Technical Note

ESR-Auto Plus® - Excellent Correlation to Modified Westergren

Abstract

This study was conducted to verify correlation of the automated Streck ESR-Auto Plus system to the Modified Westergren benchmark method. Seven ESR-Auto Plus systems were evaluated against the manual Fisherbrand™ Dispette™ 2. In summary, the average data collected indicates the ESR-Auto Plus systems meet or exceed a 98% correlation to the Modified Westergren.

Introduction

The erythrocyte sedimentation rate (ESR) continues to be one of the most widely performed laboratory tests. The Westergren method, first introduced in 1921, and recommended as the ESR method of choice in 1973 by the International Council for Standardization in Haematology (ICSH), remains the benchmark against which other ESR methods are evaluated[1]. As described in Clinical and Laboratory Standards Institute (CLSI) document H02, *Procedures for the Erythrocyte Sedimentation Rate Test,* a modification of the Westergren method employs blood anticoagulated with EDTA and then diluted with sodium citrate to reproduce results identical to those obtained by the classical Westergren method[2].

While the Westergren method is considered the benchmark for ESR analysis, it is not without significant limitations. Samples must be set up and analyzed within four hours of blood collection when samples are stored at room temperature, and within 24 hours when samples are stored at 4 °C. Sedimentation data must be visually evaluated by a technologist at precisely 60 +/- 1 minute and manually recorded. In addition, a number of variables including temperature control, vibration, tube verticality, and operator technique will affect the sedimentation rate.

Streck's ESR-Auto Plus system maintains excellent correlation to the Modified Westergren method. The ESR-Auto Plus offers a closed blood collection system that reduces exposure to potentially hazardous material and eliminates the possibility of biasing results with improper sodium chloride dilutions. The instrument simplifies the testing procedure, offers a barcode scanner to reduce errors in patient identification, and maintains a log of patient and QC results, eliminating the need for a technologist to be present to read and record results. Additionally, Streck's ESR-Vacuum Tube technology preserves sample integrity from the time of blood collection for up to 72 hours when transported / stored at 2 °C-10 °C, providing significant flexibility for the clinical laboratory[3].

Methods

Sample Collection

Blood from 10 donors was collected into five 1.2 mL Streck ESR-Vacuum Tubes and three standard EDTA tubes. Samples collected in ESR-Vacuum Tubes were immediately mixed by manually inverting eight times, allowing the air bubble to reach the end of the tube with each inversion. Samples collected in EDTA tubes were inverted six to eight times after collection. All samples were tested immediately after collection.

Sample Preparation for Modified Westergren

Blood samples collected in standard EDTA tubes were inverted six to eight times allowing the air bubble to reach the end of the tube with each inversion. Using a transfer pipet, aliquots of 1.0 mL of blood were added to the fill line of a Dispette 2 reservoir, capped and mixed by manual inversion eight times allowing the air bubble to reach the end of the tube with each inversion. Following manufacturer instructions carefully, the Dispette 2 tubes were grasped at the 180 mm region and inserted through the cap membrane of the filling reservoir. After penetrating the reservoir, the pipet was gently pushed to the bottom of the reservoir and tubes were gently transferred and placed on a level stand at room temperature. ESR levels were recorded in mm/hr at exactly 60 minutes.

Sample Preparation for ESR-Auto Plus

Identification numbers assigned to each donor were entered into the ESR-Auto Plus instrument. Samples in ESR-Vacuum Tubes were manually inverted eight times allowing the air bubble to reach the end of the tube with each complete inversion, and when prompted, were inserted into a free position in the ESR-Auto Plus to initiate testing. Results in mm/hr were automatically printed when the 30-minute QuickMode measurement was complete.

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Results

Table 1 summarizes the correlation data obtained from samples collected in EDTA tubes with aliquots transferred into: Streck ESR-Vacuum Tubes for analysis on the ESR-Auto Plus; and Dispette tubes for analysis on the Dispette 2 method.

Table 1

ESR-Auto Plus vs Modified Westergren Whole Blood Correlation

	Correlation	Sample size
ESR-Auto Plus Model 506	98.3%	n=30
ESR-Auto Plus Model 505	98.0%	n=30

Discussion

The ESR test is susceptible to a variety of errors. It is important to stress that proper specimen mixing and handling are critical for reproducing the results from this study. Testing should commence within four hours of collection if samples are being held at ambient temperature. Results can be affected by a variety of pathological factors including anemia and red blood cell size, and environmental factors such as temperature and vibration.

The clinical utility of the ESR test has long been debated. The use of the ESR as a screening test to identify patients who have serious disease is not supported by the literature. There has been some use of the ESR as a diagnostic parameter for rheumatoid arthritis but the test is a means of staging the disease, not a key diagnostic finding as the American College of Rheumatology's criteria states an elevated ESR is one of four blood work findings that may be present[4]. Although there is an enormous body of literature concerning the ESR, an elevated value remains a nonspecific finding. The FDA continues to classify all automated ESR systems, such as the ESR-Auto Plus, as class 1, 510(k) exempt medical devices[5].

Statistical tools such as total error, commonly used in more sophisticated chemistry and immunoassay testing, are most practical when applied to control material given the rapid degradation of biological material and the compound variability and total error of the manual, comparative method. The value of total analytical error for clinicians is that it provides a measure of the quality of the assay that can be directly tied to improving medical errors. The challenge lies in defining how good a test needs to be for its intended clinical use.

A note about statistical quality control

Statistical quality control (SQC), while outside the scope of this bulletin but worth a brief mention, is an essential tool for managing analytical quality, but the rules and criteria should be optimized for value and efficiency. Experts in laboratory statistical analysis are moving towards a merger of the traditional Westgard QC "multi-rules" and the Six Sigma principles, a process improvement methodology focused on eliminating defects in a product or service utilizing the following formula:

Sigma scale = (TEa – Bias) / CV

- TEa, allowable Total Error (Using Proficiency survey limits or CLIA limits)
- Bias, inaccuracy of the method (Lab Mean – Peer Mean)
- CV, imprecision of the method (Using daily quality control data or from a replication experiment)

These calculations lead to the application of the Westgard Sigma Rules™, a quicker approach to helping laboratories select the appropriate statistical quality control for their applications[6].

Conclusion

CLSI recommends that all new ESR methodologies be verified to give results in accordance with the traditional Westergren reference method and the H02 guideline suggests a traditional regression analysis for this whole blood comparison. This regression analysis serves as part of the laboratory's documentation for risk assessment to meet CLIA's IQCP regulation[7]. Automated instruments such as the ESR-Auto Plus improve the practicality of the original Westergren method. Streck's ESR-Auto Plus further reduces the potential biohazard, shortens the turn-around time, and provides excellent correlation to the Modified Westergren benchmark method.

References:

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