[F1SCHEDULE 2A

Regulation 4(8A), (9) and (13A)

Testing

Textual Amendments

F1 Sch. 2A inserted (15.12.2020) by The Health Protection (Coronavirus, International Travel) (England) (Amendment) (No. 26) Regulations 2020 (S.I. 2020/1337), regs. 1, **2(7)** (as amended by S.I. 2020/1517, regs. 1(3), **5(2)**)

Application of this Schedule

1. A person who is required by regulation 4(2) to self-isolate ("P") may undertake an appropriate test in the circumstances described in paragraph 4 for the purposes of determining whether they may cease self-isolating (as provided for in regulation 4(13A)).

Appropriate tests

2.—(1) A test is an "appropriate test" where—

(a) it is a test for the detection of coronavirus,

(b) the manufacturer of any device used for the purposes of the test states that the device has—

(i) a sensitivity of at least 97%,

(ii) a specificity of at least 99%, and

(iii) a limit of detection of less than or equal to 1000 SARS-CoV-2 copies per millilitre,

(c) any device used for the purposes of the test—

(i) can be put into service in accordance with Part 4 of the Medical Devices Regulations 2002, other than solely by virtue of regulation 39(2) of those Regulations,

(ii) has been validated no more than 18 months before the test is administered or provided to P,

(iii) is suitable to be used to administer or provide a test to a person of P's age,

(d) it is not a test provided or administered under the National Health Service Act 2006, the National Health Services (Wales) Act 2006, the National Health Service (Scotland) Act 1978, or the Health and Personal Social Services (Northern Ireland) Order 1972, and

(e) the test provider complies with paragraph 3.

(2) For the purposes of sub-paragraph (1)—

(a) "device" means an in vitro diagnostic medical device within the meaning given in regulation 2(1) of the Medical Devices Regulations 2002,

(b) "sensitivity", in relation to a device, means how often the device correctly generates a positive result,

(c) "specificity", in relation to a device, means how often the device correctly generates a negative result,

(d) "validated", in relation to a device, means confirmed as having a sensitivity of at least 97% and a specificity of at least 99% for at least 150 positive samples and 250 negative samples, by—

(i) the Secretary of State,

(ii) the National Institute for Health and Care Excellence[F2], or

(iii) a laboratory which is accredited by the United Kingdom Accreditation Service[F3] ("UKAS") to ISO standard 15189 or ISO/IEC standard 17025[F4], other than a laboratory which processes tests provided by the test provider for the purposes of this Schedule or is owned by the test provider.

Textual Amendments

F2 A body corporate established under section 232 of the Health and Social Care Act 2012 (c. 7).

F3 The United Kingdom Accreditation Service is a company limited by guarantee incorporated in England and Wales under number 3076190.

F4 ISO standards are published in Geneva by the International Organisation for Standardisation, and are available on their website (www.iso.org) or at ISO Central Secretariat, International Organization for Standardization (ISO), 1 rue de Varembé, Case postale 56, CH-1211, Geneva 20, Switzerland. ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories was published in November 2017.

Test providers

3.—(1) A test provider complies with this paragraph where—

(a) they provide appropriate tests in a single end-to-end testing service (whether or not they arrange with another person ("X") for X to provide one or more elements of the service on their behalf),

(b) they have made a declaration to the Department of Health and Social Care that they meet the minimum standards for private sector-provided testing at https://support-covid-19-testing.dhsc.gov.uk/PrivateSectorSelfDeclaration,

(c) in relation to a test which requires laboratory processing—

(i) the person responsible for the taking of samples meets the relevant requirements for accreditation to ISO standard 15189[F5] or ISO/IEC standard 17025[F4], in respect of the taking of samples, and

(ii) the laboratory used by the test provider for the processing of samples meets the relevant requirements for accreditation to ISO standard 15189 or ISO/IEC standard 17025[F4], in respect of the processing of samples,

(d) in relation to a point of care test, they meet the relevant requirements for accreditation to ISO standard 15189[F6] and ISO standard 22870[F7],

(e) a registered medical practitioner has oversight and approval of medical practices undertaken by the test provider, and responsibility for reporting medical issues,

(f) they have an effective system of clinical governance in place which includes appropriate standard operating procedures in relation to the carrying out of appropriate tests,

(g) a registered clinical scientist has oversight of clinical practices undertaken by the test provider, and responsibility for reporting clinical issues,

(h) they have systems in place to identify any adverse incidents or quality control issues in relation to appropriate tests and be able to report them as soon as reasonably practicable to the Secretary of State,

(i) they administer or provide an appropriate test to P, no earlier than the end of the fourth day after the day on which P last departed from or transited through a non-exempt country or territory, having received the information required by paragraph 4(b) and (c) (as appropriate), and

(j) if they arrange with another person ("X") for X to carry out any element of the single end-to-end testing service on their behalf, the test provider ensures that X complies with any of paragraphs (c) to (i) and 5(2), (3) and (5) as is relevant to the carrying out of that element.

(2) For the purposes of sub-paragraph (1)—

(a) "point of care test" means a test processed outside a laboratory environment,

(b) "registered clinical scientist" means a person registered as a clinical scientist with the Health and Care Professions Council pursuant to article 5 of the Health Professions Order 2001,

(c) "single end-to-end testing service" means a service which comprises accepting the booking from the person to be tested, collecting and processing the sample to be tested, and providing the test result to P.

(3) For the purposes of sub-paragraph (1)(c) and (d), a person or laboratory (as the case may be) meets the relevant requirements for accreditation to a standard where that person, or in the case of a laboratory where the person who is the operator of the laboratory—

(a) has made a valid application for accreditation to UKAS ("stage one"), and

(b) complies with the requirements of sub-paragraph (4) where relevant.

(4) The requirements of this sub-paragraph are that—

(a) in the case of a person who completed stage one—

(i) before 15th December 2020 and who is carrying out a test after 18th January 2021,

(ii) on or after 15th December 2020 and who is carrying out a test after whichever is the later of—

(aa) 18th January 2021, and

(bb) the date four weeks after the date on which they completed stage one,

they have complied with the requirements published by UKAS in relation to accreditation to that standard at http://www.ukas.com/C19-Stage2-UKAS-Appraisal ("stage two"),

(b) in the case of a person who completed stage two—

(i) on or before 18th January 2021 and who is carrying out a test on or after 1st July 2021,

(ii) after 18th January 2021 and who is carrying out a test on or after whichever is the later of—

(aa) 1st July 2021, and

(bb) the date four months after the date on which they completed stage two,

they are accredited by UKAS to that standard.

Textual Amendments

F4 ISO standards are published in Geneva by the International Organisation for Standardisation, and are available on their website (www.iso.org) or at ISO Central Secretariat, International Organization for Standardization (ISO), 1 rue de Varembé, Case postale 56, CH-1211, Geneva 20, Switzerland. ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories was published in November 2017.

F5 ISO standards are published in Geneva by the International Organisation for Standardisation, and are available on their website (www.iso.org) or at ISO Central Secretariat, International Organization for Standardization (ISO), 1 rue de Varembé, Case postale 56, CH-1211, Geneva 20, Switzerland. ISO 15189 Medical Laboratories requirements for quality and competence was published in November 2012.

F6 ISO 15189 Medical Laboratories requirements for quality and competence was published in November 2012.

F7 ISO 22870 Point-of-care testing (POCT) requirements for quality and competence was published in November 2016.

Required circumstances for undertaking testing

4. The circumstances mentioned in paragraph 1 are that—

(a) P undertakes the test on or after the fifth day after the day on which P last departed from or transited through a non-exempt country or territory,

(b) subject to paragraphs (c) and (d), at the time the test is booked P notifies the test provider that P wishes to undertake the test for the purposes of determining whether they may cease self-isolating under these Regulations, and provides the test provider with—

(i) their full name,

(ii) their sex,

(iii) their date of birth,

(iv) their NHS number (if known and applicable),

(v) their ethnicity,

(vi) their home address, and the address or addresses at which they intend to self-isolate in accordance with regulation 4 while in England (if different),

(vii) the date of their arrival in the United Kingdom,

(viii) their coach number, flight number or vessel name (as appropriate),

(ix) the date on which they last departed from or transited through a non-exempt country or territory,

(x) the country or territory they were travelling from when they arrived in the United Kingdom, and any country or territory they transited through as part of that journey,

(xi) their email address,

(xii) their telephone number,

(xiii) their passport number, or travel document reference number (as appropriate),

(c) where P is a child, or a person with a disability who is unable for that reason to provide the notification and information set out in paragraph (b) to the test provider—

(i) the notification and information set out in paragraph (b), other than in paragraph (b)(xi) and (xii), is provided to the test provider on P's behalf by another person ("X"), and

(ii) either the information set out in paragraph (b)(xi) and (xii) is provided by X to the test provider or, where appropriate, X provides their own telephone number and email address to the test provider,

(d) at the time the test is booked the test provider gives P a test reference number and, where appropriate, also provides that test reference number to X.

Notification of test results

5.—(1) Sub-paragraphs (2) to (6) apply to a test provider who administers or provides an appropriate test to P in the circumstances described in paragraph 4.

(2) The test provider must, within 24 hours of the result becoming available—

(a) notify P or, where paragraph 4(c) applies, X by email, letter, or text message, of the result of P's test, or

(b) make P's test result available to P, or to X where paragraph 4(c) applies, via a secure web portal,

in accordance with sub-paragraph (3).

(3) The notification of P's test result must include P's name, date of birth, passport number, or travel document reference number (as appropriate), the name and contact details of the test provider and P's test reference number, and must be conveyed using one of the following forms of words, as appropriate—

Form A: negative test result

Your coronavirus test result is negative. You did not have the virus when the test was done. If you are self-isolating as an international arrival you may stop self-isolating.

You should self-isolate if:

- you get symptoms of coronavirus (you should get an NHS coronavirus test and self-isolate until you get the results)
- you are going into hospital (self-isolating until the date you go in)
- someone you live with tests positive
- you have been traced as a contact of someone who tested positive

For advice on when you might need to self-isolate and what to do, go to www.nhs.uk/conditions/coronavirus-covid-19 and read 'Self-isolation and treating symptoms'.

It is a legal requirement to self-isolate when you arrive in the UK from a non-exempt country, territory or region. If you are contacted by the enforcement authorities or the police after you have received this negative result please show them this notification.

Form B: positive test result

Your coronavirus test result is positive. You had the virus when the test was done.

If you have not had symptoms of coronavirus, you must self-isolate for 10 days from your test date. If you have symptoms of coronavirus, you must self-isolate for 10 days from the day your symptoms started, if earlier than when you took your test.

People you live with or are travelling with should also self-isolate for 10 days from the day you took the test.

You may be contacted for contact tracing and to check that you, and those who you live or are travelling with, are self-isolating.

You must not travel, including to leave the UK, during self-isolation.

Contact 111 if you need medical help. In an emergency dial 999.

Form C: unclear test result

Your coronavirus test result is unclear. It is not possible to say if you had the virus when the test was done. You must, by law, continue self-isolating for the remainder of your self-isolation period as an international arrival travelling to the UK from a non-exempt country, territory or region. You may be contacted to check that you are self-isolating. If you want to shorten your self-isolation period you will need to take another test for international arrivals. For more information, go to https://www.gov.uk/guidance/coronavirus-covid-19-test-to-release-for-international-travel.

(4) The test provider must, on request, provide a constable or any other person employed in or for the purposes of any police force, with—

(a) P's passport number, or travel document reference number (as appropriate),

(b) P's test result,

(c) the date on which P undertook the test,

(d) the date on which the test result was notified or made available to P or X in accordance with sub-paragraphs (2) and (3).

(5) Where—

(a) regulation 4 or 4A of the Health Protection (Notification) Regulations 2010 applies in relation to the test provider, or

(b) if the test provider arranges with another person ("X") for X to carry out any element of the single end-to-end testing service on their behalf, either of those regulations applies to X in the carrying out of that element,

the regulation applies as if it required the information described in sub-paragraph (6) to be included in the notification to Public Health England.

(6) The information mentioned in sub-paragraph (5) is—

(a) the date on which P last departed from or transited through a non-exempt country or territory,

(b) P's coach number, flight number or vessel name (as appropriate),

(c) the country or territory P was travelling from when P arrived in the United Kingdom, and any country or territory they transited through as part of that journey,

(d) the date on which P undertook the appropriate test.**]**

Status:
Point in time view as at 15/12/2020.

Changes to legislation:
There are currently no known outstanding effects for the The Health Protection (Coronavirus, International Travel) (England) Regulations 2020 (revoked), SCHEDULE2A.