

## An Improved NAT Assay with Enhanced Sensitivity for HBV for Donor Blood Screening

Sir,

Indian blood donors show moderate prevalence rates for the infectious viruses: HIV (0.3%), HCV (1.98%), and HBV (1.2%).<sup>[1]</sup> The predominant Indian HBV genotype is genotype D, which is associated with very low viraemia,<sup>[2]</sup> high prevalence of Occult HBV,<sup>[3]</sup> and low viral load.<sup>[4]</sup> In a Thailand study,<sup>[5]</sup> nearly all anti-HBc positive occult HBV showed a viral load ranging between 12 IU/ml and 40 IU/ml. Low viraemia and higher prevalence of HBV within Indian population, underlines the importance of a highly sensitive nucleic acid testing (NAT) blood screening assay for HBV. Procleix Ultrio Plus is the next-generation NAT assay for screening HIV-1, HCV, HBV, with enhanced sensitivity for HBV (2.1 IU/ml; 95% probability). AIIMS Main Blood Bank initiated a comparative study of Ultrio Plus versus the existing Ultrio assays.

A total of 6021 samples were screened by Ultrio Plus and Ultrio, (Novartis) and by ELISA. (BIO-RAD GenscreenUltra HIV Ag-Ab, BioMerieux Hepanostika HCV Ultra, HBsAg Ultra). HBV NAT yields were tested by Anti-HBc. Ultrio Plus showed twofold greater yield rate [Table 1] than Ultrio. Ultrio Plus yield was 1:250, versus 1:501 for Ultrio. A total of 2.5-fold increased yields were observed for HBV.

Of 20 HBV NAT yields, 12 were exclusive ULTRIO PLUS yields. Remaining eight HBV-NAT yields were detected by Ultrio and Ultrio Plus. The HBV yield rate increased by 2.5-fold for Ultrio Plus. To stage HBV infection, HBV-NAT yields were tested by anti-HBc. Five cases of occult HBV were exclusively detected by Ultrio Plus. A total of 11 HBV window period cases were detected, a distribution of 30% occult and 70% window period HBV cases. Observations are in concurrence with other evaluation studies, demonstrating a similar increase in yield rates for Ultrio Plus assay.<sup>[6]</sup> HBV has a slower doubling time. Low level HBV DNA is found in anti-HBc positive/HBsAg negative donors during later

**Table 1: Ultrio and Ultrio Plus yield results for samples negative by serology**

N = 6021	Total yields	HIV-1	HCV	HBV	Non discriminated
Ultrio Plus reactive - Sero Neg	24 (1 in 250)	0	2 (1 in 3010)	20 (1 in 301)	2 (1 in 3010)
Ultrio reactive - Sero Neg	12 (1 in 501)	0	1 (1 in 6021)	8 (1 in 752)	3 (1 in 2007)
Ultrio Plus exclusive yields	12 (1 in 501)	0	0	12 (1 in 501)	0
Ultrio exclusive yields	0	0	0	0	0

stages of infection, leading to the possibility that some HBV positive donations may not be detected by current serology and NAT screening assays.

Ultrio Plus assay has increased sensitivity for HBV detection and demonstrates improved clinical utility and should be rapidly implemented in donor screening for regions having moderate to high prevalence HBV such as India, where a large number of donors are unaware that they may be carrying this infection.

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