

Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
(Medical Devices and Diagnostic Division)

Food & Drugs Administration Bhawan,
Kotla Road, New Delhi-110002

File No. 29/Misc/5/2012-DC(44)

Date: 9 NOV 2012

To,

✓ All State Drugs Controllers

Subject:- Use of Diagnostic kits of HBsAg, HIV and HCV in Blood Banks or Pathological laboratories - Reg.

Sir,

The present guidelines for use of In – Vitro Diagnostic devices for HBsAg, HIV and HCV manufactured / Imported under valid license are allowed to be used in Blood Bank as well as Pathological laboratories, as the criteria of Sensitivity (%) and Specificity (%) for evaluation of the HBsAg, HIV and HCV diagnostic kits for the Transfusion purpose (Blood Banks) and Diagnostic purpose are the same.

It is therefore, considered that there is no need for approval / posting of approved kits on CDSCO website for use in Blood Bank.

In order to ensure the quality of such diagnostic kits manufactured in the country, it is requested that samples of diagnostic kits from the manufacturing sites / market may be randomly drawn and forward to National Institute of Biologicals, Noida for testing.

Yours faithfully,



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

Copy forwarded for information to all Zonal /sub zonal /Port offices of CDSCO