[F1SCHEDULE 2A

[F1[F1Optional testing] after arrival in England]

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)**)

F1 Sch. 2A heading substituted (15.1.2021 at 4.00 a.m.) by The Health Protection (Coronavirus, Pre-Departure Testing and Operator Liability) (England) (Amendment) Regulations 2021 (S.I. 2021/38), regs. 1(2), **3(7)(a)** (with reg. 4)

F1 Words in Sch. 2A heading substituted (15.2.2021 at 4.00 a.m.) by The Health Protection (Coronavirus, International Travel) (England) (Amendment) (No. 7) Regulations 2021 (S.I. 2021/150), regs. 1(1), **18(a)** (with reg. 23)

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[F2] or ISO/IEC standard 17025[F3], 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[F3], 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[F4] and ISO standard 22870[F5],

(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

F2 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.

F3 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.

F4 ISO 15189 Medical Laboratories requirements for quality and competence was published in November 2012.

F5 ISO 22870 Point-of-care testing (POCT) requirements for quality and competence was published in November 2016.

Status:
Point in time view as at 29/03/2021. This version of this provision has been superseded.

Changes to legislation:
There are currently no known outstanding effects for the The Health Protection (Coronavirus, International Travel) (England) Regulations 2020 (revoked), Paragraph 3.