

Evaluation of the Roche B101 HbA1c Point of Care Analyzer

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Abstract:

An evaluation of the Roche Cobas B101 HbA1c Analyzer was conducted to assess analytical performance. Precision and accuracy were estimated by analyzing two control samples eleven times for the within run experiment and over eleven days for the between batch precision.

Agreement was correlated to the laboratory method, Tosoh Biosciences G8 HbA1c analyzer (n = 51, range of results = 4.7% to 15.1%) and a point-of-care method, the DCA Vantage Hemoglobin A1c System, using left over EDTA samples from laboratory analysis (n= 16, range of results = 5.5 to 14.2%). Lot to lot reproducibility was investigated using 11 patient samples analysed with two different reagent lots. Interference from the presence of Hemoglobin variants was also investigated.

The B101 Analyzer showed good precision. Within run and between batch CV was 1.6% and 3.5% for level 1 control (mean value 5.2%) and for level 2 control (mean 10.2%) CV for within run was 0.3% and 3% for between batch.

The analyzer had a good agreement with both the Tosoh G8 (r=1 and P <0.001) and DCA 2000(r=0.99:P <0.001). Comparison of two different reagent lots showed good agreement and linearity experiment confirmed the system to be linear for values from 4% to 14%.

Compared to the Tosoh G8 values, no interference from common Hemoglobin variants was found on the B101 analyzer

The B101 is smaller, lighter and has a higher result storage capacity than the DCA Vantage. Its reagent cassettes do not require refrigeration and results obtained in 6 minutes. The equipment is easy to use and will be a good choice for use in paediatric and neonatal wards, intensive care units and for mobile screening programs of our health system.