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STATUTORY INSTRUMENTS

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**2021 No. 682**

**PUBLIC HEALTH, ENGLAND**

**The Health Protection (Coronavirus, Testing Requirements and Standards) (England) (Amendment) Regulations 2021**

<i>Made</i>	- - - -	<i>7th June 2021</i>
<i>Laid before Parliament</i>		<i>8th June 2021</i>
<i>Coming into force</i>	- -	<i>29th June 2021</i>

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 45B, 45C(1) and (3)(c), 45F(2) and 45P(2) of the Public Health (Control of Disease) Act 1984<sup>(1)</sup>.

The Secretary of State considers that the requirements imposed by these Regulations are proportionate to what they seek to achieve, which is a public health response to the serious and imminent threat to public health which is posed by the incidence and spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in England.

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, and application**

1.—(1) These Regulations may be cited as the Health Protection (Coronavirus, Testing Requirements and Standards) (England) (Amendment) Regulations 2021 and come into force on 29th June 2021.

(2) These Regulations apply to England only.

**Amendments to regulation 6 of the Health Protection (Coronavirus, Testing Requirements and Standards) (England) Regulations 2020**

2.—(1) The Health Protection (Coronavirus, Testing Requirements and Standards) (England) Regulations 2020<sup>(2)</sup> are amended as follows.

(2) After paragraph (2) in regulation 6 insert paragraph (2A)—

“(2A) For the purposes of this regulation—

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(1) 1984 c. 22; Part 2A was inserted by section 129 of the Health and Social Care Act 2008 (c. 14).  
(2) S.I. 2020/1549.

- (a) a test provider who completes stage one on or before 31st December 2020 is a “first channel test provider”;
  - (b) a test provider who completes stage one on or after 1st January 2021 is a “second channel test provider”.
- (3) In paragraph (3)—
  - (a) after the word “A” insert the words “first channel”;
  - (b) omit the words from “who completes” to “31st December 2020”.
- (4) In paragraph (4)—
  - (a) after the word “A” insert the words “second channel”;
  - (b) omit the words “who completes” to “1st January 2021”.
- (5) Omit paragraphs (5) and (6) and substitute—
  - “(5A) A first channel test provider who does not achieve a positive recommendation on or before 30th June 2021 must not provide applicable tests.
  - (5B) A second channel test provider who does not achieve a positive recommendation on or before whichever is the later of—
    - (a) 30th June 2021, or
    - (b) the date four months after the date on which they completed stage twomust not provide applicable tests.
  - (5C) A test provider who does not achieve a positive recommendation by the date in paragraph (5A) or the appropriate date in paragraph (5B) (as applicable) may provide applicable tests after they have achieved a positive recommendation.
  - (6A) A first channel test provider who is not accredited by UKAS to the relevant ISO standard by 31st August 2021 must not provide applicable tests.
  - (6B) A second channel test provider who is not accredited by UKAS by the later of—
    - (a) 31st August 2021, or
    - (b) the date two months after the appropriate date in paragraph (5B)must not provide applicable tests.
  - (6C) A test provider who is not accredited by UKAS by the date in paragraph (6A) or the appropriate date in paragraph (6B) (as applicable) may provide applicable tests after they have been accredited by UKAS.”
- (6) In paragraph (7)—
  - (a) at the end of sub-paragraph (a), for “; or” substitute “.”;
  - (b) omit sub-paragraph (b).
- (7) In paragraphs (9) and (10), add “or provided” immediately after the word “administered” each time it appears.
- (8) After paragraph (11) insert—
  - “(12) In this regulation a “positive recommendation” means a written notice from UKAS which—
    - (a) reports UKAS’s assessment of the test provider’s readiness to be fully accredited, and
    - (b) informs the test provider of any actions the provider must take in order to be fully accredited,where “fully accredited” means accredited by UKAS to the relevant ISO standard.”

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

3.—(1) The Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021(3) are amended as follows.

(2) At the end of paragraph 7(3) of Schedule 8—

(a) omit “.” and insert “;”

(b) insert new sub-paragraph (c)—

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

(3) At the end of paragraph 9(3) of Schedule 8—

(a) omit “.” and insert “;”

(b) insert new sub-paragraph (c)—

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

(4) In paragraph 3 of Schedule 10, omit sub-paragraphs (3) and (4) and insert—

“(3A) For the purposes of sub-paragraph (1)(c) and (d), 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 reference to an applicable test were a reference to an appropriate test.”

7th June 2021

*Bethell*  
Parliamentary Under Secretary of State  
Department of Health and Social Care

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

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations amend the Health Protection (Coronavirus, Testing Requirements and Standards) (England) Regulations 2020 (“the Testing Requirements Regulations”). Regulation 2 introduces new steps in the process by which private providers of Covid-19 diagnostic testing must become accredited by the National Accreditation Body for the United Kingdom (UKAS) and extends the final date in the Testing Requirements Regulations by which accreditation must be completed.

Regulation 3 amends the Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021. Regulation 3(1) amends Schedule 8 to modify the application of regulation 6 of the Testing Requirements Regulations to private providers of mandatory testing after arrival in England, so that those providers only have to make one declaration of compliance to the Department. Regulation 3(2) amends Schedule 10 to apply the same accreditation process to providers of Covid-19 diagnostic testing which permits international arrivals in certain circumstances to determine whether they may cease self-isolating.

An impact assessment has not been produced for this instrument. An explanatory memorandum has been published alongside this instrument at [www.legislation.gov.uk](http://www.legislation.gov.uk).