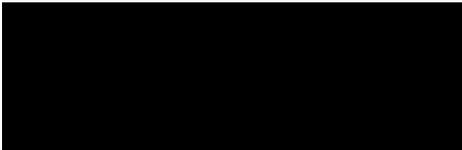
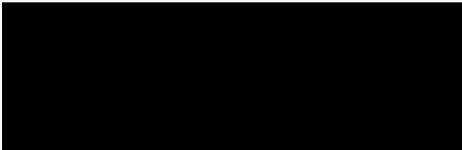
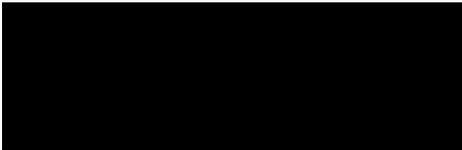
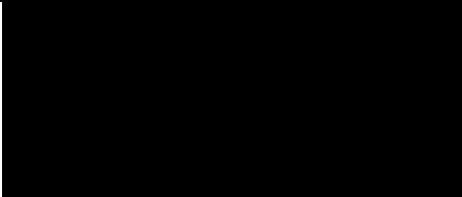
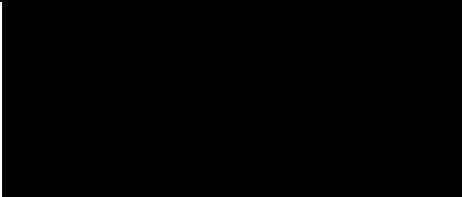
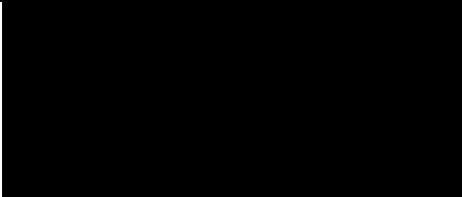
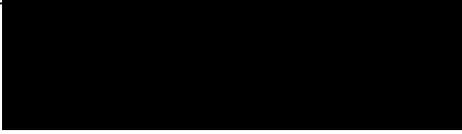


**Appendix 1**

**National Microbiology Framework Agreement  
Order Form**

**FROM**

<b>Authority:</b>	The Secretary of State for Health and Social Care as part of the Crown acting through the UK Health Security Agency 10 South Colonnade, London, E14 4PU (the "Authority").
<b>Invoice address:</b>	All invoices must be sent, quoting a valid purchase order number (PO Number), to: <a href="mailto:payables@ukhsa.gov.uk">payables@ukhsa.gov.uk</a>  UKHSA Billing Address: Accounts Payable, UK Health Security Agency, Manor Farm Road, Porton Down, Salisbury, SP4 0JG  UKHSA VAT No: GB888851648
<b>Contract Manager:</b>	Name:  Phone:  E-mail: 
<b>Secondary Contact: eg. business operational contact, project manager</b>	Name:  Phone:  E-mail: 
<b>Procurement lead</b>	Name:  Phone:  E-mail: 
<b>Name and address for notices:</b>	Name:  Address: 10 South Colonnade, London, E14 4PU
<b>Internal reference (if applicable):</b>	To be quoted on all correspondence relating to this Order Form: C406134

**TO**

<b>Supplier:</b>	HOLOGIC LTD Heron House Oaks Business Park, Crewe Road, Wythenshawe, Manchester, M23 9HZ
------------------	---

National Microbiology Framework Schedule 7 - Ordering Procedure, Award Criteria and Order Form

	Company Number 02722343
<b>Contract Manager:</b>	Name: [REDACTED] Phone: [REDACTED] E-mail: [REDACTED]
<b>Secondary Contact:</b>	Name: [REDACTED] Phone: [REDACTED] E-mail: [REDACTED]
<b>Account Manager:</b>	Name: [REDACTED] Phone: [REDACTED] E-mail: [REDACTED]
<b>Name and address for notices:</b>	Name: [REDACTED] Address: Heron House Oaks Business Park, Crewe Road, Wythenshawe, Manchester, M23 9HZ

**Applicable terms and conditions**

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

<b>Appendix A</b>	Call-off Terms and Conditions for the Supply of Goods and the Provision of Services	<b>Applicable to this Contract</b>	
<b>Appendix B</b>	Optional Additional Call-off Terms and Conditions for Installation and Commissioning Services	<input type="checkbox"/> (only applicable if this box is checked)	
<b>Appendix C</b>	Optional Additional Call-off Terms and Conditions for Maintenance Services	<input type="checkbox"/> (only applicable if this box is checked)	
<b>Appendix D</b>	Optional Additional Call-off Terms and Conditions for Bespoke Research, Development and Manufacturing Requirements	<input type="checkbox"/> (only applicable if this box is checked and to the extent the applicable terms are included in Annex A (Order Specific Key Provisions))	
<b>Appendix E</b>	Optional Additional Call-off Terms and Conditions for Reagent Rental	<input type="checkbox"/> (only applicable if this box is checked)	
<b>Appendix F</b>	Optional Additional Call-off Terms and Conditions for Managed Equipment Services	<input type="checkbox"/> (only applicable if this box is checked)	
<b>Appendix G</b>	Optional Additional Call-off Terms and Conditions for Clinical Laboratory Diagnostic Testing Services	<input type="checkbox"/> (only applicable if this box is checked and to the extent the applicable terms are included in Annex A (Order Specific Key Provisions))	
<b>Appendix H</b>	Further Optional Additional Call-off Terms and Conditions	<b>(only applicable if one or more boxes are checked)</b>	
	Each of the following clauses in Appendix H is only applicable to this Contract if the relevant box is checked:		
	1. TUPE applies at the commencement of the provision of Services		<input type="checkbox"/>
	2. TUPE on exit		<input type="checkbox"/>
	3. Different levels and/or types of insurance		<input type="checkbox"/>
	4. Induction training for Services		<input type="checkbox"/>
5. Further Authority obligations	<input type="checkbox"/>		

National Microbiology Framework Schedule 7 - Ordering Procedure, Award Criteria and Order Form

6.	Assignment of Intellectual Property Rights in deliverables, materials and outputs of the Services	<input type="checkbox"/>	
7.	Inclusion of a Change Control Process	<input type="checkbox"/>	
8.	Authority step-in rights	<input type="checkbox"/>	
9.	Guarantee	<input type="checkbox"/>	
10.	Termination for convenience	<input checked="" type="checkbox"/>	
11.	Pre-Acquisition Questionnaire	<input type="checkbox"/>	
12.	Time of the essence (Goods)	<input checked="" type="checkbox"/>	
13.	Time of the essence (Services)	<input type="checkbox"/>	
14.	Specific time periods for inspection	<input type="checkbox"/>	
15.	Specific time periods for rights and remedies under Clause 3.6 of Schedule 2 of Appendix A	<input type="checkbox"/>	
16.	Right to terminate following a specified number of material breaches	<input checked="" type="checkbox"/>	
17.	Expert Determination	<input type="checkbox"/>	
18.	Consigned Goods	<input type="checkbox"/>	
19.	Improving visibility of Sub-contract opportunities available to Small and Medium Size Enterprises and Voluntary, Community and Social Enterprises	<input type="checkbox"/>	
20.	Management Charges and Information	<input type="checkbox"/>	
21.	COVID-19 related enhanced business continuity provisions	<input type="checkbox"/>	
22.	Buffer stock requirements	<input type="checkbox"/>	
23.	Modern slavery	<input checked="" type="checkbox"/>	
The additional Order Specific Key Provisions set out at Annex A (Order Specific Key Provisions) to this Order Form shall also apply to this Contract.			<input checked="" type="checkbox"/> (only applicable if this box is checked)

<b>1. CONTRACT DETAILS</b>											
<p><b>(1.1) Commencement Date:</b> The Contract shall commence on the date of signature by the Authority.</p>											
<p><b>(1.2) Services Commencement Date (if applicable):</b> Not used.</p>											
<p><b>(1.3) Contract Price ((i) breakdown and (ii) payment profile):</b></p> <p>1.3.1. The maximum value of the Goods that can be ordered under this Contract is one million forty-nine thousand two hundred thirty-seven pounds and twenty-eight pence (£1,049,237.28) only, excluding VAT, inclusive of delivery charges and duty (the “<b>Contract Price</b>”).</p> <p>1.3.2. Full details of the Contract Price are contained in Table 1.</p> <p>Table 1</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr style="background-color: #cccccc;"> <th style="width: 35%;">Description</th> <th style="width: 15%;">Pack Size</th> <th style="width: 25%;">Product Number</th> <th style="width: 25%;">Unit Price</th> </tr> </thead> <tbody> <tr> <td>Hologic RespDirect Collection Kit</td> <td>50</td> <td>PRD-07403</td> <td style="background-color: black;"></td> </tr> </tbody> </table>				Description	Pack Size	Product Number	Unit Price	Hologic RespDirect Collection Kit	50	PRD-07403	
Description	Pack Size	Product Number	Unit Price								
Hologic RespDirect Collection Kit	50	PRD-07403									
<p><b>(1.4) Term of Contract:</b> The Contract shall commence on the date the Order Form is signed by the Authority (the “<b>Commencement Date</b>”) and shall, unless extended, in accordance with its terms, expire on 31st March 2026 (the “<b>Term</b>”).</p>											
<p><b>(1.5) Term extension options:</b> Not used.</p>											

<b>2. GOODS AND/OR SERVICES REQUIREMENTS</b>
--

**(2.1) Description of Goods / Services:** Purchase of Hologic RespDirect Collection Kit (PRD-07403): [REDACTED] (the “Goods”).

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

2.2.1 The Goods shall be delivered by the Supplier in accordance with the following instructions:  
 a) The Goods shall be delivered to the Authority at the following address (the “Premises and Location”):

Site Address	Delivery Contact	Email and Contact Number
Movianto Haydock Unit 2, Haydock Green, Penny Lane, Haydock, WA11 9SE	[REDACTED]	

2.2.2. All planned deliveries shall be pre-advised by the Supplier to the Authority’s primary delivery contact (the “Delivery Contact”) at least 2 (two) Working Days prior to attendance.

2.2.3. The Supplier shall provide the following data when notifying the Delivery Contact:  
 a. Supplier name;  
 b. Authority’s PO Number

2.2.4. The Delivery Contact will confirm:  
 a. Booking reference number;  
 b. Date and time of delivery of Goods (where applicable); and  
 c. Delivery address.

2.2.5 Delivery of the Goods shall be considered to have occurred when the Delivery Contact (or other authorised representative of the Authority) at the Authority’s nominated Premises and Location has signed the Supplier’s delivery note confirming receipt.

2.2.6. The Supplier shall carry out deliveries between Monday and Friday between 8:00am to 4:00pm excluding bank holidays unless otherwise agreed with the relevant Delivery Contact.

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

[REDACTED]



**(2.4) Performance standards:**

2.4.1. The Supplier shall ensure conformance with the Product Specification in Annex B.

2.4.2. The Supplier shall ensure the Goods are delivered in accordance with the Delivery Schedule outlined in Annex D, unless otherwise agreed with the Authority. The Supplier shall ensure all Goods are delivered and invoiced by 31<sup>st</sup> March 2026.

2.4.3. This Table 2 sets out the KPIs which shall be used to measure the Supplier’s performance of the Services and the consequences where any KPI targets are not achieved.

Table 2

KPI	Definition	Target	Remedy for Non-Compliance	Service Credit
On-Time Delivery	% of deliveries on agreed schedule, all goods invoiced by 31 Mar 2026, and Goods accepted by the Authority.	≥ 98% monthly; 100% by 31 Mar 2026	[Redacted]	[Redacted]
Shelf Life	Minimum twenty (24) months from date of manufacture; ≥95% lots with ≥22 months remaining at delivery.	100% DOM ≥24 months; ≥95% delivery ≥22		
Critical Defect Rate	[Redacted]	0% (AQL = 0%)	[Redacted]	[Redacted]



	<p>cosmetic or other imperfection/error that do not pose a hazard to the end user and will not affect the useability (e.g kit package colour). The Authority shall provide written confirmation of the Defect Rate within eight (8) Working Days from the date of the batch inspection at the manufacturer's site.</p>			
--	--	--	--	--

**(2.5) Quality standards:**

2.5.1. The Supplier shall ensure that goods are CE/UKCA marked and valid for period of stock shelf life.

2.5.2. The Supplier shall ensure that Goods have a minimum shelf life of at least twenty-four (24) months from date of manufacture and as close as possible to twenty-four (24) months at point of delivery.

2.5.3. The Supplier shall ensure compliance with current UK Medical Device/IVD regulations including Post Market Surveillance (PMS) requirements.

**Packaging Requirements:**

2.5.4. The Supplier shall ensure that all items are appropriately packed to prevent damage during handling and transportation. Packages must be tightly sealed to maintain product integrity. Damaged packs or packs with loose seals will not be acceptable.

2.5.5. The Supplier shall ensure that both internal and external packaging must be dust-free, clean, and free from microbial contamination.

2.5.6. The Supplier shall ensure that internal & external packaging must be leak-proof to ensure no spillage or seepage occurs.

2.5.7. The Supplier shall ensure that kit information, including expiry dates printed on packages (internal and external), must be indelible and not easily removable by alcohol or other cleaning agents.

2.5.8. The Supplier shall ensure that printing/colour on all packing and paper inserts should be without any smudges, missing or poor print quality, misaligned printing etc.

2.5.9. The Goods shall be stored and transported within the temperature range as detailed in the stability studies.

2.5.10. The Supplier shall ensure temperature monitoring is used throughout the full logistics arrangements. This may include but is not limited to:

- Transportation
- Warehousing
- Storage facilities

2.5.11. Temperature records to be made available to the Authority, as part of the delivery documentation.

#### **Pallet requirement**

2.5.12. The Supplier shall comply with UK standard pallet dimensions (120cm x 100cm).

2.5.13. The Supplier shall ensure that pallet does not exceed a total height of 140cm per pallet when fully loaded and ready for transit. The total height includes the pallet base, the cartons, and pallet wrapping.

2.5.14. The Supplier shall ensure the pallet does not exceed a weight of 500kg (unless explicit permission is given by the Authority on a case-by-case basis).

2.5.15. The Supplier shall ensure that the pallet is made from dry heat treated (ISPM15) wooden pallets, free from contaminants.

2.5.16. The Supplier shall ensure the pallet stackable to a maximum of 2 pallets without impairing the structural integrity of the Order Packaging or damaging the Components within the Packaging.

#### **Regulatory checklist**

2.5.17. The Supplier shall ensure that a mandatory regulatory checklist outlined in Annex C is to be completed prior to product delivery.

#### **Performance requirements**

2.5.18. The Supplier shall ensure timely delivery of the Goods in accordance with the Delivery section of this Order Form.

2.5.19. The Supplier shall deliver the Goods to the level of the manufactured specifications as sold by the Supplier to the Authority.

2.5.20. The Supplier shall ensure conformance with the Product Specification in Annex B.

2.5.21. The Supplier shall provide proof of delivery of the Goods to be supplied in accordance with this Order Form.

#### **Inspection and Quality Control**

2.5.22. The Goods are required to pass relevant quality control and functional/sterility tests, protocols for which are determined, and findings assessed by Authority, or a third party appointed by the Authority to act on its behalf.

2.5.23. The quality control and related inspections will be conducted at the point of manufacture before gaining approval to leave the factory. Functionality/Sterility checks will be done in the UK post-delivery. Supporting certifications such as certificate of analysis for each lot, detailing results of sterility testing, pH, appearance, and functional performance tests shall be provided.

2.5.24. The Authority shall produce report summarising the findings and results will be shared with the Supplier.

[Redacted] or quality control testing shall

**Defect definitions**

2.5.26. Critical Defects [Redacted]

2.5.27. Major Defects [Redacted]

2.5.28. Minor Defects [Redacted]

**Test Performance Requirements**

2.5.29. The Supplier shall ensure the Goods meet all performance claims in the IFU from sample collection to downstream processes.

2.5.27. The Supplier shall ensure that the sensitivity and specificity of the tests must comply with the values stated in the IFU or be supported by validated performance data provided by the manufacturer if different.

**(2.6) Contract monitoring arrangements:**

2.6.1. The Authority's Contract Manager (or their delegate) and Supplier's Contract Manager shall meet weekly (or such other frequency as reasonably requested by the Authority) to discuss the Supplier's performance and other matters connected to the delivery of the Contract.

**(2.7) Management information and meetings:**

2.7.1. At the Authority's request, within five (5) Working Days of such request, the Supplier shall provide such management information to the Authority as the Authority may reasonably requests from time to time (including without limit any information about the Supplier's supply chain and its compliance in relation to sustainability requirements). The Contract Managers shall meet no less than monthly to discuss the operation of this Contract.

2.7.2. Contract management meeting will be set up to monitor the following:

- a) Delivery schedules,
- b) Invoicing,
- c) Production/manufacture date,
- d) Batch expiry date,
- e) Batch number,
- f) Proof of delivery,
- g) Certificate of analysis/testing,
- h) Quality in the Goods and any manufacturing Defeats along with remedies and root cause analysis,
- i) Regulatory status of the Goods,
- j) Discuss such other matters as the Parties may consider appropriate

**3. CONFIDENTIAL INFORMATION (if applicable)**

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

- Supplier pricing.
- Contact details including, but not limited to, email addresses, landline / mobile phone numbers, etc. of Supplier representatives
- Contact details including, but not limited to, email addresses, landline / mobile phone numbers, etc. of Authority's representatives

**(3.2) Duration that the information shall be deemed 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.

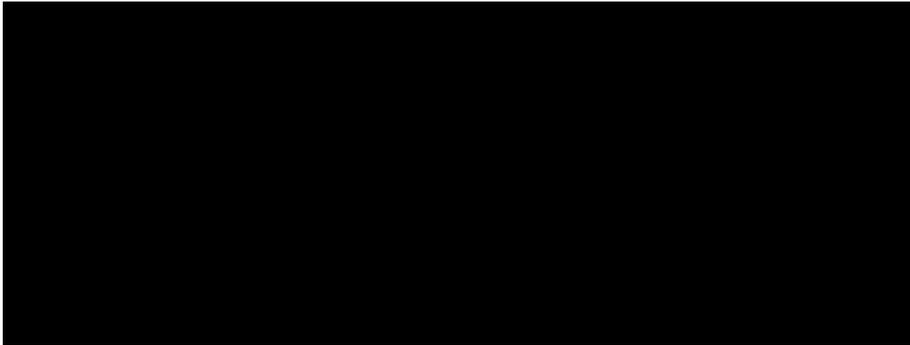
**4. DATA PROCESSING (if applicable)**

**(4.1) Personal Data to be processed by the Supplier:** In accordance with the Data Protection Protocol.

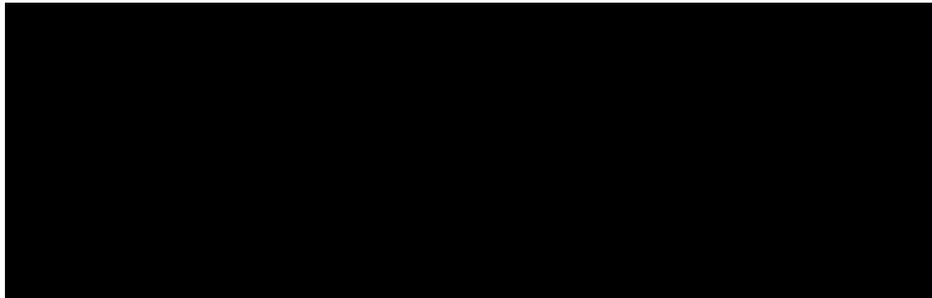
**5. LEASE / LICENSE (if applicable)**

**(5.1) The Authority is granting the following lease or licence to the Supplier:** Not applicable.

National Microbiology Framework Schedule 7 - Ordering Procedure, Award Criteria and Order Form

	
Date Signed: 23/12/25	

**For and on behalf of the Supplier**

	
Date Signed: 23.12.2025	



unique PO  
an invoice.

1.3. The Supplier shall provide an invoice to the Authority for all Goods delivered to the Authority.

1.4. All invoices must be sent for approval and shall include the proof of delivery to the Authority's designated finance mailbox e-mail: [payables@ukhsa.gov.uk](mailto:payables@ukhsa.gov.uk) and their agreed representative before being submitted for payment.

1.5. The Supplier shall provide compliant invoices that include, as a minimum, a valid PO number, PO line item number (if applicable), PO line description, and the details (name and telephone number) of the Authority's authorised representative. Non-compliant invoices will be sent back to the Supplier, which may lead to a delay in a payment.

1.6. In support of Goods delivered, the Supplier shall provide to the Authority a signed delivery note confirming receipt of the Goods at the Authority's nominated Premises and Locations.

1.7. Supplier queries regarding payment must be forwarded to the Authority's Accounts Payable section by email to: [payables@ukhsa.gov.uk](mailto:payables@ukhsa.gov.uk).

### Annex B Specification

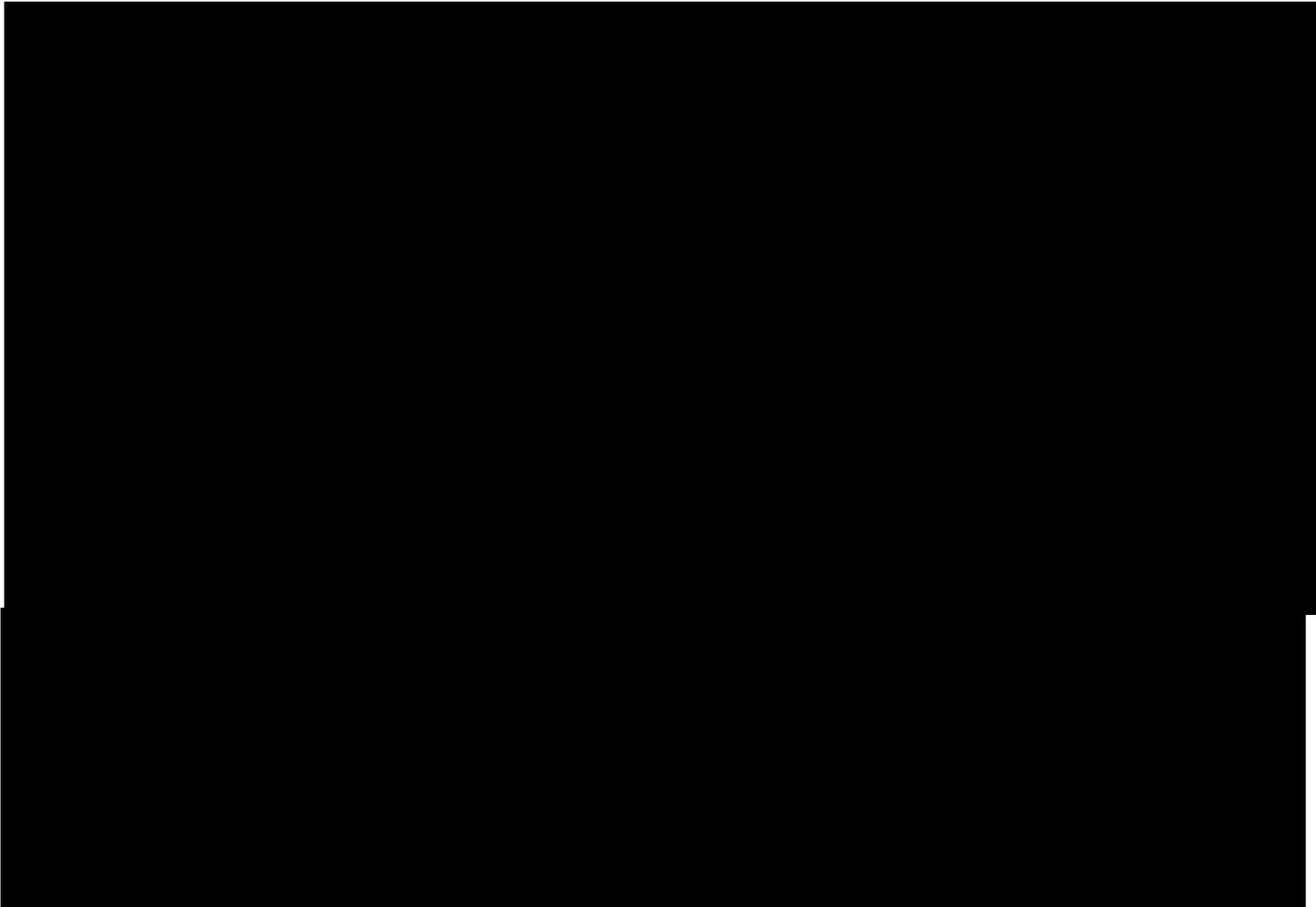
				
Hologic ISO 13485 Cert_MD 784806_Eff	Registration Confirmation Letter	TFS-00020 Attachment 23 AW-	TFS-00020 Attachment 22-3 LBL	TFS-00020 Attachment 22-4 AW
				
TFS-00020 Attachment 22-1 LBLE	ENHANCED_SPECIM TRANSPORT_ME	TFS-00020 Part H Attachment 20 VAR-	QCR-00572_003_01. pdf	TFS-00020 Part L Attachment 1 - DHM
				
TFS-00020 Part E - Attachment 1 - RSK-	DHM-12161_001_01 (1).pdf	2.g.2_SOP-Puritan Sterilization Process	Swab_Sterilization_ Safety_Doc_1021202	RespDirect Sole letter UKHSA 0

**1. Product Overview:**

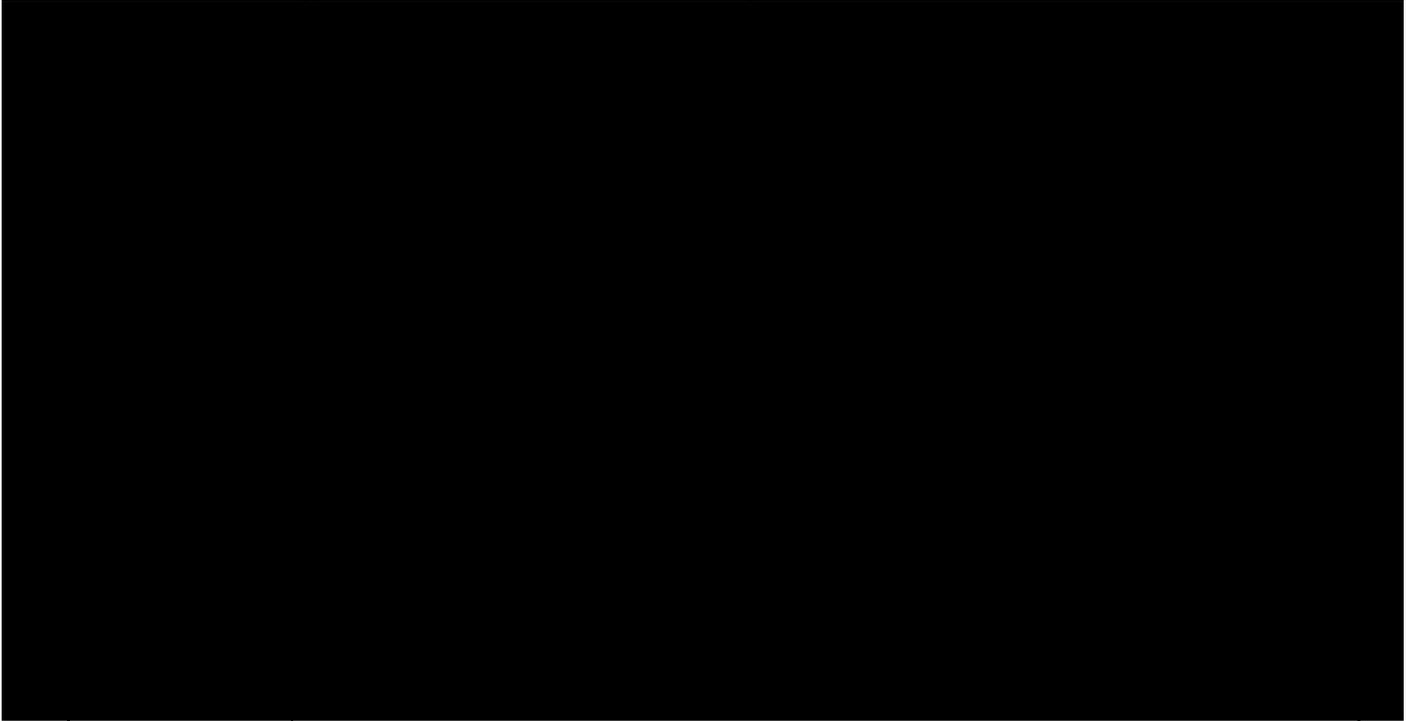
Product Name:	RespDirect Collection Kit
Product Code:	PRD-07403
Product description:	Collection Kit
Kit components:	Sterile swab and tube filled with transport medium

**2. Product/kit components:**

**NB: Please insert extra sections if you kit may contain multiple manufactures or versions for the same component. E.g. more than one swab type, extraction tube manufacture or inner test box manufacturer.**



National Microbiology Framework Schedule 7 - Ordering Procedure, Award Criteria and Order Form

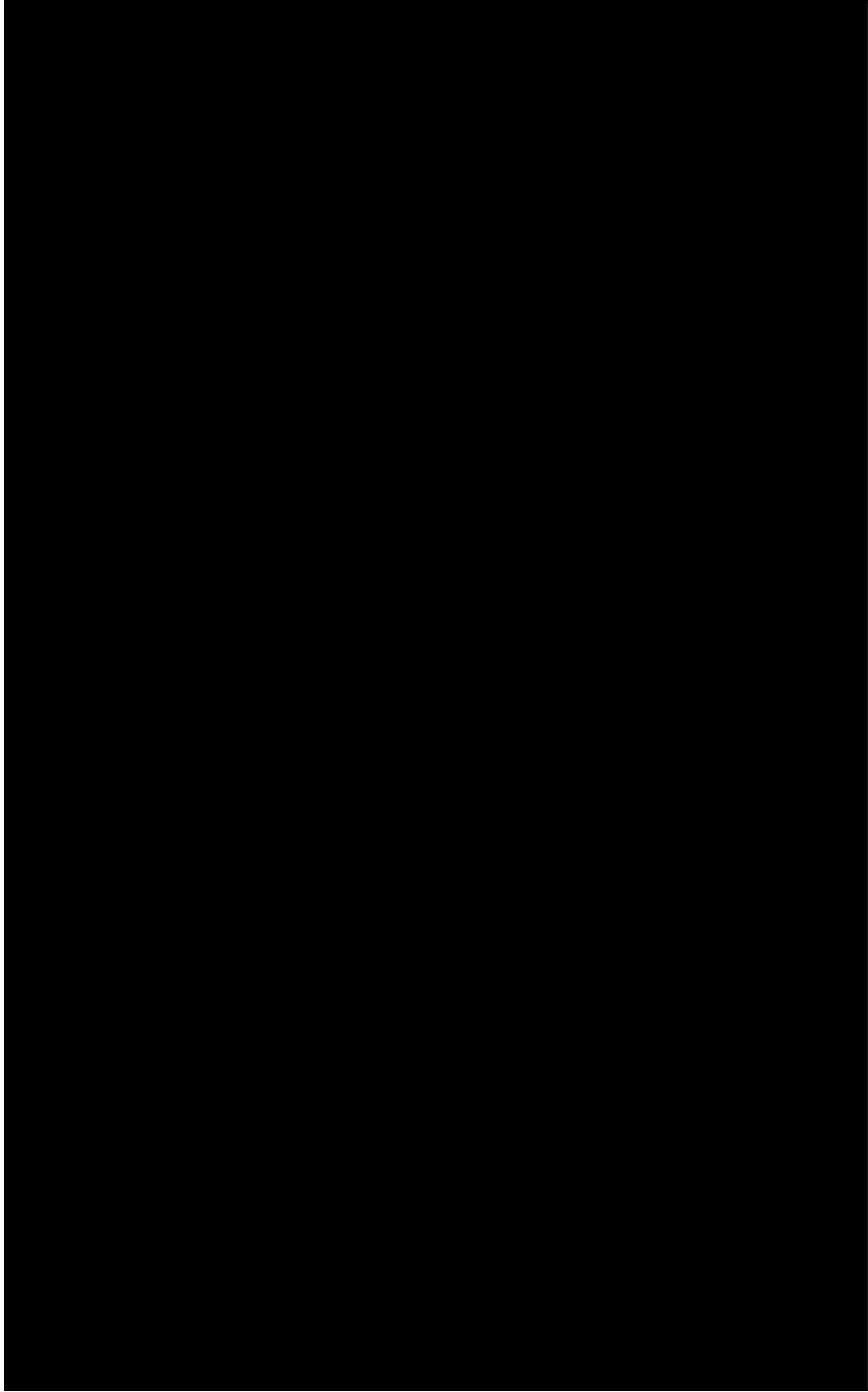


	<b>10. Artwork/Technical diagram of swab label (including dimensions):</b>

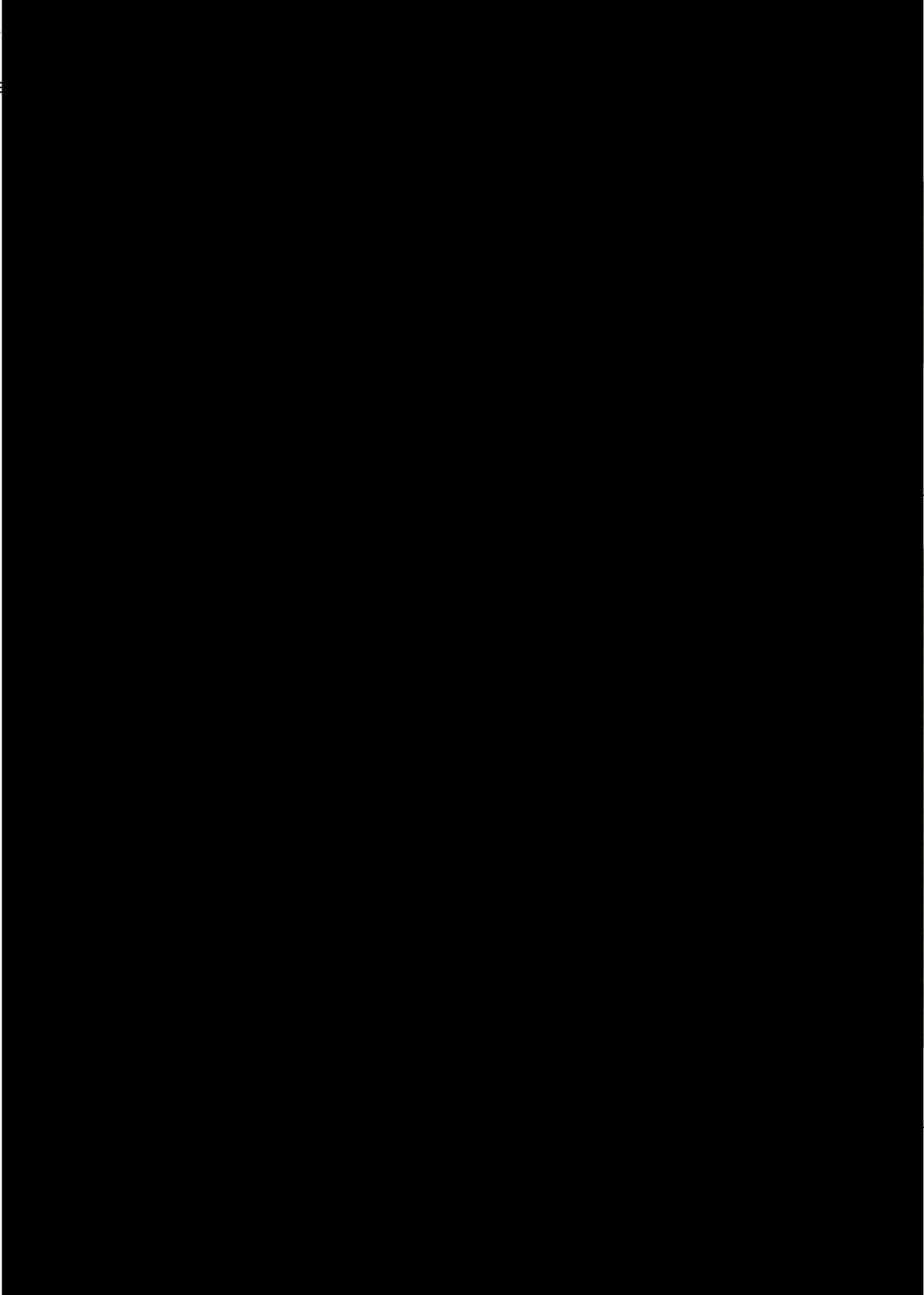
<b>2. Tube</b>	

National Microbiology Framework Schedule 7 - Ordering Procedure, Award Criteria and Order Form

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Nationa



National Microbiology Framework Schedule 7 - Ordering Procedure, Award Criteria and Order Form



**12. If applicable, image of labelling on tube sealing foil: N/A**

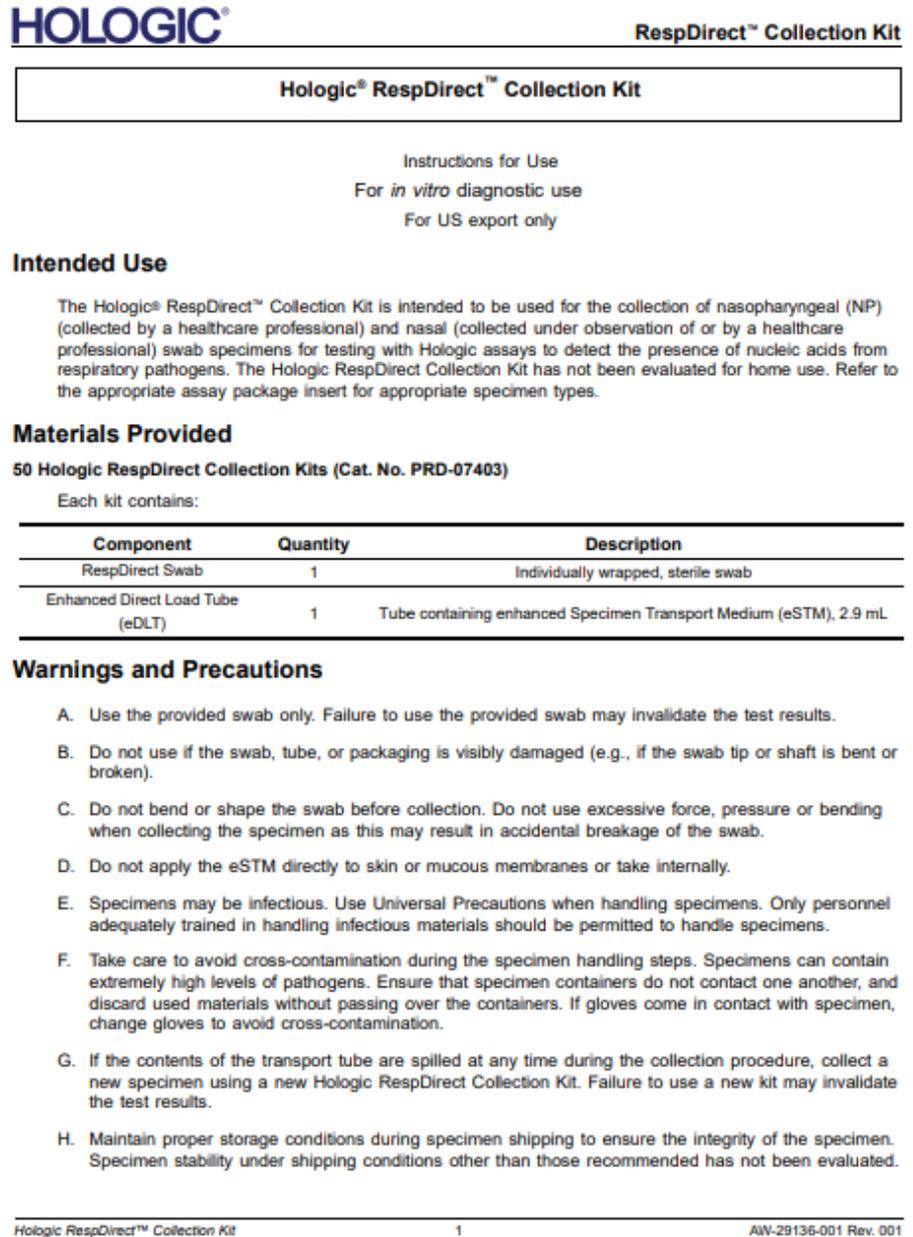
**13. If applicable, artwork/technical diagram for tube sealing foil: N/A**

**14. Shelf life from manufacture date: 24 months**

**4. Instructions for use (IFU)\***

**1. IFU Version number:** AW-29136-001, Rev.001

**2. Image of IFU front page:**



**3. Number per kit:** N/A

**3. Product packaging:**

<b>Packaging</b>	<b>Information:</b>
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National Microbiology Framework Schedule 7 - Ordering Procedure, Award Criteria and Order Form

<b>1. Internal packaging</b>	<b>1. Manufacturer:</b> [REDACTED]
	<b>2. Dimensions:</b>
	Length / mm: 255mm
	Height / mm: 25mm
	Width / mm: 55mm
	Weight (filled with contents) / g: 11.05-12.5g
<b>3. Inner packaging materials:</b> Oriented Polypropylene	
<b>4. Images of inner packaging:</b>	
	
<b>5. Image of inner packaging with complete contents:</b>	
	

National Microbiology Framework Schedule 7 - Ordering Procedure, Award Criteria and Order Form



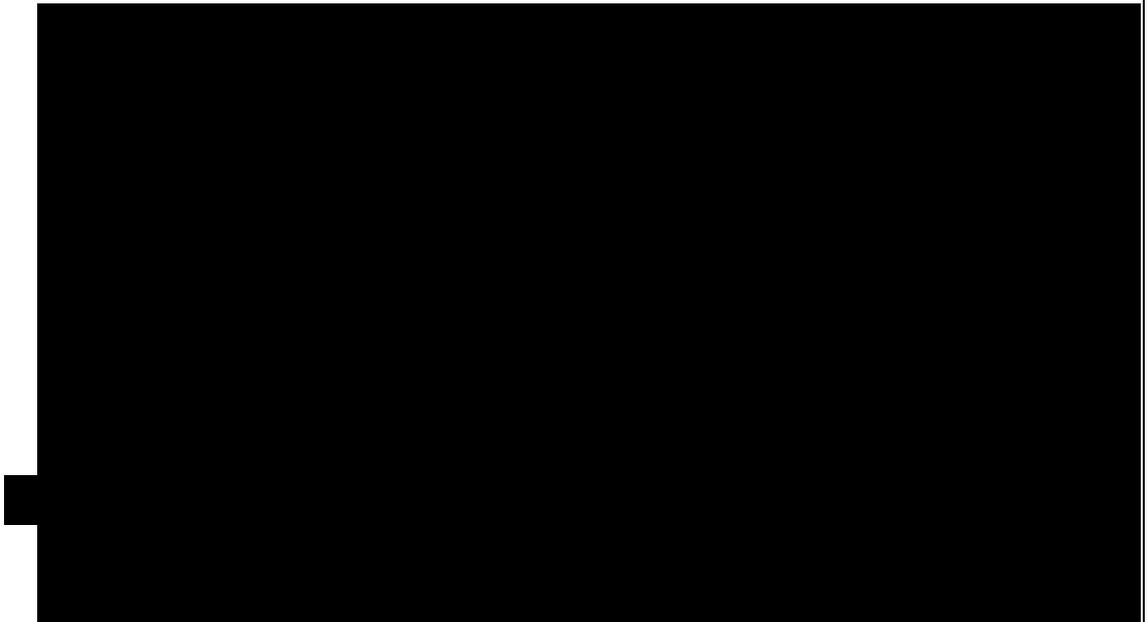
**7. Artwork/Technical diagram of the inner packaging (including dimensions):**

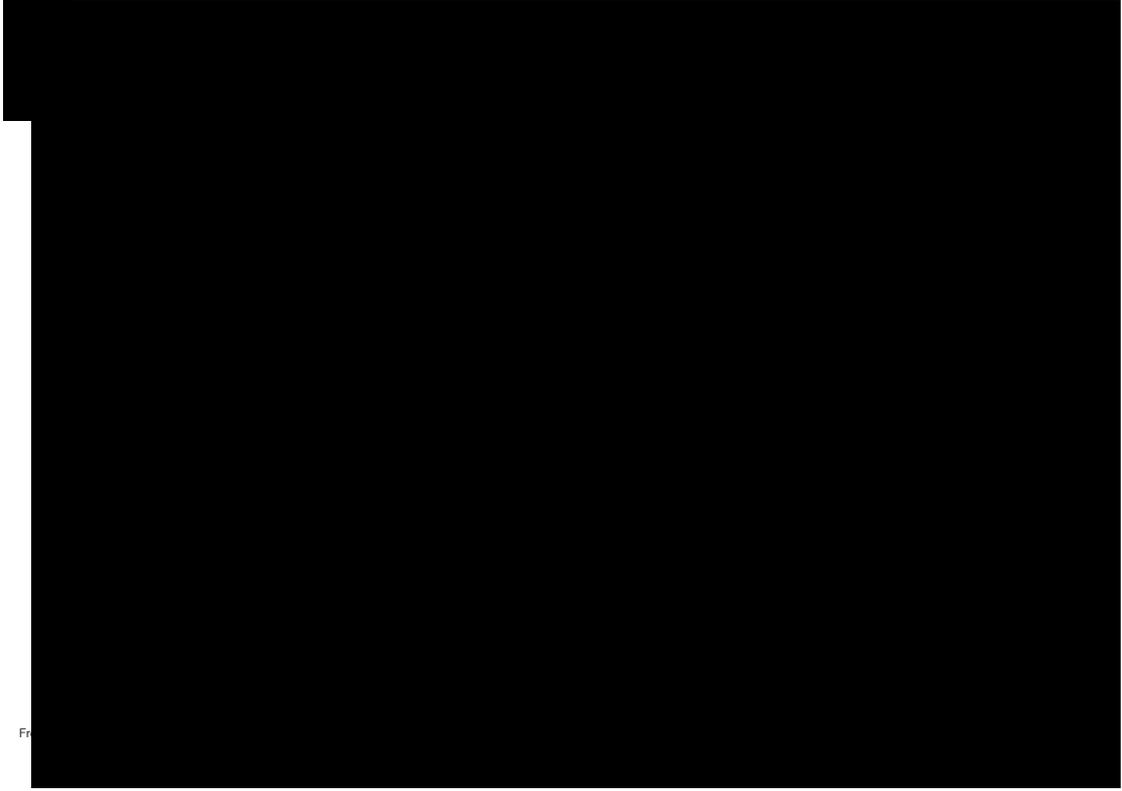
**2. Outer carton**

- 1. Manufacturer:** [REDACTED]
- 2. Dimensions:**
  - Length / mm: 240.483mm
  - Height / mm: 112.713mm
  - Width / mm: 269.875mm
  - Weight (filled with contents) / g: 723.1-782.6g
- 3. Number of Inner Test boxes per Carton: 10**
- 4. Carton materials:** Cardboard
- 5. Images of outer carton:**



**6. Artwork/Technical diagram of the outer carton (including dimensions):**



	<p><b>7. Artwork/Technical diagram of the outer carton label (including dimensions):</b></p> 
<p><b>3. Pallet configuration</b></p>	<p><b>1. Dimensions:</b></p>
	<p>Length / mm: 609.6mm</p>
	<p>Height / mm: 304.8mm</p>
	<p>Width / mm: 508mm</p>
	<p>Weight (filled with contents) / g: 44565.45g</p>
	<p><b>2. Number of cartons per pallet:</b></p>
	<p><b>3. Configuration of cartons per pallet:</b></p>
	<p>Wide:</p>
	<p>Deep:</p>
	<p>High:</p>
<p><b>4. Images of stacked pallet:</b></p>	
<p><b>5. Artwork/Technical diagram of the pallet (including dimensions):</b></p>	

National Microbiology Framework Schedule 7 - Ordering Procedure, Award Criteria and Order Form

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**Annex C Regulatory checklist**



RACUW008 RACU  
Supplier Onboarding



RACUW007  
Regulatory Review Ch

## Annex D Delivery Schedule

### Production and Delivery Schedule

1. Manufacturing - The Supplier shall manufacture one batch [REDACTED]  
[REDACTED]
2. Transport and Repackaging - Upon completion of inspection and accept of the batch by the Authority, the Supplier shall arrange transport to the United Kingdom and repackaging to the Authority's specified pallet size, ensuring delivery by 31 March 2026.
3. Delivery Split - The Authority shall indicate the preferred number of shipments and delivery dates on the Purchase Order.
4. Lots to be available for inspection as follows:
  - Lot #1 available for inspection March 4
  - Lot #2 available for inspection March 9
  - Lot #3 available for inspection March 12
  - Lot #4 available for inspection March 16