

Technical Bulletin: Private providers of COVID-19 testing and sampling - Updated legislation

05 January 2024

On 2nd January 2024 the UK Health Security Agency (UKHSA)'s Minimum standards for private sector providers of COVID-19 testing were withdrawn, and [The Health Protection \(Coronavirus, Testing Requirements and Standards\) \(England\) \(Amendment and Transitional Provision\) Regulations 2023](#) were published.

The updated legislation removes the three-stage UKAS application process for private sector providers of COVID-19 services. Any new applicant wanting to provide a private, commercial COVID-19 testing and/or sampling service is now legally required to be accredited to ISO 15189:2022 or ISO/IEC 17025:2017 before they start providing the service. New applicants will follow the standard UKAS application process, as detailed on the [UKAS website](#).

Any private sector provider of COVID-19 services accredited to ISO 15189:2012 can continue to provide a service while they transition to ISO 15189:2022. For more information about transitioning to ISO 15189:2022, see the [ISO 15189:2022 transition information hub](#) on the UKAS website.

Any current UKAS applicant who has not yet been granted accreditation to ISO 15189:2012 or 2022 may be able to continue working towards accreditation under the outgoing three-stage process, providing all relevant deadlines are met. These providers will be individually reviewed and contacted by their UKAS Assessment Manager to discuss next steps.

There are a number of changes to the legal requirements for accredited private sector providers of COVID-19 services. It is the responsibility of each provider to review the new regulations to ensure ongoing compliance with legislative and accreditation requirements.

The amended legislation does not affect the requirement for all COVID-19 test kits/devices to be approved under the Medical Devices Coronavirus Test Device Approvals (CTDA) process <https://www.gov.uk/government/publications/covid-19-test-validation-approved-products>.

If you have any questions about the new legislation, please contact UKHSA.

If you have any questions about your accreditation and next steps, please contact your UKAS Assessment Manager.