
STATUTORY INSTRUMENTS

2020 No. 1175

**The Health Protection (Notification)
(Amendment) (Coronavirus) Regulations 2020**

Amendment of regulation 4 (duty to notify causative agents found in human samples)

3. In regulation 4—

(a) for the heading substitute—

*“Duty on the operators of diagnostic laboratories to notify
Public Health England of causative agents found in human
samples and of SARS-Cov-2 or influenza virus tests processed”;*

(b) in paragraph (1)—

(i) after “where the diagnostic laboratory” insert “—”;

(ii) “identifies a causative agent in a human sample” becomes sub-paragraph (a);

(iii) after sub-paragraph (a) insert—

“; or

(b) processes a test for the detection of SARS-CoV-2 and the test result is indeterminate.”;

(c) after paragraph (1) insert—

“(1A) The operator of a diagnostic laboratory must also notify Public Health England in accordance with this regulation where the diagnostic laboratory—

(a) processes a test for the detection of SARS-CoV-2 and the test result is negative or void; or

(b) processes a test for the detection of influenza virus and the test result is indeterminate, negative or void.”;

(d) in paragraph (2)—

(i) for sub-paragraph (b) substitute—

“(b) where a causative agent is identified, the details of that agent;

(ba) where the test is for the detection of SARS-CoV-2 or influenza virus, the result of the test.”;

(ii) at the end of sub-paragraph (j) omit “and”;

(iii) in sub-paragraph (k), for “which identified the causative agent.” substitute—

“; and

(l) where the result of a test for the detection of SARS-CoV-2 is positive, a telephone number and an email address—

(i) where P is a child or a person with a disability who is unable for that reason to provide the information set out in sub-paragraphs (e) to (j), for an appropriate parent, guardian or carer of that person ;

- (ii) otherwise, for P.”;
- (e) in paragraph (3) for “The notification” substitute “A notification under paragraph (1)(a) where the causative agent identified is not SARS-CoV-2”;
- (f) after paragraph (3) insert—
 - “(3A) A notification under paragraph (1A) must be provided in writing within 7 days beginning with the day on which the diagnostic laboratory becomes aware of the test result.
 - (3B) A notification under paragraph (1)(a) where the causative agent identified is SARS-CoV-2, must be provided in writing within 24 hours of the causative agent being identified.
 - (3C) A notification under paragraph (1)(b) must be provided in writing within 24 hours of the diagnostic laboratory becoming aware of the test result.”;
- (g) in paragraph (4)—
 - (i) for “paragraph (3)” substitute “paragraphs (3) and (3A)”;
 - (ii) for “the case” substitute “a particular case to which one of those paragraphs applies”;
- (h) in paragraph (7), for “paragraph (1)” substitute “paragraph (1)(a)”;
- (i) after paragraph (7) insert—
 - “(7A) For the purposes of paragraphs (1)(b) and (1A), a diagnostic laboratory processes a test where—
 - (a) the diagnostic laboratory processes the test; or
 - (b) the test is processed by another laboratory under an arrangement made with that diagnostic laboratory.”;
- (j) in paragraph (8)—
 - (i) after “applies” insert “—”;
 - (ii) “the day on which the causative agent” to the end becomes sub-paragraph (a);
 - (iii) after sub-paragraph (a) insert—
 - “(b) the time at which the causative agent is identified for the purposes of paragraph (3B), is the time at which the diagnostic laboratory became aware of the identification by the other laboratory.”;
- (k) after paragraph (8) insert—
 - “(8A) Where paragraph (7A)(b) applies—
 - (a) the day on which the diagnostic laboratory becomes aware of the test result for the purposes of paragraph (3A), is the day on which the diagnostic laboratory became aware of the result of the test processed by that other laboratory;
 - (b) the time at which the diagnostic laboratory becomes aware of the test result for the purposes of paragraph (3C), is the time at which the diagnostic laboratory became aware of the result of the test processed by that other laboratory.”;
- (l) in paragraph (11)—
 - (i) before the definition of “causative agent” insert—
 - ““carer” has the meaning given in section 10 of the Care Act 2014(1);”;
 - (ii) after the definition of “causative agent” insert—
 - ““child” has the meaning given in regulation 2(7);”;

- (iii) at the end of the definition of “director of a diagnostic laboratory” omit “and”;
- (iv) after the definition of “director of a diagnostic laboratory” insert—
 - ““disability” has the same meaning as in the Equality Act 2010(2) (see section 6 of, and Schedule 1 to, that Act);
 - “guardian” has the meaning given in section 107 of the Children and Young Persons Act 1933(3);”
- (v) at the end of the definition of “operator of a diagnostic laboratory” insert—
 - ““parent” has the meaning give in regulation 2(7).”.

(2) 2010 c. 15.

(3) 1933 c. 12, amended by paragraph 7(a) of Schedule 13 to the Children Act 1989 (c. 41), section 64 of, and Schedule 5 to, the Children and Young Persons Act 1963 (c. 37) and paragraph 1 of Schedule 7 to the Licensing Act 2003 (c. 17); there are other amending instruments, but none is relevant.