ABSTRACT

Goals of this Study:

- Evaluate alternate Hb A1c methods that will avoid interference from the Hb variants.
- Deploy the best method for our setting.

Methods & Materials:

- What we are looking for:
  - Precision
  - Accuracy
  - Freedom from variant interference
  - Ease of use and rapid turn-around times
- Performance Standard:
  - Imprecision: SD < 0.25% Hb A1c, at 7.0%.
  - Inaccuracy: Bias < 0.25% Hb A1c at total A1c of 7.0%, vs. Beckman AU for patient samples WITHOUT Hb variants

Three assays selected to evaluate:

- Trinity Biotech Premier Hb A1c (boronate affinity)
- BioRad D-10 Hemoglobin Analyzer (cation exchange HPLC)
- Sebia Capillarys 2 flex piercing system (Capillary Electrophoresis) (boronate affinity)

Accuracy:

Accuracy was first assessed by comparing the new methods with the Beckman AU assay using samples from patients who did not harbor a Hb variant.

Conclusion:

The three methodologies evaluated were all suitable for use with common hemoglobin variants; two met our performance standard. We chose the Trinity Biotech Premier method for our laboratory based on all of our criteria.

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