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NATSPERT: A MULTIPLEX RT-PCR BASED INDIVIDUAL DONOR NUCLEIC ACID TEST FOR BLOOD DONOR SCREENING

Background: The technology to screen blood donors for transfusion transmitted infections (TTI) such as HIV, HBV and HCV has evolved rapidly over the past three decades from immunochromatographic rapid tests to tests using enzyme-linked immunosorbent assay (ELISA) or Chemiluminescent immunoassay (CLIA) platform. However, a significant risk of TTI still remains as these tests are not able to detect newly infected blood donors in the window period. Since late 1990s usage of Nucleic Acid Amplification Acid Test (NAT) in blood banks has expanded rapidly in the developed world to help detect HIV, HBV and HCV infections in the window period. However, in spite of its importance, NAT is not done routinely in developing countries such as India due to high costs of the equipment and the kits. Here we share our experience of NATSpert ID TripleH Detection test kit, a new Indian FDA approved multiplex RT-PCR based individual donor nucleic acid test (ID-NAT) for HIV, HBV and HCV blood donor screening manufactured by Mylab Discovery Solutions, India.

Aims:

- The results of HIV, HBV and HCV screening NATSpert RT-PCR based ID-NAT screening test were compared to that of the results of CLIA based assay to look for
- Concordance: Similar results on NATSpert ID-NAT and CLIA
- NAT Yield: Number of samples that were ID-NAT positive and CLIA negative
- CLIA Yield: Any samples missed by ID-NAT i.e ID-NAT negative and CLIA positive

Methods:

- The tests using blood samples from voluntary blood donors were carried out independently at separate laboratories of the hospital and the results were analysed in a blinded manner.
- NATSpert ID-NAT was carried out by extracting DNA/RNA from plasma, followed by addition of primer/probe, PCR mix and amplification and analysis on the Applied Biosystems Quant Studio 5 Real Time PCR System.
- The CLIA based blood testing was carried out on VITROS 3600 Immunodiagnostic System

Results: 1078 patients were screened for HIV, HBV and HCV on the CLIA platform and NATSpert RT-PCR based ID-NAT screening test over a period of 3 months

- Concordance: 15 blood donors (1.39%) were found to be positive on the NATSpert ID-NAT and CLIA. Out of these, 11 blood donors were positive for HBV and 4 were positive for HCV.
- NAT Yield: There were 4 samples (2 HIV and 2 HBV) that were ID-NAT positive and CLIA negative. Out of these 4, the 2 HBV samples were considered indeterminate and were ruled out for NAT yield. Overall, there were 2 samples out of 1078 (1:539) that were NAT yield that is in line with the existing data published in India.
- CLIA Yield: There wasn't a single sample that was positive on CLIA and missed by NATSpert ID-NAT, giving the confidence that the NATSpert ID-NAT was not missing a single TTI positive blood donation.

Summary / Conclusions: The NATSpert ID TripleH Detection assay from Mylab Discovery Solutions offers a sensitive and cost effective method for NAT screening of donated blood. In our short study, we confirmed the efficacy of this test as all the TTI positive samples on CLIA were found to be positive on this NATSpert RT-PCR assay, besides, 2 samples out of 1078 that were positive on the NATSpert assay only and negative on CLIA giving a yield of 1 in 539. The availability of this important screening test from an Indian manufacturer with CDSCO validated and approved kits can play a big role in making NAT a universally used screening test to provide safer blood in blood banks across India and other developing countries