STATUTORY INSTRUMENTS

2021 No. 914

The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 7) Regulations 2021

Amendment of Schedule 8

9.—(1) Schedule 8 (mandatory testing after arrival in England) is amended as follows.

(2) In sub-paragraph (2)(c)(ii) of paragraph 6 (day 2 tests: general test requirements), for the words "greater than" to the end substitute "greater than or equal to 99% (or a 95% two-sided confidence interval entirely above 97%),".

(3) In sub-paragraph (1)(g)(ii) of paragraph 7 (day 2 tests: private provider requirements)—

(a) at the end of paragraph (bb), omit "and";

(b) at the end of paragraph (cc), insert—

"; and

(dd) the test reference number given to P in accordance with sub-paragraph (5) of paragraph 10 (required circumstances for undertaking a day 2 test or a day 8 test)".

(4) In paragraph 8 (day 8 tests: general test requirements)—

(a) for sub-paragraph (2) substitute—

"(2) A test complies with this sub-paragraph where—

(a) it is a semi-quantitative test for the detection of coronavirus which—

(i) targets a minimum of two distinguishable SARS-CoV-2 genes other than the S gene and performance reference controls,

(ii) includes routine in silico assurance against every variant of concern, and

(iii) produces a test solution that provides extracted nucleic acid that is suitable for whole genome sequencing using a specified method;

(b) it is, in relation to a Schedule 11 passenger, a test that can be self-administered;

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

(i) uses an established molecular detection method,

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

(iii) has a sensitivity greater than or equal to 95% (or a 95% two-sided confidence interval entirely above 90%),

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

(v) is suitable for identifying every variant of concern; and

(d) 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(**1**), other than solely by virtue of regulation 39(2) of those Regulations, and

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

(b) for sub-paragraph (3) substitute—

"(3) For the purposes of sub-paragraph (2)—

(a) "specified method" means a targeted sequence method specific to SARS-CoV-2 or an equivalent—

(i) amplicon method, or

(ii) sequence bait capture method;

(b) "validated", in relation to a device, has the meaning given by paragraph 2(2) of Schedule 10;

(c) "variant of concern" means a variant of SARS-CoV-2 identified in a designation made by the Secretary of State for the purposes of this paragraph and published in a manner as appears to the Secretary of State to be appropriate.".

(5) For paragraph 9 (day 8 tests: private provider requirements) substitute—

"**Day 8 tests: private provider requirements**

9.—(1) For the purposes of paragraph 8(1)(b)(iii), a private provider complies with this paragraph where—

(a) they comply with the requirements of paragraph 3(1)(a) and (e) to (h) of Schedule 10 as if any reference in those provisions to an appropriate test were a reference to a day 8 test;

(b) if the provider is a laboratory that conducts diagnostic test evaluation for testing in accordance with this Schedule, 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/InternationalTesting;

(c) they have provided the Department of Health and Social Care with a list of all organisations that they work with (whether by sub-contract or otherwise) to carry out the testing service or to carry out genomic sequencing, indicating the nature of the service that each organisation is providing, and kept that list updated as appropriate;

(d) 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;

(e) the laboratory used by the test provider for the processing of samples meets the relevant requirements for ISO standard 15189 or ISO/IEC standard 17025 in respect of the evaluation of the established molecular detection method and the genomic sequencing of samples;

(f) they receive the information required by paragraph 10(3) or (4) (as appropriate), and if they administer the test to P, they do so no earlier than the end of the seventh day after the day on which P arrived in England;

(**1**) S.I. 2002/618.

(g) each day, they notify the Secretary of State in writing of—

(i) the number of tests they sold on that day, and

(ii) in relation to each test sold on that day—

(aa) the date of the arrival in England of the person in respect of whom the test was sold,

(bb) whether the person in respect of whom the test was sold is an eligible category 2 arrival or not, and

(cc) the test reference number given to P in accordance with sub-paragraph (5) of paragraph 10 (required circumstances for undertaking a day 2 test or a day 8 test);

(h) they sequence each sample with a cycle threshold less than 30 (equivalent to ~1,000 viral genome copies per millilitre);

(i) in respect of the sequencing of samples, they must secure a reference genome coverage breadth of at least 50% and at least 30 times coverage;

(j) on a request by the Secretary of State or the COVID-19 Genomics UK Consortium, they make samples available for the purpose of dual sequencing;

(k) they preserve and transport samples in a manner that enables genome sequencing;

(l) they have in place a process to remove human reads from any data submitted in a notification to Public Health England pursuant to the Health Protection (Notification) Regulations 2010; and

(m) 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 the following so far as relevant to the carrying out of that element—

(i) paragraph 3(1)(e) to (h) of Schedule 10 as applied by paragraph (a) of this sub-paragraph,

(ii) paragraph (c) to (l) of this sub-paragraph,

(iii) paragraph 11(2), (3) and (4).

(2) For the purposes of sub-paragraph (1)(m), "single end-to-end testing service" has the meaning given in paragraph 3(2)(c) of Schedule 10.

(3) For the purposes of sub-paragraph (1)(d) and (e), 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) a reference to an applicable test were a reference to a day 8 test;

(b) a reference to a test provider were a reference to a private provider;

(c) in paragraph (1), the words from "and make a declaration" to "25th November 2020" were omitted.".

(6) In paragraph 10 (required circumstances for undertaking a day 2 test or a day 8 test)—

(a) after sub-paragraph (3), insert—

"(3A) Subject to paragraph (4) and where P is required to comply with regulation 3 (requirement on passengers to provide information), at the time the test is returned for processing P provides to the test provider the unique passenger reference number provided by or on behalf of P as described in regulation 19(18).";

(b) in sub-paragraph (4)—

(i) in the opening words, after "(3)" insert "or (3A)";

(ii) in paragraph (a), after "(3)" insert "and (3A)".

(7) In sub-paragraph (5) of paragraph 11 (notification of test results), after paragraph (b) insert—

"(ba) where P is required to comply with regulation 3, the unique passenger reference number provided by or on behalf of P as described in regulation 19(18);

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

(bc) the test reference number given to P in accordance with sub-paragraph (5) of paragraph 10 (required circumstances for undertaking a day 2 test or a day 8 test);".