No. IVD/Misc/056/2021
Government of India
Central Drugs Standard Control Organisation
Directorate General of Health Services
(Diagnostic Division)

FDA Bhawan, Kotla Road,
New Delhi-110002, Dated:-

22 MAR 2021

To

All manufacturers/ importers of 4th generation HIV kits.

Sub:- Mentioning of analytical sensitivity for HIV P-24 antigen on kit insert of 4th Generation HIV In-vitro Diagnostics kit- Regarding.

Sir,

As you are aware that the National Institute of Biologicals (NIB), Noida is designated as Central Medical Device Testing Laboratory under the provision of rule 19 of Medial Device Rules, 2017 vide S.O. 2237(E) dated 01/06/2018 for carrying out test and evaluation of In-Vitro Diagnostics for human Immunodeficiency virus, Hepatitis B Surface Antigen and Hepatitis C Virus, Blood Grouping sera, Glucose Test Strip, Fully Automated Analyser Based Glucose Reagent.

Accordingly, samples of In-vitro Diagnostics of 4th generation HIV kits are being received by NIB, Noida for QC evaluation. NIB, Noida has informed this office vide letter dated 18/02/2021 that many manufacturer of such 4th generation HIV In-vitro Diagnostics kits are not mentioning sensitivity for HIV P-24 antigen on the product insert.

In view of above, all the licensees are hereby requested to update the product insert of these 4th generation HIV In-vitro diagnostics kits for inclusion of analytical sensitivity for HIV P-24 antigen, in order to avoid unnecessary delay of evalution.

Yours faithfully,

(Dr. V. G. Somani)
Drugs Controller General (I)

Copy to -

- The Director, National Institute of Biologicals (NIB), Plot No. A-32, Sector-62, Institutional Area, Noida-201307 (U.P.)
- CDSCO, Website for dissemination to the all stake holders.