Appendix 1

National Microbiology Framework Agreement
Order Form

FROM

Authority:	NHS England
Invoice address:	Post: 74T Payables M535 Phoenix House Topcliffe Lane Wakefield WF3 1WE
Contract Manager:	[redacted]
[redacted] **e.g., business operational contact, project manager**	[redacted]
Procurement lead	[redacted]
Name and address for notices:	[redacted]

	[redacted]
Internal reference (if applicable):	To be quoted on all correspondence relating to this Order Form: [redacted]

TO

Supplier:	PerkinElmer LAS (UK)Ltd.
Contract Manager:	[redacted]
Secondary Contact:	[redacted]
Account Manager:	[redacted]
[redacted] **address for notices:**	[redacted]

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:	**(only applicable if one or more boxes are checked)**
	1. TUPE applies at the commencement of the provision of Services ☐	
	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	☐	
	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)**

1. CONTRACT DETAILS

(1.1) Commencement Date:

1st October 2022

(1.2) Services Commencement Date (if applicable):

The Parties will collaborate to effectuate the program timeline below with the goal of screening for SCID commencing on April 3, 2023, on patient samples using EONISQ96 at Manchester, Sheffield and South West Thames Newborn Blood Spot screening laboratories. PerkinElmer will not be responsible for delays beyond its control or for which it is not responsible.

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

Contract with PerkinElmer for reagent rental for EONIS Q SCID evaluation:

The price set is competitive and has been fixed for the duration of the evaluation without indexation.

[redacted]

(1.4) **Term of Contract:** Contract period 1st October 2022 to 31st March 2025.

Screening of samples received in the laboratory from April 3rd, 2023, will be screened for SCID using EONISQ methodology

(1.5) Term extension options:
None

2. GOODS AND/OR SERVICES REQUIREMENTS

(2.1) Description of the Goods / Services:

In summary and as included in the reagent rental costs the supplier will provide the equipment, reagents, training and IT support to implement EONISQ into the [redacted] See below for detail)

October 2022	October	November	November	November	November	December	March 2023
24th	31st	7th	14th	21st	28th	5th	3rd
Readiness to ship							
	Instrument and reagents are shipped						
			Installation and set up				
				Training across 3 Laboratory sites			
						Validation and verification by the laboratories	

Table 1: SCID agreed timeline prior to commencement of testing live samples

Equipment/IT

The Equipment must be installed, all relevant staff trained and ready for laboratories to begin validation and verification by Friday 2nd December 2022.

Installation and set up during the week of 14th – 18th November

Equipment to be provided by Supplier as per table 2 below.

Table 2:

Participating Trust Requirements (as per section 2.2)			
Item	Quantity	Cost	Route of Procurement
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

Optical Seals	TBA	[redacted]	Provided by PE
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]			[redacted]
[redacted]			[redacted]
[redacted]			[redacted]

[redacted] The Supplier is not able to confirm at this stage if the laboratories will need 1 PC for each Eonis Q96 Thermal Cycler or if 1 PC will be sufficient to cover all. Therefore, the Supplier will provide PC's as needed to the laboratories subject to this program as defined above as per the requirements of the Eonis Q96 Thermal Cyclers.

The Supplier will be responsible for the installation and calibration of all the Equipment provided by them at no additional cost to the Authority. The Supplier will be responsible for the maintenance and servicing of all their Equipment listed in table above for the duration of this contract and Supplier shall use commercially reasonable efforts to maintain continuity of the screening programme for the duration of the contract.

The Supplier must ensure the system supports the interface between LIMS/middleware and EONISQ96 Thermal Cyclers and modification of LIMS to report SCID results (to NBSFS & Child Health), other than as provided below and any cost of integration will be borne by the Supplier. The detailed specifics of the IT requirements differ between laboratories. The Supplier team will meet with the individual laboratory services to determine the individual requirements for each site. Any specific support as needed to the SWT laboratory IT system to support the flow of SCID results from EONISQ96 to NBSFS and Child Health shall be subject of separate negotiations and

additional cost. Notwithstanding anything else in this Agreement, Supplier's interface and integration obligations under this Agreement with respect to South West Thames LIMS is to use reasonably cooperate with South West Thames to facilitate interface between the EONISQ and the South West Thames LIMS. South West Thames and/or NHS England will have all other responsibility with respect to transmission of results at South West Thames.

Training for laboratory staff

The supplier will deliver face to face dedicated training for each individual laboratory. For each Laboratory the Supplier will provide 2 days of comprehensive training and train up to 6 users per day or as per laboratory requirement on the date agreed and scheduled with the respective laboratory. The training should be conducted and completed by Friday 2nd December 2022.

The supplier will arrange for the training to take place in discussion with the Laboratories for a mutually convenient time.

Shipment of reagents (kits)

The kits are shipped in 3 parts:

- SMN1, TREC, KREC kit
  - Contain 4 PCR plates, 1 bottle of Elution solution
  - Stored in 2-8 C (the Elution solution bottle can be stored at RT)
- Elution plates
  - Stored at RT
- Kit controls
  - Contain DBS Kit controls and Zero DBS controls
  - Stored between -30^{0}C and -16^{0}C
- Each kit contains 4, 96 well plates
- Each plate contains 8 control wells enabling each plate to test 88 samples

The kits will be ordered and shipped as per the standing instructions in annexe B (below)

The Authority shall issue a Purchase Order (PO) to the Supplier in respect of any Goods to be supplied to the Authority under this Contract. The initial PO will be for the pre-evaluation run and thereafter the PO's will be issued yearly for the three years of this contract. The laboratories will then call off under the purchase order placed in line with the standing instructions (SI).

Reagents shipped as per call off requirements of the newborn screening laboratories. The Laboratories will place the order to the Supplier as per their individual requirements, however in accordance with the principles agreed herein.

The Supplier will confirm the volumes with each laboratory before dispatching the kits for delivery to ensure that there is no deviation from the standing instructions. The laboratories can request a

change at this point, based on their storage capacity and consumption of kits. This can be confirmed either via email or phone call to the laboratory. In the event of any changes to the initial PO, Supplier is released from any liability regarding delivery.

The Authority does not commit to any minimum or maximum volume or spend for the duration of this contract and any figures shown in Annex B are indicative only.

Deliveries:

The Supplier will ensure the delivery of equipment required to perform evaluation on the EONISQ96 to each site without any cost to the Authority.

Equipment shall be delivered and installed by the supplier as per the agreed timescales as per table 1

The Supplier will ship kits as per call off for supplies from the screening laboratories. The Parties will maintain continuous communication regarding Kit inventories and volumes, and the screening laboratories will notify Supplier as soon as practicable of a requirement for shipment of Kits. Kits will be shipped within three (3) working days from receipt of a written request for delivery, in order to maintain consistent supplies and mitigate for any kits which are not fit for purpose on arrival.

All delivery and shipping charges for the orders will be borne by the Supplier and are free of cost for the Authority.

Location(s) and Address for the deliveries are listed in (2.2).

Ongoing support and technical expertise

The Supplier will respond to requests from the laboratories and the Authority to provide technical expertise and support for the duration of the contract. Where required due to irreparable Equipment failure, the Supplier will ship replacement Equipment as soon as commercially practicable in order to maintain business continuity and safety of the newborn blood spot screening service.

Laboratories can make direct contact with the Supplier to ensure systems and processes are maintained and to provide continuity of the Newborn Blood Spot screening service.

The Supplier will respond

- In the first instance by email/phone call within 4 working hours of the request for support
- Where an onsite visit is required, the supplier will respond within 48hrs during the working week where there is a risk to the maintenance of normal screening services

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

- [redacted]
- [redacted]

[redacted]

- [redacted]

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

[redacted]

[redacted]

[redacted]

(2.4) Performance standards:

Performance Requirement	Threshold	Method of Reporting
To ship all equipment, in accordance with Table 2, to laboratories by the 11th November 2022.	100%	To be reported on completion and confirmed by email sent to [redacted]
To complete all installation, calibration and set up of equipment to laboratories by the 18th of November 2022.	100%	To be reported on completion and confirmed by email sent to [redacted]
To deliver 2 days of face-to-face training to each of 3 laboratories by the 2nd December 2022.	100%	To be reported on completion and confirmed by email sent to [redacted]
Supplier to provide the number of kits reported by laboratories as not fit for purpose upon delivery.		Breakdown of number and reason to be reported monthly

[redacted]		[redacted]		
[redacted]	[redacted]	[redacted]		[redacted]
[redacted]	[redacted]	[redacted]		[redacted]
[redacted]	[redacted]	[redacted]		
[redacted] within 5 workings in Supplier's Quality [redacted]	[redacted]	[redacted]		

[redacted] *"According to the Authority's specif[redacted] the Supplier's tender response, including any correspondence and clarifications."*

[redacted] Quality standards:

The supplier will reimburse NHSE for any kits which arrive and are reported by the laboratories not to be fit for purpose. Not fit for purpose includes the following. This is not an exclusive list

- Kits arrive with insufficient or no time prior to expiry
- Kits arrive after a delay in transit of more than 6 days
- Kits arrive having defrosted prior to arrival
- Kits arrive with damaged packaging making assurance about the quality of the product unclear

All reagents and consumables are shipped in ambient temperature. The supplier are undertaking ongoing stability studies to agree different storage temperatures.

The supplier will fulfil all requirements to be UKCA regulated by 3rd April 2023.

(2.6) Contract monitoring arrangements:

[redacted] [redacted] [redacted]

Monthly review meetings to be organised between the Supplier and Authority

[redacted]

(2.7) Management information and meetings:

Monthly review meetings to held with the Supplier for the duration of the contract. Issues to be raised in the interim as required. Summary notes and actions to be shared following meetings.

3. CONFIDENTIAL INFORMATION (if applicable)

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

Intellectual property

IP generated by all NHS bodies through all their activities is now recognised as an asset of value which should be used in the best interests of the NHS and the country as a whole by those best able to do so.
Innovations which are developed commercially are subject to IP and given this contract is based upon a new diagnostic NHSE want to ensure that no data or outcomes of the use of this new methodology is shared prior to the conclusion of this contract. Any early release without prior agreement with NHSE will be deemed a breach of this requirement and Clause 11 Appendix A.

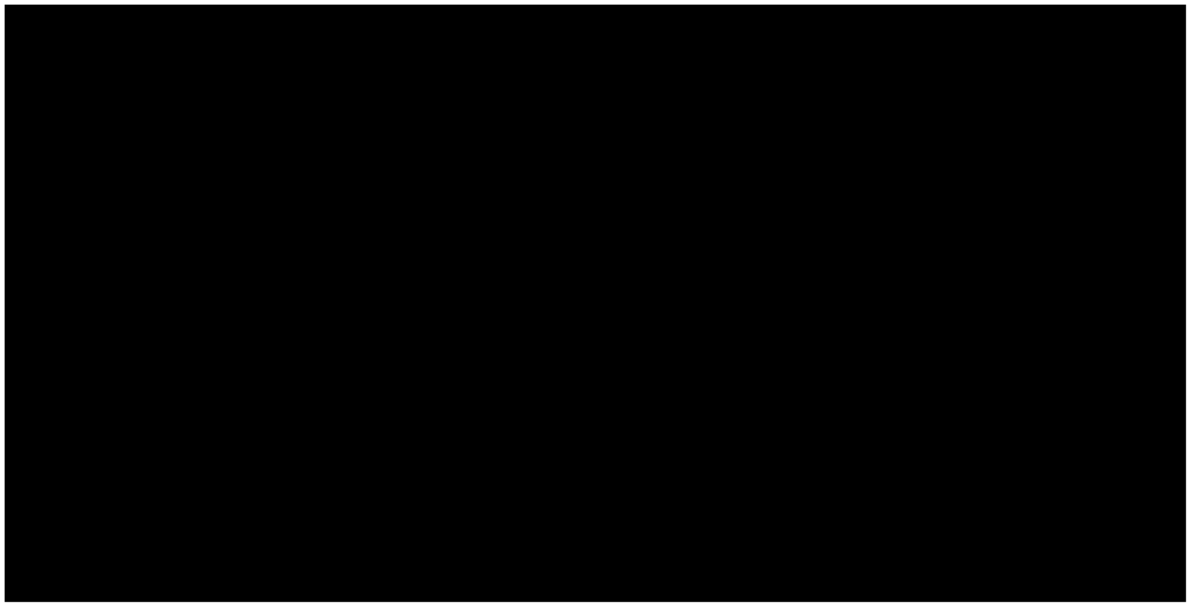
(3.2) Duration that the information shall be deemed Confidential Information:

For the duration of the contract and then for review at that stage prior to data being **shared**

4. DATA PROCESSING (if applicable)

(4.1) Personal Data to be processed by the Supplier:
It is not anticipated that personal data will be shared in connection with this Contract

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



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. [*Insert further sections as required for the purposes of the specific Order*]