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Attachment 1 - Medicspot Testing Overview

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Attachments Requested in the Self-Declaration Form

The self declaration form asks to upload multiple attachments to evidence that the criteria is being met. Links are embedded throughout the body of this document to make reference to the evidence easier. However, for ease of use an attachment schedule has been provided underneath too:

Question	**Reference/Link/Attachment**
Questions 13 to 25 (details of medical director and healthcare scientist)	Section 1 - this document
35. Please provide evidence of independent validation of the test devices, completed in the past 18 months	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/889330/Rapid_assessment_Novacyt_Primerdesign_Coronavirus__COVID-19__Genesig.pdf https://drive.google.com/file/d/1J7f1x5OBVirLd0m3eHevft2iOoD9ZRcH/view?usp=sharing
38. A display view of your PHE data reporting system	https://drive.google.com/file/d/189h1-eNCVNvTbAwZ60YNO0HsCWQkpCDI/view?usp=sharing
39. An example output of your PHE data reporting system	https://drive.google.com/file/d/1niDPApvgogVGWNokd_Hhsk82rlUkYNhs/view?usp=sharing
40. An example of an audit trail from the PHE data reporting system	https://drive.google.com/file/d/1YITJSM40ZKFU7RhpxhAI9c7YtN5E3OgS/view?usp=sharing
41. An example of your booking page to evidence that all required fields are captured	https://drive.google.com/file/d/1Ui_YyAui1OH-EerNwr9EOZV6OcEyrkBC/view?usp=sharing
43. A display view of your adverse incident reporting system	https://drive.google.com/file/d/1ftoMWWZb4BD09PrbhMnyF7d1sdF9NWEP/view?usp=sharing
44. An example output of your adverse incident reporting system	https://drive.google.com/file/d/1Ul3uVzP2Z-GCcmzLnCNcJ9uQZU5tG19t/view?usp=sharing
45. An example of an audit trail from adverse incident reporting system	https://drive.google.com/file/d/195I-PfvAJaJ8O8dxPvOWEPOyca8KgHZI/view?usp=sharing
57. Please provide an example of your organisation's notifications for a positive, negative and unclear test result	https://drive.google.com/file/d/1KWA5hhtGL2nyUP1ytRgXCWTqF6gFrL8m/view?usp=sharing

Background

Medicspot (Medic Spot Limited) is a Covid19 testing provider. Medicspot is approved by DHSC and listed as a private provider of Covid19 tests for both the general population and test to release (TTR). Medicspot is CQC registered and is an applicant to UKAS with Accreditation number 22183 under ISO 15189 and ISO22870. Medicspot is up to date with UKAS and has passed Round 2 review as of February 2021.

Medicspot has previously supplied all the required information as part of it's own self-declaration and the UKAS accreditation process - a summary of which is included in this document.

Scope of this Document

This document is written to help retailers with self-declaration for private Covid19 testing when reselling Medicspot swabs through their sales channels. In addition, it acts as a reference for DHSC to allow retailers to apply to resell Medicspot PCR swabs in an efficient manner.

Retailers are distributors of Medicspot's Covid19 testing kits and only sell these test kits to customers. Sampling, analysis and results reporting is performed wholly by Medicspot.

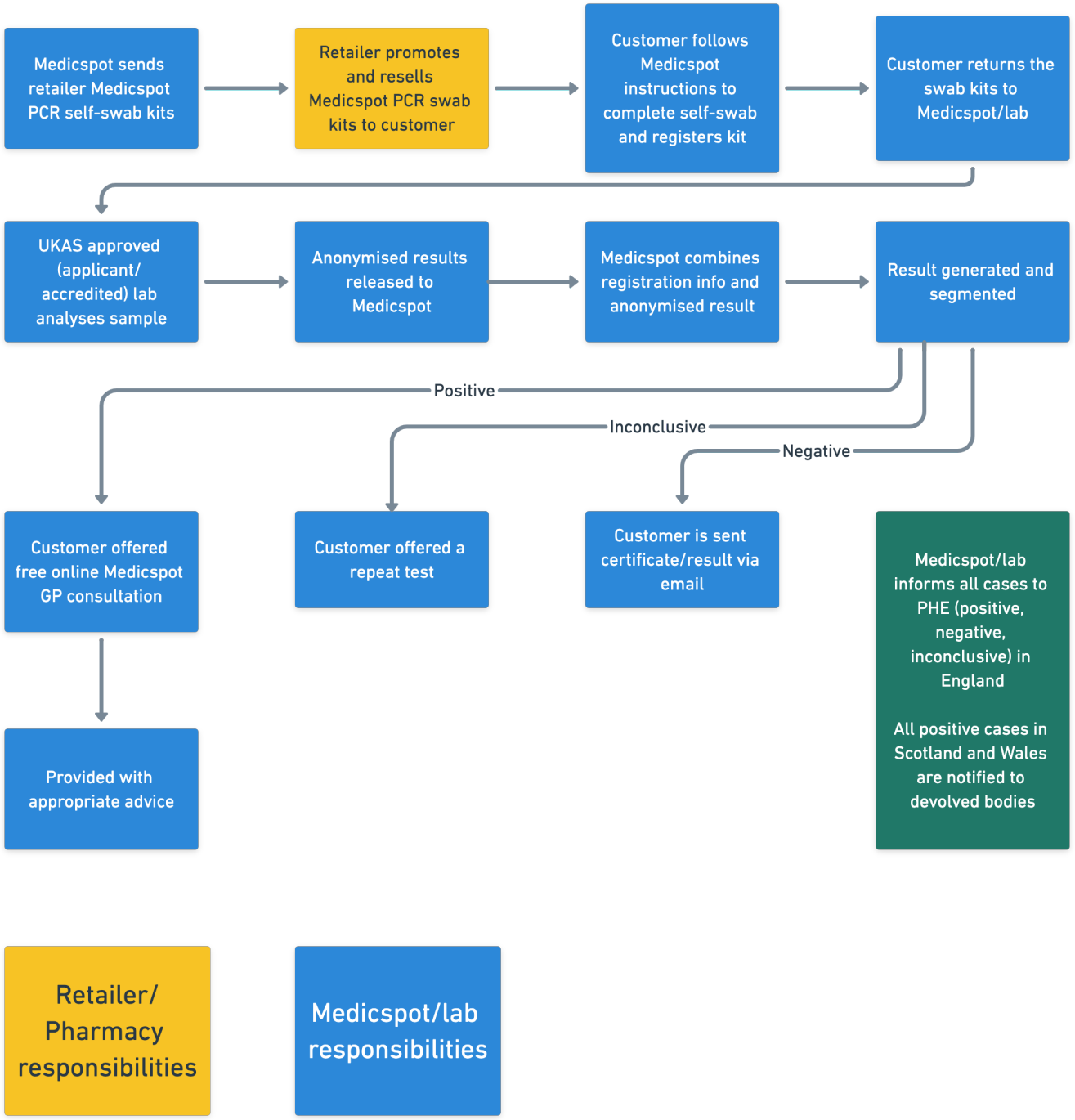
How to Use This Document

This document consists of sections - each of which generally follows a particular ordered section of the self-declaration form found at https://support-covid-19-testing.dhsc.gov.uk/PrivateSectorSelfDeclaration

The Process

As can be seen, Medicspot or its labs are responsible for the full end-to-end service. The only interaction the retailer has with the testing process is at the point of sale to the customer (yellow). Following this step of making the sale and handing the swab kit to the customer, Medicspot and/or its lab partners are fully responsible for the Covid19 PCR testing service (blue).

Medicspot believes that due to the relatively ‘low touch; input of the retailer; Medicspot is responsible for the end-to-end service delivery of Covid19 testing - with the exception of the initial sale to customer.



Section 1 - Requirement of Clinical/Medical Director or equivalent and Healthcare Scientist

The retailer has access to Medicspot's clinical support team by phoning Medicspot's dedicated pharmacy support line on 0208 1546 955 or by emailing covid@medicspot.co.uk. The Covid19 clinical support team is led by a GP Medical Director and a Biomedical Healthcare Scientist with details below:

Medical Director

Name: Dr Johnson D'Souza
Role title: Medical Director
Email: johnson@medicspot.co.uk
Telephone: 0208 1546 955
Relevant Clinical Regulatory Body/Council: General Medical Council (GMC)
Relevant Clinical Regulatory Body/Council Registration Number: 6057293

Healthcare Scientist

Name: Aneela Arshad
Role title: Biomedical Healthcare Scientist
Email: aneela.arshad@medicspot.co.uk
Telephone: 0208 1546 955
Relevant Clinical Regulatory Body/Council: Health and Care Professions Council (HCPC)
Relevant Clinical Regulatory Body/Council Registration Number: BS62005

Section 2 - Device CE Marking, Alignment to DHSC MHRA TPP Scope for General Testing and Test to Release

Testing/laboratory analysis is subcontracted by Medicspot to a UKAS ISO 17025/15189 accredited laboratory who are listed as a private provider of Covid19 testing and is in the process for UKAS Covid19 testing accreditation.

The tests performed by the laboratory are CE marked.
Novacyt Primerdesign Coronavirus (COVID-19) genesig Real-Time PCR assay

The performance of the test reflects a published TPP and the tests meet our requirements due to the following evidence:
https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/coronavirus-covid-19-serology-and-viral-detection-testing-uk-procurement-overview

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/889330/Rapid_assessment_Novacyt_Primerdesign_Coronavirus__COVID-19__Genesig.pdf

https://drive.google.com/file/d/1J7f1x5OBVirLd0m3eHevft2iOoD9ZRcH/view?usp=sharing

Test to Release

Independent validation within last 18 months:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/889330/Rapid_assessment_Novacyt_Primerdesign_Coronavirus__COVID-19__Genesig.pdf

https://drive.google.com/file/d/1J7f1x5OBVirLd0m3eHevft2iOoD9ZRcH/view?usp=sharing

Medicspot swabs are suitable to use on all age groups.

Section 3 - Public Health England Reporting & Data Collection

Medicspot works with its laboratories to report positive, negative and inconclusive results to PHE (and to appropriate devolved bodies in Scotland and Wales)

Evidence for questions 38, 39, 40 and 41 can be found at:
https://drive.google.com/drive/folders/1mZw5cutKJeUVJDXznBDIak45pejA_w61?usp=sharing

Section 4 - Relevant Systems in Place to Report Adverse Test Incidents

Medicspot uses the Yellow Card reporting System to report adverse test incidents externally.

Evidence for questions 43, 44 and 45 (screenshots demonstrating a walk through) can be found at:
https://drive.google.com/drive/folders/1zTebJmjT96xyIunfEVeSajcc78_e1UC3?usp=sharing

Medicspot Serious Incident Reporting Policy:
https://docs.google.com/document/d/1YZmkw8oEklSKCBuUt_TEc9OAu4lttnY9507ee8FOtDQ/edit?usp=sharing

Section 5 - UKAS Accreditation, Sampling and Clinical Governance

Medicspot provides self-swabs to retailers in addition to performing sampling activities (administered swabs). Medicspot is working towards UKAS ISO 15189 and ISO 22870 and has submitted evidence to UKAS (Round 2) demonstrating that minimum sampling criteria and competencies are being met in addition to clinical governance activities. Evidence can be seen at:

SOP: Performing a Combined Nasopharyngeal Swab for Covid-19 RT-PCR Test covering sample collection, transport, packaging and storage-
https://docs.google.com/document/d/1Hw9LHwnXWN_ToqCedcWjBuKWuYO5KZNh0EMu99TW8gI/edit?usp=sharing

Training document with embedded links:
https://docs.google.com/document/d/1_-P9h_fYxDM4WoPMv4OBCy3l3EZbXvL5Tz4zXWtgOjQ/edit?usp=sharing

(Self-swab sample taking)
https://drive.google.com/drive/folders/1jDegh_uJL65HQiu2ECy1wR9x17jBYPQM?usp=sharing

Further details on clinical governance policies and protocols available upon request.

Retailer's are involved in PCR lab-based testing only insofar that they sell PCR test kits which are then handled by Medicspot as per the flow (figure 1).

Section 6 - Date of Issue with Self Isolation and Test to Release

Medicspot has processes in place to comply with Test to Release standards including providing a reference number at time of booking and ensuring that tests can only be booked after the 5th day of arrival from a non-exempt country or territory.

Evidence of 5 day rule and booking ref number:
https://docs.google.com/document/d/1HTBAfvpEyEYPvVJ5ysU-GkXCq0weyeQvVK-I078bPYE/edit?usp=sharing

Example TTR Result Certificates (Positive, Negative, Inconclusive):
https://drive.google.com/file/d/1KWA5hhtGL2nyUP1ytRgXCWTqF6gFrL8m/view?usp=sharing

These certificates are emailed to the user. Medicspot confirms that it will provide the following information to a police constable upon request:

- An arrival's passport number or travel document reference number
- An arrival's test result
- The date on which an arrival took their test
- The date on which the test result was notified or made available to the arrival

Medicspot complies with the 'sub-contractors' requirements as per this document

- Requirement for a Medical Director and Healthcare Scientist
- Requirement for system of clinical governance
- Requirement to report data to PHE
- Requirement for systems in place to report adverse test incidents
- Requirement to be an applicant, to have reached appraisal status or to be accredited to the relevant ISO standard
- Requirement to only administer the test on or after the 5th full day after the traveller has departed from a non-exempt country, territory or region
- Requirement to provide results within 24 hours and in a set format

Section 7 - Data Protection and Self-Declaration

The retailer does not require to collect any personal identifiable data (PID) on the customer in order to resell Medicspot PCR test swabs. All PID is stored and processed by Medicspot.

If you require any further information, please contact covid@medispot.co.uk