
STATUTORY INSTRUMENTS

2020 No. 1549

The Health Protection (Coronavirus, Testing Requirements and Standards) (England) Regulations 2020

Provider requirements

5.—(1) A test provider must meet the following requirements in respect of any applicable test that they provide.

(2) The test provider must ensure that a registered medical practitioner has oversight and approval of medical practices undertaken by the test provider, and responsibility for reporting medical issues.

(3) The test provider must have an effective system of clinical governance in place which includes appropriate standard operating procedures in relation to the carrying out of applicable tests.

(4) The test provider must ensure that a registered clinical scientist has oversight of clinical practices undertaken by the test provider, and responsibility for reporting clinical issues.

(5) The test provider must have systems in place to—

- (a) identify any adverse incidents or quality control issues in relation to applicable tests, and
- (b) report any such incidents or issues as soon as reasonably practicable to the Secretary of State.

(6) If the test provider arranges with another person (“X”) for X to carry out any element of the testing service on their behalf, the test provider must ensure that X complies with any provision of this regulation that is relevant to the carrying out of that element.

(7) In this regulation “registered clinical scientist” means a person registered as a clinical scientist with the Health and Care Professions Council pursuant to article 5 of the Health Professions Order 2001⁽¹⁾.

(1) [S.I. 2002/254](#). There are amendments not relevant to these Regulations.