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Two years' experience of implementing molecular screening of hepatitis B virus, hepatitis C virus and human immunodeficiency virus 1, 2 in Riyadh blood donors

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ABSTRACT

Molecular screening technologies have improved blood safety by reducing the number of window-period transmissions relative to serological screening. In the two years following the introduction of molecular testing in King Khalid University Hospital, Saudi Arabia, 25,920 donor samples were screened in parallel by both serological and molecular techniques for hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV). No HCV or HIV NAT yields were detected. However, molecular screening enabled the interdiction of two confirmed HBV NAT yields. This is only the second report of confirmed HBV NAT yield in the Kingdom of Saudi Arabia, and amongst the few reports in the wider Middle East and North Africa region.

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1. Introduction

Blood transfusion is a critical component of healthcare, saving millions of lives annually. Yet, maintaining blood safety is a challenging task. Amongst these challenges is the selection of low-risk donors since blood from infected, asymptomatic and apparently healthy individuals remains the main source of infection transmitted through blood and products [1,2]. The effective and appropriate screening of blood donations is one of the key strategies in reducing the risks of transfusion transmitted infections (TTIs) [3].

The King Khalid University Hospital (KKUH) blood bank in Riyadh, Saudi Arabia, was established in 1982. Hospital records show that donation screening initially targeted primarily the hepatitis viruses as these were, and still are, endemic in the region. Donation screening for Human Immunodeficiency Virus (HIV) was also implemented in the 1980s. Screening was performed using serological techniques, which remain some of the most cost effective large-scale screening methodologies, with advances in technology resulting in major improvements in the sensitivities and specificities of serological assays. However blood donations collected from infected, but serology negative donors, often as a result of donation during the window period of infection, and sometimes due to occult infection, present a significant transfusion infection risk [4,5].

The development of automated large-scale molecular screening, commonly referred to as NAT (nucleic acid testing) platforms was a technological turning point in donor screening [6–8], enabling molecular screening to be implemented in mass screening situations. Molecular screening involves direct, sequence-specific detection of viral genomes (DNA or RNA), providing a screening methodology with an

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overall sensitivity of detection that is significantly higher than serological screening [9]. The KKUH blood bank began implementing molecular screening technology in 2011. To date, all donations are screened by both serological and molecular techniques for HBV, HCV and HIV. This study provides data on two years' experience of introducing molecular testing to the KKUH donor screening program.

2. Materials and methods

2.1. Serological screening

Serology screening was performed using the Architect system (Abbott Diagnostics, Wiesbaden, Germany), running the hepatitis B virus surface antigen (HBsAg) and core antibody (anti-HBc), hepatitis C virus antibody (anti-HCV) and human immunodeficiency virus combined antigen/antibody (HIV Ag/Ab) assays. Samples with a sample/cutoff ratio (S/CO) of ≥1.00 were considered initially reactive and were repeat tested in duplicate using the same assay. If both of the duplicate tests were negative, the donation was considered suitable for release into the clinical inventory. If one or both duplicates were still reactive, confirmatory tests were as follows. For HBsAg, reactivity was first confirmed on the Architect HBsAg qualitative II confirmatory assay (Abbott Diagnostics, Wiesbaden, Germany), followed by further testing on the Murex HBsAg assay (Diasorin Ltd, Italy). Anti-HBc reactivity was confirmed on the Murex anti-HBC total Elisa assay (Diasorin Ltd, Italy), and HCV and HIV confirmatory tests were performed on their respective immunoblot assays (INNO-LIA, Innogenetics, Belgium). Indeterminate or non-reactive confirmatory tests were flagged for donor follow-up investigations, 12 weeks post initial repeat reactive donation. For the purposes of this study, supplementary HBV quantitative (anti-HBs) and qualitative (HBe and anti-HBe) Abbott assays were also performed on confirmed HBV donations on the Architect system to differentiate infection type. An anti-HBs titre of >10 IU/ml was considered positive.

2.2. Molecular screening

Molecular screening was performed using the Roche Cobas TaqScreen MPX v2 assay (Roche Molecular Systems, NJ, USA) on the Cobas s201 system (Roche Instrument Centre, Rotkreuz, Switzerland). The MPX v2 assay is a qualitative viral multiplex test that simultaneously detects and discriminates between HBV-DNA, HCV-RNA and HIV-RNA (along with an internal control) in a single assay. Donations were screened in mini-pools of six. Mini-pool stage testing yielded either reactive or non-reactive results, but did not identify the individual infected donation(s). The constituent donations included in a reactive pool were therefore re-tested individually to identify both the infected donation and the particular infectious agent involved. Subsequent confirmatory testing was performed on the Procleix Ultrio Plus assay (Novartis, Emeryville, CA), using the multiplex format for the detection of HBV-DNA, HCV-RNA and HIV-RNA targets. Reactive specimens were further run in individual HBV, HCV and/or HIV discriminatory assays. Specimens indeterminate or non-reactive on the confirmatory assays were flagged for donor follow-up investigations. For the purposes of this study, viral loads of the two HBV NAT yields were measured using the COBAS Ampliprep/COBAS Taqman HBV assay V2.0 (Roche Molecular Systems, NJ, USA). This study was approved by and performed according to the guidelines of the KKUH and College of Medicine Institutional Review Board committee.

3. Results

During the study period, a total of 25,920 donor samples were screened for serological and molecular markers of HBV, HCV and HIV. The outcomes of these analyses are presented in Table 1. Overall, 25,818/25,920 (99.6%) donations displayed no markers of viral infection by either serology or NAT. The remaining 102/25,920 (0.4%) cases were repeat reactive on initial screening by either serological and/or molecular analyses. One hundred of these were confirmed positives by alternative assays; 83/25,920 (0.32%) were positive for markers of HBV, 12/25,920 (0.04%) for HCV and 5/25,920 (0.02%) for HIV. Two initial screen positives were negative on the confirmatory assays. However, follow-up specimens were not available for repeat testing. No donations were found to display markers of dual infection.

Supplementary serology was performed on the 83 confirmed HBV positive donations to identify likely infection type (Table 2). Seventy-five (90.3%) of these were identified as likely chronic infections based on the complete serological profile. Six HBV positive cases (7.3%) were classified as occult HBV. The remaining 2 (2.4%) pick-ups were classified as HBV NAT yield based on the detection of

Table 1
Serological and molecular screening/confirmatory testing outcomes.

n = 25,920	Serology/NAT profile	Repeat screen reactive (%)	Confirmed positive (%)
Screen negative	Serology$^-$/NAT$^-$	25,818 (99.6%)	NA
HBV positive	HBsAg$^+$/anti-HBc$^+$/HBV-DNA$^+$	76 (0.29%)	75
	HBsAg$^-$/anti-HBc$^+$/HBV-DNA$^+$	6 (0.02%)	6
	HBsAg$^+$/anti-HBc$^-$/HBV-DNA$^-$	1 (0.004%)	0
	HBsAg$^-$/anti-HBc$^-$/HBV-DNA$^+$	2 (0.008%)	2
HCV positive	Anti-HCV$^+$/HCV-RNA$^+$	12 (0.05%)	12
HIV positive	Anti-HIV$^+$/HIV-RNA$^+$	5 (0.02%)	5

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