ASSAY MIGRATION STUDIES ON THE BECKMAN COULTER DXI 9000 ACCESS IMMUNOASSAY ANALYZER†

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BACKGROUND
The U.S. FDA’s guidance for industry and staff titled “Assay Migration Studies for In Vitro Diagnostic Devices” 1 provides a least burdensome approach for the transfer of previously-approved assays from one to an existing to a new system. This approach enables use of rigorous analytical performance data in place of full clinical data to implement a cleared product on a new platform. The Beckman Coulter DxI 9000 Access Immunoassay Analyzer 1 includes numerous updates and new features designed to improve laboratory workflows and provide quality results to support patient management. Such elements include improved pipetting capabilities, updated process monitoring, increased throughput, reliability enhancements, and software features focused on the needs of the operator. The analyzer also utilizes a new alkaline phosphatase substrate reagent that provides reduced time-to-result for every test as well as other benefits including improved signal-to-noise and reduced sensitivity to endogenous alkaline phosphatase interference. The existing menu of Beckman Coulter Access reagents is being transferred to this system.

Purpose: Data herein summarize results from analytical studies described within the assay migration guidance and obtained during verification testing of assays for high sensitivity cardiac troponin I (hsTnI) and alpha-fetoprotein (AFP) on the DxI 9000 Access Immunoassay Analyzer. Analytical studies for quantitative assays were performed as directed by the assay migration guidance to compare performance of the Access hsTnI assay and the Access AFP assay on the DxI 9000 system using a protocol based on CLSI EP05-A3. 2

METHODS

Reproducibility

A multi-site study was performed to evaluate the reproducibility of the Access hsTnI assay and Access AFP assays on the DxI 9000 and Access 2 systems using a protocol based on CLSI EP05-A3. 2 Reproducibility was evaluated on three DxI 9000 & three Access 2 instruments across three external clinical laboratories. Both serum and lithium heparin plasma samples spanning the range of the assay were measured for hsTnI, while serum samples were tested for AFP. Samples were used in replicates of three (3) per run with two (2) runs per day over five (5) days on each of the three (3) instruments across the three (3) testing sites. Reproducibility was evaluated using three (3) different reagent pack lots and one calibrator lot. QC were tested daily.

RESULTS - Access AFP

Figure 1 A quantitative comparison study was completed to compare the Access hsTnI assay on DxI 9000 to the Access hsTnI assay on Access 2. Regression analysis following EP09C-ED01 was completed in addition to comparison to Allowable Total Difference (ATD) zones prescribed within the Access Migration guidance. Study design criteria were met.

Figure 2 Reproducibility of the Access AFP assay was evaluated following EP05-A3 on both DxI 9000 and Access 2 including between-sites, between-lots, between-days, between-run, and within-run variance components. DxI 9000 reproducibility was markedly improved compared to Access 2.

Figure 3 A quantitative comparison study was completed to compare the Access hsTnI assay on DxI 9000 to the Access hsTnI assay on Access 2. Regression analysis following EP09C-ED01 was completed in addition to comparison to Allowable Total Difference (ATD) zones prescribed within the Access Migration guidance.

Figure 4 Access AFP assay imprecision was evaluated following EP05-A3 on DxI 9000 on each of three reagent lots. A representative reagent lot is shown for illustration; all lots yielded acceptable performance.

RESULTS - Access hsTnI

Figure 5 Access hsTnI assay linearity was evaluated following EP05-A3 on DxI 9000 across 3 reagent lots. Independent studies were completed for serum and lithium heparin plasma. Acceptable nonlinearity was observed for each individual assay.

CONCLUSION

Individual assay data generated for the Access hsTnI and Access AFP assays on the DxI 9000 Access Immunoassay Analyzer including accuracy, imprecision, detection capability, and linearity met U.S FDA assay migration guidance study design criteria and demonstrate acceptable assay performance.

REFERENCE

1. Beckman Coulter, Inc. Reproducibility of the Access hsTnI assay was evaluated across three reagent lots and one calibrator lot. Acceptable nonlinearity was observed for each individual assay.

REFERENCES


