STATUTORY INSTRUMENTS

2021 No. 150

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

Amendment to Schedule 2A

- **18.** Schedule 2A is amended as follows—
 - (a) in the heading, for "Testing" substitute "Optional testing";
 - (b) in paragraph 1 after "to self-isolate" insert "other than in accordance with Schedule B1A";
 - (c) for paragraph 2(1)(b)(i) substitute—
 - "(i) a sensitivity greater than 95% (with 95% two-sided confidence interval entirely above 90%);";
 - (d) for paragraph 2(1)(b)(ii) substitute—
 - "(ii) a specificity greater than 95% (with 95% two-sided confidence interval entirely above 90%);";
 - (e) in paragraph 2—
 - (i) in sub-paragraph (1)(b)(ii) omit "and";
 - (ii) at the end of sub-paragraph (1)(b)(iii) insert "and";
 - (iii) after sub-paragraph (1)(b)(iii) insert—
 - "(iv) uses an established molecular detection method."
 - (iv) omit sub-paragraph (1)(c)(iii);
 - (v) in the introductory words to sub-paragraph (2)(d) for the words from "a sensitivity of at least" to "250 negative samples" substitute—
 - "the required sensitivity and specificity using at least 150 positive clinical samples and 250 negative clinical samples against a laboratory-based RT-PCR test that is itself within the performance specification of the target product profile published by the Medicines and Healthcare Products Regulatory Agency(1) for laboratory based SARS-CoV-2 PCR tests";
 - (vi) in sub-paragraph (2)(d)(iii) at the end insert "or the device manufacturer";
 - (f) in paragraph 4(a), for the words "last departed" to the end substitute "arrived in England";
 - (g) in paragraph 5(3), in Form B (positive test result)—
 - (i) in the second paragraph for "your test date" substitute the day after your test date";
 - (ii) in the third paragraph for "the day you" substitute "the day after you".

⁽¹⁾ The target product profile was published on 20 January 2021 and is available at https://www.gov.uk/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work/target-productprofile-antibody-tests-to-help-determine-if-people-have-recent-infection-to-sars-cov-2-version-2