

Circulated to:

SAMM Medical Testing Laboratories
SAMM Medical Testing Assessors
Accreditation Officers



SAMM CIRCULAR 1/2021

SAMM MEDICAL TESTING: GUIDELINES FOR REMOTE ASSESSMENT

1. Introduction and Scope

This circular is to provide Department of Standards Malaysia's (Standards Malaysia) guidelines to its accredited/applicant medical testing laboratories. This circular is applicable with any current government directive in force and Accreditation Circular 2/2021.

To ensure Standards Malaysia continued compliance with the ISO/IEC 17011, Standards Malaysia has established a procedure for remote assessment. Remote assessment provides the opportunity for increased efficiency, increased safety, better timing, inclusion of laboratory personnel that may not be easily accessible, and avoidance of travel delays and restrictions.

For this purpose, the remote assessment is a hybrid mechanism which consist of desktop assessment and virtual assessment. The laboratory shall provide information and documentation as required by LA 401 RA MT. If the information provided is insufficient or needs further clarification, to ensure conformity to the accreditation requirements, the laboratory shall provide additional documentation prior to the assessment.

Please be informed that the expectation of this remote assessment will not be similar to the onsite assessment due to limitations in accessibility. However, sufficient evidence shall be collected to ensure requirements of MS ISO 15189 are satisfactorily complied by the laboratory for the remote assessment.

2. Remote Assessment Process

The processes involved are as follows:

- | | |
|----|--|
| i) | SAMM MT lab complete Remote Assessment Request Form (AF 117-1) and submit to Standards Malaysia. |
|----|--|

| | |
|------|---|
| ii) | Within two (2) weeks after received assessment notification by Standards Malaysia, SAMM MT Lab shall upload Remote Assessment Form (LA 401 RA MT) and relevant/required documents into the link given by Standards Malaysia. |
| iii) | Assessment team will review the submitted documents/records within two (2) weeks and give feedback in LA 401 RA MT at least 3 days before virtual assessment and findings are raised (if any) in e-Accreditation. |
| iv) | Virtual assessment consists of opening meeting, discussion with laboratory and closing meeting which normally perform within half or one day. However, for the compliance and an extension of scope, the duration of the virtual assessment may be extended depending on the complexity of the scope applied. |
| v) | The assessment team and laboratory shall agree on the medium of assessment such as Skype, WhatsApp Video Call, Zoom etc. The laboratory shall provide the link for the online session to Standards Malaysia, at least 3 days prior to the assessment date. The link should accommodate for each appointed assessor. |
| vi) | SAMM MT laboratory shall close-out all the NCRs according to SAMM Policy (SP) 10. |

Flowchart of the above processes as in Appendix 1.

Appendix 1: FLOW CHART FOR SAMM MT REMOTE ASSESSMENT

