

Notification on accreditation for SARS-CoV-2 testing

NF27

1) Introduction

SARS-CoV-2 testing is a relatively new area of testing for ISO 15189 accredited medical laboratories. In order to understand the changing testing pathways and the role INAB accredited medical laboratories have within these testing pathways, INAB is requesting the information as outlined in section 2 of this document from all laboratories seeking accreditation for SARS-CoV-2 testing, in addition to the normal assessment documentation (PS10).

Accreditation for the detection of SARS-CoV-2 is not mandatory at present. However, to support laboratories that wish to become accredited for this testing, INAB will process these applications as outlined below in section 3 of this document.

Accreditation for antibody, antigen and point of care testing for SARS-CoV-2 is now available. Please note the requirements outlined in section 3 of this document are applicable for these test methods.

This policy reflects the position at time of issue. As testing regimes evolve during this pandemic, INAB will review its policy and communicate to laboratories and stakeholders.

2) **Information on testing pathways for all applicants:**

- Procedure and/or process flow for how samples are received into the laboratory;
- Referral laboratories used and their accreditation status;
- Confirmation of advisory services in place;
- Information available for laboratory users, including sample requirements;
- Reporting of results, including procedures for reporting to national authorities

3) **If you wish to apply for accreditation for SARS-CoV-2 testing the following process will apply ;**

The process for extension to scope for SARS-CoV-2 testing will depend on the current accreditation scope for each laboratory. The following shall apply in all cases:

- The kits use for SARS-CoV-2 testing are CE marked, with the manufacturer's validation available for review
- The laboratory can demonstrate a minimum of one successful result from participation in an external proficiency testing scheme (NEQAS or similar)
- Successful verification as per PS11 and PS24
- The INAB assessment team will assess the application and the normal recommendation and decision making process will follow.

- For ISO 15189 accredited laboratories with flexible scope awarded for microbiology and the technique¹ used for SARS-CoV-2 testing. We ask the laboratory to inform INAB when it is in a position to report the testing as accredited and to provide the information in section 2. As with normal additions to flexible scope, the assessment team will assess the verification records and witness the test at the next INAB surveillance visit.
 - For ISO 15189 accredited laboratories with fixed scope awarded in microbiology. An onsite assessment to witness key stages in the test procedure will be necessary.
- a. For ISO 15189 accredited laboratories accredited for microbiology but not for the technique used for SARS-CoV-2 testing:
 - An onsite assessment to witness key stages in the test procedure will be necessary.
 - b. For Point of Care testing (POCT) of SARS-CoV-2, the laboratory shall be accredited to ISO 15189 and ISO 22870 (POCT testing standard) in the area of microbiology. Note this does not mean utilising an alternate site for laboratory testing. For INAB policy on addition sites to the scope of accreditation, see PS19.
 - An onsite assessment to witness key stages in the test procedure will be necessary.
 - c. For ISO 15189 accredited laboratories not accredited for microbiology.
 - An onsite assessment to witness key stages in the test procedure will be necessary.
 - d. ISO 15189 accredited laboratories may refer samples for SARS-CoV-2 testing to another ISO 15189 accredited laboratory to increase testing capacity. As per section 4.5 of ISO 15189, the referring laboratory is responsible for ensuring that the requirements as set out in 4.5.1 and 4.5.2 are met. The referring laboratory shall make it clear on the test report where the sample was referred to and the accreditation status of the test in the referring laboratory.
 - e. ISO 15189 accredited laboratories may refer samples for SARS-CoV-2 testing to an ISO 17025 accredited laboratory to increase testing capacity. Again, the requirements of 4.5.1 and 4.5.2 of ISO 15189 will apply. The referring laboratory shall ensure it is clear on the test report where the sample was referred to and that the result is not accredited.
 - f. INAB does not offer accreditation to ISO 17025 laboratories for SARS-CoV-2 testing at this time. However, INAB will consider this further in consultation with relevant stakeholders and will communicate if the position changes.
 - g. For all applications for accreditation for CE marked kits, the laboratory must have the manufacturer's validation available for review.
 - h. Note: While INAB's policies PS1 and PS11 reference the possibility that inter-laboratory comparisons (ILCs) may be a valid alternative in the absence of an external quality assurance (EQA) scheme, for accreditation of SARS-CoV-2 testing at this time only EQA is acceptable.
 - i. Accreditation is available for:
 - Antibody testing, either under the microbiology or immunology scope discipline. All conditions 3a-3j above apply in terms of assessment processes;

¹ PCR based technique

- Antigen testing, under the microbiology scope discipline only. All conditions 3a-3j above apply in terms of assessment processes.

4) References

Laboratories are advised to regularly consult with testing advice issued by the relevant authorities (WHO, EU Commission, HSE etc.).

INAB policy PS11: Flexible scope of accreditation for ISO 17025 and ISO 15189 testing laboratories.

INAB Policy PS24: Minimum verification requirements for ISO 17025 and ISO 15189 testing laboratories.

INAB Policy PS1: Policy statement on proficiency testing.

INAB Policy PS3: Policy on laboratories performing tests on biological agents.