

**EXPLANATORY MEMORANDUM TO**  
**THE HEALTH PROTECTION (CORONAVIRUS, TESTING REQUIREMENTS AND**  
**STANDARDS) (ENGLAND) REGULATIONS 2020**

**2020 No. 1549**

**1. Introduction**

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care (“DHSC”) and is laid before Parliament by Command of Her Majesty.

**2. Purpose of the instrument**

2.1 The purpose of this instrument is to ensure that all private providers offering COVID-19 testing services on a commercial basis in England provide services that are of a sufficiently high standard.

2.2 This is to be achieved by imposing requirements on such providers, including an obligation to make an application to the United Kingdom Accreditation Service (“UKAS”) accreditation scheme, which involves three stages. The final stage is a requirement to be fully accredited by UKAS to one of ISO 15189 or ISO/IEC 17025 for laboratory-based testing and ISO 15189 and ISO 22870 for point of care testing.

**3. Matters of special interest to Parliament**

*Matters of special interest to the Joint Committee on Statutory Instruments*

3.1 None.

*Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)*

3.2 This entire instrument applies to England only.

3.3 In the view of the Department, for the purposes of House of Commons Standing Order No. 83P of the Standing Orders of the House of Commons relating to Public Business, the subject-matter of this instrument would not be within the devolved legislative competence of any of: the Northern Ireland Assembly as a transferred matter; the Scottish Parliament; or the Welsh Parliament, if equivalent provision in relation to the relevant territory were included in an Act of the relevant devolved legislature.

**4. Extent and Territorial Application**

4.1 The territorial extent of this instrument is England and Wales.

4.2 The territorial application of this instrument is set out in Section 3 under “Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)”.

**5. European Convention on Human Rights**

5.1 The Secretary of State for Health and Social Care, the Rt Hon Matt Hancock MP, has made the following statement regarding Human Rights:

“In my view the provisions of the Health Protection (Coronavirus, Testing Requirements and Standards) (England) Regulations 2020 are compatible with the Convention rights.”

## **6. Legislative Context**

- 6.1 Part 2A of the Public Health (Control of Disease) Act 1984 (“the Act”), as inserted by the Health and Social Care Act 2008, provides a legal basis for protecting the public from threats arising from infectious disease or contamination from chemicals or radiation. Overall, the Act sets out a framework for health protection, with the detailed provisions to be delivered through regulations in response to public health threats as they arise from time to time.
- 6.2 Section 45C of the Act provides a power for the appropriate Minister to make regulations to prevent, protect against, control or provide a public health response to the incidence or spread of infection or contamination in England and Wales. The threat can come from outside England and Wales. Section 45C includes power to impose requirements or restrictions on persons in response to a public health threat. The Secretary of State is the appropriate Minister in relation to England (section 45T(6) of the Act).
- 6.3 This instrument is made under section 45C of the Act to impose requirements on companies providing private sector COVID-19 testing services in order to support an effective response to the public health risks posed by the incidence and spread of SARS-CoV-2. This instrument, along with the draft Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 2) Regulations 2020 (“the CQC Statutory Instrument”), is designed to simplify the complex regulatory environment for COVID-19 testing, as described in the explanatory memorandum to the CQC Statutory Instrument.
- 6.4 Section 45D of the Act includes some restrictions on the power to make regulations under section 45C. Section 45D(1) provides that regulations made under section 45C may not include a restriction or requirement unless the Minister is satisfied that the restriction or requirement is proportionate to what is sought to be achieved by it. The Secretary of State is satisfied that it is necessary to impose requirements on private test providers through this instrument in order to address the public health risks posed by SARS-CoV-2, for the reasons explained in section 7 of this explanatory memorandum.
- 6.5 Section 45D(4) includes provisions which are relevant when regulations made under section 45C include special restrictions or requirements, which are those which can be imposed by a justice of the peace by virtue of section 45G(2), 45H(2) or 45I(2) of the Act. These include requiring people to isolate or wear protective clothing. This instrument does not impose special restrictions or requirements.

## **7. Policy background**

### *What is being done and why?*

- 7.1 Private COVID-19 testing is a significantly growing market. As new and more accurate testing technologies are developed, testing becomes cheaper, and results are available more quickly. The Government is actively encouraging private testing – both the provision of private testing services and the private demand to procure testing either at the individual or the organisational level. This will complement Government

testing, reducing pressure on the NHS and ensuring that NHS Test and Trace can focus testing on where it is needed the most.

- 7.2 The Government aims to reduce barriers to enter the market for private test providers, while ensuring that testing is of a high quality. The Government also aims to ensure that organisations and members of the public are able to identify and procure the most suitable test and testing service and have confidence in the quality of this provision. “Test providers” are considered to be organisations offering end-to-end testing services, from arranging to provide the test, to sample collection and analysis, to communication of the result. This is different from a test manufacturer, who manufactures the tests. More details about this can be found at paragraphs 7.10-7.11 of this explanatory memorandum.
- 7.3 This instrument relies on public health powers in order to support a critical part of the government’s response to this pandemic. It is necessary to use these powers to set out standards, which all private providers of testing services must meet, and to enable the private sector to play an increasing role in the national public health response to the pandemic. Mandatory, uniform standards are required to enable consumer confidence in private testing services and to ensure that results sent to Public Health England and NHS Test & Trace systems are of a high standard. This is especially important as these results can trigger legal duties e.g. to self-isolate. These aims cannot be met without legislation to ensure that all private test providers offering commercial testing services meet the same standards.
- 7.4 Without legislation members of the public would lack the necessary assurance of the test services they procure. With the growth of the private testing market, it is becoming increasingly difficult to ascertain which test providers offer an appropriate standard of testing. By implementing this legislation, we will ensure confidence in the ability of a test offered by a private test provider to trigger legal obligations if positive and enable engagement in society if negative, allowing the private testing market to play an increasing role in the pandemic response.
- 7.5 Certain elements of COVID-19 testing are currently regulated. However, there are no mandatory standards that regulate or assure the end-to-end testing service.
- 7.6 The requirement to register with the Care Quality Commission (CQC) when carrying out the activity of COVID-19 testing (the removal of bodily cells, tissue or fluid samples and the analysing and reporting of these) will, subject to Parliamentary approval, be removed in parallel with this instrument by the CQC Statutory Instrument (<https://www.legislation.gov.uk/ukdsi/2020/9780348215717>). Those regulations were laid in draft on 23 November 2020.
- 7.7 This instrument will impose new requirements, filling the gap left by the removal of the CQC registration requirement. They will require accreditation with UKAS which provides a national accreditation service to assess providers against internationally agreed standards for certification, testing, inspection and calibration. For COVID-19 testing, UKAS already provides a service that assesses providers and laboratories against International Standards – ISO 15189 or ISO/IEC 17025 (for laboratory-based testing) and ISO 15189 and ISO 22870 (for point of care testing).
- 7.8 DHSC published in October 2020 a set of minimum standards for commercial providers of COVID-19 testing services and a voluntary process for all privately provided testing services to self-declare they meet these standards. These were updated on 25<sup>th</sup> November 2020. These minimum standards and a list of providers that

have self-declared they meet the standards are available here:

<https://www.gov.uk/guidance/self-declare-as-a-private-sector-covid-19-testing-provider>. The standards include having in place a medical director and a clinical scientist, having systems in place to report adverse test incidents, and having clear clinical governance procedures. They also reflect the requirements in regulation 5 of this instrument, existing legal obligations, and Target Product Profiles published by the Medicines and Healthcare products Regulatory Agency.

- 7.9 This instrument makes self-declaration to the minimum standards mandatory, as explained below. This instrument will apply to an organisation who provides end-to-end COVID-19 testing to the general public on a commercial basis.
- 7.10 “End-to-end” means the process from booking patients in, sample collection, transporting samples and tests for analysis, to test analysis and communication of the results. There may be different organisations involved in the end-to-end process, for example part of it may be sub-contracted, in this case the person who has overall responsibility for the service is subject to the requirements in this instrument and ensuring that sub-contractors meet them too.
- 7.11 The requirements will only fall on organisations who are offering or providing the testing service in the course of business, so for commercial profit. This instrument will not capture charities or organisations who solely test, for free, employees within their own organisations without contracting a private test provider, such as employers who develop their own testing capabilities and only use these for testing staff.
- 7.12 Companies offering testing services will need to work, in stages, towards accreditation with UKAS against the relevant ISO standards. Stage 1 UKAS Applications will require the test providers who are covered by the Regulations to apply to UKAS against the relevant ISO standards and make a self-declaration against the minimum standards published by DHSC. For those companies who wish to offer test services for Test To Release for international arrivals there are additional minimum standards that must be met and are set out in <https://www.legislation.gov.uk/ukxi/2020/1337/regulation/2/made>.
- 7.13 This instrument will mandate that, by 31st December 2020, existing providers must achieve Stage 1 UKAS Application (UKAS Applicant). New providers after this date must achieve Stage 1 before they begin delivering testing. Once UKAS has agreed that a provider meets the minimum standards to provide testing privately, they will be listed as a private coronavirus (COVID-19) testing provider on [GOV.UK](https://www.gov.uk).
- 7.14 Stage 2 UKAS Appraisal will require that providers to meet a set of requirements set out by UKAS (<https://www.ukas.com/C19-Stage2-UKAS-Appraisal/>) as published on the 24<sup>th</sup> November 2020. This will ensure that providers are progressing towards full accreditation. This instrument will mandate that, by 31st January 2021, existing providers must have completed Stage 2 UKAS Appraisal (to become UKAS Appraised). New providers entering the market on or after 1<sup>st</sup> January 2021 must complete this stage within four weeks of completing Stage 1, or by 31st January 2021, whichever date is later.
- 7.15 Stage 3 is UKAS Accreditation to the relevant ISO standard. This instrument will mandate that, by 30th June 2021, existing providers must achieve full UKAS Accreditation. New providers must achieve Stage 3 within 4 months of completing Stage 2 or by 30th June 2021, whichever date is later. In this stage providers must pass all assessments and be fully accredited by UKAS for COVID-19 testing.

7.16 In addition this instrument (regulation 4) will mandate that test providers will be required to use test products which have been independently validated to ensure that they meet the specificity and sensitivity standards that the manufacturer declares they do, by either a) an independent lab which is accredited by UKAS to ISO/IEC 15189 or ISO/IEC 17025 or b) a UK government agency including the scientific validation process within NHS Test and Trace.

7.17 An organisation must not provide the services mentioned above without having complied with the obligations in this instrument (although they will be able to complete any tests where samples have already been taken). If they do, they will be acting unlawfully and this will be punishable on summary conviction by a fine.

## **8. European Union (Withdrawal) Act 2018/Withdrawal of the United Kingdom from the European Union**

8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act 2018.

## **9. Consolidation**

9.1 This instrument does not consolidate any legislation.

## **10. Consultation outcome**

10.1 A range of test manufacturers, test providers, industry representative groups and employers with employee testing programmes were consulted in relation to the simplification of regulation and development of the UKAS Scheme. Overall, the feedback from these key stakeholders was strongly in favour of this approach to a UK accreditation scheme.

10.2 In order to assuage stakeholder concerns about mandating the accreditation scheme, we have developed with UKAS a staged approach to accreditation, allowing test providers to prepare for the new requirements. In addition, UKAS have stated that early notice of proposed change by providers to UKAS can reduce assessment timelines to a matter of days in order to help providers to meet deadlines.

## **11. Guidance**

11.1 The Government will update its guidance on the assurance of COVID-19 testing in the private sector and this will be available on <https://www.gov.uk/coronavirus>. Further information on the UKAS accreditation process is available on <https://www.ukas.com/the-route-to-accreditation/how-to-apply/>.

## **12. Impact**

12.1 The impact on business, charities or voluntary bodies, which is in relation to the mandating the UKAS accreditation scheme for private sector providers of COVID-19 testing for commercial purposes, is expected to be low to businesses. This is due to the removal of a requirement to incur the cost of CQC registration fees, which is replaced by the requirement to attain and maintain UKAS registration.

12.2 The removal of the requirement for CQC registration for COVID-19 test sampling and test examination is dealt with in The Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 2) Regulations 2020.

12.3 There is no significant impact on the public sector.

12.4 An Impact Assessment has not been prepared for this instrument because it has not been assessed to exceed the +/- £5m threshold that would require a detailed impact assessment. This assessment includes expected costs related to the replacement requirement for UKAS application for COVID-19 test sampling and test examination. These costs are built up of accreditation costs (registration, pre and initial assessment fee), compliance costs, and administration costs. To present a worst-case scenario estimate, it was assumed all firms had little or no experience of accreditation or are new providers. The appraisal also assumes that the cost of administration is up-front so does not recur in future years. However, the worst-case present value of total costs in every year is within the +/- £5m threshold.

### **13. Regulating small business**

- 13.1 The legislation applies to activities that are undertaken by small businesses.
- 13.2 No specific action is proposed to minimise regulatory burdens on small businesses. However, as this legislation and the related CQC instrument will reduce the overall regulatory burden on all businesses, it should be seen by small businesses as a positive step and will reduce barriers to entry into the market for COVID-19 testing.

### **14. Monitoring & review**

- 14.1 The approach to monitoring of this legislation is based on UKAS's ongoing requirement to monitor the providers present on their register. If, as a result of this SI, UKAS receives enquiries on CQC registration, then UKAS's contact centre will engage DHSC to ensure that appropriate action is taken.
- 14.2 This instrument includes a requirement on the Secretary of State to review the need for the requirements imposed by the instrument before the end of the period of six months beginning with the day on which they come into force.

### **15. Contact**

- 15.1 Lucie Meggitt at the Department of Health and Social Care [lucie.meggitt@dhsc.gov.uk](mailto:lucie.meggitt@dhsc.gov.uk), can be contacted with any queries regarding this instrument.
- 15.2 Matt Russell, Deputy Director for Private Sector Testing Strategy, at the Department for Health and Social Care can confirm that this explanatory memorandum meets the required standard.
- 15.3 The Rt Hon Matt Hancock MP, Secretary of State for Health and Social Care at the Department of Health and Social Care can confirm that this explanatory memorandum meets the required standard.