructions for Use C226058_Serosep_Q13_Exit Plan for UKHSA C226058_Serosep_Q14_2021 Anaerobe GDH vs PCR Michael Perry C226058_Serosep_Q14_2022 JMM Holliday & Perry GP2 PHW C226058_Serosep_Q14_2023 Ampath EntericBio GP2 Comparison with stool culture C226058_Serosep_Q14_2023 ECCMID Poster Evaluation of Viral Panel 3 NWLP C226058_Serosep_Q14_2019 ASM Multicenter Evaluation EntericBio Dx assay C226058_Serosep_Q16_Implementation Plan for UKHSA_V2 C226058_Serosep_Q23_EBRT APP 02 (04) Training Manual for end Users of EntericBio assays - with software PDF C226058_Serosep_Q23_EBRT APP 06 (01) Site Requirements for EntericBio Equipment C226058_Serosep_Q23_EBRT APP 38 (02)EntericBio® Dx Plugin Shortcut Sheet C226058_Serosep_Q23_EBRT TS 83 (03) USER PROCEDURE for Decontamination of EntericBio equipment C226058_Serosep_Q23_EBRT TS 101 (01) EntericBio Workstation Sample Tracking Shortcut Sheet – Dx C226058_Serosep_Q23_Human factors and user experience Serosep_Q24_Downtime report C226058_Serosep_Q26_Serosep Sustainability Programme
Authority Clarification Questions	20231201-Authority Question Log
Authority Question Log Serial 19 Attachment	C226058_Serosep_Q14_2019 ASM Multicenter Evaluation EntericBio Dx assay Biofire Vibrio & Yersinia false positives Biofire ReCall GI Film Array Customer Letter 2019 US Appendix II_m_Method Comparison_Line Item Data_FastFinder
Authority Question Log Serial 19.1 Attachment	NWLP EntericBio VP3 Adenovirus C226058_Serosep_Q14_2023 ECCMID Poster Evaluation of

	Viral Panel 3 NWLP
Authority Question Log Serial 20 Attachment	Enteric Bio VP3 Validation_010219- Adenovirus NVRL Labtests NZ EB Dx prospective results Labtests NZ EB Dx retrospective results Labtests NZ EntericBio Dx Validation Report