SCHEDULES

SCHEDULE 10

Regulation 9(16)

Optional testing after arrival in England

Application of this Schedule

1. A person who is required by regulation 9(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 9(16)).

Commencement Information

I1 Sch. 10 para. 1 in force at 17.5.2021 at 4.00 a.m., see reg. 1(2)

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—

[F1(i) a sensitivity greater than or equal to 95% (or a 95% two-sided confidence interval entirely above 90%),**]**

[F2(ii) a specificity greater than or equal to 97% (or a 95% two-sided confidence interval entirely above 95%),**]**

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

(iv) uses an established molecular detection method;

(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;

(d) it is not a test provided or administered under the National Health Service Act 2006, the National Health Service (Wales) Act 2006 M1, the National Health Service (Scotland) Act 1978 M2, or the Health and Personal Social Services (Northern Ireland) Order 1972 M3; and

(e) the test provider complies with paragraph 3.

(2) For the purposes of sub-paragraph (1), "validated", in relation to a device, means confirmed as having the required sensitivity and specificity using at least 150 positive clinical samples and 250 negative clinical samples against a laboratory-based RT-PCR test that is itself within the performance specification of the target product profile published by the Medicines and Healthcare Products Regulatory Agency for laboratory based SARS-CoV-2 PCR tests, by—

(a) the Secretary of State;

(b) a laboratory which is accredited to ISO standard 15189 or ISO/IEC standard 17025 [M4] by—

(i) the United Kingdom Accreditation Service [M5] ("UKAS"), or

(ii) an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation ("ILAC") Mutual Recognition Arrangement [M6] or the European co-operation for Accreditation ("EA") Multilateral Agreement [M7],

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 or the device manufacturer. [M8]; or

(c) a laboratory which is accredited by UKAS to ISO standard 15189 or ISO/IEC standard 17025 [M9], 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 or the device manufacturer.

Textual Amendments

F1 Sch. 10 para. 2(1)(b)(i) substituted (23.8.2021) by The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 7) Regulations 2021 (S.I. 2021/914), regs. 1(3), **10(2)(a)** (with reg. 12(b))

F2 Sch. 10 para. 2(1)(b)(ii) substituted (23.8.2021) by The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 7) Regulations 2021 (S.I. 2021/914), regs. 1(3), **10(2)(b)** (with reg. 12(b))

Commencement Information

I2 Sch. 10 para. 2 in force at 17.5.2021 at 4.00 a.m., see reg. 1(2)

Marginal Citations

M1 2006 c. 42.

M2 1978 c. 29.

M3 S.I. 1972/1265 (N.I. 14).

M4 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.

M5 The United Kingdom Accreditation Service is a company limited by guarantee incorporated in England and Wales under number 3076190.

M6 ILAC is an international organisation which coordinates the work of its signatory national accreditation bodies which are themselves involved in the accreditation of conformity assessment bodies, testing laboratories, and medical testing laboratories.

M7 EA is a regional organisation which coordinates the work of its signatory national accreditation bodies. EA is recognised by and works closely with ILAC.

M8 A body corporate established under section 232 of the Health and Social Care Act 2012 (c. 7).

M9 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. ISO 15189 Medical Laboratories requirements for quality and competence was published in November 2012.

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 **[**F3and the Department has confirmed in writing that it considers the provider meets those standards**]**;

[F4(ba) they continue to meet the minimum standards to which the declaration mentioned in paragraph (b) relates;**]**

(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 or ISO/IEC standard 17025, 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, 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 and ISO standard 22870 M10;

(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, on or after the fifth day after the day on which P arrived in England 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 M11;

(c) "single end-to-end testing service" means a service which comprises accepting the booking from the person to be tested, **[**F5providing the test,**]** collecting and processing the sample to be tested, carrying out genomic sequencing and providing the test result to P.

[F6(3A) 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 the person who is the operator of the laboratory complies with the requirements of regulation 6 of the Health Protection (Coronavirus, Testing Requirements and Standards) (England) Regulations 2020 as if a reference to an applicable test were a reference to an appropriate test.**]**

Textual Amendments

F3 Words in Sch. 10 para. 3(1)(b) inserted (12.11.2021) by The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 16) Regulations 2021 (S.I. 2021/1179), regs. 1(2)(b)(3), **11(a)(i)**

F4 Sch. 10 para. 3(1)(ba) inserted (12.11.2021) by The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 16) Regulations 2021 (S.I. 2021/1179), regs. 1(2)(b)(3), **11(a)(ii)**

F5 Words in Sch. 10 para. 3(2)(c) inserted (24.10.2021 at 4.00 a.m.) by The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 16) Regulations 2021 (S.I. 2021/1179), regs. 1(2), **11(b)**

F6 Sch. 10 para. 3(3A) substituted for Sch. 10 para. 3(3)(4) (29.6.2021) by virtue of The Health Protection (Coronavirus, Testing Requirements and Standards) (England) (Amendment) Regulations 2021 (S.I. 2021/682), regs. 1(1), **3(4)**

Commencement Information

I3 Sch. 10 para. 3 in force at 17.5.2021 at 4.00 a.m., see reg. 1(2)

Marginal Citations

M10 ISO 22870 Point-of-care testing (POCT) requirements for quality and competence was published in November 2016.

M11 S.I. 2002/254.

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 arrived in England;

(b) subject to sub-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 9 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 category 2 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);

[F7(xiv) information as to whether or not P has received a vaccine against SARS-CoV-2.**]**

F8(ba) . . . . . .

(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) F9... to the test provider—

(i) the notification and information set out in paragraph (b) F10..., 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 and payment made the test provider gives P a test reference number in the format specified in sub-paragraph (e) and, where appropriate, also provides that test reference number to X;

(e) a test reference number must consist of 12 characters comprising 5 letters followed by 7 digits.

Textual Amendments

F7 Sch. 10 para. 4(b)(xiv) inserted (19.7.2021 at 4.00 a.m.) by The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 6) Regulations 2021 (S.I. 2021/865), regs. 1(2), **19(a)** (with reg. 23)

F8 Sch. 10 para. 4(ba) omitted (30.8.2021 at 4.00 a.m.) by virtue of The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 9) Regulations 2021 (S.I. 2021/966), regs. 1(2), **17(2)(a)**

F9 Words in Sch. 10 para. 4(c) omitted (30.8.2021 at 4.00 a.m.) by virtue of The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 9) Regulations 2021 (S.I. 2021/966), regs. 1(2), **17(2)(b)(i)**

F10 Words in Sch. 10 para. 4(c)(i) omitted (30.8.2021 at 4.00 a.m.) by virtue of The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 9) Regulations 2021 (S.I. 2021/966), regs. 1(2), **17(2)(b)(ii)**

Commencement Information

I4 Sch. 10 para. 4 in force at 17.5.2021 at 4.00 a.m., see reg. 1(2)

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, **[**F11within 48 hours of the time when the sample taken for the purposes of the test is received by the diagnostic laboratory**]**—

(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—

[F12Form A: negative test result

Your coronavirus (COVID-19) test result is negative. You did not have the virus when the test was done. If you are self-isolating as an international arrival from a non-red country, region or territory, who was subject to a 10 day isolation period on entry, you may stop self-isolating.

You should self-isolate again if you get symptoms of coronavirus (COVID-19) – get an NHS coronavirus (COVID-19) test from https://www.gov.uk/get-coronavirus-test and self-isolate until you get the results.

For advice on when you might need to self-isolate and what to do, go to https://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-red list country, territory or region if you do not meet eligibility criteria to remove the requirement to self-isolate. 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 the day after 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.

F13…

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 **[**F14a non-eligible international arrival**]** travelling to the UK from an **[**F15non-red list**]** 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 from **[**F15non-red list**]** countries, territories or regions. 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 M12 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 **[**F16the United Kingdom Health Security Agency**]**.

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

(a) the date on which P last departed from or transited through a category 2 country or territory;

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

F17(ba) . . . . . .

(bb) P's passport number or travel document number (as appropriate);

(bc) the test reference number given to P in accordance with sub-paragraph (d) of paragraph 4 (required circumstances for undertaking testing);

(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;

(e) the fact that the test is an appropriate test for the purposes of this Schedule.

[F18(f) whether or not P has received a vaccine against SARS-CoV-2.**]**

Textual Amendments

F11 Words in Sch. 10 para. 5(2) substituted (21.9.2021) by The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 9) Regulations 2021 (S.I. 2021/966), regs. 1(4)(f), **17(3)(a)**

F12 Sch. 10 para. 5(3) form A substituted (4.10.2021 at 4.00 a.m.) by The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 13) Regulations 2021 (S.I. 2021/1107), regs. 1(2), **24(2)(a)**

F13 Words in Sch. 10 para. 5(3) form B omitted (4.10.2021 at 4.00 a.m.) by virtue of The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 13) Regulations 2021 (S.I. 2021/1107), regs. 1(2), **24(2)(b)**

F14 Words in Sch. 10 para. 5(3) form C substituted (4.10.2021 at 4.00 a.m.) by The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 13) Regulations 2021 (S.I. 2021/1107), regs. 1(2), **24(2)(c)(i)**

F15 Words in Sch. 10 para. 5(3) form C substituted (4.10.2021 at 4.00 a.m.) by The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 13) Regulations 2021 (S.I. 2021/1107), regs. 1(2), **24(2)(c)(ii)**

F16 Words in Sch. 10 para. 5(5) substituted (1.10.2021) by The Public Health England (Dissolution) (Consequential Amendments) Regulations 2021 (S.I. 2021/974), regs. 1(1), **8(3)**

F17 Sch. 10 para. 5(6)(ba) omitted (30.8.2021 at 4.00 a.m.) by virtue of The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 9) Regulations 2021 (S.I. 2021/966), regs. 1(2), **17(3)(b)**

F18 Sch. 10 para. 5(6)(f) inserted (19.7.2021 at 4.00 a.m.) by The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 6) Regulations 2021 (S.I. 2021/865), regs. 1(2), **19(b)** (with reg. 23)

Commencement Information

I5 Sch. 10 para. 5 in force at 17.5.2021 at 4.00 a.m., see reg. 1(2)

Marginal Citations

M12 S.I. 2010/659; regulation 4 was amended by S.I. 2013/235, 2020/1175, 2020/764, 2021/150 and regulation 4A was inserted by S.I. 2020/1175.

Status:
Point in time view as at 12/11/2021.

Changes to legislation:
There are currently no known outstanding effects for the The Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021, SCHEDULE 10.