

## ABSTRACT

### **Internal quality control for HIV testing of Blood Donors - Dried Tube Specimen as a cost effective alternative**

**Background:** Serological testing for HIV is mandatory in every blood bank to prevent its transmission by transfusion. The practice of third party internal controls is however uncommon. Most often cited reason for this is the cost, lack of easy access to reliable material and the need for freezers for storage of plasma. We explore an alternative cost-effective method for production and maintenance of in-house controls to overcome these issues.

**Aim:** Validation of Dried tube specimen (DTS) from HIV positive blood donor plasma as a low cost, stable material for use as Internal Quality Control material in blood banks.

**Methods and Materials:** Fresh frozen plasma prepared from consenting blood donors, confirmed HIV positive by serological and molecular methods was retained over a period of six months and pooled (4 bags). Equal numbers of seronegative FFP bags were pooled together. Aliquots of 20µl were made in plastic micro-centrifuge tubes and air dried overnight in a biosafety cabinet at room temperature. These samples were stored at 2-6° C refrigerators and tested once every week on a variety of platforms that included three rapid tests, a second generation ELISA and a fourth

generation Chemiluminescence immunoassay. A fourth generation ELISA was included on a monthly basis. This protocol was followed over a 6 month period to study extended stability of the control material.

**Results:** Epidata™, MS Excel™ and SPSS™ were used to tabulate and analyse the data. A total of 109 positive samples (DTS aliquots) were tested with 100% samples showing consistent positive results on all the platforms over the test period of 6 months. Similarly the negative samples (n=109) showed consistent negative results on all assay platforms over the six month period. It was observed that the procedure for reconstitution of DTS if not followed rigorously resulted in change of expected results.

**Conclusion:** The plasma in the form of DTS maintained stability when stored at 2-8°C, over the study period of 6 months. The results were consistent and samples did not show any deterioration. Issues to be highlighted include the need to follow stringent safety measures when handling the plasma during preparation and the reconstitution of the DTS prior to use. This provides evidence that the DTS can be a modality for production of cost effective stable in-house control material for resource restricted countries.