

Central Drugs Standard Control Organisation  
Directorate General of Health Services  
Ministry of Health & Family Welfare  
(Diagnostic Division)  
FDA Bhawan, Kotla Road, New Delhi-110002

F. No. IVD/Misc/115/DCGI/18

Dated: 24 JUL 2018

To,

**All State Drugs Controller  
All Zonal/ Sub Zonal/ Port Offices of CDSCO**

**Subject:- Quality Control testing of Viral load Monitoring kits for HIV, HCV & HBV - Reg.**

Sir,

This is to inform you that Disease specific In-Vitro Diagnostic laboratory of NIB is engaged in doing quality testing of serological as well as molecular diagnostic kits (Qualitative) of HIV, HCV & HBV. The Institute has been notified as Central Medical Device Testing Laboratory (CMDTL) by Government of India vide Gazette no. S.O.2237 (E) dated 1<sup>st</sup> June 2018 for diagnostics for HIV, HCV & HBsAg. Laboratory has a Quality Management System in place and is NABL accredited in accordance with the standard ISO/IEC 17025:2005 for HIV, HCV, HBV and Syphilis serology. The laboratory is regularly participating in PT/EQAS for serology organized by NRL, Australia since 2009 and has been scoring successfully 100% results in every quarter of every year.

Further, the Institute has **standardized and validated the Quality Control testing of Viral Load Monitoring (Quantitative) for kit for HIV, HCV & HBV**. The Institute is now fully equipped to do Quality Control Testing and Lot release of these kits. Therefore it is requested that viral load monitoring (Quantitative) kits for HIV, HCV & HBV may be referred to NIB for Test/ evaluation purpose along with copy of Import/ Manufacturing licence. The sample size required for test/evaluation purpose is 48 tests plus kit specific control and calibrator.

This is for your information and necessary action

Yours faithfully,

  
(Dr. S Eswara Reddy)  
Drugs Controller General (I)

Enclosure :- Copy of NIB letter no.1/Dir.off/2018/NIB, dated 28/06/2018

Copy to;

1. The Director, National Institute of Biological, A-32, Sector-62 (Industrial Area), Noida.
2. CDSCO website.

राज्य जैविक संस्थान

स्वास्थ्य एवं परिवार कल्याण मंत्रालय

NATIONAL INSTITUTE OF BIOLOGICALS

Ministry of Health & Family Welfare, Government of India



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Dated : 28.06.2018

No.1/Dir.off./2018/NIB/

To,

The Drugs Controller General (India)  
Directorate General Health Services,  
FDA Bhawan, Kotla Road,  
New Delhi-110002.

**Subject: Quality control testing of Viral Load Monitoring Kits for HIV, HCV & HBV - reg.**

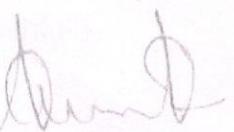
Sir,

Disease Specific In-vitro Diagnostic Laboratory of NIB is engaged in doing quality testing of serological as well as molecular diagnostic Kits (Qualitative) of HIV, HCV, & HBV. The Institute has been notified as Central Medical Device Testing Laboratory (CMDTL) by Government of India vide Gazette No. S. O. 2237 (E), dated 1<sup>st</sup> June, 2018 for diagnostics for HIV, HCV and HBsAg. Laboratory has a Quality Management System in place and is NABL accredited in accordance with the standard ISO/IEC 17025:2005 for HIV, HCV, HBV and Syphilis serology. The laboratory is regularly participating in PT/EQAS for serology organized by NRL, Australia since 2009 and has been scoring successfully 100% results in each quarter of every year.

It is to further inform that the Institute has standardized and validated the Quality Control Testing of Viral Load Monitoring (Quantitative) Kits for HIV, HCV & HBV. The Institute is now fully equipped to do Quality Control Testing and Lot Release of these kits. Therefore, it is requested that Viral Load Monitoring (Quantitative) Kits for HIV, HCV & HBV may be referred to NIB for test/ evaluation purpose along with copy of import / manufacturing license by the Zonal / Sub-zonal / Port Offices of CDSCO. The sample size required for test / evaluation purpose is 48 tests plus kit specific control and calibrator.

Your early action in this regard will be highly appreciated.

Yours sincerely

  
(Dr. Surinder Singh)  
Director