

No. 26-1/Misc/2003-DC
Directorate General of Health Services
(Drugs Control Section)

Nirman Bhawan, New Delhi
Dated the 12/6/2003

To, All State Drugs Controllers

Subject: Use of rapid test kits for testing of HIV and HCV in Blood Banks.

Sir,
This is refer to this office letter No. 18-10/2001-DC dated 29.11.2002 in respect of the above subject.

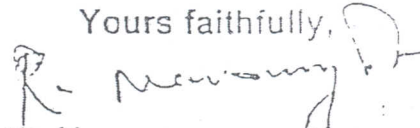
In this connection, it is requested that the samples of Rapid HIV and HCV Diagnostic Kits (500 tests of each kit) from all the manufacturers in your state shall be forwarded to National Institute of Biologicals, Noida for the assessment of the quality performance in respect of sensitivity and specificity of the said kits.

If the rapid HIV 1/2 and HCV Diagnostics Kits on evaluation at NIB Noida are found to be equally sensitive as ELISA for HIV 1/2 and HCV as per following specifications then only the rapid kits shall be permitted to be used in the Blood Banks:-

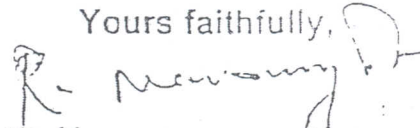
Name of Kit	Sensitivity	Specificity
Rapid HIV	≥ 99.5 %	≥ 98.0 %
Rapid HBsAg	≥ 99.0 % (0.5ng/ml)	≥ 98.0 %
Rapid HCV	≥ 99.0 %	≥ 98.0 %

Early action in the matter will be highly appreciated.

Yours faithfully,


(R. Narayanaswamy)
Dy. Drugs Controller (I)

Copy to; All zonal & Sub-Zonal Offices, CDSCO

Handwritten notes and stamps:
23/6/03
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Name of Kit Sensitivity Specificity
Rapid HIV ≥ 99.5 % ≥ 98.0 %
Rapid HBsAg ≥ 99.0 % (0.5ng/ml) ≥ 98.0 %
Rapid HCV ≥ 99.0 % ≥ 98.0 %
Early action in the matter will be highly appreciated.
Yours faithfully,

(R. Narayanaswamy)
Dy. Drugs Controller (I)
Copy to; All zonal & Sub-Zonal Offices, CDSCO
COMMISSIONERATE
Drugs Control Section
GOVT. STATE
15 JUN 2003
IND. NO. CR-599