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

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Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

Date: 13 JUN 2017

OFFICE ORDER

The Ministry of Health and Family Welfare vide gazette notification no. GSR 601(E) notified in vitro diagnostic devices for HIV, HBsAg and HCV to be considered as "Drug" under Section 3, Clause (b), Sub clause (iv) of the Drugs and Cosmetic Act.

The Immunodiagnostic Kit Laboratory at NIB, Noida is carrying out quality control evaluation of Immunodiagnostic kits intended to be used for diagnosis of HBsAg, HCV & HIV.

In continuation of earlier office order no. 26-1/Misc./2003-DC dt. 12.06.2003 regarding the approved acceptance criteria and considering the criticality in the diagnosis of theses diseased conditions, the Technical Committee of NIB has reconsidered the need for revision in the criteria of acceptance for the said kits. Therefore, the Technical Experts Committee has reviewed the criteria for acceptance and has recommended the following criteria of acceptance of sensitivity and specificity for the said kits:

Analyte	ELISA / CLIA / ELFA / ECLIA / CMIA / MEIA etc.		Rapid Kit	
	Sensitivity	Specificity	Sensitivity	Specificity
Anti-HIV-1/2 and / or HIV-1 p24Ag	100%	≥ 98%	100%	≥ 98%
HBsAg	100%	≥ 98%	100%	≥ 98%
Anti-HCV	100%	≥ 98%	99%	≥ 98%

In view of the above, based on recommendations of the technical committee, the revised criteria have been approved for quality control testing and lot release of the above immunodiagnostic kits.

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

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