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Guidance

Self-declare as a private sector COVID-19 testing provider

How to declare that you meet the minimum standards for private sector-provided testing and be listed as a private sector coronavirus (COVID-19) testing provider.

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From:
Department of Health and Social Care (https://www.gov.uk/government/organisations/department-of-health-and-social-care)

Contents

The government has published this guidance on the minimum standards for private sector providers of COVID-19 testing.

To request to be added to the indicative list of providers on GOV.UK, providers must declare that they meet these minimum standards by completing the form, as well as providing some additional information to support our due diligence checks.

The government envisages that UKAS (UK Accreditation Service) accreditation will become a minimum standard for all private sector providers of COVID-19 testing at a future stage and is planned to be established by September 2021.

Further information on the UKAS accreditation process (https://www.ukas.com/the-route-to-accreditation/how-to-apply/) is available on the UKAS website.

Requirements

The current minimum standards are summarised as follows (more detail is provided in the form):

1. Requirement of a clinical or medical director or equivalent and healthcare scientist

The provider must have a designated resourced role that has oversight and approval of medical or clinical practices undertaken by the provider and responsibility for reporting medical/clinical issues. The individual shall be registered with a clinical regulatory body, for example, the General Medical Council, Health and Care Professions Council, etc.

Additionally, the provider shall employ a regulated healthcare scientist who is registered with the Health and Care Professions Council. These can be the same individual, providing both roles are satisfied

2. Use of CE-marked tests that have a UK/European-based authorised representative and are registered in the country where that representative is based

A CE mark is a logo that is placed on an in vitro diagnostic (IVD) medical device to show that it conforms to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, as implemented by the Medical Devices Regulations 2002 (note: it is an offence under the Consumer Protection Act 1987 to place a device on the market or supply with without a CE mark, unless a derogation has been obtain from MHRA under regulation 12(4) of the Medical Devices Regulations 2002).

A CE mark shows that the device is fit for its intended purpose stated and meets legislative requirements relating to safety.

- guidance on CE marking (https://www.GOV.UK/guidance/ce-marking)
- In Vitro Diagnostic Medical Devices Directive (https://www.GOV.UK/government/publications/in-vitro-diagnostic-medical-devices-guidance-on-legislation)

3. Alignment to DHSC MHRA target product profile scope

The Medicines and Healthcare products Regulatory Agency (MHRA) has published target product profiles (TPPs) for different types of test, setting out the ‘scope’ of what that test should be used for, including target use, target user and target use settings.

The provider must declare that they’re using the test in line with its published scope. MHRA has set out guidance explaining how both virus and antibody tests work.

- MHRA (https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency)
- MHRA guidance (https://www.GOV.UK/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work/for-patients-the-public-and-professional-users-a-guide-to-covid-19-tests-and-testing-kits)
- government guidance on the suite of antibody tests (the antigen TPPs once published will be published here) (https://www.GOV.UK/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work/target-product-profile-antibody-tests-to-help-determine-if-people-have-recent-infection-to-sars-cov-2-version-2)

4. Public Health England (PHE) data reporting system

The provider must have a system in place for reporting positive, and negative and inconclusive test results cases to PHE in accordance with public health legislation.

- PHE guidance for reporting notifiable diseases (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/739854/PHE_Laboratory_Reporting_Guidelines.pdf)

5. Relevant systems in place to report adverse test incidents

The provider must be able to demonstrate that it has systems in place to identify any adverse incidents or quality control issues and be able to report them in a timely manner to the relevant regulatory body. MHRA has a dedicated COVID-19 Yellow Card portal to report adverse incidents with medicines, medical devices and diagnostics.

- MHRA COVID-19 Yellow Card portal (https://www.GOV.UK/drug-safety-update/coronavirus-covid-19-new-dedicated-yellow-card-reporting-site-for-medicines-and-medical-devices)

6. Samples shall be taken by a provider meeting or working towards ISO standard ISO15189 or ISO/IEC17025

MHRA has published target product profiles (TPPs) for different types of test, which outlines who should collect test samples under the 'Target User' description.

The provider must have relevant competency-based trained test operators undertaking or overseeing sample collection dependent on test sample collection requirements.

- TPPs (https://www.GOV.UK/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work/for-industry-and-manufactures-covid-19-tests-and-testing-kits)

The ISO standard and technical specifications set out the key components that should be considered to provide safe and reliable sample collection service.

It is expected that UKAS accreditation to ISO 15189 or ISO/IEC 17025 will become a mandatory minimum standard by June 2021.

Sampling can be accredited as part of a wider lab-based activity, or sampling can be the scope of a standalone, separately accredited legal entity.

- UKAS (https://www.ukas.com/)
- ISO 15189 (https://www.iso.org/standard/56115.html)
- ISO 17025 (https://www.iso.org/standard/66912.html)

7. Clinical governance

The provider must have clear clinical governance procedures in place. For example:

- clear governance and lines of accountability such as senior responsible officer, clinical lead, quality lead, training lead
- staff are appropriately trained and there is evidence of competency assessment and participation in relevant external quality assessment (EQA)
- liability and indemnity cover for staff
- a verification report for the laboratory element of the test (known as the assay), in line with national protocols for laboratory-based testing
- information management systems to monitor sample delivery and tracking
- systems to meet the provisions for handling, transportation and analysis of test samples
- working to containment level CL3 or CL2+ with Health and Safety Executive (HSE) approval for laboratory-based testing
- systems, processes and record management to support the delivery of safe and reliable service

Private providers must tell employers of any positive results for COVID-19, and employers must inform relevant staff to self-isolate. For more information on what employers should do in the case of a positive test result, please see employer guidance (https://www.gov.uk/government/publications/coronavirus-covid-19-testing-guidance-for-employers).

8. For PCR lab-based testing: providers shall be or use a UKAS-accredited lab or applicant laboratory to either ISO 15189 (Medical Laboratories – requirements for quality and competence) or ISO/IEC 17025 (general requirements for the competence of testing and calibration laboratories)

For polymerase chain reaction (PCR) testing, all samples must be processed by a UKAS accredited laboratory, or UKAS applicant laboratory (the laboratory has applied for UKAS accreditation but has not yet achieved it), and have quality management systems operating according to ISO 15189 and/or ISO/IEC 17025. ISO 15189 is the standard used in all NHS laboratories.

UKAS accreditation provides an assurance of the competence, impartiality and integrity of laboratories. This accreditation is an important element in establishing and maintaining confidence in a testing service. The government envisages that UKAS accreditation will become a mandatory minimum standard for all private sector providers of COVID-19 testing at a future stage and is planned to be established by June 2021.

- UKAS (https://www.ukas.com/)
- ISO 15189 (https://www.iso.org/standard/56115.html)
- ISO 17025 (https://www.iso.org/standard/66912.html)

9. For point-of-care testing: providers need to meet ISO standards ISO 15189 and ISO 22870 ‘point-of-care testing (POCT) – requirements for quality and competence’. Samples shall be processed by a UKAS accredited or applicant provider

These ISO standards and technical specifications set out the key components that should be considered to provide safe and reliable POCT service.

It is expected that UKAS accreditation to ISO 15189 and ISO 22870 will become a mandatory minimum standard by June 2021.

Providers are encouraged to adhere to ISO 22583 “Guidance for supervisors and operators of point-of-care testing (POCT) devices”.

- ISO 22870 (https://www.iso.org/standard/71119.html)
- Link to ISO 22583 (https://www.iso.org/standard/73506.html)

10. Compliant with all legal and regulatory requirements for sample collection, processing and sharing of results including the requirements of data protection legislation

The legal and regulatory requirements for private testing are set out in the guidance for employers and third-party healthcare providers below. This includes GDPR considerations.

The Information Commissioner’s Office (ICO) has set out FAQs on data collection and data protection relating to COVID-19 that provide further information.

- Coronavirus (COVID-19) testing: guidance for employers and third-party healthcare providers (https://www.GOV.UK/government/publications/coronavirus-covid-19-testing-guidance-for-employers/coronavirus-covid-19-testing-guidance-for-employers-and-third-party-healthcare-providers)
- ICO FAQs (https://ico.org.uk/global/data-protection-and-coronavirus-information-hub/coronavirus-recovery-data-protection-advice-for-organisations/testing/)

Self-declare as a provider

Start the private sector provider self-declaration process (https://urldefense.com/v3/__https:/support-covid-19-testing.dhsc.gov.uk/PrivateSectorSelfDeclaration__;!!E1R1dd1bLLODlQ4!Xojk0NBxusxNCkPQc6esuZTRTgMNnRFkAnlkEThuNsb0G4cCv7C_UFXtTBzYol7TSK0zjok%24)

A list of successful self-declared private sector providers of COVID-19 testing will be published shortly on GOV.UK.

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1. 22 October 2020
   Added link to further information on the UKAS accreditation process.
2. 20 October 2020
   First published.

Related content

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- UK Biobank COVID-19 antibody study: round 1 results (https://www.gov.uk/government/statistics/uk-biobank-covid-19-seroprevalence-study-round-1-results)
- Privacy notice for Covid-19 response activity (https://www.gov.uk/government/publications/privacy-notice-for-covid-19-response-activity)
- Warfarin and other anticoagulants – monitoring of patients during the COVID-19 pandemic (https://www.gov.uk/government/publications/warfarin-and-other-anticoagulants-monitoring-of-patients-during-the-covid-19-pandemic)
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