**Keywords: Chemiluminescent microparticle Immunoassay, human Immunodeficiency virus type 1 and/or type and HIV Ag/Ab Combo assay**

**Introduction:** The ARCHITECT i2000 and the ALINITY i HIV Ag/Ab Combo assays are based on a two-step chemiluminescent microparticle immunoassay (CMA) principle, for the simultaneous qualitative detection of HIV p24 antigen and antibodies to human immunodeficiency virus type 1 and/or type 2 (HIV-1/HIV-2) in human serum or plasma (Figure 1). The objective is to compare and validate the performance of the new Abbott ALINITY i HIV Ag/Ab Combo assay against the current ARCHITECT i2000 HIV Ag/Ab Combo by statistically analysing the data collected from running patient samples, kit controls, in-house controls and external quality assessment (EQA) samples.

**Method:** 123 samples, previously tested on the ARCHITECT i2000 analyser, were tested on the ALINITY system. Of these samples, 114 were selected based on various ranges. Values below 1.00 S/CO (sample per cut-off) were considered non-reactive, while values greater than 1.00 S/CO were considered reactive. All reactive and discrepant results were confirmed using a third platform (Vidas immunoassay analyser).

**Findings:** Four out of 123 samples tested were identified as discrepant. These were analysed by VIDAS confirmatory testing and concurred with ALINITY results (Table 1). From this, the ALINITY met the laboratory and manufacturer acceptance criteria (stated specificity of 99.89% [95%CI: 99.67% to 99.98%]). Analysis of EQA NEQAS HIV samples on the ALINITY did not deviate from the expected results. The within-run and within-laboratory precision coefficient of variation (CV%) was estimated using ALINITY QC positive materials 1,2 and 3 (Table 2). The analysis of the CV% revealed that the HIV testing performed as reported by the manufacturer CV% (using the F statistical analysis described by Forkman J (2009)) and found that based on average CV % of (5.56%) from the QC data for the ALINITY a measurement of 1 S/CO carries a Measurement of Uncertainty of (0.8888 to 1.1112). A good correlation was found between the ARCHITECT and the ALINITY measurements ($R^2=0.9926$) (Figure 2). Bland-Altman analysis of the ARCHITECT and the ALINITY (Figure 3) showed a positive bias. Based on these findings, the ALINITY HIV Ag/Ab Combo assay has met the laboratory acceptance criteria for assay comparability with the ARCHITECT HIV Ag/Ab Combo measurements.

| Architect | ALINITY vs ARCHITECT raw data comparison. *Four samples identified as discrepant. Following VIDAS resolution of discrepant results the ALINITY i HIV specificity was 100% against the ARCHITECT VIDAS result. This shows the ALINITY met the laboratory and manufacturer acceptance criteria (stated specificity of 99.89% [95%CI: 99.67% to 99.98%].

| Manufacturer | Raw Data Comparison | ALINITY vs ARCHITECT raw data comparison. *Four samples identified as discrepant. Following VIDAS resolution of discrepant results the ALINITY i HIV specificity was 100% against the ARCHITECT VIDAS result. This shows the ALINITY met the laboratory and manufacturer acceptance criteria (stated specificity of 99.89% [95%CI: 99.67% to 99.98%].

**Table 1:** Alinity vs Architect raw data comparison. *Four samples identified as discrepant. Following VIDAS resolution of discrepant results the ALINITY i HIV specificity was 100% against the ARCHITECT VIDAS result. This shows the ALINITY met the laboratory and manufacturer acceptance criteria (stated specificity of 99.89% [95%CI: 99.67% to 99.98%].

**Table 2:** Statistical analysis of the manufacturers reported precision CV% and the observed verification precision CV% using the ALINITY i HIV Combo positive kit controls 1,2 and 3.

**Conclusion:** The ALINITY HIV Ag/Ab Combo demonstrated a better sensitivity and specificity than the ARCHITECT and met the manufacturers and laboratory acceptance criteria. In addition, its ease of use is anticipated to have positive implications in meeting turnaround times, subsequently enhancing the quality and efficiency of the service. Overall the ALINITY HIV Ab/Ag Combo assay is considered fit for purpose and ready for future diagnostic use.

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**References:**

**Figure 1:** Chemiluminescent microparticle immunoassay (CMA) principle and components for the qualitative detection of antigen and antibodies to HIV-1 and HIV-2 in human serum or plasma.

**Figure 2:** Analysis of correlation between S/CO measurements indicate good correlation between Architect measurements and the ALINITY i with $R^2$ value of 0.9926.

**Figure 3:** Bland-Altman analysis of ARCHITECT and ALINITY i S/CO measurements showed a positive bias. The two analysers show good agreement in measuring the same parameter (HIV Ab/Ag Combo assay).