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 currently not available at this time. This will be reviewed as these techniques develop.

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 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 manufacturers 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.

a. *For ISO 15189 accredited laboratories with flexible scope awarded for Microbiology and the technique[1] used for SARS-CoV-2 testing.*
   - We ask that the laboratory to inform INAB when they are in a position to report the testing as accredited and 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.

b. *For ISO 15189 accredited laboratories with fixed scope awarded in Microbiology and the technique used for SARS-CoV-2 testing.*
   - An onsite assessment to witness key stages in the test procedure will be necessary.

c. 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.

d. For ISO15189 accredited laboratories not accredited for Microbiology
   - An onsite assessment to witness key stages in the test procedure will be necessary.

e. 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 to ensure 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.

f. ISO 15189 accredited laboratories may refer samples for SARS-CoV-2 testing to a 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.

g. INAB will not offer accreditation to ISO 17025 laboratories for SARS-CoV-2 testing at this time. However, INAB shall consider this further in consultation with relevant stakeholders and communicate if the position changes.

h. For all applications for accreditation for CE marked kits, the laboratory must have the manufacturer's validation available for review.

i. 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 and external quality assurance (EQA) scheme, for accreditation of SARS-CoV-2 testing at this time only EQA is acceptable.

4) References

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

[1] PCR based technique

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