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EuroMedlab – IFCC Abstracts Atellica DCA Analyzer

Effect of labile glycated hemoglobin on HbA1c measurement by the Atellica DCA Analyzer
Tilghman, C., Mayfield. J.

Atellica DCA Hemoglobin A1c Assay is Not Affect by the Hemoglobin J Variant.
Mayfield, J., Lynch, M., Stradinger, J.T.

Performance Evaluation of the New Siemens Analyzer, Atellica DCA for Point of Care HbA1c Measurement
E. Miler, E. English, G. John

Performance of the Atellica DCA ACR Assay Under Typical Prozone Conditions,
Chaney, J., Stradinger, J.

Effect of Hemolysis on HbA1c Measurement by the Atellica DCA Analyzer
Tilghman, C.

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Effect of labile glycated hemoglobin on HbA1c measurement by the Atellica DCA Analyzer

Tilghman, C., Mayfield, J.

"Diabetes, obesity, metabolic syndrome" *Clinical Chemistry and Laboratory Medicine (CCLM)*, vol. 59, no. s1, 2021, pp. s362-s401. https://doi.org/10.1515/cclm-2021-5015

Key Highlights

- Labile HbA1c is an intermediate formed during glycation to form stable HbA1c, the well-known diabetes marker.
- Labile HbA1c is increased with high blood glucose levels often observed after a meal.
- Labile HbA1c levels have minimal impact on immunoassay (Atellica® DCA analyzer) and ion-exchange chromatography results (Tosoh G8 chromatography system), but negatively impact the boronate affinity method (Abbott Afinion 2 analyzer).

Overview

Blood samples at varying HbA1c levels (normal, pre-diabetic and diabetic) were manipulated with glucose to generate multiple concentrations of labile hemoglobin ranging from 2->14%. Samples were tested for %HbA1c using the Atellica DCA Analyzer, the Tosoh G8, and the Abbott Afinion 2 devices. Results indicate that the Atellica DCA Analyzer and Tosoh G8 results are not impacted by high levels of the labile intermediate while the Afinion 2 showed significant bias with increased labile HbA1c compared to low labile HbA1c. These data indicate that the Atellica DCA HbA1c assay can be used regardless of blood sugar levels or timing of meals that can influence the amount of labile HbA1c.

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Atellica DCA Hemoglobin A1c Assay is Not Affected by the Hemoglobin J Variant

Mayfield, J., Lynch, M., Stradinger, J.T.

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Key Highlights

- Hemoglobin J is variant of hemoglobin characterized by mutations that typically lead to the introduction of charged amino acid residues.
- A total of 15 blood samples with Hb J levels between 50-54% were tested on the Atellica® DCA analyzer HbA1c assay, with 11 samples below and 4 above the medical decision level for HbA1c (6.5%).
- The mean bias of Atellica DCA Analyzer results compared to the Premier Hb9210 system for each set of samples (above and below medical decision point) was <2%.
- Results show that Hb J does not impact assay performance on the Atellica DCA HbA1c assay.

Overview

To examine the impact of mutated hemoglobin variant hemoglobin J (HbJ) 15 samples with characterized %HbA1c levels and HbJ percentage were tested. After correction for inherent bias relative to the Premier 9210, the mean bias between the Atellica DCA Analyzer HbA1c results was <2%. These data indicate that the assay is not impacted by the HbJ variant.

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Performance Evaluation of the New Siemens Analyzer, Atellica DCA Analyzer for Point of Care HbA1c Measurement

E. Miler, E. English, G. John

"Diabetes, obesity, metabolic syndrome" *Clinical Chemistry and Laboratory Medicine (CCLM)*, vol. 59, no. s1, 2021, pp. s362-s401. https://doi.org/10.1515/cclm-2021-5015

Key Highlights

- Sixty-two whole blood samples were tested on the device and compared to the A. Menarini Hb9210 analyzer and showed good correlation with slope of 1.004 (95% CI 0.977 – 1.030) and an intercept of -1.9 (95% CI -3.8 – 0.0).
- Assay precision was assessed by testing three patient blood pools at low, medium and high HbA1c. Results show good within run, between run, and total precision for each pool with total %CV at 3.1, 2.1, and 2.5 for each level respectively.
- Linearity of the assay was examined by mixing a high an low patient pool and results showed acceptable performance.

Overview

An evaluation of the Siemens Healthineers Atellica® DCA Analyzer for point of care HbA1c measurement was performed examining a method comparison, precision, and linearity study. Results suggest that the device is comparable to the A. Menarini Hb9210 analyzer and is capable of being used for the clinical applications related to diabetes management.

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Performance of the Atellica DCA ACR Assay Under Typical Prozone Conditions

Chaney, J., Stradinger, J.
"Urinalysis" *Clinical Chemistry and Laboratory Medicine (CCLM)*, vol. 59, no. s1, 2021, pp. s985-s998. https://doi.org/10.1515/cclm-2021-5038

Key Highlights

- Many immunoassays are susceptible to “hook” effects at high levels of analyte that results in falsely low or negative results.
- The Atellica® DCA Analyzer ACR assay is not susceptible to the hook effect and in manipulated samples up to 10,000 mg/L the system reports >300 mg/L, the high end of the assay reporting range.
- Clinical samples with urine albumin ranging from 1,000 – 3,000 mg/L were tested to confirm.

Overview

To demonstrate assay performance at extremely high levels of analytes the Atellica DCA Analyzer ACR assay was tested with artificially high levels of urine albumin. Samples with up to 10,000 mg/L repeatedly gave >300 mg/L result showing that no hook effect is observed. This observation was confirmed using multiple clinical samples with elevated urine albumin (1,000 – 3,000 mg/L). This study shows that high levels of urine albumin will not give erroneous results.

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Effect of Hemolysis on HbA1c Measurement by the Atellica DCA Analyzer

Tilghman, C.

"Diabetes, obesity, metabolic syndrome" *Clinical Chemistry and Laboratory Medicine (CCLM)*, vol. 59, no. s1, 2021, pp. s362-s401. https://doi.org/10.1515/cclm-2021-5015

Key Highlights

- Red blood cell lysis has minimal impact on HbA1c results using the Atellica® DCA Analyzer.
- Results from the assay fall within the acceptable bias limits (<2%) independent of the level of red blood cell hemolysis, especially those observed during routine clinical practice.

Overview

Sample rejection due to hemolysis is a common occurrence in the clinical lab. It can either cause analyzers not to perform properly or give erroneous results. To demonstrate that the Atellica DCA Analzyer HbA1c assay results are not impacted by red blood cell hemolysis multiple blood samples below and above the medical decision level for diabetes (6.5% HbA1c) were analyzed at varying levels of hemolysis. When HbA1c values are plotted as a function of percent hemolysis no significant slope was observed indicating that the level of hemolysis does not influence results. Additionally, the mean value of all replicates fell within ± 2 SD from the control samples. These data demonstrate the Atellica DCA Analzyer HbA1c assay delivers accurate results independent of the level of hemolysis.

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