INTRODUCTION

As HbA1c is now used for both monitoring and diagnosis of diabetes mellitus point of care testing (POCT) will become more appropriate. The Roche cobas b 101 is used for the quantitative measurement of HbA1c in human whole blood using venous samples (lithium heparin or K2-EDTA) or capillary samples. In this study we evaluated the analytical performance of the analyser in venous blood samples.

SOFTWARE DETAILS

The analyser has a comprehensive software package and connectivity options to link and download data to external computers.

MATERIALS and METHODS

Cartridges

There are 10 cartridges per pack. Single lot number of cartridges was used in the study (REF: 063788676; Lot: 431025-01; expiry: Aug 2015).

Analytical Principle

The following is performed automatically by the system in a self-contained disc. The haemoglobin is released from red cells with TRIS buffer. It is then mixed with sodium lauryl sulphate (SLS) to form SLS-Hb complex which is measured at 525 nm. A separate sample fraction has HbA1c denatured by potassium ferricyanide and sucrose laurate. The denaturedHbA1c bonds with a HbA1c antibody on the latex particles. The latex agglutination inhibition reaction absorbance is measured at 625 nm to provide the concentration of HbA1c.

Evaluation Protocol

The evaluation protocol included precision studies, patient comparisons in normal and a smaller number of samples with variants, a haemolysis study and analysis of a single sample with an elevated HfB.

RESULTS and DISCUSSION

Patient Comparison

The comparison was assessed using Passing Bablok and the (difference) Bland-Altman.

A. Normal Patient Comparison

Precision cobas b 101

<table>
<thead>
<tr>
<th>Sample</th>
<th>Haemolysis level (mg/dL)</th>
<th>Jeppesen</th>
<th>DCA Vantage</th>
<th>ALR AS100</th>
<th>Biore Rad D10</th>
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</table>

Table 3. Results of A1c in in samples with increasing level of haemolysis. # Error 217 – test cartridge or analyser failure on 2 occasions rather than the Error 204 – haemolysed blood

Haemolysis study

The Afinion AS100 is not recommended for analysis with haemolysed samples. The haemolysis study was performed to determine if variation in patient sample haemolysis level will affect the HbA1c estimation in any of the methods available during this study. An EDTA whole blood sample from a healthy volunteer was sub-aliquoted into 6 aliquots and the aliquots were haemolysed by passing each of the samples through a small needle to produce incremental increase in haemolysis levels. The haemolysis level was measured on a Beckman DxC800 general chemistry analyser.

DISCUSSION

The consecutive run and between day precision results were <2.5%. The patient correlation studies with normal patient samples versus the Bio Rad D10 showed an increasing negative bias as the concentration increased while the correlation with the Siemens DCA Vantage was very good and consistent across the entire concentration range. The patient containing samples correlation study of the Roche cobas b 101 showed much better correlation than the Bio Rad D10 versus the Afinion AS100. The literature from both Roche and Siemens indicates HbF>10% may result in lower than expected HbA1c values. There is no indication on the extent of this decrease in HbA1c values with proportional rise in Hf. Concentration estimate from this single result indicates the decrease was around 1.0% for both the cobas b 101 and DCA Vantage methods compared with the Afinion AS100 result in this sample. Bio Rad recommends the methods are not suitable when the Hf exceeds 10%. The D10 method did not correctly identify the HfB as HfB but rather as LA1c/CHb-1, Liliaver Carbohydrate fraction.

CONCLUSION

The analytical evaluation of the Roche cobas b 101 showed the analyser performance was comparable to the methods currently used in our laboratories using normal and haemoglobin variant containing samples.