ELISA-NAT assay for simultaneous detection of gene amplification products of HIV-1 & 2 RNA/HCV RNA/HBV DNA by ELISA in plasma samples

- This is a highly sensitive and highly specific assay for simultaneous detection and identification of hepatitis B virus (HBV), hepatitis C virus (HCV) and HIV-1 & 2 by ELISA in plasma or serum samples.

- This assay is very effective in making blood transfusion safe.

- **Milestones achieved:**

  - ***IP Status:*** An Indian patent application has been filed and is under examination.

  - ***Validation:*** Performance Characteristics / Validation of the assay have been determined using WHO International Standards as per CLIA guidelines. These include: Analytical sensitivity (LOD study), Precision testing, Analytical Specificity (interference), Accuracy and Reproducibility of the assay was tested.

- ***USP of technology:***

  i) ***Simple technology***: The assay is not highly technically demanding, unlike RT-PCR and TMA.

  ii) Single tube multiplex PCR products are analyzed by ELISA based liquid hybridization assay.

  iii) LOD_{95} of the assay for: HIV1= 13 geq/ml; HIV2= 6 geq/ml; HCV= 15 geq/ml; HBV= 11 geq/ml

  iv) ***Cost effective***: Technology is cost effective with or without pooling. The assay does not require expensive equipments like Real-time PCR machine or luminometer. It only requires a PCR Thermocycler and ELISA-reader.

  v) ***Time saving***: The test results are available in less than 10 hours.

- Technology was developed at Seth Research Foundation Gurgaon and supported by ICMR.

- ICMR is seeking potential agencies for the third party validation of technology.