Order Form

1. Contract Reference	852
2. Commencement Date	The date on which this Order Form is signed by the last Party to sign
3. Authority	Secretary of State for Health and Social Care 39 Victoria Street, Westminster, London SW1H 0EU
4. Supplier	Medco Solutions Ltd Innovation House, 99 Park Drive, Milton Park, OX14 4RS
5. The Sub-Contractor(s) (including the legal manufacturer, any other manufacturer involved in the creation or assembly process where applicable and a UK Responsible Person)	[redacted]
6. The Contract	On receipt of a Committed Order, the Supplier shall supply the Goods described below on the terms set out in this Order Form, the Call Off Terms and Conditions, the Schedules and any Annexes.
7. Goods to be Supplied and Order Process	The product to be supplied by the Supplier to the Authority is the Coronavirus Ag Flowflex L031-118Y5 Rapid Antigen Test (the "**Goods**"). The Goods are lateral flow testing devices for the detection of COVID-19 viral antigens and, include, without limitation, the supply of an IFU and packaging for each box of 7 units of the Goods. The Supplier shall: (a) comply with its obligations set out in; and (b) ensure that the Goods are manufactured, supplied and transported in accordance with, the Specification attached to the DPS Information Document issued to the Supplier on 5 March 2021, the Statement of Requirements and the Supplier's Tender Response and Responses to Clarification Questions included at Annex 3. The Statement of Requirements shall take precedence in the event of any conflict with the Specification attached to the DPS Information Document, the Supplier's Tender Response and Responses to Clarification Questions as set out in Annex 3 or the Call-Off Terms and Conditions. At all times during the Term, the Supplier shall ensure that it is capable of supplying a minimum of 20 million units of the Goods per week to the Authority at the Delivery Locations specified in Row 10 below on no less than 21 calendar days' notice from the Authority.

	The Authority reserves the right, at its absolute discretion, to purchase Goods from the Supplier on the terms set out in this Order Form by way of placing any number of orders with the Supplier during the Term (each a "**Committed Order**"). If the Authority wishes to exercise its option to place a Committed Order, an authorised representative from the Authority's commercial team shall provide the Supplier with written notice by email to the Supplier's Authorised Representative of the Committed Order setting out the required: a) quantity of Goods; b) timescales for delivery (which shall provide a lead time from the date of notice of Committed Order to delivery in the UK of no less than 21 calendar days unless otherwise agreed with the Supplier); and c) location for delivery of the Goods (in accordance with Row 10 below). The Supplier shall promptly acknowledge receipt of the Committed Order by email to the Authority's Authorised Representative. The Supplier shall supply the quantity of Goods specified in the Committed Order to the Authority to the delivery location and in accordance with the delivery schedule specified in the written notice of Committed Order, or as otherwise agreed with the Authority. The Supplier shall ensure that the label on the outer box of the packaging contains the SKU (Stock Keeping Unit) number which must be labelled/printed clearly and attached to the outer box of the pallet in accordance with the Statement of Requirements. The Supplier shall include a copy of the packaging labelling and Instructions for Use (IFU) within each inner-box of the product in accordance with the Statement of Requirements. The Supplier shall print the barcode directly onto the test cassette and shall ensure that the barcode and batch (or lot) numbering used meets the traceability requirements set out in the Statement of Requirements. The Goods shall have a remaining minimum shelf life of at least 12 months following delivery.
8. Batch	[redacted] units of the Goods shipped (or intended to be shipped) to the Authority in consecutive deliveries.
9. Delivery Instructions	The Supplier shall deliver the Goods to the delivery location(s) specified in Row 10 below in accordance with the delivery schedule as set out in the Authority's notice of Committed Order, on a Delivery Duty Paid ("**DDP**") basis and in accordance with the Authority's logistics requirements set out in the Statement of Requirements. Where the Supplier is delivering to the delivery location(s) specified in Row 10 below, the Authority shall be responsible for unloading the Goods at the delivery location unless agreed otherwise with the Supplier. If required by the Authority, the Supplier shall provide information and evidence to the Authority to demonstrate its capability regarding logistics and transportation of the Goods on a DDP basis.

	The Supplier shall comply with all instructions for storage and/or transportation applicable to the Goods (including but not limited to temperature control requirements in relation to the transportation of the Goods). The Supplier shall maintain records of such compliance, which it shall make available to the Authority on the Authority's request. The Supplier shall provide logistics information to the Authority on the Authority's request, by no later than 1 Business Day following the Authority's request. The logistics information shall be in a format which shall be notified by the Authority to the Supplier. The logistics information to be provided may include, but not be limited to, the following: (a) Stock Keeping Unit (SKU) number; (b) Status of Contract; (c) Expected collections; (d) Collections from manufacturer; (e) Cumulative expected collections; (f) Cumulative collections; (g) Differential between cumulative expected collections and cumulative collections; (h) Collections as per delivery schedule; (i) Volume in warehouse; (j) Goods departed by air; (k) Goods arrived by air; (l) Volume in UK not delivered; (m) Goods delivered to distribution centre.
10. Delivery Location(s)	The Supplier shall deliver the Goods to each of the following locations as specified by the Authority and in quantities and instalments as required by the Authority at each location and agreed by the Parties prior to delivery: [redacted]

	[redacted]
11. Date(s) of Delivery	The Supplier shall supply the Goods to the Authority in such instalments as agreed with the Authority to the delivery location and in accordance with the dates of delivery specified in the Authority's notice of Committed Order, or as otherwise agreed in accordance with the terms of this Contract. If the Goods have not been approved by the Authority in accordance with Row 12 below and have not received the necessary regulatory approvals required by this Contract on or before 15 October 2021, the Authority shall be entitled to terminate this Contract with immediate effect and re-allocate any volumes that would have been awarded to the Supplier to another supplier. Notwithstanding clause 4.1 of the Terms and Conditions, the Authority may, acting reasonably and on at least 5 days' written notice to the Supplier and without additional cost to the Authority, amend the following: (a) delivery location(s) within the UK (including Northern Ireland); (b) delivery times and dates; and/or (c) delivery instructions, as set out in this Order Form or as otherwise agreed by the Parties.
12. Quality Assurance Standards	The Supplier shall work in good faith with the Authority in a timely fashion to ensure that the Authority's requirements in relation to the assessment of samples of the Goods (including (without limitation) review of the IFUs as well as the labelling and packaging of the Goods) are met and any changes to the IFU, labelling and packaging have received all of the necessary regulatory approvals for supply to, distribution in and use in the UK. The Authority shall have the right to audit and inspect the records and/or premises and facilities of the Supplier or its Sub-Contractors at any time on reasonable notice to confirm that the Goods are latex-free and manufactured in a latex-free environment. The Supplier shall cooperate with any such audit and inspection and shall accompany the Authority or its authorised representative if requested.

<table>
<tr><td></td><td>The Supplier shall fully and promptly cooperate with the Authority during the Authority's service evaluation process and in relation to any requests for provision of samples of the Goods. For the avoidance of doubt, the Authority shall be under no obligation to order, receive or pay for any deliveries of the Goods until the Supplier has provided samples of the Goods as required by the Authority and the samples have been approved by the Authority.</td></tr>
<tr><td>13. Term</td><td>The Term shall commence on the Commencement Date (as stated above) and shall continue until (and including) 31 January 2022 (the "Expiry Date"), unless it is otherwise extended or terminated in accordance with the terms and conditions of the Contract. The maximum length of any extension beyond the Expiry Date shall be 6 months.</td></tr>
<tr><td>14. Charges</td><td>The Charges for the Goods shall be set out below:

<table><tr><th>Goods</th><th>Volume Banding (number of units)</th><th>Landed Price per unit based on DDP</th></tr><tr><td>[redacted]</td><td>[redacted]</td><td>[redacted]</td></tr><tr><td>[redacted]</td><td>[redacted]</td><td>[redacted]</td></tr><tr><td>[redacted]</td><td>[redacted]</td><td>[redacted]</td></tr></table></td></tr>
<tr><td>15. Payment</td><td>[redacted]

All invoices must be sent to:

mb-paymentqueries@dhsc.gov.uk

Within 10 Business Days of sending a Committed Order, we shall send you a unique Purchase Order number (the "PO Number"). If we provide you with a PO number you must quote it with any invoice.

Every payment request must be accompanied by a current statement of accounts; this is a standard commercial process and should show all invoices raised and amounts outstanding. Copy invoices requiring payment must be sent with all statement of accounts with supporting documents. The minimum supporting documents required are an invoice and packing list.

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

	If you have a query regarding an outstanding payment please contact our Accounts Payable section by email to: mb-paymentqueries@dhsc.gov.uk	
16. Additional Authority Obligations (if any)		
17. Authority Authorised Representative(s)	For general liaison your contact will continue to be [redacted]	
18. Supplier's Authorised Representative(s) and Regulatory Representative	For general liaison your contact will continue to be [redacted] or, in their absence, [redacted] **For regulatory and clinical queries your contact will be:** [redacted] (the "**Regulatory Representative**")	
19. Address for notices	**Authority:** Department of Health and Social Care, 39 Victoria Street, Westminster, London SW1H 0EU Attention: [redacted] Email: [redacted] Tel: [redacted]	**Supplier:** Medco Solutions Ltd Innovation House, 99 Park Drive, Milton Park, OX14 4RS Attention: [redacted] Email: [redacted] Tel: [redacted]
20. Social Value and Sustainability	The Supplier shall give due consideration to the wider social, economic and environmental benefits that can be secured through the delivery of this Contract and shall comply with any commitments to support the Authority's goal of maximising social value as set out the Supplier's Tender Response and Responses to Clarification Questions to the social value questions set out in Annex 3. In consultation with the Authority, the Supplier shall implement strategies to reduce waste and increase the sustainability of the Goods without reducing the performance and effectiveness of the Goods, whether by changing the design of the Goods (subject to the Authority's approval and the provisions of Clause 18) or by implementing new processes suggested by the Authority or the Supplier. The Supplier shall nominate an individual member of its organisation who will be dedicated	

	to working with the Authority on this initiative and shall notify the Authority of that person's name, title and contact details. Where there is more than one individual, the most senior individual shall be the relevant point of contact.
21. Key Performance Indicators	The Authority shall monitor the Supplier's performance of the Contract on an ongoing basis, including in respect of: 1. delivery by the Supplier in accordance with the delivery schedule; 2. quality control of the Goods through sampling and batch testing by the Authority or its nominated representatives; 3. satisfactory results of inspection reports on delivery; 4. the Supplier's monitoring and reporting of any issues relating to new or emerging variants of the SARS-CoV-2 virus in accordance with the terms of this Contract; and 5. delivery of social value commitments as described in Row 20 above and monitored on a quarterly basis.

BY SIGNING AND RETURNING THIS ORDER FORM THE SUPPLIER AGREES to enter a legally binding contract with the Authority to provide the Goods specified in this Order Form in accordance with the terms set out in this Order Form, the Call-Off Terms and Conditions (as attached to this Order Form) and in accordance with the DPS Agreement entered into by the Supplier and the Authority on 14 May 2021.

For and on behalf of THE AUTHORITY:

DocuSigned by:
[redacted]
B7F5CE2526TB493...
Full Name: [redacted]
Job Title/Role: Commercial Director
Date: 02/09/2021

For and on behalf of THE SUPPLIER:

DocuSigned by:
[redacted]
E2E9CCAA5C62487...
Full Name: [redacted]
Job Title/Role: [redacted]
Date: 02/09/2021

Terms and Conditions of Contract for the Purchase of Goods

1 Background

1.1 The Authority placed a contract notice in the Find a Tender Service under the following reference C22033 on 5 March 2021 (the "**FTS Notice**") seeking requests to participate from providers of lateral flow testing kits (divided into Lots) in a dynamic purchasing system ("**DPS**") for the supply of such goods to the Authority. The FTS Notice is accompanied by further documentation issued by the Authority detailing how to apply to the DPS and how the DPS will operate (the "**DPS Information Document"**).

1.2 In response to the FTS Notice and as required by the DPS Information Document, the Supplier submitted a request to participate in the DPS to the Authority on 15 March 2021 (the "**Application**") through which it represented to the Authority that it is capable of supplying the lateral flow testing kits accordance with the Authority's requirements as set out in the DPS Information Document and, in particular, the Supplier made representations to the Authority in the Application in relation to its competence, suitability, financial standing and ability to meet the requirements in an efficient and cost effective manner.

1.3 On the basis of the Application, the Authority admitted the Supplier to the DPS as a potential provider for such goods to the Authority from time to time on a call off basis in accordance with the DPS Agreement.

1.4 The DPS Agreement sets out the Call for Competition Procedure for the award of Contracts for the supply of Goods required by the Authority (either for itself or such other bodies as it may from time to time decide).

1.5 The Authority has selected the Supplier to supply the Goods specified in this Contract in accordance with the terms and conditions of this Contract.

Agreed terms

2 The Contract

2.1 This Contract is made on the date set out in the Order Form subject to the terms set out in the DPS Agreement, the Order Form and in the terms and conditions, schedules and annexes below. The Authority and the Supplier undertake to comply with the provisions of the DPS Agreement and this Contract in the performance of their respective obligations.

2.2 The terms and conditions of the DPS Agreement will apply to and be incorporated into this Contract.

2.3 The definitions in the DPS Agreement shall apply to the use of all capitalised terms in this Contract except as otherwise set out in Schedule 1.

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

3 Supply of Goods

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

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

(b) in accordance with all other provisions of this Contract;

(c) using reasonable skill and care in their delivery and supply;

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

(e) in accordance with any quality assurance standards as set out in the Order Form;

(f) in accordance with the Law and with Guidance;

(g) in accordance with Good Industry Practice;

(h) in accordance with the Policies; and

(i) in a professional and courteous manner.

3.2 The Supplier shall comply fully with its obligations set out in the Statement of Requirements and the Order Form (to include, without limitation, all obligations in relation to the quality standards, performance characteristics, supply, delivery and training in relation to use of the Goods). The Supplier's performance of the Contract may be monitored using the key performance indicators set out in the Order Form, if any.

3.3 Unless otherwise agreed by the Parties in writing, the Goods shall be new, consistent with any sample, and shall comply with any applicable specification set out in this Contract (to include, without limitation, the provisions of the Authority's requirements set out in the Order Form, Statement of Requirements and the Supplier's response to such requirements and any clarification questions) and any applicable manufacturers' specifications.

3.4 The Supplier shall ensure that all relevant consents, authorisations, licences and accreditations required to supply the Goods are in place prior to the delivery of any Goods to the Authority, including the rights, consents and authorisations needed for the Supplier to supply and distribute the Goods to the UK Government.

3.5 The Supplier shall, and shall procure that its legal manufacturer shall, notify the Authority in the event of a Serious Incident as soon as possible, but in any event within ten (10) calendar days of the legal manufacturer becoming aware of such a Serious Incident. In addition, the Supplier shall report to the Authority as soon as reasonably practicable, and in any event the Supplier shall report monthly to confirm whether or not there have been any incidents, performance and/or quality issues that in any way relate to or involve the use of the Goods by the Authority. The Supplier shall cooperate fully with the Authority's application of the Policies on reporting and responding to all incidents, including serious incidents, and performance and/or quality issues requiring investigation. The Supplier shall have appropriate protocols and processes in place to enable it to (and it shall) promptly respond to any reasonable and proportionate queries, questions and/or requests for information that the Authority may have in this context in relation to the Goods.

3.6 If there are any quality, performance and/or safety related reports, notices, alerts or other communications issued by the Supplier or any regulatory or other body in relation to the Goods, whether in the UK or other countries, or if there are other issues that might cause reputational damage to the Supplier, the Supplier shall provide the Authority with a copy of any such reports, notices, alerts or other communications within 24 hours of receipt by the Supplier. This Clause 3.6 shall survive termination or expiry of this Contract for a period of two years following the final delivery of the Goods, or until the Goods expiration date, whichever is longer, unless otherwise agreed in writing by the Parties.

3.7 Upon receipt of any such reports, notices, alerts or other communications pursuant to Clauses 3.5 and 3.6, the Authority shall be entitled to request further information from the Supplier and/or a meeting with the Supplier (and may require the Supplier's Regulatory Representative to attend such a meeting), and the Supplier shall cooperate fully with any such request, including procuring that the Supplier's Regulatory Representative shall attend such a meeting if requested by the Authority.

4 Delivery

4.1 The Supplier shall deliver the Goods in accordance with any delivery timescales, delivery dates and delivery instructions (to include, without limitation, as to Delivery Location and delivery times) set out in the Order Form, or as otherwise agreed with the Authority in writing. Time is of the essence as to any delivery dates under this Contract and if the Supplier fails to meet any delivery dates the Authority shall be entitled to cancel the delivery of the Goods without charge and the delay in delivery shall be deemed to be a breach incapable of remedy for the purposes of Clause 14.5.

Delivery and collection

4.2 Delivery shall be completed when the Goods have been unloaded at the location specified by the Authority and such delivery has been received by a duly authorised agent, employee or location representative of the Authority. The Authority shall procure that such duly authorised agent, employee or location representative of the Authority is at the Delivery Location at the agreed delivery date and times in order to accept such delivery. In the event that there is an arrangement by which the Goods are collected by the Authority (or by third party collection agents appointed directly by the Authority from time to time ("**Authority Collection Agents**")) in return for a discount on the Charges shall be agreed by the Parties in writing (where due to an emergency such arrangements cannot be committed to writing prior to collection, the Parties shall confirm such arrangements in writing as soon as possible following collection). Where the Authority collects the Goods, the Supplier shall (subject to any confidentiality obligations set out in this Contract) work directly with the Authority Collection Agents to ensure that they provide necessary support and assistance to the Authority Collection Agents in order to arrange such collection, and collection is deemed delivery for the purposes of the Contract.

Delivery note

4.3 The Supplier shall ensure that a delivery note shall accompany each delivery of the Goods. Such delivery note shall contain the information required in the Order Form, or as otherwise agreed with the Authority in writing, including (without limitation) any Purchase Order number. Where such information requirements as to the content of delivery notes are not specified or separately agreed, such delivery notes shall, as a minimum, contain the Authority's order number, the name and address of the Authority, a description, the quantity and specific storage instructions (if any) of the Goods, the date or batch (or lot) numbers, any special handling instructions (including a local reference, if appropriate), the manufactured on and use by dates, the ASN number (where required) and shall show separately any extra agreed charges for containers and/or any other item not included in the Charges or, where no charge is made, whether the containers are required to be returned.

Part deliveries

4.4 Part deliveries and/or deliveries outside of the agreed delivery times/dates may be refused unless the Authority has previously agreed in writing to accept such deliveries. Where delivery of the Goods is refused by the Authority in accordance with this Clause 4.4, the Supplier shall be responsible for all risks, costs and expenses associated with the re-delivery of the Goods in accordance with the agreed delivery times/dates. Where the Authority accepts delivery more than ten (10) days before the agreed delivery date, the Authority shall be entitled to charge the Supplier for the costs of insurance and storage of the Goods until the agreed date for delivery.

Transport and other related costs

4.5 Unless otherwise agreed with the Authority in writing, the Supplier shall be responsible for carriage, insurance, transport, all relevant licences, all related costs, and all other costs associated with the delivery of the Goods to the Delivery Location specified in the Order Form and unloading of the Goods at that Delivery Location. Without limitation to the foregoing provision of this Clause 4.5, unless otherwise agreed with the Authority in writing, the Supplier shall be responsible for obtaining all export and import licences for the Goods to the Delivery Location and shall be responsible for any delays to the delivery time due to such licences not being available when required. In the case of any Goods supplied from outside the United Kingdom, the Supplier shall ensure that accurate information is provided to the Authority as to the country of origin of the Goods and shall be liable to the Authority for any extra duties or taxes for which the Authority may be accountable should the country of origin prove to be different from that set out in the Order Form.

Use of third party carriers

4.6 Save for any Authority Collection Agents, all third party carriers or any Sub-Contractors engaged to deliver the Goods shall at no time be an agent of the Authority and accordingly the Supplier shall be liable to the Authority for the acts and omissions of all third party carriers and Sub-Contractors engaged to deliver the Goods to the Authority.

Late delivery

4.7 In the event that the Supplier becomes aware that it may not be able to meet any of the delivery dates set out in this Contract, it shall notify the Authority in writing as soon as possible of the issue and likely impact on delivery timescales.

5 Passing of risk and ownership

5.1 Risk in the Goods shall pass to the Authority when the Goods are delivered as specified in this Contract.

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

(a) delivery of the Goods;

(b) full payment for such Goods; or

(c) 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 5, then the full Charges 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.

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

6 Inspection, rejection, return and recall

6.1 As relevant and proportionate to the Goods in question and subject to reasonable written notice, the Supplier shall permit any person authorised by the Authority, to inspect work being undertaken in relation to the Goods and/or the storage facilities used in the storage of the Goods at all reasonable times at the Supplier's premises or at the premises of any Sub-Contractor or agent of the Supplier in order to confirm that the Goods are being manufactured and/or stored in accordance with Good Industry Practice and in compliance

with the requirements of this Contract and/or that stock holding and quality assurance processes are in accordance with the requirements of this Contract.

6.2 The Supplier shall perform quality control procedures to ensure that the Goods meet the requirements of this Contract, including the Statement of Requirements prior to the dispatch of the Goods and shall provide evidence of the completion of such procedures in respect of each shipment of the Goods to the Authority (or a third party appointed by it) on request. The Supplier shall, on request by the Authority, cooperate with an independent third party such that the nominated third party is able to perform sample quality tests on the units of Goods. The Supplier shall not release any shipment of Goods where any test or quality control procedure indicates or is likely to indicate a failure rate in 2% or more of the units of Goods.

6.3 Without prejudice to the provisions of Clause 6.6 and subject to Clause 6.7, the Authority (or one or more third parties appointed by it) shall inspect the Goods within a reasonable time following delivery (or such other period as may be set out in the Order Form, if any) or, where agreed with the Supplier, prior to shipment at their place of manufacturing or storage. The Authority may, by written notice, reject any Goods found to be damaged or otherwise not in accordance with the requirements of this Contract or where any of the rights for the Authority to terminate set out in Clauses 14.5 to 14.9 have arisen ("**Rejected Goods**"). The whole of any delivery may be rejected if a reasonable sample of the Goods taken indiscriminately from that delivery is found not to conform in all material respects to the requirements of the Contract. The sample size shall be calculated in accordance with internationally recognised standards for sampling.

6.4 Without prejudice to the provisions of Clause 6.5, upon the rejection of any Goods in accordance with Clause 6.3, the Supplier shall at the Authority's written request:

(a) collect the Rejected Goods at the Supplier's risk and expense within ten (10) Business Days of issue of written notice from the Authority rejecting the Goods and reimburse the Authority for any Charges paid in connection with the Goods (including without limitation any pre-payment or advance payments) along with any costs reasonably incurred by the Authority as a result of any such rejection; and

(b) without extra charge, promptly (and in any event within twenty (20) Business Days or such other time agreed by the Parties in writing acting reasonably) supply replacements for the Rejected Goods to the Authority subject to the Authority not cancelling its purchase obligations in accordance with Clause 6.5.

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

6.5 Risk and title in respect of any Rejected Goods shall pass to the Supplier on the earlier of: (a) collection by the Supplier in accordance with Clause 6.3; or (b) immediately following the expiry of ten (10) Business Days from the Authority issuing written notification rejecting the Goods. If Rejected Goods are not collected within ten (10) Business Days of the Authority issuing written notification rejecting the Goods, the Authority may return the Rejected Goods at the Supplier's risk and expense and charge the Supplier for the cost of storage from the expiry of ten (10) Business Days from the date of notification of rejection.

6.6 Without prejudice to any other provisions of this Contract or any other warranties or guarantees applicable to the Goods supplied and subject to Clause 6.8, if at any time following the date of the delivery of any Goods, all or any part of the Goods are found to be defective or otherwise not in accordance with the requirements of this Contract, (including the Statement of Requirements, the warranties in relation to the Goods set out in Clause 9, and any requirements relating to Phase 3A Validation and Phase VOC

Validation, as defined in the DPS Information Document, and where the control line does not activate at the time of carrying out a test (such that no result, either positive or negative is given)) ("**Defective Goods**"), the Supplier shall, without extra charge, promptly (and in any event within twenty (20) Business Days or such other time agreed by the Parties in writing acting reasonably) supply replacements for the Defective Goods to the Authority. In the event of failure of more than 3.0% of the units of Goods in any Batch (as defined in the Order Form) to deliver a result in accordance with the requirements of this Contract, evaluated using a reasonable sample taken by the Authority from such Batch to determine the applicable failure rate (such sample size to be calculated on the basis of 100 units per one million units supplied), the Authority may notify the Supplier in writing that the Goods in the entire Batch are to be treated as Defective Goods.

6.7 Where the Authority rejects any Goods in accordance with Clauses 6.3 and/or any Goods are deemed to be Defective Goods in accordance with Clause 6.6 and the Authority no longer requires replacement Goods, the Authority may by written notice cancel its purchase obligations in relation to the Rejected Goods (or Defective Goods, as the case may be). Should the Authority have paid (in whole or in part) for such Rejected Goods (or Defective Goods, as the case may be) the Supplier shall refund and pay to the Supplier such payment along with any costs reasonably incurred by the Authority as a result of any such rejection to the Authority within thirty (30) days of the Authority cancelling such purchase obligations and informing the Supplier that the Authority does not require replacements for such Rejected Goods (or Defective Goods, as the case may be). In addition, the Authority reserves the right to cancel any future deliveries of the Goods under this Contract where it has any concerns that the Goods may not be effective to the required level of sensitivity in detecting any relevant established, new or emerging variants of the SARS-CoV-2 virus.

6.8 The Supplier shall be relieved of its liabilities under Clauses 6.3 and/or 6.6 to the extent only that the Goods are damaged, the Goods are Defective Goods and/or the Goods fail to comply with the requirements of this Contract due, in each case, to any acts or omissions of the Authority.

6.9 The Authority's rights and remedies under Clause 6.6 shall cease within a reasonable period of time from the date on which the Authority discovers or might reasonably be expected to discover that the Goods are Defective Goods or within such other period as may be set out in the Order Form, if any. For the avoidance of doubt, Goods not used before their expiry date shall in no event be considered Defective Goods following the date of expiry provided that at the point such Goods were delivered to the Authority they met any shelf life requirements set out in the Order Form.

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

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

(b) from the date of the Requirement to Recall treat the Goods the subject of such recall as Defective Goods in accordance with Clause 6.6;

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

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

6.11 Without prejudice to any other provisions of this Contract or any other warranties or guarantees applicable to the Goods supplied, where a new variant of the SARS-CoV-2 virus is identified after the date of delivery, whether by the Supplier acting in accordance with its obligations under Clause 19.4 of the DPS Agreement, or otherwise notified to the Supplier, and the Goods are found not to be effective in detecting the new variant to the level of sensitivity required by the Authority then, provided that the Goods have been stored, transported, handled and/or administered by or on behalf of the Authority in accordance with the manufacturer's specifications, the Supplier agrees to use reasonable endeavours to seek an alternative purchaser for any such Goods that have been delivered to the Authority which can no longer be used by the Authority. In the event and to the extent that the Supplier is able to find an alternative purchaser for the Goods, the Supplier shall consult with the Authority as to the most efficient method of executing the return of the Goods and the Supplier shall, as agreed with the Authority, either refund a fair and reasonable proportion of the price paid by the Authority for the relevant Goods or provide replacements for the relevant Goods where the manufacturer has been able to adapt the specification of the Goods to ensure that the new variant is detected to the required level of sensitivity.

7 The Authority's obligations

7.1 Subject to the Supplier supplying the Goods in accordance with this Contract, the Authority will pay the Supplier for the Goods in accordance with Clause 8.

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

7.3 The Authority shall comply with the Authority's Obligations, as may be referred to in the Order Form.

7.4 The Authority shall provide the Supplier with any reasonable and proportionate cooperation necessary to enable the Supplier to comply with its obligations under this Contract. The Supplier shall at all times provide reasonable advance written notification to the Authority of any such cooperation necessary in circumstances where such cooperation will require the Authority to plan for and/or allocate specific resources in order to provide such cooperation.

8 Price and payment

Charges

8.1 The Charges shall be calculated as set out in the Order Form.

8.2 Unless otherwise stated in the Order Form, the Charges:

(a) shall remain fixed during the Term; and

(b) are the entire price payable by the Authority to the Supplier in respect of the provision of the Goods to the Delivery Location and includes, without limitation:

(i) packaging, packing materials, addressing, labelling, loading, delivery to and unloading at the Delivery Location, the cost of any import or export licences where applicable, all applicable taxes (excluding VAT), duties and tariffs, any expenses arising from import and export administration, any installation costs and associated works, the costs of all associated documentation and information supplied or made accessible to the Authority in any media, and any training in relation to the use, storage, handling or operation of the Goods;

(ii) any royalties, licence fees or similar expenses in respect of the making, use or exercise by the Supplier of any Intellectual Property Rights for the

purposes of performing this Contract, and any licence rights granted to the Authority;

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

Invoices

8.3 Unless stated otherwise in the Order Form, the Supplier shall invoice the Authority for Goods at any time following confirmation of completion of each delivery of the Goods in compliance with this Contract. Each invoice shall contain such information and be addressed to such individual as the Authority may inform the Supplier from time to time.

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

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

8.6 The Authority shall verify and pay each valid and undisputed invoice received in accordance with Clause 8.3 within thirty (30) days of receipt of such invoice at the latest. However, the Authority shall use its reasonable endeavours to pay such undisputed invoices sooner in accordance with any applicable government prompt payment targets. If there is undue delay in verifying the invoice in accordance with this Clause 8.6, the invoice shall be regarded as valid and undisputed for the purposes this Clause 8.6 after a reasonable time has passed.

8.7 Where the Authority raises a query with respect to an invoice the Parties shall liaise with each other and agree a resolution to such query within thirty (30) days of the query being raised. If the Parties are unable to agree a resolution within thirty (30) days the query shall be referred to dispute resolution in accordance with the Dispute Resolution Procedure. For the avoidance of doubt, the Authority shall not be in breach of any of its payment obligations under this Contract in relation to any queried or disputed invoice sums unless the process referred to in this Clause 8.7 has been followed and it has been determined that the queried or disputed invoice amount is properly due to the Supplier and the Authority has then failed to pay such sum within a reasonable period following such determination.

8.8 The Authority reserves the right to set-off:

(a) any monies due to the Supplier from the Authority as against any monies due to the Authority from the Supplier under this Contract; and

(b) any monies due to the Authority from the Supplier as against any monies due to the Supplier from the Authority under this Contract.

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

8.10 If a Party fails to pay any undisputed sum properly due to the other Party under this Contract, the Party due such sum shall have the right to charge interest on the overdue

amount at the applicable rate under the Late Payment of Commercial Debts (Interest) Act 1998, accruing on a daily basis from the due date up to the date of actual payment, whether before or after judgment.

9 Warranties

9.1 The Supplier warrants and undertakes that:

(a) the Goods shall be suitable for the purposes as referred to in the Order Form, be of satisfactory quality, fit for their intended purpose and shall comply with the standards and requirements set out in this Contract, including the Statement of Requirements, and the requirement to hold both Phase 3A Validation and Phase VOC Validation;

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

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

(d) without prejudice to the generality of the warranty at clause 9.1(a) it shall ensure that, the Goods are manufactured, stored and/or distributed in accordance with good manufacturing practice and/or good warehousing practice and/or good distribution practice, as may be defined under any Law, Guidance and/or Good Industry Practice relevant to the Goods, and in accordance with any specific instructions of the manufacturer of the Goods;

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

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

(g) it will ensure sufficient stock levels to comply with its obligations under this Contract;

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

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

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

(k) all Goods delivered to the Authority shall comply with any shelf life requirements set out in the Order Form;

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

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

(n) it shall not make any changes to the Goods (including any labelling, Sub-Contractors, the Notified Body or UK Approved Body certificate for the Goods, legal manufacturer's declaration of conformity and/or the EN ISO 13485:2016 certification) without the prior written consent of the Authority, such consent not to be unreasonably withheld or delayed and for the avoidance of doubt, unless otherwise set out in the Order Form, any such changes or substitute goods, if accepted, shall not lead to an increase in the Charges;

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

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

(q) it has and shall as relevant maintain all rights, consents, authorisations, licences, regulatory approvals and accreditations required to supply the Goods, including the right to supply and distribute the Goods to the UK Government;

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

(s) it will comply with all Law, Guidance, Policies and the Supplier Code of Conduct in so far as is relevant to the supply of the Goods;

(t) it will promptly (and in any event within one (1) Business Day) notify the Authority of any health and safety hazard which has arisen, or the Supplier is aware may arise, in connection with the Goods and take such steps as are reasonably necessary to ensure the health and safety of persons likely to be affected by such hazards;

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

(v) it shall at all times conduct its business in a manner that is consistent with any anti-slavery Policy of the Authority that is notified to the Supplier and shall provide to the Authority any reports or other information that the Authority may request as evidence of the Supplier's compliance with this Clause 9.1(v) and/or as may be requested or otherwise required by the Authority in accordance with its anti-slavery Policy;

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

(x) all information included within the Supplier's responses to any documents issued by the Authority as part of the procurement relating to the award of this Contract (to include, without limitation, as referred to in the Order Form and the Supplier's tender attached at Annex 3) and all accompanying materials is accurate and in English;

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

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

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

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

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

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

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

9.2 The Supplier warrants that:

(a) at the point such Goods are supplied to the Authority, all such Goods shall have a valid Product Authorisation (whether held by the Supplier or legal manufacturer) enabling the test to be used in the UK as an in vitro diagnostic test and that all relevant marking, authorisation, registration, approval and documentation requirements as required under Law and Guidance relating to the sale, manufacture, assembly, importation, storage, distribution, supply, delivery, or installation of such Goods shall have been complied with. Without limitation to the foregoing provisions of Clauses 9.1 and 9.2, the Supplier shall, upon written request from the Authority, make available to the Authority evidence of the grant of such valid Product Authorisation, and evidence of any other authorisations, registrations, approvals or documentation required; and

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

9.3 If the Supplier is in breach of Clause 9.2 then, without prejudice to any other right or remedy of the Authority, the Authority shall be entitled to reject and/or return the Goods and the Supplier shall, subject to Clause 12.2 indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings suffered or incurred by the Authority as a result of such breach.

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

9.5 The Supplier warrants that all information, data and other records and documents required by the Authority as set out in the Order Form shall be submitted to the Authority in the format and in accordance with any timescales set out in the Order Form.

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

9.7 The Supplier warrants and undertakes to the Authority that, as at the Commencement Date, it is not and throughout the Term of this Contract it will not be, involved in any Occasion of Tax Non-Compliance.

9.8 The Supplier warrants that the Goods will be effective to the Authority's required level of sensitivity in detecting the variants of the SARS-CoV-2 virus which are identified in the Statement of Requirements, identified (or should have been identified) by the Supplier acting in accordance with its obligations under Clause 19.4 of the DPS Agreement, or which have otherwise been notified to the Supplier prior to the date of delivery of the Goods. The Supplier shall inform the Authority in writing immediately on becoming aware at any time that the performance of the Goods may be adversely affected in relation to any identified variants of the SARS-CoV-2 virus. The Authority reserves the right to cancel any future deliveries of the Goods under this Contract where it has any concerns that the Goods may not be effective to the required level of sensitivity in detecting any established, new or emerging variants of SARS-CoV-2 virus.

9.9 The Supplier further warrants and undertakes to the Authority that it will inform the Authority in writing immediately upon becoming aware that any of the warranties set out in Clause 9 have been breached or there is a risk that any warranties may be breached.

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

10 Intellectual property

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

10.2 The Supplier acknowledges and agrees that it shall and shall procure that its Sub-Contractors shall, if required by the Authority, enter into a separate intellectual property licence for the sharing and use of materials supplied by the Authority to the Supplier or its Subcontractors in connection with the development of Goods and associated instructions document.

11 Indemnity

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

(a) any injury or allegation of injury to any person, including injury resulting in death;

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

(c) any breach of Clause 9.1(r) and/or Clause 10,

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

11.2 Liability under Clauses 11.1(a) and 11.1(c) shall be unlimited. Liability under Clauses 6.10(d), 9.3 and 11.1(b) shall be subject to the limitation of liability set out in Clause 12.

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

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

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

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

12 Limitation of liability

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

(a) for death or personal injury resulting from its negligence;

(b) for fraud or fraudulent misrepresentation; or

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

12.2 Subject to Clauses 11.2, 12.1, 12.3 and 12.5, the total liability of each Party to the other under or in connection with this Contract whether arising in contract, tort, negligence, breach of statutory duty or otherwise shall be limited in aggregate to the greater of: (a) five million GBP (£5,000,000); or (b) one hundred and twenty five percent (125%) of the total Charges paid or payable by the Authority to the Supplier for the Goods.

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

(a) extra costs incurred purchasing replacement or alternative goods;

(b) costs incurred in relation to any product recall;

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

(d) the costs of extra management time; and/or

(e) loss of income due to an inability to provide health care services,

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

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

12.5 If the total Charges paid or payable by the Authority to the Supplier over the Term:

(a) is less than or equal to one million pounds (£1,000,000), then the figure of five million pounds (£5,000,000) at Clause 12.2 shall be replaced with one million pounds (£1,000,000);

(b) is less than or equal to three million pounds (£3,000,000) but greater than one million pounds (£1,000,000), then the figure of five million pounds (£5,000,000) at Clause 12.2 shall be replaced with three million pounds (£3,000,000);

(c) is equal to, exceeds or will exceed ten million pounds (£10,000,000), but is less than fifty million pounds (£50,000,000), then the figure of five million pounds (£5,000,000) at Clause 12.2 shall be replaced with ten million pounds (£10,000,000) and the figure of one hundred and twenty five percent (125%) at Clause 12.2 shall be deemed to have been deleted and replaced with one hundred and fifteen percent (115%); and

(d) is equal to, exceeds or will exceed fifty million pounds (£50,000,000), then the figure of five million pounds (£5,000,000) at Clause 12.2 shall be replaced with fifty million pounds (£50,000,000) and the figure of one hundred and twenty five percent (125%) at Clause 12.2 shall be deemed to have been deleted and replaced with one hundred and five percent (105%).

12.6 Clause 12 shall survive the expiry of or earlier termination of this Contract for any reason.

13 Insurance

13.1 Subject to Clause 13.2 and unless otherwise confirmed in writing by the Authority, as a minimum level of protection, on receipt of a Committed Order and prior to any shipment of the Goods the Supplier, shall put in place and/or maintain in force at its own cost with a reputable commercial insurer and in accordance with Good Industry Practice, insurance arrangements in respect of:

(a) employer's liability with the minimum cover per claim of five million pounds (£5,000,000);

(b) public liability with the minimum cover per claim of ten million pounds (£10,000,000);

(c) professional indemnity (financial loss) with the minimum cover per claim of five million pounds (£5,000,000); and

(d) product liability with the minimum cover per claim of twenty million pounds (£20,000,000),

or any higher sum as required by Law however, the Supplier shall have responsibility for ensuring that it is adequately insured to cover all potential liability under this Contract, including any insurance arrangements set out in the Statement of Requirements.

13.2 The amount of any indemnity cover shall not relieve the Supplier of any liabilities under this Contract. It shall be the responsibility of the Supplier to determine the amount of indemnity cover that will be adequate to enable it to satisfy its potential liabilities under this Contract. Accordingly, the Supplier shall be liable to make good any deficiency if the proceeds of any indemnity cover is insufficient to cover the settlement of any claim.

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

13.4 The Supplier shall from time to time and in any event within five (5) Business Days of written demand provide documentary evidence to the Authority that insurance arrangements taken out by the Supplier pursuant to Clause 13 are fully maintained and that any premiums on them and/or contributions in respect of them (if any) are fully paid.

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

14 Term and termination

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

14.2 The Authority shall be entitled to terminate this Contract for convenience by issuing a Termination Notice to the Supplier at any time on one (1) month's written notice.

14.3 The Authority shall be entitled to extend the Term on one or more occasions by giving the Supplier written notice no less than fifteen (15) Business Days' prior to the date on which this Contract would otherwise have expired, provided that the duration of this Contract shall not extend beyond the maximum Term specified in the Order Form.

14.4 In the case of a breach of any of the terms of this Contract by either Party that is capable of remedy (including and not limited to any breach of any payment obligations, under this Contract), the non-breaching Party may, without prejudice to its other rights and remedies under this Contract, issue a Breach Notice and shall allow the Party in breach the opportunity to remedy such breach in the first instance via a remedial proposal put forward by the Party in breach ("**Remedial Proposal**") before exercising any right to terminate this Contract. Such Remedial Proposal must be agreed with the non-breaching Party (such agreement not to be unreasonably withheld or delayed) and must be implemented by the Party in breach in accordance with the timescales referred to in the agreed Remedial Proposal. Once agreed, any changes to a Remedial Proposal must be approved by the Parties in writing. Any failure by the Party in breach to:

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

(b) comply with such Remedial Proposal (including, without limitation, as to its timescales for implementation, which shall be ten (10) Business Days unless otherwise agreed between the Parties); and/or

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

shall be deemed a material breach of this Contract by the Party in breach not remedied in accordance with an agreed Remedial Proposal.

14.5 Either Party may terminate this Contract by issuing a Termination Notice to the other Party if such other Party commits a material breach of any of the terms of this Contract which is:

(a) not capable of remedy; or

(b) in the case of a breach capable of remedy, not remedied in accordance with a Remedial Proposal.

14.6 The Authority may terminate this Contract immediately by issuing a Termination Notice to the Supplier if:

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

(b) the Supplier purports to assign, sub-contract, novate, create a trust in or otherwise transfer or dispose of this Contract without the prior written consent of the Authority;

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

(d) the right arises pursuant to and in accordance with the Order Form or Clauses 14.7, 19.6 or any other applicable rights under the DPS Agreement; or

(e) any of the warranties given by the Supplier pursuant to Clause 9 are found to be materially untrue or misleading;

(f) the warranty given by the Supplier pursuant to Clause 9.7 is materially untrue, the Supplier commits a material breach of its obligation to notify the Authority of any Occasion of Tax Non-Compliance as required by Clause 9.7, or the Supplier fails to provide details of proposed mitigating factors as required by Clause 9.7 that in the reasonable opinion of the Authority are acceptable.

14.7 If the Authority, acting reasonably, has good cause to believe that there has been a material deterioration in the financial circumstances of the Supplier and/or any third party guaranteeing the obligations of the Supplier under this Contract and/or any material Sub-Contractor of the Supplier when compared to any information provided to and/or assessed by the Authority as part of any procurement process or other due diligence leading to the award of this Contract to the Supplier or the entering into a Sub-Contract by the Supplier, the following process shall apply:

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

(b) a failure or refusal by the Supplier to provide the financial or other security and/or assurances requested in accordance with Clause 14.7(a) in accordance with any reasonable timescales specified in any such notice issued by the Authority shall be deemed a breach of this Contract by the Supplier and shall permit the Authority to terminate the Contract immediately by issuing a Termination Notice to the Supplier.

14.8 The Authority shall be entitled to terminate this Contract immediately if at any time during the term of this Contract the Supplier fails to meet the requirements of the General Admission Phase or the requirements of the Category (Lot) Admission Phase for the relevant Lots (as such requirements are defined in the DPS Information Document or in any updated requirements amending the DPS Information Document, permitted by the Regulations and notified to the Supplier from time to time) or if the Supplier fails to provide the information required or in the timescale required in accordance with Clause 5.3 of the DPS Agreement.

14.9 Notwithstanding any other provision in the Contract, the Authority shall be entitled to terminate this Contract with immediate notice should any information supplied by the Supplier, contained in this Contract or obtained by the Authority (including but not limited to certifications of the Goods, financial or other due diligence information provided by the Supplier or obtained by the Authority) be inaccurate, misleading and/or otherwise give rise to reasonable suspicion by the Authority of fraud.

15 Consequences of expiry or early termination of this Contract

15.1 Subject to Clause 15.2, upon expiry or earlier termination of this Contract (including where the Authority exercises its right to terminate pursuant to Clause 14.2), the Authority agrees to pay the Supplier for the Goods which have been delivered by the Supplier to the Authority in accordance with Clause 4 (Delivery) prior to the date of expiry or date of termination set out in the relevant Termination Notice.

15.2 The Authority shall not pay for Defective Goods or Rejected Goods delivered by the Supplier to the Authority prior to or after the date of expiry or date of termination set out in the relevant Termination Notice. The Supplier shall within thirty (30) days of the expiry or early termination of this Contract, reimburse the Authority for any Charges paid (including without limitation any pre-payment or advance payments) in connection with Goods not delivered or for Defective Goods or for Rejected Goods. During any applicable notice period for termination, the Supplier shall, acting reasonably, minimise and/or mitigate the costs that the Supplier incurs during the notice period in connection with the termination by the Authority.

15.3 Upon termination of the Contract for convenience in accordance with Clause 14.2, the Supplier may seek to recover from the Authority any reasonable unavoidable losses incurred by the Supplier directly as a result of the early termination of the Contract which:

(a) are proven, evidenced (including a fully itemised breakdown of costs) and not capable of recovery by any other reasonable means, including an insurance claim; and

(b) are incurred in connection with bespoke, customised features, designs or packaging for the Goods required by the Authority and cannot be used by another customer of the Supplier or in relation to any other contract with the Authority or other Contracting Authority, and are surplus to the Supplier's requirements after the date set out in the relevant Termination Notice.

15.4 The Supplier shall take all reasonable steps to minimise and mitigate the costs set out in Clause 15.3.

15.5 The Authority shall not be liable under Clause 15.3 to pay any sum which:

(a) was claimable under insurance held by the Supplier, and the Supplier has failed to make a claim on its insurance, or has failed to make a claim in accordance with the procedural requirements of the insurance policy;

(b) when added to any sums paid or due to the Supplier under this Contract, exceeds the total sum that would have been payable to the Supplier if this Contract had not been terminated prior to the expiry of the Term; or

(c) is a claim by the Supplier for loss of profit, due to early termination of this Contract.

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

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

16 Packaging, identification and end of use

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

16.2 Unless otherwise agreed with the Authority in writing, the Goods shall be securely packed in trade packages of a type normally used by the Supplier for deliveries of the same or similar goods in the same quantities within the United Kingdom and in relation to Goods imported into the United Kingdom for the purposes of the Producer Responsibility Obligations (Packaging Waste) Regulations 2007 and all applicable product and safety liability legislation in force in the United Kingdom from time to time, the Supplier shall assume all obligations for all activities performed outside the United Kingdom in relation to the Goods and the packaging, in addition to any other obligations the Supplier may have pursuant to such regulations and other legislation.

16.3 The Supplier shall comply with any labelling requirements in respect of the Goods: (a) specified in the Order Form; (b) agreed with the Authority in writing; and/or (c) required to comply with Law or Guidance and shall ensure that any labelling in respect of the Goods is in English.

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

17 Coding requirements

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

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

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

18 Change management

18.1 The Supplier acknowledges to the Authority that the Authority's requirements for the Goods may change during the Term and the Supplier shall not unreasonably withhold or delay its consent to any reasonable variation or addition to the Contract (which may include amendments to the pack size and volumes), as may be requested by the Authority from time to time.

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

18.3 The Supplier shall not be relieved of its obligations to supply the Goods in accordance with the terms and conditions of this Contract nor be entitled to an increase in the Charges as a result of a Change in Law.

19 Force majeure

19.1 Subject to Clause 19.2, neither Party shall be liable to the other for any failure to perform all or any of its obligations under this Contract nor liable to the other Party for any loss or damage arising out of the failure to perform its obligations to the extent only that such performance is rendered impossible by a Force Majeure Event.

19.2 The Supplier shall only be entitled to rely on a Force Majeure Event and the relief set out in Clause 19 and will not be considered to be in default or liable for breach of any obligations under this Contract if:

(a) the Supplier has fulfilled its obligations under the Contract to the extent that it is able to do so in accordance with Clause 19.4;

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

(c) the Supplier has complied with the procedural requirements set out in Clause 19.

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

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

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

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

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

19.8 If the Supplier is prevented from performance of its obligations as a result of a Force Majeure Event, the Authority may at any time if the Force Majeure Event subsists for thirty (30) days or more, terminate this Contract by issuing a Termination Notice to the Supplier.

19.9 Following such termination in accordance with Clause 19.8 and subject to Clause 19.10, neither Party shall have any liability to the other.

19.10 Any rights and liabilities of either Party which accrued prior to such termination in accordance with Clause 19.8 shall continue in full force and effect unless otherwise specified in this Contract.

20 Personal Data

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

(a) administer and provide the Goods;

(b) request and receive the Goods;

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

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

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

(f) comply with their respective regulatory obligations.

20.2 Processing of Personal Data relating to each Party's representatives for the purposes set out in Clause 20.1 shall only be done by each Party in accordance with their respective privacy policies. The Parties acknowledge that they may be required to share Personal Data with their affiliates, group companies and other relevant parties, within or outside of the country of origin, in order to carry out the activities listed in Clause 20.1, and in doing so each Party will ensure that the sharing and use of this Personal Data complies with applicable Data Protection Laws.

20.3 The Supplier acknowledges and agrees that it shall and shall procure that its Sub-Contractors shall, if required by the Authority, enter into a separate data sharing agreement for the sharing and use of Personal Data collected in connection with the use of Goods supplied by the Supplier under this Contract.

21 Records retention and rights of audit

21.1 Subject to any statutory requirement and Clause 21.2, the Supplier shall keep secure and maintain for the Term and six (6) years afterwards, or such longer period as may be agreed between the Parties, full and accurate records of all matters relating to this Contract.

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

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

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

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

(a) the examination and certification of the Authority's accounts; or

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

21.6 The Comptroller and Auditor General may examine such documents as they may reasonably require which are owned, held or otherwise within the control of the Supplier and may require the Supplier to provide such oral and/or written explanations as they consider necessary. Clause 21 does not constitute a requirement or agreement for the examination, certification or inspection of the accounts of the Supplier under sections 6(3)(d) and 6(5) of the National Audit Act 1983.

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

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

22 Notices

22.1 Subject to Clause 23.5 of the DPS Agreement, any notice required to be given by either Party under this Contract shall be in writing quoting the date of the Contract and shall be delivered by hand or sent by prepaid first class recorded delivery or by email to the person referred to in the Order Form or such other person as one Party may inform the other Party in writing from time to time.

22.2 A notice shall be treated as having been received:

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

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

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

23 Confidentiality

23.1 In respect of any Confidential Information it may receive directly or indirectly from the other Party ("Discloser") and subject always to the remainder of Clause 23, each Party ("Recipient") undertakes to keep secret and strictly confidential and shall not disclose any such Confidential Information to any third party without the Discloser's prior written consent provided that:

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

(b) the provisions of Clause 23 shall not apply to any Confidential Information:

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

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

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

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

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

23.2 Nothing in Clause 23 shall prevent the Recipient from disclosing Confidential Information where it is required to do so by judicial, administrative, governmental or regulatory process in connection with any action, suit, proceedings or claim or otherwise by applicable Law, including the Freedom of Information Act 2000 ("**FOIA**"), Codes of Practice on Access to Government Information, on the Discharge of Public Authorities' Functions or on the Management of Records ("**Codes of Practice**") or the Environmental Information Regulations 2004 ("**Environmental Regulations**").

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

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

(b) on a confidential basis, to any consultant, contractor or other person engaged by the Authority, a Contracting Authority, or by any of the entities described in Clause 23.3(d) (or any benchmarking organisation) receiving such information for any purpose relating to or connected with this Contract;

(c) on a confidential basis to any Central Government Body for any proper purpose of the Authority or of the relevant Central Government Body;

(d) to the extent that the Authority (acting reasonably) deems disclosure necessary or appropriate in the course of carrying out its public functions;

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

(f) on a confidential basis for the purpose of the exercise of its rights under this Contract, including audit rights under Clause 21 (Records retention and right of audit) or to any relevant party for any examination pursuant to section 6(1) of the National Audit Act 1983 of the economy, efficiency and effectiveness with which the Authority has used its resources;

(g) to Parliament and Parliamentary Committees or if required by any Parliamentary reporting requirements; or

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

and for the purposes of this Contract, references to disclosure "on a confidential basis" shall mean the Authority making clear the confidential nature of such information and that it must not be further disclosed except in accordance with Law or this Clause 23.3.

23.4 The Supplier may only disclose the Authority's Confidential Information, and any other information provided to the Supplier by the Authority in relation to this Contract, to the Supplier's Staff or professional advisors who are directly involved in the performance of or advising on the Supplier's obligations under this Contract. The Supplier shall ensure that such Staff or professional advisors are aware of and shall comply with the obligations in Clause 23 as to confidentiality and that all information, including Confidential Information, is held securely, protected against unauthorised use or loss and, at the Authority's written discretion, destroyed securely or returned to the Authority when it is no longer required. The Supplier shall not, and shall ensure that the Staff do not, use any of the Authority's Confidential Information received otherwise than for the purposes of performing the Supplier's obligations in this Contract.

23.5 For the avoidance of doubt, save as required by Law or as otherwise set out in this Contract, the Supplier shall not, without the prior written consent of the Authority (such consent not to be unreasonably withheld or delayed), announce that it has entered into this Contract and/or that it has been appointed as a Supplier to the Authority and/or make any other announcements about this Contract.

23.6 Clause 23 shall remain in force:

(a) without limit in time in respect of Confidential Information which comprises Personal Data or which relates to national security; and

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

24 General

24.1 The Supplier shall use reasonable endeavours to ensure its Business Continuity Plan operates effectively alongside the Authority's business continuity plan where relevant to the supply of the Goods. The Supplier shall also ensure that its Business Continuity Plan complies on an ongoing basis with any specific business continuity requirements, including supply chain resilience, as may be set out in the Contract. Throughout the Term, the Supplier will ensure its Business Continuity Plan provides for continuity during a Business Continuity Event. The Supplier confirms and agrees such Business Continuity Plan details and will continue to detail robust arrangements that are reasonable and proportionate to:

(a) the criticality of this Contract to the Authority; and

(b) the size and scope of the Supplier's business operations,

regarding continuity of the supply of Goods during and following a Business Continuity Event. Should a Business Continuity Event occur at any time, the Supplier shall implement and comply with its Business Continuity Plan and provide regular written reports to the Authority on such implementation. During and following a Business Continuity Event, the Supplier shall use reasonable endeavours to continue to supply the Goods in accordance with this Contract.

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

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

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

24.5 Any provision of this Contract which is held to be invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining provisions of this Contract and any such invalidity or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provisions in any other jurisdiction.

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

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

24.8 The rights and remedies provided in this Contract are independent, cumulative and not exclusive of any rights or remedies provided by general law, any rights or remedies provided elsewhere under this Contract or by any other contract or document. In this Clause 24.8, right includes any power, privilege, remedy, or proprietary or security interest.

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

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

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

24.12 Subject to clause 23 of the DPS Agreement, the Parties irrevocably agree that the courts of England and Wales shall have non-exclusive jurisdiction to settle any Dispute or claim that arises out of or in connection with this Contract or its subject matter.

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

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

25.1 The Parties recognise that the circumstances created as a result of the Covid-19 pandemic are exceptional and fast-moving. As a consequence, the Parties agree that they will act reasonably and in good faith together to seek to resolve any difficulties or challenges which may impact upon the manufacture, supply and transport of Goods and in relation to the wider Covid-19 issues so as to ensure that public health is protected and preserved.

25.2 In this context:

(a) the Supplier recognises that there may be a shortage of supply of raw materials and Component Parts and accordingly, the Supplier shall take all reasonable steps to safeguard and protect all stocks of raw materials and Component Parts held by it or its Sub-Contractors from time to time which may be required to manufacture the Goods;

(b) the Supplier shall notify the Authority promptly of any exceptional events or circumstances referred to in Clause 25.1 which may impact upon the Supplier's ability to supply Goods in accordance with this Contract and the Authority's requirements;

(c) the Supplier recognises and agrees that the exceptional circumstances referred to in Clause 25.1 may mean that it is necessary for the Authority to involve itself in the Supplier's inbound supply chain for raw materials and Component Parts, and for transport and/or logistics arrangements. The Authority shall notify the Supplier in advance if it considers that this step is reasonably necessary and the Supplier shall provide all information and assistance as the Authority may require in order for it to take this step;

(d) the Supplier agrees to provide transparency to the Authority to ensure that the Authority has sufficient visibility of the Supplier's supply chain, manufacturing process, transport arrangements and timelines for the manufacture, supply and delivery of Goods to allow it to plan and adjust order scheduling across the Authority's supply chain for products equivalent to or similar to the Goods; and

(e) if the Supplier is or is likely to be subject to delays in manufacturing or transport of the Goods due to supply chain, warehousing or freight shortages, the Authority shall be entitled by notice in writing to cancel all or part of an order.

Schedule 1

Definitions and Interpretation

1 Definitions

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

"**ASN**"	means advance shipping notice;
"**Authority**"	means the authority named on Order Form;
"**Authority's Obligations**"	means the Authority's obligations set out in Clause 7 or otherwise agreed in the Order Form;
"**Breach Notice**"	means a written notice of breach given by one Party to the other, notifying the Party receiving the notice of its breach of this Contract;
"**Business Continuity Event**"	means any event or issue that could impact on the operations of the Supplier and its ability to supply the Goods including an influenza pandemic and any Force Majeure Event;
"**Business Continuity Plan**"	means the Supplier's business continuity plan which includes its plans for continuity of the supply of the Goods during a Business Continuity Event;
"**Business Day**"	means any day other than Saturday, Sunday or a statutory bank holiday in England and Wales;
"**Central Government Body**"	a body listed in one of the following sub- categories of the Central Government classification of the Public Sector Classification Guide, as published and amended from time to time by the Office for National Statistics: (a) Government Department; (b) Non-Departmental Public Body or Assembly Sponsored Public Body (advisory, executive, or tribunal); (c) Non-Ministerial Department; or (d) Executive Agency;
"**Change in Law"**	means any change in Law which impacts on the supply of the Goods (including taxation or duties of any sort affecting the Supplier) which comes into force after the Commencement Date;
"**Charges**"	means the price exclusive of VAT that is payable to the Supplier by the Authority under the Contract for the full and proper performance by the Supplier of its obligations under the Contract;
"**Codes of Practice**"	shall have the meaning given to the term in Clause 23.2;

"**Commencement Date**"	means the date of this Contract as stated in the Order Form;
"**Component Part**"	means any constituent element or part of the Goods including any raw materials which when processed or combined become part of the Goods or which are used in the process of the production or assembly of the Goods; and "Component Parts" shall be construed accordingly;
"**Confidential Information**"	means information, data and material of any nature, which either Party may receive or obtain in connection with the conclusion and/or operation of the Contract including any procurement process which is: (a) Personal Data; (b) designated as confidential by either party or that ought reasonably to be considered as confidential (however it is conveyed or on whatever media it is stored); and/or (c) Policies and such other documents which the Supplier may obtain or have access to through the Authority's intranet;
"**Contract**"	means the form of contract at the front of this document and includes the Order Form, the Schedules and Annexes attached to the form of contract, the terms of the DPS Agreement and the Schedules and Annexes attached to the DPS Agreement;
"**Contracting Authority**"	means any contracting authority as defined in Regulation 2 of the Public Contracts Regulations 2015 (SI2015/102) (as amended), other than the Authority;
"**Controller**"	shall have the same meaning as set out in the Data Protection Act 2018;
"**Cross Government Decision Making**"	means the committee as referred to in the Guidance for new high volume manufacturers of COVID-19 personal Protective Equipment, Office for Product Safety & Standards, April 2020;
"**Data Protection Laws**"	means (i) the Data Protection Act 2018 to the extent that it relates to processing of personal data and privacy; (ii) the GDPR, the Law Enforcement Directive (Directive (EU) 2016/680) and any applicable national implementing Law as amended from time to time; and (iii) all applicable Law about the processing of personal data and privacy;
"**Defective Goods**"	has the meaning given under Clause 6.6;
"**Dispute(s)**"	means any dispute, difference or question of interpretation or construction arising out of or in connection with this Contract, including any dispute, difference or question of interpretation relating to the Goods, any matters of contractual construction and interpretation relating to the Contract, or any matter where this Contract directs the Parties to resolve an issue by reference to the Dispute Resolution Procedure;
"**Dispute Notice**"	means a written notice served by one Party to the other stating that the Party serving the notice believes there is a Dispute;

"**Dispute Resolution Procedure**"	means the process for resolving Disputes as set out in Clause 23 of the DPS Agreement;
"**DOTAS**"	means the Disclosure of Tax Avoidance Schemes rules which require a promoter of tax schemes to tell HM Revenue and Customs of any specified notifiable arrangements or proposals and to provide prescribed information on those arrangements or proposals within set time limits as contained in Part 7 of the Finance Act 2004 and in secondary legislation made under vires contained in Part 7 of the Finance Act 2004 and as extended to National Insurance Contributions by the National Insurance Contributions (Application of Part 7 of the Finance Act 2004) Regulations 2012, SI 2012/1868 made under s.132A Social Security Administration Act 1992;
"**DPS Agreement**"	means the DPS Agreement entered into between the parties in relation to the supply of the Goods on 14 May 2021;
"Environmental Regulations"	shall have the meaning given to the term in Clause 23.2;
"**eProcurement Guidance**"	means the NHS eProcurement Strategy available via: https://www.gov.uk/government/collections/nhs-procurement together with any further Guidance issued by the Department of Health in connection with it;
"**Equality Legislation**"	means any and all legislation, applicable guidance and statutory codes of practice relating to equality, diversity, non-discrimination and human rights as may be in force in England and Wales from time to time including, but not limited to, the Equality Act 2010, the Part-time Workers (Prevention of Less Favourable Treatment) Regulations 2000 and the Fixed-term Employees (Prevention of Less Favourable Treatment) Regulations 2002 (SI 2002/2034) and the Human Rights Act 1998;
"**Exit Day**"	shall have the meaning in the European Union (Withdrawal) Act 2018;
"**FOIA**"	shall have the meaning given to the term in Clause 23.2;
"**Force Majeure Event**"	means any event beyond the reasonable control of the Party in question to include, without limitation: (a) war including civil war (whether declared or undeclared), riot, civil commotion or armed conflict materially affecting either Party's ability to perform its obligations under this Contract; (b) acts of terrorism; (c) flood, storm or other natural disasters; (d) fire; (e) unavailability of public utilities and/or access to transport networks to the extent no diligent supplier could

reasonably have planned for such unavailability as part of its business continuity planning;

(f) government requisition or impoundment to the extent such requisition or impoundment does not result from any failure by the Supplier to comply with any relevant regulations, laws or procedures (including such laws or regulations relating to the payment of any duties or taxes) and subject to the Supplier having used all reasonable legal means to resist such requisition or impoundment;

(g) compliance with any local law or governmental order, rule, regulation or direction applicable outside of England and Wales that could not have been reasonably foreseen;

(h) industrial action which affects the ability of the Supplier to supply the Goods, but which is not confined to the workforce of the Supplier or the workforce of any Sub-contractor of the Supplier; and

(i) a failure in the Supplier's and/or Authority's supply chain to the extent that such failure is due to any event suffered by a member of such supply chain, which would also qualify as a Force Majeure Event in accordance with this definition had it been suffered by one of the Parties;

but excluding, for the avoidance of doubt, any event or other consequence arising as a result of or in connection with the withdrawal of the united Kingdom from the European Union or as a result of or in connection with the COVID-19 pandemic except for circumstances caused by or related to the COVID-19 pandemic which are changes in applicable Law and/or governmental guidance which mean that the Goods cannot be provided as set out in this Contract (in all material respect) without such Laws and/or government guidance being breached, or if the Supplier can reasonably demonstrate that despite all reasonable endeavours, it is unable to secure non-COVID-19 infected personnel to provide the Goods due to the levels of COVID-19 infections in the population of the United Kingdom;

"**Fraud**" means any offence under any law in respect of fraud in relation to this Contract or defrauding or attempting to defraud or conspiring to defraud the government, parliament or any Contracting Authority;

"**General Anti-Abuse Rule**" means

(a) the legislation in Part 5 of the Finance Act 2013; and

(b) any future legislation introduced into parliament to counteract tax advantages arising from abusive arrangements to avoid national insurance contributions;

"**Good Industry Practice**" means the exercise of that degree of skill, diligence, prudence, risk management, quality management and foresight which would reasonably and ordinarily be expected from a skilled and experienced supplier engaged in the manufacture and/or supply of goods similar to the Goods under the same or similar circumstances as those applicable to this Contract, including in

	accordance with any codes of practice published by relevant trade associations;
"**Goods**"	means all goods, materials or items that the Supplier is required to supply to the Authority under this Contract (including, without limitation, as stated in the Order Form which sets out the requirements of the Authority as issued to tenderers as part of the procurement process and the Supplier's response to these requirements) and shall include parts of such Goods which have been repaired or replaced by or on behalf of the Supplier;
"**Guidance**"	means any applicable guidance, direction or determination and any policies, advice or industry alerts which apply to the Goods, to the extent that the same are published and publicly available or the existence or contents of them have been notified to the Supplier by the Authority and/or have been published and/or notified to the Supplier by the Department of Health and Social Care, Monitor, NHS England, NHS Improvement, the Medicines and Healthcare Products Regulatory Agency, the Health & Safety Executive, the Office for Product Safety & Standards, the European Medicine Agency the European Commission, the Care Quality Commission and/or any other regulator or competent body;
"**Halifax Abuse Principle**"	means the principle explained in the CJEU Case C-255/02 Halifax and others;
"**Incident**"	means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect;
"**Intellectual Property Rights**"	means all patents, copyright, design rights, registered designs, trademarks, know-how, database rights, confidential formulae and any other intellectual property rights and the rights to apply for patents and trademarks and registered designs;
"Law"	means any applicable legal requirements including, without limitation: (a) any applicable statute or proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument as applicable in England and Wales; (b) any applicable European Union obligation, directive, regulation, decision, law or right (including any such obligations, directives, regulations, decisions, laws or rights that are incorporated into the law of England and Wales or given effect in England and Wales by any applicable statute, proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument); (c) any enforceable community right within the meaning of section 2(1) European Communities Act 1972;

(d) any applicable judgment of a relevant court of law which is a binding precedent in England and Wales;

(e) requirements set by any Regulatory Body as applicable in England and Wales;

(f) any relevant code of practice as applicable in England and Wales; and

(g) any relevant collective agreement and/or international law provisions (to include, without limitation, as referred to in (a) to (f) above);

"**NHS**"	means the National Health Service;
"**Occasion of Tax Non- Compliance**"	means: (a) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 is found on or after 1 April 2013 to be incorrect as a result of: (i) a Relevant Tax Authority successfully challenging the Supplier under the General Anti-Abuse Rule or the Halifax Abuse Principle or under any tax rules or legislation that have an effect equivalent or similar to the General Anti-Abuse Rule or the Halifax Abuse Principle; or (ii) the failure of an avoidance scheme which the Supplier was involved in, and which was, or should have been, notified to a Relevant Tax Authority under the DOTAS or any equivalent or similar regime; and/or (b) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 gives rise, on or after 1 April 2013, to a criminal conviction in any jurisdiction for tax related offences which is not spent at the Effective Date or to a civil penalty for fraud or evasion;
"**Order Form**"	means the order form set out at the front of the Contract in the form substantially similar to the template set out in Schedule 4 of the DPS Agreement;
"**Party**"	means the Authority or the Supplier as appropriate and Parties means both the Authority and the Supplier;
"**Personal Data**"	shall have the same meaning as set out in the Data Protection Act 2018;
"**Policies**"	means the policies, rules and procedures of the Authority as notified to the Supplier from time to time;
"**Processing**"	shall have the same meaning as set out in the Data Protection Act 2018;
"Product Authorisation"	means any of the following: (a) CE marking (or CE UKNI where applicable); or (b) UK Conformity Assessed (UKCA) marking; or

	(c) authorisation granted by MHRA; or (d) other authorisation accepted by the Authority as confirmation that the Goods meet all legal requirements to be used as an in vitro diagnostic test in the UK (or relevant parts of the UK as specified by the Authority), each as required by Law and Guidance;
"**Purchase Order**"	means the purchase order required by the Authority's financial systems, if a purchase order is referred to in the Order Form;
"**Regulatory Representative**"	has the meaning given to it in Row 18 of the Order Form;
"**Rejected Goods**"	has the meaning given under Clause 6.3;
"**Relevant Tax Authority**"	means HM Revenue and Customs, or, if applicable, a tax authority in the jurisdiction in which the Supplier is established;
"**Remedial Proposal**"	has the meaning given under Clause 14.4;
"**Requirement to Recall**"	has the meaning given under Clause 6.10;
"**Serious Incident**"	means any Incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat;
"**Staff**"	means all persons employed or engaged by the Supplier to perform its obligations under this Contract including any Sub-Contractors and person employed or engaged by such Sub-Contractors;
"**Statement of Requirements**"	means the statement issued by the Authority detailing its Goods requirements issued in accordance with the Call for Competition Procedure in respect of this Contract, as attached at Annex 2 and including the responses to any clarification questions;
"**Sub-Contract**"	means a contract between two or more suppliers, at any stage;
"**Supplier**"	means the supplier named on the Order Form;
"**Term**"	means the term as set out in the Order Form;
"**Termination Notice**"	means a written notice of termination given by one Party to the other notifying the Party receiving the notice of the intention of the Party giving the notice to terminate this Contract on a specified date and setting out the grounds for termination;
"**UK Responsible Person**"	has the meaning given to the term in the UK Medical Devices Regulation 2002 (as amended); and

"**VAT**"	means value added tax chargeable under the Value Added Tax Act 1994 or any similar, replacement or extra tax.

2 Interpretation

2.1 References to any Law shall be deemed to include a reference to that Law as amended, extended, consolidated, re-enacted, restated, implemented or transposed from time to time.

2.2 Reference in this Contract which immediately before Exit Day was a reference to (as it has effect from time to time):

(a) any EU regulation, EU decision, EU tertiary legislation or provision of the EEA agreement ("EU References") which is to form part of domestic law by application of section 3 of the European Union (Withdrawal) Act 2018 shall be read on and after Exit Day as a reference to the EU References as they form part of domestic law by virtue of section 3 of the European Union (Withdrawal) Act 2018 as modified by domestic law from time to time; and

(b) any EU institution or EU authority or other such EU body shall be read on and after Exit Day as a reference to the UK institution, authority or body to which its functions were transferred.

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

2.4 References in this Contract to a "Schedule", "Annex", or to a "Clause" are to schedules, annexes and clauses of this Contract.

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

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

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

2.8 References to any Law shall be deemed to include a reference to that Law as amended, extended, consolidated, re-enacted, restated, implemented or transposed from time to time.

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

2.10 Where there is a conflict between the Supplier's responses to the Authority's requirements (the Supplier's responses being set out in the order form) and any other part of this Contract, such other part of this Contract shall prevail.

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

2.12 Any guidance notes highlighted in yellow do not form part of this Contract.

2.13 Any Breach Notice issued by a Party in connection with this Contract shall not be invalid due to it containing insufficient information. A Party receiving a Breach Notice ("**Receiving**

Party") may ask the Party that issued the Breach Notice ("**Issuing Party**") to provide any further information in relation to the subject matter of the Breach Notice that it may reasonably require to enable it to understand the Breach Notice and/or to remedy the breach. The Issuing Party shall not unreasonably withhold or delay the provision of such further information as referred to above as may be requested by the Receiving Party but no such withholding or delay shall invalidate the Breach Notice.

2.14 Any terms defined as part of a Schedule or other document forming part of this Contract shall have the meaning as defined in such Schedule or document.

Annex 1
Commercially Sensitive Information

NOT USED

Annex 2
Statement of Requirements

NHS Test and Trace

Statement of Requirements

Lateral Flow Antigen Self-Test

NHS Test and Trace

Introduction

This document sets out the Department for Health and Social Care (DHSC) Statement of Requirements covering the specifications that support the manufacture, delivery, and regulatory requirements for the lateral flow antigen self-tests, to be used within the NHS Test and Trace Programme.

The Statement of Requirements will provide suppliers who wish to participate in this tender with up to date and detailed information to ensure all products procured by DHSC meet not only the clinical needs of the NHS Test and Trace Programme, but provide a high quality, regulated service, from the initial order to on-time delivery at the final destination, ensuring all products continue to meet the maximum safety standards and comfort for the end user, maintaining the strict governance of the Programme.

The outcome of the tender is for the DHSC to work with suitable, qualified partners who fully support the aims and ambitions of the DHSC Test and Trace programme.

This tender aims to deliver best value in terms of price, quality, and customer care by working collaboratively with our supply chain partners, to innovate, reduce cost and deliver further improvements to the Lateral Flow Devices and associated services.

Full details of our requirements can be found in the individual service specifications.

Section 1	**DHSC Rapid COVID-19 Antigen Self-Test**
Section 2	**Logistics Requirements**

NHS Test and Trace

SECTION 1

DHSC Rapid COVID-19 Antigen Self-Test

Technical Specification

NHS Test and Trace

DHSC Rapid COVID-19 Antigen Self-Test Technical Specification

Table of Contents

NHS
Test and Trace

1.0 Introduction:

1.1 This document sets out the DHSC specifications for lateral flow antigen (LFD) self-tests, to be used within the NHS Test and Trace Programme. These specifications enable DHSC to work closely with LFD suppliers and suppliers to ensure products procured by DHSC meet the clinical needs of the NHS Test and Trace Programme, and that these products provide maximum safety and comfort for the end user, as well as strict governance for the Programme.

2.0 Individual pack sizes and flexibility:

2.1 The current demand for this competition is for pack sizes of **7**. In the future the DHSC may wish to explore other pack sizes.

3.0 Test specification

Your test must:

- Have full regulatory approval from either a Notified Body (CE mark) *or* a UK Approved Body (UKCA Mark) *or* the MHRA (EUA)
- Be indicated for use on both asymptomatic and symptomatic users, with supporting study data for this claim
- Be indicated for use on a range of ages, including children, adults, and those requiring assistance/supervision, with study data to support these claims.
- Have a swab collection method which is one of the following:
    - Anterior nares *or*
    - Mid Turbinate *or*
    - Nose and Throat (anterior nares *or* mid turbinate *and* oropharyngeal) *or*
    - Saliva
- Have a shelf life no less than 12 months (evidenced by study data)
- Provide results within 30 minutes from the time the end user applies the specimen and buffer to the test well (evidenced by study data)

You must:

- Provide an EN ISO 13485 certification for both the test manufacturer and the sampling swab manufacturer
- Provide a declaration that no natural rubber latex has been used in the manufacture of this test
- Confirm that the manufacturer agrees to undergo a latex audit undertaken by a third party and to facilitate any other auditing process performed by a third party for assurance that the product is manufactured with appropriate parameters in place
- Commit to providing a minimum of 20m tests a week, with a 3-week notice period
- Appoint a UKRP for this test prior to contract signature (if the manufacturer is based outside of the UK)
- Register the device with the MHRA prior to placing on the market

Packaging:

3.1 Dimensions of inner test box

All LFD inner test boxes must be suitable for home delivery via Royal Mail postal service. Hence it must be able to fit through a standard letterbox and conform within the dimensions/metrics of a ***Large Letter*** as set out by Royal Mail. The inner test box must NOT be larger than this but can be smaller.

Format	Maximum weight / g	Maximum length / mm	Maximum width / mm	Maximum thickness / mm
Large Letter	750	353	250	25

3.2 Packaging materials

The inner test box needs to be robust enough and made of strong cardboard material to provide protection to the device. It must also be recyclable. The packaging material needs to be made of waterproof material to avoid kit components getting wet and tamper seal stickers need to be added to opening flaps of the inner test-box, for additional security. Supplier to clearly indicate which side of the inner test box is to be opened.

3.3 Mailing address section

A mailing address section can be placed on either the back or front of the inner test box, whilst ensuring no vital labelling information is obscured. The space on the inner test box required for this label is 105mm x 148mm (Royal Mail Address Label size). This address label will be applied in the form of a sticker, it will not be printed directly onto the box. A space of this size (105mm x 148mm) is required for this sticker.

3.4 Pallet configurations

All suppliers are expected to work flexibly with the NHS Test and Trace Logistics Team to optimise packing and transport efficiency. Currently it is expected that:

- All deliveries must be made using wooden 4-way pallets that follow the UK standard of length and width (100 cm x 120 cm).
- Each pallet must contain 24 cartons
- All cartons must be full – partially loaded cartons will not be accepted.
- The total height of the product and packaging (including the pallet base) must not exceed 160 cm in height.
- The structural integrity of the packaging should also allow pallets to be stacked two high without leading to any damage to the inner test colour boxes.
- The weight of each loaded pallet should not exceed 500 kg unless prior permission/consultation is sort.
- To help us provide a supplier agnostic ordering and distribution system we are aiming to standardize the number of tests contained in each carton to 400 (+/- 10 tests).

A further detailed specification is detailed in the appendix section of this document below: *3.0 LFD Inbound Logistics Requirements*

NHS Test and Trace

4.0 Branding:

4.1 Inner test box

The inner test box can be branded in the supplier's own style and design, carrying supplier's brand and colours. It will not be branded with NHS Test and Trace.

The exterior of each individual inner test box must include the lines:

Supplied by NHS Test and Trace
Not for resale
Please read instructions carefully
Report your results to the NHS

It is preferrable that these statements should not be placed on the same side of the box where the mailing address label will be placed. These statements should be clearly legible. Final positioning, font size and colour to be discussed and agreed with each supplier.

If applicable the following line must also be displayed on the inner text box:

The product has not been made with natural rubber latex

4.2 Test name

The legal supplier's name, test name and product code should be displayed clearly on the outside of the inner test box. For example, "**Manufacturer XXX *Test Name XXXX* Product Code XXXX**".

4.3 Safety and user symbols

The inner test box packaging must include all safety and user symbols to comply with the correct international labelling standards.

5.0 IFU

5.1 IFU Customisation

NHS Test & Trace are committed to ensure there is an optimal consistent user experience for people taking tests across all touch points. We conduct regular research to help us develop testing products and services to better meet user needs.

Therefore, we require suppliers to customise the design of their instructions for use for the DHSC Self-Test product variant.

Each test is unique, and it is critical that users understand the differences between test kits they receive. We provide a design template for the DHSC customised instructions for use. This is representative of the style we require, and we will work with successful applicants to finalise content. This may be updated going forward, as new improvements become incorporated.

The DHSC customised IFU will carry the NHS Test and Trace brand and colours. The supplier's brand will be incorporated in the back page.

DHSC will provide

- Branding guidelines and assets for NHS Test and Trace (pdf provided separately)
- A design template for the instructions for use (pdf provided separately). This template includes mandatory content (e.g. reporting results). This template can be provided to successful bidders in an editable format, if required.
- Approved illustrations and design assets for the instructions for use, new illustrations can be produced as required with support from the DHSC
- If a supplier wishes to use DHSC illustrations, these will be provided under licence for use for this UK product variant.
- Supplier may develop their own illustrations in line with DHSC customised style (subject to DHSC review)
- Content design and visual design resource provided to ensure the final print designs are best suited to the wider testing user journey

We expect suppliers to

- Work collaboratively with DHSC to support the customised design
- Ensure the DHSC-customised IFU is IVDD compliant
- Update their CE or UKCA certification with their notified body / UK approved body to incorporate this UK DHSC product variant
- If applicable, update Exceptional Use Authorisation, to include this product variant
- Appoint a UKRP to represent this self-test product variant (if non-UK based)
- Register this device with the MHRA and comply with other UK requirements as applicable
- Set out their regulatory approved IFU within this template. No test usability steps, or processes contained within the supplier's approved IFU will be changed
- Articulate the steps on how to use the kit, as per the CE marked IFU
- Produce the IFU using industry standard design software: Adobe InDesign
- Produce the IFU as an A5 sized booklet
- Use the NHS-approved Frutiger font (NHS brand guidelines provided by DHSC)
- Place *only* this insert in the inner test box. Quick Reference Guides **cannot** be included.
- Place company branding in the allocated spaces on the box and instructions for use
- Produce the approved printed material as part of the kits, to be included within the test kits
- Collate and sign off on a summary of their testing processes and rationale, supported by their technical file. These steps may be used in communications to end users to support differences in testing processes.
- Provide a final draft copy of the customised IFU to DHSC for review

After production of this customised IFU and product DHSC will

- Co-ordinate with you to produce the content for a demonstration video on "how to take the test".
- Publish digital versions of the instructions
- Work with you to ensure that the IFU content is accessible to the widest possible audience and complies with accessibility standards and regulations (such as WCAG 2.0). This may include creating an "accessible" electronic document that is optimized for screen readers and other assistive devices used by persons with disabilities. Further details of accessibility requirements are in the appendix section of this document: 4.0 Accessibility Considerations.

Please note also that we are currently looking at options for instructions in different languages, large-print and easy-read instructions. The DHSC will work closely with suppliers on this. DHSC will share improvements to the IFU template based on user testing and research.

6.0 Digital:

6.1 Labelling and data spec

It is a requirement that all LFD tests used as part of the National Testing Program are compatible with the DHSC's digital solution for publishing results. DHSC will provide a specification to suppliers for the printing of QR codes onto each LFD. Stickers are not acceptable. Information on the required specification can be found below in *appendix 1.0 Digital Solution - LFD Labelling and Data Specification.*

6.2 EAN Barcode and traceability

All suppliers must have the capability to print a scannable GTIN/EAN barcode on all the inner test boxes and outer cartons. NHS Test and Trace will provide our suggested SKU in the format: TK ####. The supplier is expected to produce and provide a GTIN/EAN Barcode with the product code and product name embedded in the description. This is to allow for improved traceability for both program analytics but also as part of our effective PMS system.

We are continually working on improving our traceability system and will inform suppliers of any changes in barcoding formats.

6.3 Digital reader requirements

All suppliers must be willing to work with the Test and Trace Programme to ensure their devices are compatible with the LFD Digital Reader Service, should they be required to be trained and implemented into the system. A further detailed specification is detailed in the appendix section of this document below: *2.0 LFD Digital Reader: Technical Specification for LFD Vendors Version 0.2.*

7.0 Kit Contents

7.1 Buffer

The buffer must be pre-aliquoted in individual containers within individual ampules, vials, sachets, or pre-filled extraction tubes. The total number of individually packaged buffer aliquots must be equal to or greater than the number of tests contained within each inner test box. There is a strong preference to have the buffer contained within the extraction tube (pre-filled) and to have dropper tops attached to the vials, as this allows for greater ease of use.

7.2 Swabs and packaging

The total number of swabs must be equal to or greater than the number of tests contained within each inner test box. Each swab must be CE marked, individually packaged and sterilised.

7.3 Cassette packaging

All cassettes must be individually wrapped in a sealed pouch. Each wrapper must at a minimum clearly display the product code, LOT number and expiry date of the cassette contained within as well as all regulatory required symbols. To reduce non-recyclable waste, we encourage suppliers to remove excess material and the size of their sealed pouch.

7.4 Innovation in sustainability and accessibility

Sustainability

DHSC is keen for suppliers to implement strategies to reduce waste and increase the sustainability of their kits without sacrificing performance whether by changing the kit design or by working through new processes suggested by themselves or DHSC. It is a requirement that suppliers who are awarded a contract are committed to working collaboratively with us on this and that suppliers must dedicate a member of their team to lead on sustainability innovations. This work will be required to commence immediately following contract award. We have a team of experts to support on this and would like to hear from suppliers on initiatives you may have in mind.

Here are some of the initial ideas from DHSC:

- Create an outer box that neatly organises the contents without the need for an inner sleeve.
- Reduce/remove the high gloss coating while maintaining the structural integrity and sufficient water holdout.

- Remove the need for a separate plastic extraction tube holder by integrating the extraction tube holder into the packaging (perforated hole) or provide a card flat pack extraction tube holder.
- Combine the Vial and Buffer into one unit to avoid having multiple parts. Which reduces components and potentially space needed in the box.
- Make the foil wrapper that holds the test device smaller to help reduce the use of the foil laminate.

Any product changes which impact on product performance and usability will require supporting evidence, in the form of studies.

Accessibility

DHSC is also keen for suppliers to develop innovative strategies to improve the accessibility for users who may currently require additional assistance when carrying out a test. Suppliers will commit to working with DHSC on implementing new developments in this area and that suppliers dedicate a member of their team to this lead on accessibility innovations.

8.0 Regulatory checklist

DHSC recommends that suppliers are aware of the Target Product Profile set out by the MHRA. Target Product Profile: In Vitro Diagnostic (IVD) self-tests for the detection of SARS-CoV-2 in people without symptoms - GOV.UK (www.gov.uk) This is aspirational and demonstrates the level of quality desired from LFDs.

Suppliers are required to submit evidence to support their claims in their instructions for use and are therefore requested to provide the following:

8.1 Product

- The product code offered to DHSC
- A list of IVDD harmonised standards applicable to the device and indication of which standards have been met. Provide a rationale for any that have not been met or are partially met.
- Instructions for use
- Product description which lists each individual component in the test kit. Successful bidders will be required to provide a full technical product specification.
- Images of the test kit and its individual components
- Any changes to any component of the product initially offered must be discussed and agreed with DHSC before regulatory approval is sought.

8.2 Study data

You must provide:

- Clinical, analytical and usability studies for this product, which support IFU claims, detailing the exact product components used in these studies
- Equivalence reports if the components in the device offered to DHSC differ to those used in the studies
- A demographic breakdown of subjects included in these studies (by age) and indicate where assistance (if any) was provided by those requiring it
- Your test must be suitable for all age ranges.
- You must provide an indication of where supervision and assistance may be required and why (in the form of study data). For patients 18 years+, age *alone* cannot be the sole factor to determine exclusion or the need to have supervision and/or assistance.
- Bidders are requested to indicate how many subjects were included in their self-test studies (clinical and/or usability) for the following categories, where claimed:

    - Symptomatic
    - Asymptomatic
    - Children (please provide age ranges)
    - Adolescents (please provide age ranges)
    - Adults (please provide age ranges)
    - Those requiring supervision and why

- Bidders must evidence that at least 1 subject from each of these categories has been included in their studies *where* claims have been made. Preference is given to larger cohorts of various study groups, to provide evidence for claims made in IFUs.
- Bidders are requested to indicate how many subjects were included in their self-test studies (clinical and usability) who required assistance and why.
- Bidders to provide an assessment of what the study data and findings pertaining to each of these groups means for their test and IFU claims.
- Please indicate if any of your study data has been generated with your professional test.

8.3 Regulatory documents

You must provide:

- Antigen test – Manufacturer's Declaration of conformity
- Antigen test - EC Certificate from Notified Body, or UKCA certificate issued by UK Approved Body, which lists the specific product codes offered to DHSC as part of this tender
- Sampling swab - Declaration of conformity
- Sampling swab - EC Certificate
- Sampling swab – certificate of sterility
- Copies of transportation studies to comply with international standards, including temperature stress.
- Copies of stability studies, to support shelf-life claims, including temperature stress.
- Safety Data Sheet detailing the composition of the buffer solution – this should be non-hazardous in accordance with CLP regulations
- Devices should not contain latex, phthalates or similar hazardous substances. Bidders to provide a declaration that no natural rubber latex or phthalates has been used in the making of this test
- EN ISO 13485 certificate for both the test manufacturer and swab manufacturer
- Copies of biocompatibility studies (sensitivity, irritation, and toxicity) for swabs
- Details of swab sterilisation method and justification if using Ethylene Oxide
- Certification of sub-contractors performing sterilisation of the device
- Please advise of any regulatory actions which have been raised against your Covid-19 antigen lateral flow products in any jurisdiction in the last 3 years, and whether these have been addressed and closed or are still open.
- Please provide study reports for any post market performance follow-up studies (PMPF) which have been undertaken for this product. These studies should be in accordance with EN 13612 and EN 13532.

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APPENDIX

1.0: Digital Solution – LFD Labelling and Data Specification:

NHS T&T - COVID-19 Testing

LFD Labelling and Data Specification

Version: 1.5
Version Date: 30th June 2021

1.0 Introduction

The T&T COVID-19 Testing Digital Platform uses unique Sample Identifiers (Sample IDs) to track tests end to end through the system. In order to ensure that data has accuracy and integrity, there is a set of requirements that need to be complied with for tests being used through the national system.

For Lateral Flow Tests, T&T relies on the individual LFD cassettes being uniquely identifiable in order to link the test to an individual subject, and to prevent repeated submission of the same device for multiple subjects.

2.0 Key Requirements

Unique Identifiers	
REQ 001	Every test cassette MUST be individually identifiable using a unique Sample ID. The Sample ID must be unique within the NHS T&T testing ecosystem.
REQ 002	Sample IDs MUST comply with the specified NHS T&T formatting and validation rules
REQ 003	Sample IDs MUST only be issued from an allocated range provided to the supplier by NHS T&T
REQ 004	The supplier MUST ensure that Sample IDs are issued uniquely within their assigned ranges. Sample IDs used for test production runs MUST be excluded from use in live production runs.
Cassette Labelling	
REQ 005	Cassettes MUST be identified using a standard QR code (https://www.iso.org/standard/62021.html). The value of the QR code MUST be the unique Sample ID as a text string.
REQ 006	QR codes MUST be visible on the front face of the cassette. This allows cassettes to be easily identified, alongside a result, from a single photo.
REQ 007	QR codes MUST have consistent alignment, orientation, and sizing across cassettes.
REQ 008	QR codes MUST be accompanied by a printed alphanumeric representation of the value. The printed value MUST be large and clear enough font to be easily human-readable.
REQ 009	QR codes SHOULD be displayed as clearly and as large as possible to maximise usability with lower-end mobile phones
REQ 015	QR codes and labels MUST be printed directly onto the cassettes – labels should not be used.
Traceability Data	
REQ 013	Suppliers MUST provide full traceability data for tests supplied to NHS T&T. The traceability data MUST meet the minimum requirements in this document.
REQ 014	The traceability data MUST be provided in a computable format (e.g. CSV)

3.0 Example printed QR code

QR codes must be printed directly onto the cassette plastic housing, to help avoid inconsistent positioning and reduce risk of labels peeling off or tampering.

The text label should be clear to read, printed as large as possible, and the font used should provide clear differentiation between similar characters such as I and 1, B and 8. The preference is for either the letter I or the number 1 to be printed with 'tails' so as to clearly distinguish them apart. O and 0 should also be easily differentiated.

4.0 Sample ID Definition

The T&T COVID-19 standard Sample ID format is:

AAANNNNNNNC

Where A is an alpha character (A-Z), N is a numeric character (0-9) and C is a numeric checksum character (0-9).

The 7 digits (**N**) represent a number between 0000000 and 9999999 (10 million values).

The final (**C**) checksum digit must be calculated using the provided formula (see Appendix A in this document for the full calculation) and appended to the end of the identifier. The use of the checksum protects against mistakes in Sample IDs by detecting mistyped or missing digits.

The combination of the three-letter alpha prefix (**A**), the 7-digit numeric value (**N**), and the checksum digit (**C**) form the unique Sample ID for an individual test.

5.0 Allocation of Sample ID Ranges

Suppliers will be issued Sample ID ranges in blocks of 10m. Ranges will be allocated as prefixes.

*e.g. a supplier may be issued 50 million identifiers by allocation of prefixes **AAA, AAB, AAC, AAD, and AAE***

Suppliers **MUST ONLY** use their allocated prefix ranges on their products, and must ensure the identifiers are issued uniquely from within those allocated ranges.

If Sample IDs are used for testing purposes (e.g. test runs), the supplier MUST ensure that those Sample IDs are not used again in production stock

Suppliers cannot assume that the next issued range will be consecutive. **Always get written confirmation from T&T of new issued ranges before allocating from them.**

6.0 Traceability Data

Suppliers MUST ensure they have full traceability data available for tests in a computable format.

Data must be kept of every manufactured cassette which can be mapped back to individual Sample IDs. That data must at a minimum include:

Manufactured date	The manufactured date of a test device
Expiry date	The expiry date of a test device
Supply date	The date on which the test device was supplied / shipped to NHS T&T
Lot number	The lot number to which a test device belongs
Batch number	The batch number to which a test device belongs, if different to lot number *[Optional]*
Model	A model number / descriptor for the test device to assist with differentiation between different models or products a supplier may produce

The data should be provided in a computable format (e.g. CSV) so that it can be easily imported into NHS T&T systems for traceability.

This data must be in addition to any other labelling / provision of manufacturing information (e.g. on the boxes, foils, devices) – it does not supersede or negate any other data requirements placed on the supplier by NHS T&T.

7.0 Future developments

It is expected that this specification will evolve along with the requirements of T&T.

In the future, device identifiers may be expanded to include more manufacturing information within a computer-readable format – this will be communicated through issuance of a new specification version.

In the event of a change to this specification, a transition period would be expected to allow suppliers to adapt their approaches and for stock to rotate.

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Appendix A - Sample ID Checksum Calculation (MOD 10)

Weighting Key

This MOD 10 uses a weighting system of 1 – 3 alternating based on digit position.

Digits in odd positions are multiplied by 1.

Digits in even positions are multiplied by 3.

Alpha Numeric Conversion Table

A – 1	K – 1	U – 1
B – 2	L – 2	V – 2
C – 3	M – 3	W – 3
D – 4	N – 4	X – 4
E – 5	O – 5	Y – 5
F – 6	P – 6	Z – 6
G – 7	Q – 7	
H – 8	R – 8	
I – 9	S – 9	
J – 0	T – 0	

Formula

Firstly, each Alpha character, is allocated a number based on the above Alpha Numeric Conversion Table.

So, **AAA0708501** becomes **1110708501**.

Each digit is given a weight using the above Weighting Key. Odd-positioned digits are weighted by 1, even-positioned digits are weighted by 3. As shown below:

1 1 1 0 7 0 8 5 0 1
1 3 1 3 1 3 1 3 1 3 (weighting number)

Each digit is multiplied by its weighting number, as follows:

(1 x 1) (1 x 3) (1 x 1) (0 x 3) (7 x 1) (0 x 3) (8 x 1) (5 x 3) (0 x 1) (1 x 3)

To give the following multiplied values:

1 3 1 0 7 0 8 15 0 3

Then sum those values together:

1+3+1+0+7+0+8+15+0+3 = 38

Then do a Modulus 10 calculation on the sum (divide the sum by 10, and take the remainder).

38 % 10 = 8 *where % is the Modulo operator*

https://en.wikipedia.org/wiki/Modulo_operation)

Then subtract the remainder (8) from 10 to get our check digit. If the answer is 10, use 0.

10 - 8 = 2

2 is the check digit used. Meaning the full Sample ID value is: **AAA07085012**

LFD Digital Reader: Technical Specification for LFD Vendors

1.0 Purpose

This document sets out the specification so that supply chain and any LFD manufacturer can be clear what is required to introduce any new LFD type for use with the Digital Reader.

2.0 Introduction

The LFD Digital reader allows selected cohorts of users of the Self Report LFD service (Report a Covid-19 Result on GOV.UK) to supply a photograph of their LFD and have the system provide them with an accurate reading of their result in real time (positive, negative or void).

When a new LFD type is introduced for use in the LFD Self Report journey by DHSC supply chain, the digital reader needs to be retrained to recognise the new LFD test kit type and the service re-validated for an Exceptional Use Authorisation (EUA) by MHRA for use as Software as a Medical Device (SaaMD).

The LFD Self Report user interface will only allow access to the Digital Reader functionality for those LFD types for which it has received an updated EUA as SaaMD from MHRA. It does this by filtering on the Sample ID (QR Code) on each test strip, as the prefixes are manufacturer specific. Derogated prefixes are allowed access to the Digital Reader while non-derogated ones are not.

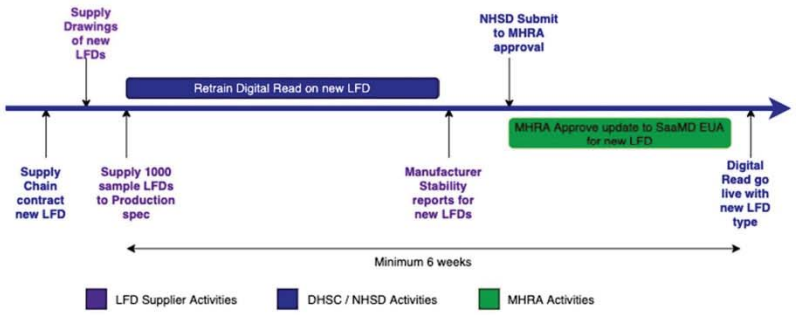
In order to retrain the digital reader and to allow NHSD digital teams to conduct full end to end testing of new software releases, a number of physical samples of production ready LFDs of each new type will be required, together with supporting technical documentation from each manufacturer.
It takes around 6 weeks from the point at which the NHSD Digital Reader team receives the physical samples of the new LFD type (requirement 3 below), for the system to be retrained and for MHRA to approve a change the EUA as SaaMD for the new LFD type.

3.0 LFDs not derogated for use with Digital Reader

LFDs not yet authorised for use as part of the SaaMD EUA granted by MHRA to the Digital Reader can still be used within the LFD Self Report journey (subject to their own specific MHRA EUA or CE/CA marking), but users of these kits will not be offered the Digital Reader functionality. This filtering is done based upon the Sample ID (QR Code) prefix that is manufacturer test kit specific.

4.0 Indicative timeline

The following timeline shows the key activities and milestones for LFD vendors supplying information on new LFD types in order to be derogated for use by MHRA with Digital Reader.



5.0 Requirement specification

	Requirement	Specification	Purpose	When required
1	Photographic images of production specification LFDs from manufacturer	At least one clear image taken directly above in good lighting of each variant of LFD with at 1920x 1080(horizontal) resolution with the LFD occupying at least 80% of the vertical height of the image, must contain positive test strip to show colours of C and T lines.	Allows digital read teams to get early visibility of new LFD geometry and determine if there are any major variations from existing design parameters (for example if we were moving from predominately rectangular to a circular test cartridge) that might affect standard lead times to introduce a new LFD to digital read.	ASAP
2	Technical drawings of new LFD from manufacturer	Technical drawings showing all elevations (top, side, bottom etc.) with all dimensions shown in mm for height width, sample well, location of Barcode etc.	To allow digital read teams to prepare digital reader for specific geometries of new tests	ASAP
3	1000 Physical samples of production ready LFDs for retraining and system testing.	1000 production ready LFDs together with buffer solution.	So NHSD clinical team can produce LFD images in a variety of photographic conditions titrated with various concentrations of antigen for purpose of retraining digital reader on new LFD type. Also to support NHSD teams in functional testing of digital ready by having physical tests kits.	ASAP - There is a expected 6 week timeframe between when NHSD received these samples and earliest date we can expect the digital reader to be derogated for use with the new LFD type, so sooner these are provided the better.
4	Stability reports	Test reports from manufacturer showing stability of LFD tests at various intervals up to 48 hours.	To understand how long after applying sample to test strip the test result can be reliably read.	Within 2 weeks
5	IFUs	Copies (PDF or paper) of IFUs that will accompany production specification LFDs	Ensuring digital journey aligned with IFUs	Within 2 weeks

3.0: Inbound Logistics Requirements:

LFD Inbound Supply Load Criteria

1.0 Supplier Performance Measures

DEMAND MANAGEMENT (OTIF)

- Every load to be 95%> accurate to paperwork.
- A correct delivery is defined when the right quantity of part (volume) and pallet load matches the final vehicle load upon receipt at the designated warehouse > loads will be matched at point of receipt (planned V actual) for compliance.
- OVER > defined as when greater quantities of parts/pallets arrives to the required on latest delivery plan = **NON-COMPLIANCE**.
- UNDER > defined as when a lesser quantity of parts/pallets arrives to that required on the latest delivery plan = **NON-COMPLIANCE**.

VEHICLE ARRIVAL PERFORMANCE (OTIF)

- Vehicles to arrive on time and to the agreed booking slot reference (+/- 30 minutes).
- Vehicles arriving greater than 30 minutes of booking slot = **NON-COMPLIANCE**.
- Vehicles arriving 30 minutes earlier of booking slot = **NON-COMPLIANCE**.
- Non-compliance will be communicated on day of happening.

2.0 Pallet Build Specification

- Maximum pallet height of 1.6m (Inc Pallet Base).
- All inbound deliveries should be on UK standard 4-way entry pallets (120 x 100 cm).
- The number of test kits and number of cartons per pallets must remain consistent across all deliveries (unless agreed by both parties).
- Ability to double stack pallet, should be confirmed by the supplier with stress tests completed. Where pallets are double stacked these should be wrapped as a single unit.
- There should be no mixed batches on a pallet.
- All pallet deliveries must be made on heat treated (ISPM15) wooden pallets free from contaminants.

3.0 Packaging Requirement

- The number of test kits per carton must remain consistent across all deliveries.
- There should be no mixed batches per carton.
- Carton labelling should clearly record:
  - Batch Number;
  - Expiry Date
  - Quantity of test kits
  - DHSC SKU ID

The label should be clearly visible on each side of the carton.

4.0 Inbound Deliveries (PODs)

- Booking In instructions must be adhered to at each site. Info can be obtained from DHSC.
- The delivery note for each delivery truck should record the following information:
  - SKU ID and description
  - Quantity of test kits
  - Quantity of cartons
  - Quantity of pallets
  - Batch Numbers
  - Warehouse Booking reference

NB. Every attempt will be made to offload expeditiously, however waiting times will not be paid for delays.

5.0 Pallet Presentation

Poor pallet presentation on inbound loads is causing safety issues and costly rework for the Goods In teams. The below must be adhered to at all times for the conformity of pallet construction.

Label: Attach label towards the top left or top right of the pallet.
Height: Max height is 1.6 meters, including wooden pallet.
Broken pallets: No Broken pallets, check before you pick and build pallet.
Stacking: The pallet must be organised and stable enough for double stacking.
Wrapping: Poor wrapping is the most common pallet presentation problem.
Cartons: Must stay within the pallet area and not overlay the sides.

Good practices

Ensure that the pallet is safe and fit for transit and care is taken when crouching down to secure the wrap to the pallet corner.

This wrap as shown has been secured and **double wrapped** to the pallet base. The pallet has then been wrapped with a minimum of **60%** overlapping as it has been worked up the stock.

The method to ensure correct tension on the wrap is to over shoot the corner and then apply controlled tension as you proceed around the pallet. Follow over the top wrapping of stock with at least **two layers** of wrap.

Bad practices

This load could be unsafe and have the potential to cause injury. Under no circumstances should you attach the wrap between stock when starting to wrap your pallet.

The wrap as shown is too loose on this pallet

(Pinch an Inch) to do your check before leaving the pallet in the loading area.

The tension on the wrap on this pallet has not been applied correctly and the wrap is now loose. This does not secure all the stock to the pallet.

4.0: Accessibility Considerations

4.0 Accessibility Considerations

DHSC will work with you to ensure that the IFU content is accessible to the widest possible audience and complies with accessibility standards and regulations (such as WCAG 2.0). This may include creating an "accessible" electronic document that is optimized for screen readers and other assistive devices used by persons with disabilities.

1. Creating an accessible PDF

It is critical that content is accessible to the widest possible audience and complies with accessibility standards and regulations (such as WCAG 2.0). An "accessible" electronic document is one that is optimized for screen readers and other assistive devices used by persons with disabilities. Producing accessible content also plays a key role in optimizing PDF documents for successful indexing by Internet search engines.

Achieving this kind of accessibility requires tagging all document content based on its hierarchical structure (headings, paragraphs, lists, tables, and so on) and ordering the content in a linear path from start to finish. An additional requirement for accessible documents is identifying non-text content, such as graphics and images, in context and describing what is shown.

Most of the tasks are executed within InDesign, with only a few final steps required in Adobe Acrobat. This allows hierarchical and structural information to reside in the InDesign file, making updates faster and easier when you need to generate a revised accessible PDF document.

Steps in InDesign (overview)

- Use paragraph styles consistently throughout your document
- Establish export tag relationships between InDesign styles and PDF tags
- Anchor images within the content flow
- Add alternative text for images
- Incorporate internal document navigation mechanisms
- Establish content order in the Articles panel
- Specify a document title and description as metadata
- Export as PDF with settings optimized for accessibility
- Consider the reading order (left to right / top to bottom) when styling up tables

Steps in Acrobat DC (overview)

- Set the language in Document Properties
- Change display name from Filename to Document Title
- Set the tab order to use the document structure in the Page Thumbnails pane
- Run the Acrobat accessibility check

SECTION 2

Logistics Requirements

Index

1.0 International Commercial Terms (INCOTERMS)

1.1 The Incoterms 2020 are an internationally established method of incorporating agreed contractual terms into a contract. The Incoterms are drafted and maintained by the International Chamber of Commerce (ICC), and define the responsibilities as between a seller and a buyer in relation to paying for and managing shipment, insurance, documentation, customer clearance and other logistics activities.

2.0 Delivery Duty Paid

2.1 The DHSC requires suppliers to provide DDP services for the delivery of LFD's.

2.2 The seller delivers the goods to the buyer:

2.2.1 at the named place of destination.

2.3 The seller is responsible for all steps up to the point of unloading at the final destination. This includes customs formalities and responsibility for clearing the goods for export and import, and payment of any import duty. It is the seller's responsibility to arrange the contracts of carriage and insurance to provide the delivery / transport documents to the buyer to enable it to take over the goods.

2.4 The Authority would also like to be clear that with DDP services, all applicable taxes and duties to be paid such as VAT / GST are the responsibility of the supplier.

3.0 Supplier Responsibilities

3.1 The supplier has full responsibility for the following requirements forming the DDP services which include but may not be limited to:

- Pre-carriage / warehousing
- Export customs clearance
- Handling at departure
- Primary transport to UK
- Handling on arrival
- Import customs clearance and payment of any duties or taxes due
- Unloading from inbound arrival and palletisation for onward delivery
- Delivery to designated DHSC warehouse

4.0 Suppliers and Sub-Contractors

4.1 The Authority requests that details of all suppliers and sub-contractors used in expediting the delivery of LFDs to the final named delivery locations are provided below:

Please add details:

Name of Supplier / Sub-Contractor	Email Contact	Location

5.0 Quality Control Inspection Process

5.1 Onsite inspections will be undertaken to ensure the required standards of control are being met. These onsite inspections will be carried out by a third party on behalf of the Authority and will be formally agreed with the supplier on award of contract.

5.2 Typically, the Authority will require the supplier to carry out checks of the finished products and how they have been packaged ready for transportation at the point of pick up as part of the agreed quality control procedures.

5.3 All relevant documentation should be fully completed, signed and copies provided to the DHSC confirming the checks have been made in line with DHSC requirements.

5.4 Supplier should have the ability to facilitate these third-party inspections and must provide the third-party service with a production schedule and forecasted expected volumes in advance of inspections being carried out.

5.5 Supplier must "ring-fence" samples of product for validation processes as part of the Authority Quality Assurance. These "ring-fenced" samples will typically be 100 kits per 1,000,000 produced.

5.5.1 These sample kits will be packaged using yellow tape so they are identifiable from remaining stock. These cartons will be marked such that they include lot numbers correlating to the samples taken.

5.5.2 Validation samples are required to be expedited to the UK. Supplier is expected to notify 3PL accordingly for assurance that these samples will be prioritised for inbound shipments.

5.5.3 Under DDP terms, 3PL freight service must liaise with the Authority for collection of validation samples to be sent to laboratory as required.

6.0 Temperature Control and Monitoring

6.1 The Authority is seeking to maintain the effectiveness of the LFDs through use of temperature controls throughout the full logistics arrangements. This may include but is not limited to: use of temperature-controlled freight vehicles, warehousing, and storage facilities.

6.2 Suppliers are expected to store and transport product within the temperature range as detailed in the specific product specifications.

6.3 Authority expects Supplier to regularly monitor all consignments throughout their journey from the production facility to the dedicated DHSC distribution centre (DC) or nominated location in compliance with the upper and lower temperature storage limits.

6.4 This information should be made available to the DHSC as a written report on a frequency agreed between both parties but not less than daily.

7.0 Moisture Protection

7.1 All consignments are to be protected from any form of moisture or water ingress and as such should be packed and stored in regulated environments to ensure all consignments do not arrive at the final named destination in a wet condition.

7.2 The controls to mitigate moisture or water ingress also applies to all overseas handling facilities.

8.0 Batch Rejection

8.1 A batch may be rejected for some or all of the following reasons and may not be limited to:

- Damaged stock including outer cartons, inner boxes or individual kit components.
- Partial order received including but not limited to part-filled outer cartons received (excluding those which are clearly marked as containing samples for validation).
- Incorrectly stacked pallets
- Opened packaging or missing product/ kit components.
- Packaging damaged by water or showing signs of water ingress.
- Product which could be considered contaminated. For example, presence of foreign objects or dirt marks present on kit components.
- Incorrect packaging or labelling that risks inability to provide end-to-end traceability of product.
- Expired product.

9.0 On Time Delivery

9.1 Suppliers must confirm acceptance of the delivery details including the delivery date and named place of delivery.

9.2 Suppliers will confirm acceptance of the above providing the necessary documentation as required by the DHSC.

9.3 Suppliers must follow the Booking In instructions below. However please refer to the DHSC Rapid COVID-19 Antigen Self-Test Specification, Appendix 3, Supply Chain Logistics Requirements for full details.

- Booking In instructions must be adhered to at each site. Info can be obtained from DHSC.
- The delivery note for each delivery truck should record the following information:
  - SKU ID and description
  - Quantity of test kits
  - Quantity of cartons
  - Quantity of pallets
  - Batch Numbers
  - Warehouse Booking reference

NB. Every attempt will be made to offload expeditiously, however waiting times will not be paid for delays.

10.0 Shipment Delays – Notification from Suppliers

10.1 The Authority will expect to be notified by the supplier immediately should there be a perceived risk of delay to any planned delivery schedules.

10.2 The Authority expects the supplier to have in place an escalation and mitigation process for any form of delay including supply chain timelines to maintain the integrity of the product.

10.3 Please confirm insurance cover is in place to cover complete loss of product cargo prior to delivery

11.0 List of Delivery Locations

11.1 Below is the current list of delivery locations suppliers will be expected to delivery to one or all of these locations. This list may change and as such notification of any changes will be provided to the supplier as per the contract.

Name	Address
[redacted]	

12.0 Disposal of damaged goods

12.1 The Authority will expect all suppliers to dispose of damaged goods in accordance with the appropriate environmental standards.

12.2 The waste from Lateral Flow Devices is classified as non-hazardous healthcare offensive and chemical waste.

Please see: https://www.gov.uk/government/publications/coronavirus-covid-19-lateral-flow-tests-waste-codes/waste-codes-for-mass-testing-with-lateral-flow-antigen-testing-devices

12.3 Bulk waste must be collected by an appropriately licensed waste carrier. This waste must then be either taken directly to a municipal waste incinerator temporarily permitted to accept this waste by the Environment Agency under a Regulatory Position Statement (RPS C23: Incinerating specified healthcare wastes at a municipal waste incinerator); or to a waste transfer facility that has demonstrated to the Environment Agency that they can store these wastes in a safe and controlled manner, and have been granted a temporary formal local enforcement position to safely store and then transfer these wastes to municipal waste incinerators.

13.0 Evidence / Certification Requirements

13.0 Suppliers must provide regulatory evidence by way of a valid destruction certificate when disposing of stock, this requirement also includes overseas facilities.

13.1 Suppliers should also expect to coordinate daily meetings regarding production, transit and delivery schedules and provide a daily update on transit, production, and delivery schedules.

14.0 Commercial Insurance

14.1 Supplier to confirm they have Full Commercial Insurance cover is in place to cover complete loss of product cargo to arrival at the buyers designated premises.

14.2 Please refer to clause 13 of the contract.

Annex 3
Supplier's Tender Response and Responses to Clarification Questions

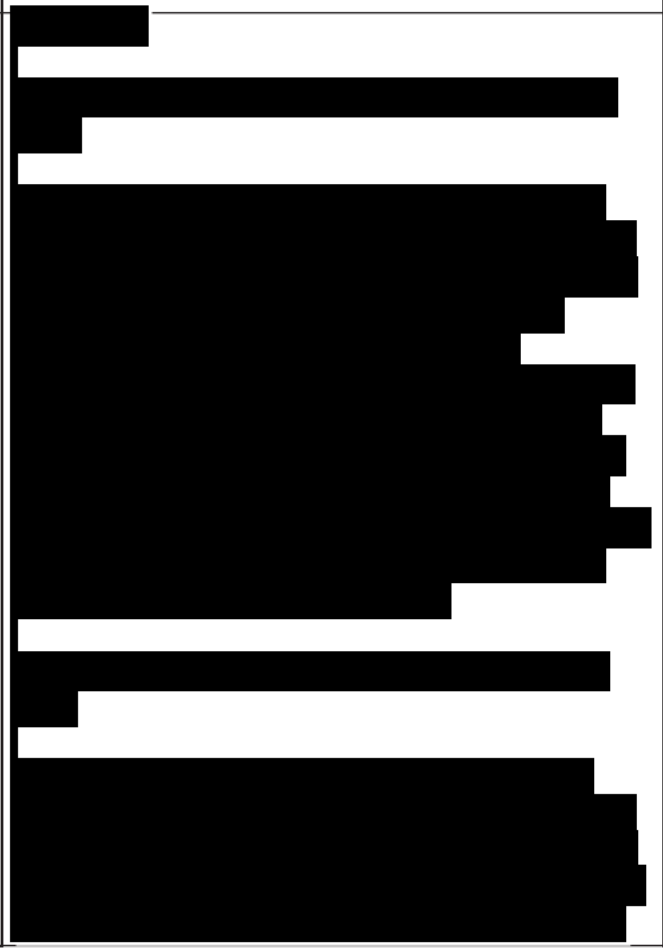
Tender Response

For the avoidance of doubt, the link above is to the Supplier's response submitted on 10 August 2021 to the invitation to tender and is incorporated into this Contract.

Responses to Clarification Questions

URN	Message	Message Date	Response	Response Date
1	[redacted]	13/08/2021 19:20	[redacted]	17/08/2021 09:38

	[redacted]		[redacted]	
1a	[redacted]	18/08/2021 09:55	[redacted]	18/08/2021 18:48

				
2		23/08/2021 15:28		24/08/2021 09:29

				
2a				24/08/2021 09:50