Technical Bulletin – Guidance on application for accreditation to include COVID-19 testing

19 June 2020

Introduction

Communication has been issued to laboratories and published on the UKAS website making it clear that UKAS is currently ready and able to accept applications to include COVID-19 testing within scopes of accreditation. UKAS continues to be in regular contact with key stakeholders to ensure the service UKAS provides continues to meet the needs of its customers.

The purpose of this document is to provide guidance to applicant laboratories for COVID-19 testing. Some may be brand new applicants and others extending to include COVID-19 within their scope. To process applications as quickly as possible and as a result of discussions with stakeholders, new forms have been introduced. Also, there is guidance here as the context of the testing may be different in that some laboratories may be performing diagnostic testing and providing clinical diagnosis and interpretation on site, others may be performing the testing in order for clinical interpretation to be provided elsewhere. This document explains when an ISO 15189:2012 or an ISO/IEC 17025:2017 application may be most appropriate.
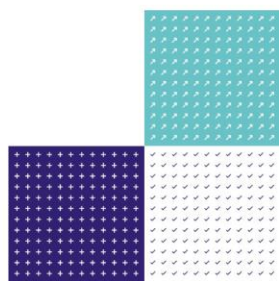
Pre-application

Prior to submitting an extension to scope for COVID-19, a laboratory should contact their Assessment Manager to discuss the application. Where a laboratory is not currently accredited, direct contact should be made to the Technical Focus Person for Microbiology and Virology, mark.prescott@ukas.com or the Section Head for Healthcare ben.courtney@ukas.com.

Contact should be made at the earliest opportunity in order that applications can be progressed in the timeliest way. Your UKAS contact will discuss the purpose and the context of the testing and discuss the relevant application documentation.

Application

UKAS customers wishing to extend their scope of accreditation to include COVID-19 need to complete the relevant AC form, available on the UKAS website. A new form specific for COVID-19 applications, the AC COV, is available which is designed to make it absolutely clear which documents are required to be submitted with the application. (Please note: If an AC4 or AC 6 is submitted in error, the application will not be rejected). Brand new applicants would also need to complete and submit the UKAS Application form and UKAS Agreement.

UKAS is working closely with government to support the national effort to increase capacity of reliable testing. As a result, UKAS will liaise with DHSC/NHSEI and PHE, to ensure that the appropriate priority is assigned to requests and therefore UKAS will request permission from applicants to notify DHSC of applications received. A confidentiality waiver has been published on the website which must be submitted with each application for extension to scope and new application.

Laboratories accredited to ISO 15189:2012 or ISO/IEC 17025:2017 can apply to include COVID-19 testing in their accreditation, using the above AC COV form. It is acknowledged that to increase the national testing capacity, it may be necessary for non-clinical laboratories accredited to ISO/IEC 17025:2017 to be utilised and, in some circumstances, it may be entirely appropriate to do so. What is crucial is for a laboratory not to apply for accreditation to a standard that is clearly not applicable to them. Broadly, for a laboratory to be considered for ISO 15189:2012 accreditation, both of the following statements would be true for the service they provide:

- The testing performed is for the purpose of clinical diagnosis
- Clinical opinion and interpretation on the testing is provided by the laboratory

Where both statements do not apply, accreditation to ISO/IEC 17025:2017 is almost certain to be the most appropriate route. In such instances, it is important for laboratories to be able to consider the clinical governance and how the right service is delivered to the right patients. For instance, following production of the result by an ISO/IEC 17025:2017 testing laboratory, there still needs to be consideration for where this is reported to for clinical interpretation and by whom. It is acknowledged that there are many different testing scenarios and an applicant laboratory should speak to their Assessment Manager or the other contacts listed at the end of this document for guidance.

Assessment

UKAS is committed to progressing COVID-19 extensions to scope as quickly as possible. Any new applicants looking for accreditation to include COVID-19 will also be progressed. Assessments will be conducted remotely, in line with our current assessment approach during the Coronavirus outbreak (see also UKAS Publication TPS 73). UKAS has a dedicated technical resource that will be able to assess the application to include COVID-19 testing quickly. To ensure the assessment is as timely and efficient as possible, it is essential that all documents, whether these are required as part of the application or requested separately by your Assessment Manager, be sent to UKAS as soon as possible.

The assessment will naturally focus on fitness for purpose of the assay but also what happens with the reporting of the test results and how they are handled. This is particularly important for applications that fall under ISO/IEC 17025:2017, as referred to above. To reflect the service provided, it may be necessary for UKAS to be very clear on the schedule of accreditation regarding what the limitations of the testing service are and the specific purpose of the testing.

As with any assessment, laboratories will be provided with an Assessment Report and Improvement Action Report after the assessment and be provided with timescales for clearance of the findings. UKAS will have dedicated resource available to review evidence submitted to clear findings to progress the extension to scope further as quickly as possible.

Contacts

If you have any queries regarding the accreditation of COVID-19 testing, please contact our Technical Focus Person at mark.prescott@ukas.com or the Healthcare Section Head at ben.courtney@ukas.com.