

ANNEXURE - I



National Accreditation Board for Testing and Calibration Laboratories

(A Constituent Board of Quality Council of India)

NABL / M-1137

27.05.2020

S.MARY LILLY

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Subject: Grant of accreditation for extended scope in accordance with ISO 15189:2012

Dear Sir,

This is to inform you that NABL has reviewed assessment report of your laboratory and pleased to recommend grant of accreditation in accordance with ISO 15189:2012 in the field of Medical testing for the discipline of Molecular Testing as per the scope recommended by the assessment team.

The following is also advised which the laboratory has to address and the same to be verified in the next assessment:

- Lab to use known positive and negative samples for lot to lot verification.
- The frequency of use of biological indicators in discard autoclave should be as per standard guidelines.

'Specific Test Performed' will be corrected as 'HCV RNA Qualitative' for tests at Sl. No. 1 & 2 of Form 72.

'Test Method' will be corrected as 'Real Time RT PCR (Open System)' for tests at Sl. No. 1 & 2 of Form 72.

'Detected/Not Detected' will be mentioned in the 'Range of Testing' for tests at Sl. No 1 & 2 of Form 72.

All the personnel proposed by the laboratory to review the results and authorize the release of reports are accepted.

Your Accreditation certificate and scope (with certificate no.MC-2772, Issue date:25.07.2018, Valid up to: 24.07.2020, date of amendment: 27.05.2020) is under preparation and will be available on the portal soon.

With respect to the persons to review the results and authorize the release of reports, it is the responsibility of laboratory to abide by the National/ Regional/ State/ Local regulatory requirement/ Acts/ Rules/ Legal orders/ Court Decisions/ Orders issued by Government/ Statutory Bodies as applicable and effective from time to time.

Yours Sincerely,
Chandrakant Solanki
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