A Novel Method for the Measurement of Serum Viscosity: Evaluation of the Rheosense microVISC™ Viscometer

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Abstract

Background: Measurement of serum viscosity is used to evaluate Hyperviscosity Syndrome (HVS), which is associated with plasma cell dyscrasia, myeloma, connective tissue diseases, and other inflammatory conditions. Rapid treatment of HVS is critical to ensure effective reduction of risk from serious complications. Increased viscosity, caused by the excessive intravascular paraproteins, leads to impaired transit of blood through the microcirculatory system. The vascular stasis and resultant hypoperfusion can cause severe complications which include cardiopulmonary symptoms such as shortness of breath, hypoxemia, acute respiratory failure, and hypotension; neurological effects such as confusion / mental status changes; ocular damage including dilation of the retinal veins and retinal hemorrhages; bleeding from the mucous membranes; and renal failure. Measurement of serum viscosity is essential for an accurate diagnosis, but traditional methods are labor intensive and not amenable to STAT analysis. We have evaluated a new instrument, the Rheosense microVISC™, for the rapid analysis of serum viscosity.

Methods: The microVISC™ (Rheosense, Inc., San Ramon, CA) is a small portable instrument which uses VROC® (Viscometer/Rheometer-on-a-Chip) technology. The VROC® sensor obtains a viscosity reading by measuring the pressure drop as a sample flows through a flow channel. Pressure is measured at positions of increasing distance from the inlet. The slope of the straight line in the plot of the pressure vs. sensor position is proportional to the viscosity. We evaluated this new instrument for use in the clinical laboratory. The performance evaluation in this study included within-in run and between-run precision and linearity, using standards purchased from Rheosense, Inc. Accuracy was determined by correlation of the microVISC™ (Rheosense, Inc.) to a cone and plate viscometer using patient samples. We used serum samples from patients with a normal comprehensive metabolic panel to verify the reference range. Statistical analyses were performed using EP Evaluator® (Data Innovations).

Results:

The within-run precision for normal and abnormal controls was < 1%. Mean/standard deviation/ % CV for between-run precision were 1.54 cP/0.05 cP/3.25% and 4.12 cP/0.10 cP/2.43% for normal and abnormal controls respectively. The linear range was verified for 0-6.38 cp. The microVISC correlated well with the cone and plate method: y= 0.836x + 0.064 (r= 0.979). The small negative bias was reflected in a slightly lower reference range of 1.10-1.60 cP for serum samples.

Conclusions: We validated the microVISC instrument for the rapid, accurate, and reproducible measurement of serum viscosity in a clinical laboratory setting. The instrument is small, portable, and easy to use and maintain.

Rheosense microVISC viscometer

Introduction

The definition of viscosity is the measurement of the resistance of a liquid or fluid to flow. It is a characteristic property of a fluid and a constant for a given liquid at a given temperature (for Newtonian fluids). The fluid must be in motion for the property of viscosity to be observed. . Plasma and serum are Newtonian fluids. Their viscosities are the same regardless of the speed at which they are flowing. Methods for the measurement of plasma, serum, and whole blood viscosity all require the sample to flow. To measure the viscosity of a sample, modern viscometers measure the rate of fluid flow at a specified force or pressure. The conventional unit of viscosity measurement in the metric system is the *poise.* Viscosity values for biologic fluids are in centipoise (cP), which is equal to 1/100 of a poise.

The microVisc requires only 100 uL of sample and results are available in 60 seconds. It is a small portable instrument weighing only 1.6 lbs. The microVISC TC, a precise temperature controller, can keep the temperature constant to minimize variability.

Method and Procedure

All samples were analyzed at 37° C.

Calibration: The microVISC is calibrated from the factory with a sensor cartridge or chip which is re-calibrated annually by company, Rheosense. Several sensor chips are available which measure different ranges of viscosity. The chip used for serum measurements is designed to test viscosities from 0.0 -10.0 cP.

Accuracy: 40 patient serum samples were assayed using the Rheosense microVISC™ viscometer. Aliquots of the 40 serum samples were shipped to a reference laboratory for analysis using a cone and plate viscometer. Deming regression analysis was used for statistical correlation.

Precision: Within-run precision was determined with multiple measurements of a “normal” control (MGVS60) and a “High/Abnormal” control (MGVS20) purchased from Rheosense, Inc,) . Between-run precision was determined by analyzing the controls (MGVS60 and MGVS20), daily for 25 days.

Linearity: Linearity was determined by analyzing 3 samples of known concentration (water, and 2 standards) in quadruplicate.

Reference range Verification was performed using 30 patient samples with normal comprehensive metabolic panels.

Statistical Analyses were cslculated using EP Evaluator.

Rheosense microVISC viscometer within temperature controller

Results

Figure 1: Method Correlation for microVISC versus cone & plate

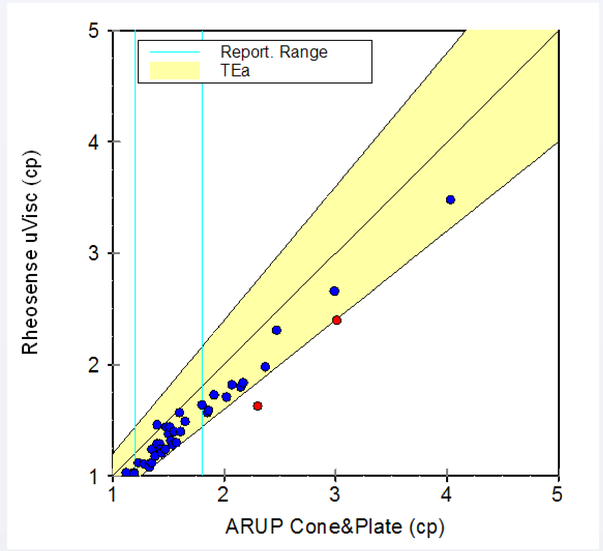
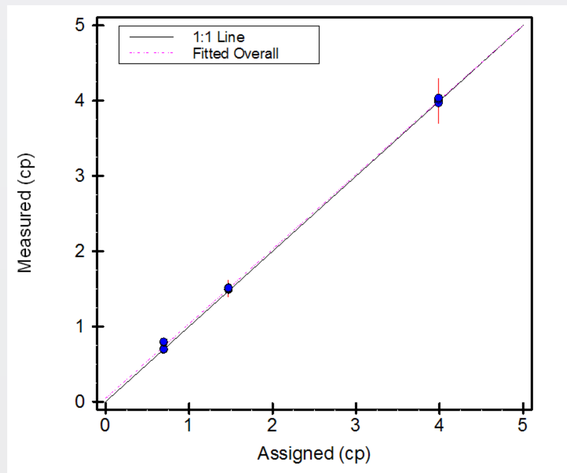


Table 1: Precision

	Within Run Precision			Between Run Precision		
	Mean (cP)	SD (cP)	%CV	Mean (cP)	SD (cP)	%CV
Normal (MGVS60)	1.50	0.050	0.64	1.54	0.05	3.25
High/Abnormal (MGVS20)	4.00	0.021	0.57	4.12	0.10	2.43

Figure 2: Linearity



Conclusion

1. The microVISC viscometer is an instrument that has been validated successfully for application with clinical specimens.
2. The microVISC viscometer provides accurate and precise results for clinical serum samples.
3. The microVISC viscometer is simple to use and provides rapid results for serum viscosity in a clinical setting