(iii) a limit of detection of less than or equal to 1000 SARS-CoV-2 copies per millilitre, and

(iv) uses an established molecular detection method;

(c) any device used for the purposes of the test—

(i) can be put into service in accordance with Part 4 of the Medical Devices Regulations 2002, other than solely by virtue of regulation 39(2) of those Regulations,

(ii) has been validated no more than 18 months before the test is administered or provided to P;

(d) it is not a test provided or administered under the National Health Service Act 2006, the National Health Service (Wales) Act 2006(**a**), the National Health Service (Scotland) Act 1978(**b**), or the Health and Personal Social Services (Northern Ireland) Order 1972(**c**); and

(e) the test provider complies with paragraph 3.

(2) For the purposes of sub-paragraph (1), "validated", in relation to a device, means confirmed as having 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 for laboratory based SARS-CoV-2 PCR tests, by—

(a) the Secretary of State;

(b) a laboratory which is accredited to ISO standard 15189 or ISO/IEC standard 17025(**d**) by—

(i) the United Kingdom Accreditation Service(**e**) ("UKAS"), or

(ii) an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation ("ILAC") Mutual Recognition Arrangement(**f**) or the European co-operation for Accreditation ("EA") Multilateral Agreement(**g**),

other than a laboratory which processes tests provided by the test provider for the purposes of this Schedule or is owned by the test provider or the device manufacturer. (**h**); or

(c) a laboratory which is accredited by UKAS to ISO standard 15189 or ISO/IEC standard 17025(**i**), other than a laboratory which processes tests provided by the test provider for the purposes of this Schedule or is owned by the test provider or the device manufacturer.

(**a**) 2006 c. 42.

(**b**) 1978 c. 29.

(**c**) S.I. 1972/1265 (N.I. 14).

(**d**) ISO standards are published in Geneva by the International Organisation for Standardisation, and are available on their website (www.iso.org) or at ISO Central Secretariat, International Organization for Standardization (ISO), 1 rue de Varembé, Case postale 56, CH-1211, Geneva 20, Switzerland. ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories was published in November 2017.

(**e**) The United Kingdom Accreditation Service is a company limited by guarantee incorporated in England and Wales under number 3076190.

(**f**) ILAC is an international organisation which coordinates the work of its signatory national accreditation bodies which are themselves involved in the accreditation of conformity assessment bodies, testing laboratories, and medical testing laboratories.

(**g**) EA is a regional organisation which coordinates the work of its signatory national accreditation bodies. EA is recognised by and works closely with ILAC.

(**h**) A body corporate established under section 232 of the Health and Social Care Act 2012 (c. 7).

(**i**) ISO standards are published in Geneva by the International Organisation for Standardisation, and are available on their website (www.iso.org) or at ISO Central Secretariat, International Organization for Standardization (ISO), 1 rue de Varembé, Case postale 56, CH-1211, Geneva 20, Switzerland. ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories was published in November 2017. ISO 15189 Medical Laboratories requirements for quality and competence was published in November 2012.