

Call-Off Schedule 20 (Call-Off Specification)

This Schedule sets out the characteristics of the Deliverables that the Supplier will be required to make to the Buyers under this Call-Off Contract

1. PURPOSE

- 1.1 Department of Health & Social Care is seeking to establish a Call-Off Agreement for the Home Channel Fulfilment services.
- 1.2 The Call-Off Agreement shall be for an initial period of 5 months; the Contracting Authority may extend the duration of the Agreement for any period up to a maximum of 7 months in total from the expiry of the Initial Contract Period, subject to the satisfactory performance.

2. SCOPE OF REQUIREMENT

- 5.1 The scope of the Requirement covers the Home Fulfilment of test kits and associated services and activities including but not limited to the delivery of testing kits to addresses in the UK and Northern Ireland.
- 5.2 Headline requirements:
 - Must have fulfilment capability and capacity to deliver at least 30,000 test-kits per day by January 2021 following a period of ramp up
 - Must ensure 7 days of inventory held at all times
 - Must have the capability to provide next day delivery to UK and NI following order fulfilment if ordered by 8pm
 - Is responsible for the picking, packing, address labelling and delivery of test-kits
 - Must have a Warehouse Management System (WMS) to control first expired first out (FEFO) and batch control of testing kits
 - Must be able to report on the end to end chain of custody reporting and MI (Realtime / Near Realtime)

3. DETAILED REQUIREMENT

3.1 Operational Management

- 3.1.1 Must have the ability to scale up to a minimum of 30,000 test kits to be delivered per day by 31 Jan 2021.
- 3.1.2 Hours of operation should be agreed in advance with DHSC. It is expected deliveries will be 7 days per week including Bank Holidays 365 days per year.

Call-Off Schedule 20 (Call-Off Specification)

Call-Off Ref:

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- 3.1.3 Operational 'down-time' in Fulfilment Operations, for example, planned maintenance should be agreed with the Contracting Authority 14 days prior to the event
- 3.1.4 Must ensure Staff numbers can be flexibly shifted up and down to rapidly ramp-up surge capacity to deliver test-kits if the need for testing increases or reduces.
- 3.1.5 The Warehouse must have sufficient capacity to hold a minimum of 7 days inventory of test-kits assuming a minimum of 30,000 test kits per day
- 3.1.6 Must have the ability to provide the Contracting Authority with data on the number of orders received, the number of outbound shipments and the number of outbound shipments On Time in Full (OTIF).
- 3.1.7 Must meet all regulatory requirements (e.g. MHRA) and quality guidelines defined by the Contracting Authority. Please refer to sections 7 to 8 and 13 to 17 of this document for regulatory requirements.
- 3.1.8 Must ensure all MHRA regulations are met relating to the storage and handling of sealed test-kits throughout the pick, pack and address labelling processes.
- 3.1.9 Must have the ability to fulfil large letter format products.
- 3.1.10 Must have the ability to fulfil small to large parcel format products.
- 3.1.11 Must ensure all products in transport and storage are held within the required temperature range of an ambient temperature between 2 – 25 degrees.

3.2 Receipt, Store, Pick, Deliver

3.2.1 Receipt

- 3.2.1.1 Must have the ability to receive and store finished products ready for Fulfilment and next day shipping
- 3.2.1.2 Must have sufficient storage capacity and processes to store and pick kits, with a minimum of 7 days of inventory at a minimum of 30,000 kits per day
- 3.2.1.3 Must have the ability to place into storage fulfilment stock from at least two suppliers within 8hrs of receipt of stock.
- 3.2.1.4 Must have the ability to list new products within 3 days of receipt of a new product description

Call-Off Schedule 20 (Call-Off Specification)

Call-Off Ref:

Crown Copyright 2018

3.2.2 **Store**

- 3.2.2.1 Must ensure it has a Warehouse Management System (WMS) capable of tracking stock and orders
- 3.2.2.2 The Warehouse Management System must be used and updated in real-time.
- 3.2.2.3 The WMS system must have the capability to interface directly with the supply chain organisations systems.
- 3.2.2.4 Must have the ability to maintain inventory levels as set by the Contracting Authority. These must be sufficient to cover 7 days at a minimum of 30,000 test-kit orders per day
- 3.2.2.5 Must have the ability to provide 100% of batch information. Chain of custody must be recorded and shared with the Contracting Authority.
- 3.2.2.6 Must have the ability to track expiry dates to ensure FEFO process.

3.2.3 **Pick**

- 3.2.3.1 Must have the ability to deploy FEFO (First Expired First Out) principles.
- 3.2.3.2 Must have the ability to demonstrate a waste disposal process to capture products that are recalled or expired.
- 3.2.3.3 Must have the ability to receive orders in near-real-time daily for home test kits and subsequently satisfy orders nationally in UK and NI. This involves picking and labelling of finished product SKUs.

3.2.4 **Deliver**

- 3.2.4.1 Must have the ability to track the processing of finished kits and make kits ready for onwards transport.
- 3.2.4.2 Must have the ability to demonstrate full traceability of input component batches within each shipped kit.
- 3.2.4.3 Must have the method for delivering the test kits to home addresses in UK and Northern Ireland, identifying the most appropriate delivery route/parcel network and ensure the agreed SLA and KPI are adhered to.

Call-Off Schedule 20 (Call-Off Specification)

Call-Off Ref:

Crown Copyright 2018

- 3.2.4.4 Must use an optimisation tool/procedure to select preferred delivery network to optimise fulfilment deliveries and meet SLAs
- 3.2.4.5 Must have a process in place to enable dispatch of the kits to meet next day delivery SLAs.
- 3.2.4.6 Must have the ability to ship 100% of their agreed daily volume of test kits to UK & NI addresses.
- 3.2.4.7 Should have the ability to deliver to UK and NI addresses next day if the order is placed before 8pm the previous day.
- 3.2.4.8 Must have the ability to deliver to UK and NI addresses within 24hrs of receipt of order.
- 3.2.4.9 Must have a tracking capability for use by recipients of the tests kits. This must include communication of delivery window (Advanced Shipping Notification).
- 3.2.4.10 Must be able to provide the Contracting Authority with data on the utilisation of the tracking facility
- 3.2.4.11 Must have the ability to receive and acknowledge orders from the Contracting Authority's digital ordering platform
- 3.2.4.12 Must have the ability to demonstrate a process to fast track expedited orders.
- 3.2.4.13 Must have the ability to provide next day shipping arrangements for expedited delivery.
- 3.2.4.14 Must have the ability to notify Customer of failed delivery and next attempted delivery time.
- 3.2.4.15 Must have the ability to demonstrate a process for two delivery attempts.
- 3.2.4.16 Must have the ability to demonstrate a process for delivery issues/failures following 2 delivery attempts.
- 3.2.4.17 If a delivery is made and it is damaged, incomplete or delivered to the wrong address then the recipient should dispose of the delivery. In the case of damaged or incomplete deliveries a replacement item should be sent out.
- 3.2.4.18 Must provide Information on Delivery (IOD) confirmation to the Contracting Authority through an agreed system,

Call-Off Schedule 20 (Call-Off Specification)

Call-Off Ref:

Crown Copyright 2018

which must have the capability to interface directly with the Contracting Authority's systems consuming specified interfaces. The level of detail required for the proof of delivery shall be agreed with the Contracting Authority at Call Off stage.

3.3 Protection

- 3.3.1 Must have the ability to integrate their fulfilment systems with NHS Digital (NHSD) ordering portal via an Open API to receive customer order information
- 3.3.2 Will be acting as a Data Processor and therefore must have GDPR controls in place to manage personal data.

3.4 Customer Service

- 3.4.1 Shall make available to the Contracting Authority a single point of contact, capable of recording and dealing with all enquiries from Contracting Authority Personnel in relation to the services being provided.
- 3.4.2 As a minimum, customer and complaints service and support hours will cover 07.00 to 23.00 7 days a week, including UK Bank Holidays. It is expected the operator will work the hours required to meet the required service levels.
- 3.4.3 Must provide a complaints management process integrated with the Contracting Authority.
- 3.4.4 Must provide a 7 day a week service to manage complaints.
- 3.4.5 Must have the ability to interface with users in order to manage complaints relating to delivery completion.

3.5 Risk Management, Quality Control and Procedures

- 3.5.1 Must have a Business Continuity plan agreed with the Contracting Authority within 14 days of the award of the contract and the ability to review and update this monthly.
- 3.5.2 Must carry out a visual inspection upon receipt of stock to check for damage.
- 3.5.3 Upon being notified of a quality issue or discovering a quality issue the Supplier must ensure all affected stock is quarantined both physically and in the system immediately. The Contracting Authority must be informed of quarantined stock within 1 hour of the incident.
- 3.5.4 Must have the ability to ensure all products have full traceability
- 3.5.5 Must have the ability to demonstrate a process to address delivery issues/failures.

Call-Off Schedule 20 (Call-Off Specification)

Call-Off Ref:

Crown Copyright 2018

- 3.5.6 Must allow for quality and regulatory audits by external companies given 48 hrs notice as a minimum.

4. STORAGE SPECIFICATIONS

- 4.1 Must have systems and procedures in place to ensure any test-kit received under quarantine status, are not released into allocated stock until all necessary remediation's, agreed with the Contracting Authority and evidenced have been met.
- 4.2 Must have a process for the handling of non-conforming test-kits identified at goods-in, describing how the test-kit is stored, what documentation is completed and how the stock is controlled on the inventory management system.
- 4.3 Must maintain the storage requirements set out by the manufacturer
- 4.4 Must review calibration certificates for temperature monitoring devices to ensure that the accuracy of the devices is acceptable. Documentation must be available for inspection demonstrating that this review has occurred.
- 4.5 Must perform and document continuous temperature monitoring in order to ensure that the appropriate conditions are maintained, if applicable. This applies to all areas where test-kits are stored (e.g. bulk storage, pick-face, quarantine and returns areas). At a minimum, a calibrated max/min type thermometer should be used. The maximum and minimum temperatures reached should be recorded every day and the thermometer reset after the readings have been taken. They must have a system in place to ensure that quarantined stock is not available for picking or returned to saleable stock inadvertently. An inventory of quarantined stock must be maintained on a Warehouse Management System.
- 4.6 Is responsible for preserving the test-kits through correct storage and transportation as applicable. Therefore it is recommended that a pest control programme is in place. At a minimum this should include rodent control.

5. TRANSPORT SPECIFICATIONS

- 5.1 Must follow all test-kit traceability requirements
 - 5.1.1 Including: responsibilities and procedural aspects in terms of recall and withdrawal procedures, handling returns, complaints (related to distribution and/or device safety and performance) and review provision for ensuring the agreement maintains relevance to the ongoing operation

6. NOT USED

Call-Off Schedule 20 (Call-Off Specification)

Call-Off Ref:

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7. MANAGEMENT INFORMATION/REPORTING

- 7.1 Must have the ability to share data with NHS Digital (NHSD) systems. Suppliers should provide near real-time data to the National Testing Programme relating to stock control, orders received/fulfilled/delivered and incidents.
- 7.2 Must provide Management Information which includes but is not limited to:
 - 7.2.1 Delivery to home confirmation provided to the Contracting Authority through the .gov.uk digital ordering portal
 - 7.2.2 Publish exception delivery report (late, rescheduled, refused) including reason codes.
 - 7.2.3 Report number of deliveries involving 2 delivery attempts (up to 2 maximum).
 - 7.2.4 Report number of delivery issues/failures following 2 delivery attempts.
 - 7.2.5 Reporting on deliveries achieved and due.
 - 7.2.6 Reporting on proof of deliveries.
 - 7.2.7 Exception delivery report (late, rescheduled, refused) including reason codes.
 - 7.2.8 Reporting of OTIF deliveries.
 - 7.2.9 Fleet utilisation report.
 - 7.2.10 Reporting of stock levels to the Contracting Authority to ensure visibility.
 - 7.2.11 Number of orders received.
 - 7.2.12 Number of outbound shipments.
 - 7.2.13 Order completion rates.

8. CONTINUOUS IMPROVEMENT

- 8.1 Will be expected to continually improve the way in which the required Services are to be delivered throughout the Contract duration.
- 8.2 Should present new ways of working to the Authority during monthly/quarterly Contract review meetings.
- 8.3 Changes to the way in which the Services are to be delivered must be brought to the Authority's attention and agreed prior to any changes being implemented.

Call-Off Schedule 20 (Call-Off Specification)

Call-Off Ref:

Crown Copyright 2018

9. QUALITY STANDARDS

- 9.1 Must provide details demonstrating that they have a Comprehensive Quality Assurance Policy in place.
- 9.2 Must have a Quality Management System in place including but not limited to a Quality plan, Internal Audit Schedule, Document control process CAPA process and Quality Management Meeting.
- 9.3 Must provide documents, flowcharts and procedural details showing a controlled approach to Quality Assurance.
- 9.4 Must have an effective quality system that provides assurance that only medical devices which comply with legislative requirements are distributed, that noncompliant, defective or unsuitable medical devices can be detected, that traceability is maintained and that non-conformances and the introduction of changes are controlled.
- 9.5 Must establish Standard operating procedures (SOPs) to clearly describe how key activities are carried out.
- 9.6 SOPs must describe the different operations which may affect the performance of the medical devices; Training - Documentation control - Approval of suppliers and customers - Order processing and deliveries - Waste management - Audits - Change control - Management review - Quality risk management - Management of Field Safety Corrective Actions/recalls - Non-conformance management - Corrective and preventive actions.

10. RECORDS

- 10.1 Must keep adequate records, including records of customers and suppliers to and from whom test kits have been distributed.
 - 10.1.1 Records should include but are not limited to: medical device name and/or code, batch or serial number, quantities and delivery or receipt date.
- 10.2 Must keep records of checks completed (for example labelling checks for CE marks) and the approval of test kits into available stock
- 10.3 Must have a change control procedure and associated forms should be implemented and appropriately documented.
 - 10.3.1 The purpose of the procedure should be to ensure that all changes to the operation are fully evaluated in terms of impact on the medical device's performance and traceability.

11. VALIDATION OF PROCESSES

- 11.1 Must have validation processes in place where the resulting output cannot be or is not verified by subsequent monitoring or measurement. Validation must demonstrate the ability of these processes to achieve planned results consistently

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Call-Off Schedule 20 (Call-Off Specification)

Call-Off Ref:

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11.2 Must include key critical steps for validation such as; goods-in, storage, order processing and dispatch

12. TRAINING

12.1 Must have the appropriate personnel with suitable training and experience to adequately conduct their assigned duties

12.2 Must have documented and recorded all training.

13. PEST CONTROL

13.1 Must demonstrate adequate pest control measures are in place for the facility.

13.2 Must provide a schedule of pest control for the facility and must review its effectiveness on a periodic basis.

13.3 Must take action upon information provided by the appointed Pest Control solution.

14. SERVICE LEVELS AND PERFORMANCE

14.1 The Authority will measure the quality of delivery by:

KPI/SLA	Service Area	KPI/SLA description	Target
1	Operational Management	Meet the minimum required volumes by the timeline 10,000 test kits per day in November 20,000 test kits per day in December 30,000 test kits per day in January 30,000 test kits per day for the remainder of the agreement	100%
2	Receipt - Ability to receive and putaway items	Receipt of stock, checking quantity and quality to be putaway and on the WMS, available to pick within 8 hours	100%

Call-Off Schedule 20 (Call-Off Specification)

Call-Off Ref:

Crown Copyright 2018

3	Store - Ability to store finished products	Hold 7 days of inventory for all SKU's, and order product in time to ensure stock levels are maintained	100%
4	Store – inventory accuracy	Weekly evidence of stock accuracy of 7 days stock cover and matched physical to system with minimal damage	99.5%
5	Delivery- Receive orders daily for home test kits and subsequently satisfy orders nationally. This involves picking and labelling of finished product SKUs	Next day delivery of orders on time to home destinations, up to the agreed quantity of kits per day	98%
6	Delivery - Receive orders daily for home test kits and subsequently satisfy orders nationally. This involves picking and labelling of finished product SKUs	Next day delivery of orders in full to home destinations (no damage) up to the agreed quantity of kits per day	98%
7	Delivery	Delivery of items with compliance to 2 tries for delivery	100%
8	Delivery	Delivery complaints to be kept to a minimum and all dealt with within 24hrs of point of contact.	1% complaints of the total number of deliveries
9	Use of Warehouse Management System	Batch information and chain of custody recorded and shared with the Contracting Authority in real time when requested.	100%

Call-Off Schedule 20 (Call-Off Specification)

Call-Off Ref:

Crown Copyright 2018

10	Use of Warehouse Management System	All stock must be quarantined both physically and in the system immediately upon being notified of any quality issues or discovering an issue that requires quarantining. The Contracting Authority must be informed of quarantined stock within 1 hour of the incident.	100%
11	Customer Service - Complaints management process integrated with DHSC	Provision of 7 days a week customer service between 07.00 to 23.00 and all complaints/issue responded to in 24 hours of the point of contact	100%

15. PAYMENT AND INVOICING

- 15.1 Submit an invoice monthly in arrears as per the Order Form
- 15.2 Payment can only be made following satisfactory delivery of pre-agreed certified products and deliverables.
- 15.3 Before payment can be considered, each invoice must include a detailed elemental breakdown of work completed and the associated costs.
- 15.4 Invoices should be submitted to:

Department of Health and Social Care
Finance
REDACTED
39 Victoria Street
Westminster,
London SW1H 0EU

16. CONTRACT MANAGEMENT

- 16.1 The Supplier shall attend regular Contract Management meetings as set out below:

Meeting type	Frequency	Purpose
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Framework Ref: RM6017

Project Version: v1.0

Model Version: v3.0

Call-Off Schedule 20 (Call-Off Specification)

Call-Off Ref:

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Operational	Daily/Weekly	Review and monitor the operational performance of the Services.
Contract/Performance	Monthly	Review and monitor the commercial aspects of the Services, including: - SLA's/KPI's, - Service Delivery - Financials - Risk - Innovation / Improvement
Strategic	Quarterly	Review and monitor the overall performance of the Service Provider in the provision of the Services, including strategic forward planning

- 16.2 The content, structure and attendance requirements of these meetings shall be agreed within 5 days of contract signature.
- 16.3 Attendance at Contract Review meetings shall be at the Supplier's own expense.
- 16.4 Shall produce a Monthly Reporting Pack which includes but is not limited to:
- SLA's / KPI's;
 - Service delivery;
 - Financials;
 - Risk; and
 - Customer service.
- 16.5 The structure, format and content of the reporting pack shall be agreed between the parties.
- 16.6 The first Monthly Reporting Pack shall be submitted within one month of contract commencement.

17. LOCATION

- 17.1 The location of the Services will be carried out at the agreed locations.