

[^{F1}SCHEDULE 2A

[^{F1}[^{F1}Optional 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)

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—
 - [^{F2}(i) a sensitivity greater than 95% (with 95% two-sided confidence interval entirely above 90%);]
 - [^{F3}(ii) a specificity greater than 95% (with 95% two-sided confidence interval entirely above 90%);]^{F4}...
 - (iii) a limit of detection of less than or equal to 1000 SARS-CoV-2 copies per millilitre,
[^{F5}and]
[uses an established molecular detection method,]
 - ^{F6}(iv)
 - (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,
 - ^{F7}(iii)
 - (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)—
- ^{F8}(a)
 - ^{F9}(b)
 - ^{F10}(c)
 - (d) “validated”, in relation to a device, means confirmed as having [^{F11}the required sensitivity and specificity using at least 150 positive clinical samples and 250 negative clinical

Status: Point in time view as at 15/02/2021. This version of this provision has been superseded.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 2. (See end of Document for details)

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—

- (i) the Secretary of State,
- (ii) the National Institute for Health and Care Excellence^{F12}, or
- (iii) a laboratory which is accredited by the United Kingdom Accreditation Service^{F13} (“UKAS”) to ISO standard 15189 or ISO/IEC standard 17025^{F14}, 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 [^{F15}or the device manufacturer].]

Textual Amendments

- F2** Sch. 2A para. 2(1)(b)(i) 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(c)** (with [reg. 23](#))
- F3** Sch. 2A para. 2(1)(b)(ii) 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(d)** (with [reg. 23](#))
- F4** Word in Sch. 2A para. 2(1)(b)(ii) omitted (15.2.2021 at 4.00 a.m.) by virtue of [The Health Protection \(Coronavirus, International Travel\) \(England\) \(Amendment\) \(No. 7\) Regulations 2021 \(S.I. 2021/150\)](#), regs. 1(1), **18(e)(i)** (with [reg. 23](#))
- F5** Word in Sch. 2A para. 2(1)(b)(iii) inserted (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(e)(ii)** (with [reg. 23](#))
- F6** Sch. 2A para. 2(1)(b)(iv) inserted (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(e)(iii)** (with [reg. 23](#))
- F7** Sch. 2A para. 2(1)(c)(iii) omitted (15.2.2021 at 4.00 a.m.) by virtue of [The Health Protection \(Coronavirus, International Travel\) \(England\) \(Amendment\) \(No. 7\) Regulations 2021 \(S.I. 2021/150\)](#), regs. 1(1), **18(e)(iv)** (with [reg. 23](#))
- F8** Sch. 2A para. 2(2)(a) omitted (15.1.2021 at 4.00 a.m.) by virtue of [The Health Protection \(Coronavirus, Pre-Departure Testing and Operator Liability\) \(England\) \(Amendment\) Regulations 2021 \(S.I. 2021/38\)](#), regs. 1(2), **3(7)(b)** (with [reg. 4](#))
- F9** Sch. 2A para. 2(2)(b) omitted (15.1.2021 at 4.00 a.m.) by virtue of [The Health Protection \(Coronavirus, Pre-Departure Testing and Operator Liability\) \(England\) \(Amendment\) Regulations 2021 \(S.I. 2021/38\)](#), regs. 1(2), **3(7)(b)** (with [reg. 4](#))
- F10** Sch. 2A para. 2(2)(c) omitted (15.1.2021 at 4.00 a.m.) by virtue of [The Health Protection \(Coronavirus, Pre-Departure Testing and Operator Liability\) \(England\) \(Amendment\) Regulations 2021 \(S.I. 2021/38\)](#), regs. 1(2), **3(7)(b)** (with [reg. 4](#))
- F11** Words in Sch. 2A para. 2(2)(d) 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(e)(v)** (with [reg. 23](#))
- F12** A body corporate established under section 232 of the [Health and Social Care Act 2012 \(c. 7\)](#).
- F13** The United Kingdom Accreditation Service is a company limited by guarantee incorporated in England and Wales under number 3076190.
- F14** 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.

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F15 Words in Sch. 2A para. 2(2)(d)(iii) inserted (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(e)(vi)** (with reg. 23)

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