

Software Support for a Donor Screening Laboratory

Background

Currently available NAT processes include many manual tracking steps. The manual nature of the process is inherently complicated, which creates cGMP compliance challenges and occasional process deviations. The purpose of this project was to develop software applications to reduce manual tracking of in-process steps and thereby increase accuracy and reduce deviations.

Assay Reagent Tracking for eSAS (ARTe) is a data entry system that verifies expirations and appropriate usage of components used in eSAS and automates time calculations.

HCTP Check is a reporting system that was developed when American Association of Tissue Banks (AATB), National Marrow Donor Program (NMDP), and AABB published information regarding the requirement to test Human Cells, Tissues, and Cellular and Tissue-Based Products (HCTP) individually (IDS) instead of in mini-pools.

These two software applications were developed to improve compliance (reducing deviations) and accuracy (verification that the correct test mode was used) of NAT donor screening.

Methods

Using Access database software a program tracks essential elements, security, audit trail information. The following requirements are verified:

- One Master Lot in use at a time per assay
- All components belong to same lot
- Lot has not expired
- Reagents have not been used past 30 days
- Reagents or aliquots have not been used past 40 hours total at room temperature (RT)
- Reagents have not been used past 8 hours at RT in a rolling 24 hour period
- Controls and Calibrators have not been used past 8 hours at RT
- Fluids have not been used past 30 days
- Runs contain all required components

Appropriate alerts display if any component expires during a run.

HCTP Check verifies samples accessioned into LIS specific contracts are IDS tested. The application generates a report that is used to compare these samples to the NAT LIS to determine whether they were IDS or mini-pool tested. Results are not released until all samples on the check-in batch and shipping document have been verified as IDS tested.

Results

ARTe was implemented in October 2007. Deviation reports were compared for 6 months before implementation (April 2007 – September 2007) to 6 months after implementation (October 2007 – March 2008). There were 5 incidents related to test kit component management before implementation and 0 incidents since implementation.

Since the implementation of HCTP Check in January 2006, there were 12 incidents where the HCTP report discovered that samples were tested in mini-pools and retested IDS.

Conclusion

Implementation of the ARTe and HCTP Check applications improved compliance, as evidenced by reduced deviations, and enhanced accuracy, as demonstrated by detection of 12 inappropriately tested samples, for NAT screening.

The screenshot shows an 'ARTe Run Report' with the following sections:

- Test Information:** TTI#, Module Lot, Exp Date, Performed By.
- Calibrators and Controls:** A table listing various calibrators and controls with their respective IDs and expiration dates.
- Reagents:** A table showing reagent usage, including Target Capture, Amplification Reagent, Enzyme Reagent, and HIV-1 Detection Probe, with columns for Reagent ID, Run Time, Total Time Used, and Run Used.
- Room Temperature Reads:** A table listing various components like DI, Wash Buffer, Substrate, Auto Detection 1, Auto Detection 2, and Detection Buffer.
- Incubation Information For Current Cycle:** A table with columns for Cycle #, Run #, Begin incubation, End incubation, Avg Temp, and Max Temp.
- Operator/Printing/Security:** Fields for Operator Name, Run File, Print Name, and Security Name.

ARTe Report

Poster ID AP184

Session # II

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