Chemiluminescence brings renaissance in TTI screening: Primi experientia

Sir,

India with a population of 1.26 billion has seroprevalence rates ranging from 0.2–1%, 0.4–1.09%, and 1.8–4% for HIV, hepatitis C virus (HCV), and hepatitis B virus (HBV), respectively, in the blood donors population.[1-4] Majority of the blood banks in India are using ELISA-based serologic screening for transfusion-transmissible viral infections (TTIs). The automated platform for chemiluminescence (ACLS) has been introduced in the recent past, as a newer serological screening tool that offers good precision, reliability, and high throughput.[5] Although ACLS appears to be an effective replacement for ELISA, the paucity of published research works in support of ACLS, makes this a mere assumption only. Performance evaluation and feasibility assessment of ACLS for routine TTI screening were done at our center based on its concordance with that of ELISA and nucleic acid test (NAT).

Routine TTI screening of all the blood units collected from 1st to 30th September 2015, was done simultaneously by ELISA (DaVinci, Biomérieux, France) for anti-HIV (4th generation kits), anti-HCV (3rd generation kits), and hepatitis B surface antigen (HBsAg) (3rd generation kits); ACLS (Architect i1000 SR, Abbott, USA) for anti-HIV (4th generation kits), anti-HCV (3rd generation kits), and HBsAg (3rd generation kits); and NAT (Procleix Ultrio, Grifols, Hong Kong) for HIV-RNA, HCV-RNA, and HBV-DNA. All the NAT nonreactive units with discordant serology results were subjected to viral load quantification by real-time polymerase chain reaction (RT-PCR) (Cobas TaqMan, Roche, USA) for confirming the infectious status.

Overall, 2.33% (75 of 3213) units were found to be TTI reactive by ≥1 method. Thirty-four (1.05%) units were found to be concordant reactive by all 3 methods, whereas 41 (1.27%) units were reported to have discordant results. Of these 41 discordant units, 29 (70.7%) units were serology only reactive (9 ELISA only, 15 ACLS only, and 5 by both) and 12 (29.3%) units were NAT-reactive irrespective of their serological results [Table 1]. Repeat serological tests for these 29 samples gave consistent results with that of earlier tests though neither NAT nor the RT-PCR could detect the infectious viral markers. However, these donors were kept under follow-up category to ascertain their infectious status as seroyields. Taking NAT as gold standard, the relative sensitivity and specificity of ELISA were 80.43% and 99.55%, respectively, and those of ACLS were 76.08% and 99.36%, respectively. The observed discrepancies among the 3 methods used, may be due to the different principles of the serological and molecular techniques or of chance occurrence due to the smaller study population. Our preliminary result with ACLS warrants a further study with a larger donor population for confirmation.

The shorter turn-around time and option for STAT tests give ACLS a definite edge over ELISA, especially during the preprocedural TTI screening for apheresis donors. Therefore, with comparable detection rates and faster turnaround time, ACLS appears as an acceptable alternative for ELISA when used with NAT.

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Conflicts of interest

There are no conflicts of interest.

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Table 1: Details of transmissible viral infection reactivity by different testing techniques

Viral marker	Number of samples tested - 3213 overall reactive - 75 (2.33%) Status of test results							
	ELISA– CHEMI– NAT–	ELISA+ CHEMI+ NAT+	ELISA+ CHEMI– NAT–	ELISA– CHEMI+ NAT–	ELISA+ CHEMI– NAT+	ELISA– CHEMI+ NAT+	ELISA+ CHEMI+ NAT–	ELISA– CHEMI– NAT+
HBV	3175	22 (+1)*	2	1	2	1	1	8‡
HCV	3179	8 (+1)†	7	6	1	0	3	
HIV	3193	2 (+1)*	0	8	0	0	1	
Total	-	34	9	15	3	1	5	8

*HIV/HBV co-infection, †HCV seroconcordant but discriminatory nonreactive, ‡NAT only includes 2-HBV yields, 4-RNR, and 2-DNR. HBV: Hepatitis B virus, NAT: Nucleic acid test, CHEMI: Chemiluminescence, HCV: Hepatitis C virus , -: Non-reactive/ Negative, +: Reactive/ Positive.

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