F. No. 29/Misc./4/2016-DC (65)
Drugs Controller General (India)
Directorate General of Health Services
(FDA Bhawan, Kotla Road, New Delhi)

Date: 12 JUL 2017

CORRIGENDUM

Sub: Corrigendum with respect to revised specification / criteria of acceptance for quality test for Ant-HCV (Rapid Kit)- Regarding

This is with reference to the Office Order of even no. dated 13 Jun. 2017 regarding revised specification / criteria of acceptance for quality test for HIV-1 &/ or 2-Ab, HIV-1p24 Ag, HCV-Ab and HBsAg kits. The criteria of Sensitivity of Rapid Anti-HCV diagnostic kit is hereby amended as follows:

In place of:

Anti-HCV (Rapid Kit) –Sensitivity- 99%

Read as:

Anti-HCV (Rapid Kit) –Sensitivity- ≥ 99%

Further, the acceptance criteria for the other immunodiagnostic kits will remain same.

(Dr. G. N. Singh)
Drugs Controller General (India)

Copy to:

1. All State Licensing Authorities
2. All Zonal/ Sub-Zonal/ Port Offices of CDSCO
3. All the concerned Stakeholders
4. The Director, NIB, Noida