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Introduction:

Glycated Serum Protein (GSP) or fructosamine, estimates the average blood glucose over a 2-3 week period versus over a 3-4 months period for HbA1c. GSP may be used to monitor diabetics with hemoglobinopathies or with conditions that affect RBC (red blood cell) lifespan.

HbA1c is falsely decreased when the RBC lifespan is less than 120 days, while GSP is not affected. Fructosamine assays are widely used as an alternate test for certain diabetes patients with hemoglobinopathies, and for pregnant woman. However, most of the fructosamine assays that are currently in the market are nitro blue tetrazolium (NBT) based colorimetric assays, and they suffer from a variety of interferences like vit-c, bilirubin, glutathione which lead to inaccurate results.

These analytical issues led us to investigate for an alternate assay that could be adapted to our existing Siemens Vista analyzer.

Objective:

The objective of this study is to evaluate and validate a user-defined application protocol for the GSP assay on the Siemens Vista chemistry analyzer. In addition to the method validation, we also established the specimen stability and adult reference ranges for GSP.

Materials and Methods:

The GSP LiquiColor® assay from EKF Diagnostics inc. USA is a new FDA cleared three step enzymatic colorimetric assay based on trinder endpoint reaction, measured at 546-600 nm for quantifying GSP in serum.

The assay was evaluated on the Vista chemistry analyzer using an open channel user defined method. Performance of the assay was evaluated for inter and intra assay precision, accuracy, linearity, reference ranges and specimen stability.

Results and Discussion

Precision:

	Intra Assay	Inter Assay
Low control	267.01±11.2 (4.2%)	263.9±17.0 (6.5%)
High control	728.39±18.4 (2.5%)	715.1±26.7 (3.7%)

Analytical Measurement Range & Accuracy:

Analytical measurement range (AMR) was verified using five level calibrators and acceptable across the range.

Accuracy and recovery of the assay was acceptable with a mean recovery of 100±5 % across the AMR.

Correlation:

Comparisons between laboratory assay and vendor predicted assay on Stanbio Sirrus clinical chemistry analyzer compared well (r-square=0.996, slope=1.0 and intercept=-1.49).

Stability Studies:

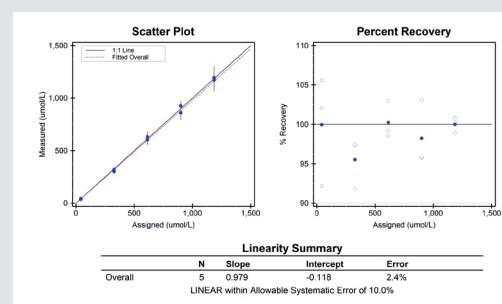
Stability studies proved that samples stored at 2-4 °C are stable up to 7 days with no significant variations.

Reference Range Verification:

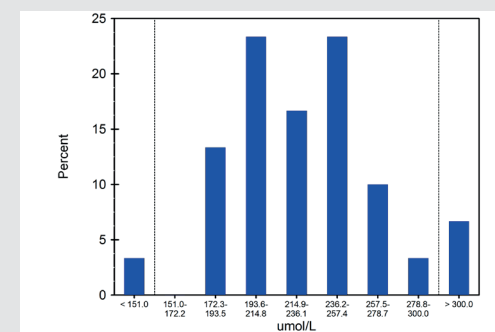
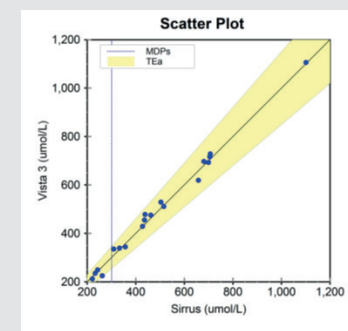
Lab also verified the reference interval as 151-300 µmol/L using adult patient population (18-65 yrs).

Conclusion:

- The user defined application for the GSP assay enhances the versatility of the Vista system for specialized glycemic monitoring for specific diabetic subpopulations, where the patient has either a genetic variant of hemoglobin, or a condition or treatment that affects RBC turnover.
- The assay provides labs with a simple, sensitive and fast alternative glycemic monitoring test with no endogenous substance interference that are typically observed in NBT based colorimetric assays.



AMR : 41.0 to 1185.2 umol/L



Reference Interval Verification (n=30)