
STATUTORY INSTRUMENTS

2021 No. 1179

**The Health Protection (Coronavirus, International
Travel and Operator Liability) (England)
(Amendment) (No. 16) Regulations 2021**

Amendment of Schedule 8

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

(2) In sub-paragraph (1)(d)(ii) of paragraph 1 (interpretation of this Schedule), for “7, 10 and 11” substitute “7, 7B, 10, 11 and 11A”.

(3) In the opening words of sub-paragraph (1) of paragraph 6 (day 2 tests: general test requirements), for “3J(10)” substitute “3J(10)(a)(i)”.

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

(a) at the end of paragraph (b) insert “and the Department has confirmed in writing that it considers the provider meets those standards”;

(b) after paragraph (b) insert—

“(ba) they continue to meet the minimum standards to which the declaration mentioned in paragraph (b) relates”;

(c) in paragraph (g)—

(i) at the end of sub-paragraph (i), omit “and”;

(ii) at the end of sub-paragraph (ii)(dd) insert—

“, and

(iii) in relation to each test the purchase of which was cancelled on that day, the information set out in sub-paragraph (ii)(aa) to (dd)”.

(5) After paragraph 7 insert—

“Day 2 tests: general requirements for lateral flow device tests

7A.—(1) For the purposes of regulation 3J(10)(a)(ii), a day 2 test complies with this paragraph where—

(a) it is a test provided by a public provider; or

(b) it is a test provided by a private provider where—

(i) the test complies with sub-paragraph (2); and

(ii) the private provider complies with paragraph 7B.

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

(a) it is a test for the detection of coronavirus which uses one or more of—

(i) mid-turbinate or anterior nares nasal swabbing;

(ii) tonsillar swabbing;

(iii) saliva;

- (b) it is uniquely identifiable;
- (c) it is provided in accordance with the test manufacturer's instructions for use including, in particular, instructions as to the target use, target user and target use settings; and
- (d) any device used for the purposes of the test 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.

Day 2 tests: private provider requirements for lateral flow device tests

7B.—(1) For the purposes of paragraph 7A(1)(b)(ii), a private provider complies with this paragraph where—

- (a) they comply with the requirements of paragraph 3(1)(a) and (d) to (h) of Schedule 10 (including, in relation to paragraph 3(1)(d), the requirements of paragraph 3(3A) of that Schedule) as if in those provisions—
 - (i) any reference to an appropriate test were a reference to a day 2 test;
 - (ii) the term “single end-to-end testing service” has the meaning given by sub-paragraph (2) of this paragraph;
- (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 published at gov.uk/guidance/day-2-lateral-flow-tests-for-international-arrivals-minimum-standards-for-providers on 21st October 2021 and the Department has confirmed in writing that it considers the provider meets those standards;
- (c) they continue to meet the minimum standards to which the declaration mentioned in paragraph (b) relates;
- (d) 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, indicating the nature of the service that each organisation is providing, and kept that list updated as appropriate;
- (e) 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 later than the end of the second day after the day on which P arrived in England;
- (f) they ensure that they only accept results from the first use of a device;
- (g) each day, they notify the Secretary of State in writing of—
 - (i) the number of tests they sold on that day,
 - (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 it is a polymerase chain reaction or lateral flow device, 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), and
 - (iii) in relation to each test the purchase of which was cancelled on that day, the information set out in sub-paragraph (ii)(aa) to (cc);

(h) 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)(d) to (h) of Schedule 10 as applied by paragraph (a) of this sub-paragraph;
- (ii) paragraph (c) to (g) of this sub-paragraph
- (iii) paragraph 11A(2) and (4).

(2) For the purposes of sub-paragraph (1)(h), “single end-to-end testing service” means a service which comprises any of the following elements where they are part of the service offered by the test provider—

- (a) accepting the booking from the person to be tested;
- (b) providing the test;
- (c) collecting and processing the test once it has been undertaken;
- (d) analysing the test;
- (e) verifying the test result;
- (f) providing notification of the test result.

(3) Where a private provider provides a day 2 LFD test, the Health Protection (Coronavirus, Testing Requirements and Standards) (England) Regulations 2020(2) apply to a private provider as if regulation 6(1)(b) were omitted.”

(6) In sub-paragraph (1) of paragraph 9 (day 8 tests: private provider requirements)—

- (a) at the end of paragraph (b) insert “and the Department has confirmed in writing that it considers the provider meets those standards”;
- (b) after paragraph (b) insert—
 - “(ba) they continue to meet the minimum standards to which the declaration mentioned in paragraph (b) relates;”;
- (c) in paragraph (g)—
 - (i) at the end of sub-paragraph (i), omit “and”;
 - (ii) at the end of sub-paragraph (ii)(cc) insert—
 - “, and
 - (iii) in relation to each test the purchase of which was cancelled on that day, the information set out in sub-paragraph (ii)(aa) to (cc)”.

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

- (a) in sub-paragraph (2)—
 - (i) in paragraph (a), after “undertakes the test” insert “in accordance with the manufacturer’s instructions for use”;
 - (ii) in paragraph (b), after “undertakes the test” insert “in accordance with the manufacturer’s instructions for use”;
- (b) for sub-paragraph (3) substitute—
 - “(3) Subject to sub-paragraph (4)—
 - (a) at the time the test is booked P provides the test provider with the information set out or referred to in sub-paragraph (3B), and
 - (b) where—

- (i) P’s day 2 test is a day 2 LFD test, and
- (ii) the test has not been administered—
 - (aa) by the test provider, or
 - (bb) at a site operated for the purpose of administering such tests by or on behalf of the test provider,

P provides the test provider with the information set out in paragraph (3C) within 15 minutes of the test’s read time as determined by the manufacturer’s instructions for use.
- (3B) The information to be provided at the time the test is booked is—
 - (a) notification that P is to undertake the test under these Regulations,
 - (b) the information set out in paragraph 4(b)(i) to (v) and (vii) to (xiv) of Schedule 10, and
 - (c) P’s home address, and—
 - (i) where P is a person intending to undertake a test in accordance with regulation 3J, the address or addresses at which they intend to stay while they remain in England (if different from their home address);
 - (ii) where P is a person to whom regulation 9(1)(a) or (b) applies, the address or addresses at which they intend to self-isolate, or are self-isolating, in accordance with regulation 9 (if different from their home address);
 - (iii) where P is a person to whom regulation 10 applies, the address of the accommodation designated for the purposes of Schedule 11.

(3C) The information to be provided where a day 2 LFD test is undertaken in the circumstances described in sub-paragraph (3)(b) is—

 - (a) a single photograph clearly showing—
 - (i) the test device in such a way that it is identifiable as having been provided by the test provider,
 - (ii) the test reference number given in accordance with paragraph 10(5) of Schedule 8, and
 - (iii) the test result, and
 - (b) the address at which P is able to receive a confirmatory test pursuant to regulation 3K(4A).”.
 - (c) in sub-paragraph (4)(a), for “(3)” substitute “(3B) and (3C)”;
 - (d) in sub-paragraph (5), for “a test reference number” substitute “a separate test reference number in respect of each test to be provided to P”.

(8) In sub-paragraph (1) of paragraph 11 (notification of test results), after “a test” insert “, other than a day 2 LFD test.”.

(9) After paragraph 11 insert—

“Notification of test results: lateral flow device tests

11A.—(1) This paragraph applies to a private provider who administers or provides a day 2 LFD test to P in the circumstances described in paragraph 10.

- (2) The private provider must, within 24 hours of the relevant event—
 - (a) notify P or, where paragraph 10(4) applies, Y by email, letter, or text message, of the result of P’s test; or

(b) make P’s test result available to P, or where paragraph 10(4) applies, to Y via a secure web portal,

in accordance with sub-paragraph (4).

(3) In sub-paragraph (2), “relevant event” means—

(a) where the test provider administered the test, the time at which the test provider determined the results of the test;

(b) where the test provider did not administer the test, the time at which the test provider received the information required to be provided by paragraph 10(3)(b).

(4) 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 LFD test result

Your coronavirus (COVID-19) test result is negative. You did not have the virus when the test was done.

You are not required to quarantine.

You should self-isolate again if you get symptoms of coronavirus (COVID-19) – get an NHS coronavirus (COVID-19) test from 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 www.nhs.uk/conditions/coronavirus-covid-19 and read ‘Self-isolation and treating symptoms’.

Form B: positive LFD test result

Your coronavirus test result is positive. This means that you probably have the virus.

Even if you have not had symptoms of coronavirus, you must now self-isolate for 10 days from the day after your test date.

You must obtain, take and return a free follow up PCR test from NHS Test and Trace to confirm this. You can obtain your confirmatory PCR test by visiting gov.uk/get-coronavirus-test or by calling 119. This test will be free of charge and will be sent to you as a home test kit. You must take this test in accordance with this notice. If this confirmatory test is negative, you no longer need to self-isolate.

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 LFD 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 self-isolate for 10 days from the day after your test date.

You may choose to take another test, and if comes back with a negative result, you no longer need to self-isolate. You may be contacted to check that you are self-isolating.”.

(10) In sub-paragraph (1) of paragraph 12 (charge for day 2 tests and day 8 tests), for “mandatory tests provided by a public provider” substitute “any test provided in accordance with this Schedule by a public provider”.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.
