

2021 No. 1179

PUBLIC HEALTH, ENGLAND

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

Made - - - - at 9.50 a.m. on 22nd October 2021

Laid before Parliament at 1.30 p.m. on 22nd October 2021

Coming into force in accordance with regulation 1

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 45B, 45C, 45F(2), 45P(2) and 60A of the Public Health (Control of Disease) Act 1984(a).

In accordance with section 45Q(3) of that Act, the Secretary of State is of the opinion that these Regulations do not contain any provision made by virtue of section 45C(3)(c) of the Act which imposes or enables the imposition of a special restriction or requirement or any other restriction or requirement which has or would have a significant effect on a person's rights.

Citation, commencement, extent and application

1.—(1) These Regulations may be cited as the Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 16) Regulations 2021.

(2) Except for—

- (a) paragraphs (4) and (6) of regulation 10, and
- (b) paragraph (a) of regulation 11,

these Regulations come into force at 4.00 a.m. on 24th October 2021.

(3) The provisions referred to in paragraph (2)(a) and (b) come into force on 12th November 2021.

(4) These Regulations extend to England and Wales, and apply in relation to England only.

Amendments to the Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021

2. The Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021(b) are amended in accordance with regulations 3 to 12.

(a) 1984 c. 22. Part 2A and section 60A were inserted by, respectively, section 129 and 170 of the Health and Social Care Act 2008 (c. 14).

(b) S.I. 2021/582 amended by S.I. 2021/589, 670, 731, 766, 795, 865, 914, 923, 966, 974, 1003, 1033, 1066, 1107, 1130 and 1155.

Amendment of regulation 2

3. In paragraph (1) of regulation 2 (interpretation and introduction of Schedules 1 to 4), after the definition of “cruise ship” insert—

““day 2 LFD test” means a test for coronavirus which complies with paragraph 7A of Schedule 8 and is undertaken in the circumstances described in paragraph 10 of that Schedule;”.

Amendment of regulation 3J

4.—(1) Regulation 3J (testing requirements on eligible travellers (non-workers)) is amended as follows.

(2) For paragraph (10)(a) substitute—

“(a) “day 2 test” means a test for coronavirus which complies with—

- (i) paragraph 6 (day 2 tests: general test requirements) of Schedule 8, or
- (ii) paragraph 7A (day 2 tests: general requirements for lateral flow device tests) of Schedule 8,

and is undertaken in the circumstances described in paragraph 10 of that Schedule;”.

Amendment of regulation 3K

5.—(1) Regulation 3K (self-isolation requirements on eligible travellers) is amended as follows.

(2) For paragraph (1)(b), substitute—

“(b) P or, where P is a child, an adult with responsibility for P (“R”) receives notification that the day 2 test has generated an inconclusive result, paragraph (3) applies;

(c) P or, where P is a child, R receives notification that the day 2 test has generated a positive result and—

- (i) the test is a day 2 PCR test, paragraph (4) applies;
- (ii) the test is a day 2 LFD test, paragraphs (4A) and (4B) apply.”

(3) After paragraph (4) insert—

“(4A) P must as soon as reasonably practicable undertake a confirmatory test provided by a public provider for the purposes of this paragraph.

(4B) The Self-Isolation Regulations apply to P or, where P is a child, to R, as if—

- (a) the notification of the positive result were notification from a relevant person under regulation 2A(1) of those Regulations that P has tested positive for coronavirus, and
- (b) P’s period of self-isolation begins on receipt of the notification of the positive test result and ends on the earlier of—
 - (i) the end of the 10th day after the day P undertook the day 2 LFD test;
 - (ii) the time that P is notified that the result of the confirmatory test undertaken in accordance with paragraph (4A) is negative.

(4C) For the purposes of this regulation, a person is deemed to receive notification of a result in relation to a day 2 LFD test when the person determines the result in accordance with the test manufacturer’s instructions for use.”.

(4) In paragraph (5)—

- (a) before sub-paragraph (a) insert—

“(za) “day 2 PCR test” means a test for coronavirus which complies with paragraph 6 of Schedule 8 and is undertaken in the circumstances described in paragraph 10 of that Schedule;”;

(b) after sub-paragraph (a) insert—

“(ab) “public provider” has the meaning given by paragraph 1(1)(f) of Schedule 8;”.

Amendment of regulation 18A

6.—(1) Regulation 18A (requirements on test providers) is amended as follows.

(2) In paragraph (1), after “undertake tests)” insert “, other than a day 2 LFD test,”.

(3) After paragraph (1) insert—

“(1A) A private provider who provides a day 2 LFD test must comply with the requirements set out in the following provisions of Schedule 8—

(a) paragraphs (a) to (h) of paragraph 7B(1) (day 2 tests: private provider requirements for lateral flow device tests);

(b) paragraph 10(5);

(c) paragraph 11A(2) (notification of test results: lateral flow device tests).”.

Amendment of regulation 18B

7.—(1) Regulation 18B (requirements on other persons carrying out testing services) is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (a), after “or 6,” insert “other than in relation to a day 2 LFD test;”;

(b) after sub-paragraph (a) insert—

“(ab) in relation to a day 2 LFD test, paragraph 7B(1)(h)(i) to (iii) of Schedule 8;”.

(3) For paragraph (2) substitute—

“(2) In this regulation, “single end-to-end testing service” has—

(a) for the purposes of paragraph (1)(a), (b) and (c), the meaning given by paragraph 3(2)(c) of Schedule 10;

(b) for the purposes of paragraph (1)(ab), the meaning given by paragraph 7B(2) of Schedule 8.”.

Amendment of regulation 19

8.—(1) Regulation 19 (offences and penalties) is amended as follows.

(2) In paragraph (1)(c), after “(non-workers))” insert “, 3K(4A) (confirmatory UKHSA test)”.

(3) In the opening words of paragraph (4)(b), after “(7)” insert “, 3K(4A)”.

(4) In paragraph (13B)(a), after “18A(1)” insert “, (1A)”.

Amendment of Schedule 6

9. In the opening words of paragraph 5 of Schedule 6 (passenger information), after “Where” insert “regulation 3J (testing requirements on eligible travellers (non-workers)) requires a day 2 test or”.

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(a), 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;

(a) S.I. 2002/618.

- (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](https://www.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(a) 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);

(a) S.I. 2020/1549, to which there are no relevant amendments.

(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](https://www.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”.

Amendment of Schedule 10

11. In paragraph 3 (test providers) of Schedule 10 (optional testing after arrival in England)—

(a) in sub-paragraph (1)—

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

(ii) after sub-paragraph (b) insert—

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

(b) in sub-paragraph (2)(c), after “the person to be tested,” insert “providing the test.”

Amendment of Schedule 14

12.—(1) Schedule 14 (amounts of fixed penalties) is amended as follows.

(2) In paragraph 5 (regulation 19(1)(c))—

(a) in sub-paragraph (d), after “(7), or (8)” insert “, 3K(4A)”;

(b) in sub-paragraph (e), after “(7), or (8)” insert “, 3K(4A)”.

(3) In paragraph 16B (regulation 19(13B)(a)), after “18A(1)” insert “, (1A)”.

Amendment of the Health Protection (Notification) Regulations 2010

13.—(1) The Health Protection (Notification) Regulations 2010(a) are amended as follows.

(2) In paragraph (1)(b) of regulation 4, after “SARS-CoV-2” insert “, other than a test in relation to which regulation 4B (duty to report the results of LFD tests undertaken by eligible travellers) applies,”.

(3) In paragraph (1) of regulation 4A, after “SARS-CoV-2” insert “, other than a test in relation to which regulation 4B (duty to report the results of LFD tests undertaken by eligible travellers) applies,”.

(4) After regulation 4A insert—

“Duty to notify the United Kingdom Health Security Agency of the results of lateral flow device tests undertaken by eligible travellers

4B.—(1) This regulation applies where a test provider administers or provides a test for the detection of SARS-CoV-2 in accordance with regulation 3J(10)(a)(ii) (lateral flow device tests for eligible travellers) of the Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021 (“the International Travel and Operator Liability Regulations”).

(2) The test provider must notify the United Kingdom Health Security Agency of the result of the test in accordance with paragraphs (3) to (5).

(3) A notification must be provided in writing—

(a) where the test was administered—

(i) by the test provider, or

(ii) at a site operated for the purpose of administering such tests by or on behalf of the test provider,

within 24 hours of the result being determined;

(b) where the test was administered other than in accordance with sub-paragraph (a), within 24 hours of receiving the information provided pursuant to paragraph 10(3)(b) of Schedule 8 to the International Travel and Operator Liability Regulations.

(4) A notification must include the following information, insofar as it is known to the test provider—

(a) in relation to the person who undertook the test (“P”), their—

(i) full name;

(ii) sex;

(iii) date of birth;

(iv) NHS number;

(v) ethnicity;

(vi) home address (including postcode);

(vii) the address provided to the test provider as the place where P is able to receive a confirmatory test;

(viii) telephone number and email address, where the test result is positive or indeterminate;

(b) whether or not P has received a vaccine against SARS-CoV-2;

(c) P’s passport number or travel document number (as appropriate);

(a) S.I. 2010/659, which has been amended by S.I. 2010/954, 2013/235, 2018/387, 2020/237, 674, 1175, 2021/150, 223, 442, 582, 914, 923, 966 and 974.

- (d) the coach number, flight number, or vessel name of the conveyance on which P arrived in England;
- (e) the test reference number given to P in accordance with paragraph 10(5) of Schedule 8 to the International Travel and Operator Liability Regulations;
- (f) the country or territory P was travelling from when P arrived in England, and any country or territory they transited through as part of that journey;
- (g) the date on which P undertook the test;
- (h) confirmation that the test complies, and was undertaken in accordance, with the requirements applicable under the International Travel and Operator Liability Regulations;
- (i) confirmation that the test is a lateral flow device test undertaken by an eligible traveller within the meaning of the International Travel and Operator Liability Regulations;
- (j) where the test provider did not administer the test, the date and time that the test provider received the information required to be provided by regulation 3J(7A) of the International Travel and Operator Liability Regulations;
- (k) the following information about the test—
 - (i) the name of the test provider and a description of its operations;
 - (ii) the specimen number;
 - (iii) the specimen type;
 - (iv) the specimen date;
 - (v) the test method;
 - (vi) the result;
 - (vii) the date on which the test was carried out;
 - (viii) the name of the testing equipment manufacturer.

(5) Where P is a child, or a person with a disability who is unable for that reason to provide the information set out in paragraph (4)(a) to the test provider, the test provider must provide the United Kingdom Health Security Agency with, insofar as it is known to the test provider—

- (a) the information set out in paragraph (4)(a)(i) to (vii) in relation to P, having obtained it from an appropriate parent, guardian or carer of P (“X”); and
- (b) where the test result is positive or indeterminate, X’s telephone number and email address.

(6) It is an offence for a test provider to fail without reasonable excuse to comply with this regulation.

(7) A test provider that commits an offence under this regulation is liable on summary conviction to a fine.

(8) In this regulation, “carer”, “child”, “disability”, “guardian”, and “parent” have the meanings given in regulation 4.”.

(5) In paragraph (1)(a) of regulation 7 (electronic communications), for “4ZB and 4A(3)” substitute “4ZB, 4A(3) and 4B(2)”.

At 9.50 a.m. on 22nd October 2021

Maggie Throup
Parliamentary Under Secretary of State
Department of Health and Social Care

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend, primarily, the Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021 (S.I. 2021/582) (“the International Travel Regulations”). The amendments introduce lateral flow device (“LFD”) tests for the detection of SARS-CoV-2 as an alternative to existing requirements on arrivals deemed to be “eligible travellers” to undertake day 2 polymerase chain reaction tests.

Regulations 4, 5 and 10 amend regulations 3J and 3K of, and Schedule 8 to, the International Travel Regulations to provide for the use of LFD tests, and the consequences of the results of those tests.

Regulation 6 and 7 amend regulations 18A and 18B of the International Travel Regulations to impose requirements on test providers and on others providing testing services in relation to LFD testing.

Regulations 8 and 12 amend regulation 19 of, and Schedule 14 to, the International Travel Regulations to provide for updated offences and fixed monetary penalties in connection with the LFD test obligations.

These Regulations make further minor and consequential amendments to the International Travel Regulations.

Regulation 13 amends the Health Protection (Notification) Regulations 2010 (S.I. 2010/659) (“the Notification Regulations”) to insert new regulation 4B, which imposes an obligation to notify the United Kingdom Health Security Agency of certain information in relation to LFD tests. Regulation 13 makes further minor and consequential amendments to the Notification Regulations.

An impact assessment has not been produced for this instrument. An explanatory memorandum has been published alongside this instrument at www.legislation.gov.uk.

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