True sed rate testing: An established tool for the clinical laboratory

Discover the importance of a true ESR measurement, instead of data extrapolation.

THE QUEEN'S AWARDS FOR ENTERPRISE: INTERNATIONAL TRADE 2021

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STRECK

Introduction

The erythrocyte sedimentation rate (ESR) is a diagnostic blood test that is routinely used as a non-specific marker of inflammation and infection. This established testing method is a staple in the clinical laboratory as a first-line indicator due to its simplicity of use and inexpensive implementation.

The traditional Westergren method is considered the gold standard for ESR testing and remains the method of choice among clinicians around the world. These quantifiable results are based on well-known sedimentation techniques that measure the rate at which red blood cells (RBCs or erythrocytes) gradually aggregate and settle as sediment at the bottom of a vertical sample tube.

Manufacturers are continually developing alternative techniques that build on this tried and tested sedimentation method to promise faster and equivalent results. However, certain alternative rapid "sed rate" methods developed using Photometrical rheoscope only provide extrapolated ESR values rather than true sedimentation rates based solely

Contents

on the sample as measured by the Streck, Diesse platform.

These newly developed methods are also often difficult to correlate with established normal patient ranges, as changes to the benchmark ESR approach have the potential to create unexpected variations in the quantified results that clinicians expect and rely on.

The Diesse MINI-CUBE and its higher-throughput counterpart, the Diesse CUBE 30 Touch from Streck, are two pieces of ESR instrumentation that are designed to provide a "true" sedimentation rate.

In utilizing a sedimentation technique, these instruments provide results with excellent correlation to benchmark methods. Compare their performance to the modified Westergren method and evaluate this precision in the correlating studies below:

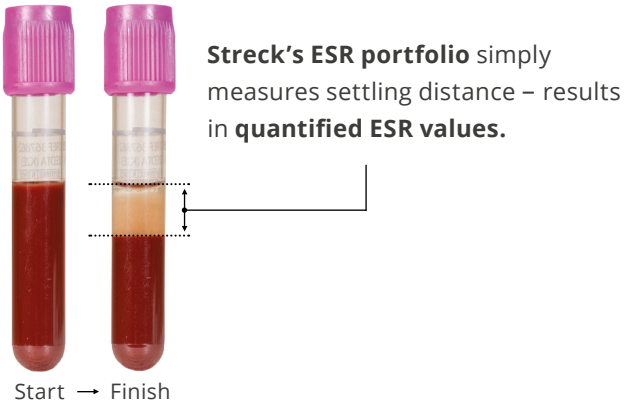
- MINI-CUBE correlation study
- MINI-CUBE precision study
- CUBE 30 Touch correlation study
- CUBE 30 Touch precision study

Find out more about Streck's Diesse portfolio here and achieve true sed rates with:

- No sample contamination
- No sample reduction
- No biohazardous waste

The Diesse closed-system instruments perform their analysis directly from multiple EDTA tubes, which eliminates extra steps from your workflow, reduces turnaround time to results, and ultimately results in a more flexible and streamlined approach to ESR testing.

This method doesn't open or pierce the EDTA tubes. There is no sample contamination or reduction in sample volume. This eliminates sample volume concerns for further testing and the potential of contamination. Finally, this method does not produce any biohazardous waste material that would otherwise need appropriate disposal.



***Is a true sed rate technique important?** The Diesse CUBE 30 Touch and Diesse MINI-CUBE both utilize the Modified Westergren sedimentation, providing a traditional 'true' sed rate measure and result.*

Streck's history of innovation has led to providing a comprehensive ESR portfolio of instrumentation and controls to ensure accurate test results.

Superior Science

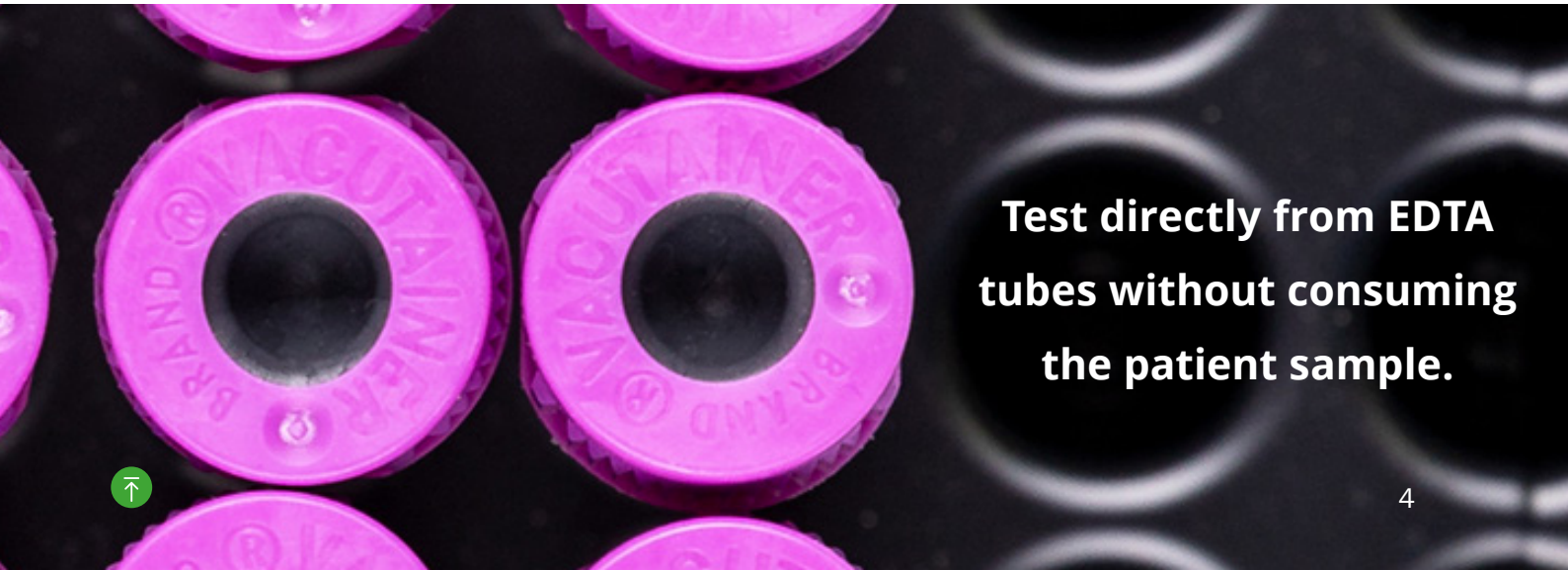
+ Utilization of traditional sed-rate technique that measures the difference in a start point versus end point of the red blood cells settling during a specific time limit.
  - Correlated with Modified Westergren Method.
+ Optimal size and capabilities to meet the needs of your lab:
  - Diesse CUBE 30 Touch – higher volume instrument for up to 60 samples per hour.
  - Diesse MINI-CUBE – expanded sample options that include EDTA, BD Microtainer® and BD Microtainer MAP tubes.
+ Closed system:
  - NO pipetting.
  - NO sample consumption. Eliminate the possibility of low volume for other tests.
  - NO contamination risk.
  - NO waste material collected.
+ ESR control that utilizes actual red blood cells that replicate a patient sample.
+ Results are trusted by clinicians.

Ease of Use

+ User-friendly touchscreen interface with external barcode scanner and printer.
+ Ability to interface with most Lab Information Systems (LIS).
+ Instrument footprint that optimizes lab bench space.
+ No reagents or pipetting required.

Comprehensive Support

+ Technical Support team consists of Medical Laboratory Scientists, to assist with product questions.
+ Dedicated Sales and Customer Care team available at 800.228.6090.
+ Streck *STATS*-Link® program is an effective way to evaluate the results of your lab versus a peer group.



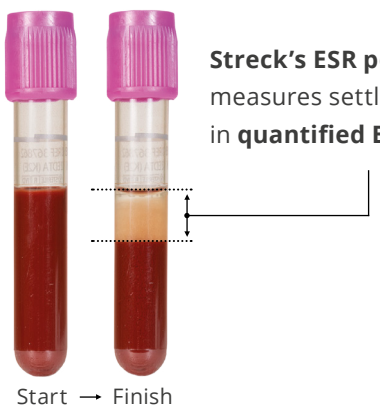
Is a true sed-rate technique important?

Two different techniques are referred to as "sed-rate," but only the Diesse platform provides a true sed-rate result.

The sed-rate is one of the most established tests in the clinical laboratory, providing clinicians with insights into general inflammation and health of a patient. The quantified results are well known based on sedimentation techniques.

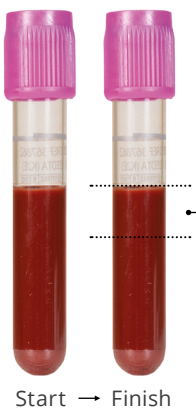
Does a change in approach or technique create a potential difference in the results clinicians expect as a first line indicator for their patients? It is critical to maintain both rapid results and established sedimentation rate methodology to provide results that correlate well with established normal patient ranges for years.

+ Diesse CUBE 30 Touch and Diesse MINI-CUBE both utilize the Modified Westergren sedimentation method.
  - The Diesse sed-rate platform:
    - » Requires no piercing of the tube.
    - » Does not consume sample. Eliminate the possibility of a low volume for other tests.
    - » Does not collect biohazardous waste material.
+ Other rapid "sed-rate" instrument manufacturers utilize capillary photometric-kinetic technology, a method which only measures the degree of red blood cell aggregation and extrapolates the ESR value from this measurement.
  - This technique:
    - » Requires piercing of the patient tube.
    - » Consumes the patient sample: risks contamination and possibly limits sample use for additional testing.
    - » Collects biohazardous waste material that requires disposal.



Start → Finish

Streck's ESR portfolio simply measures settling distance – results in **quantified ESR values.**



Start → Finish

The competitor uses **capillary photometric-kinetic technology** which measures the degree of aggregation – results in **extrapolated ESR values.**

no sedimentation

Scan tube

Insert tube

Diesse MINI-CUBE

+ Clear results in 20 minutes – test up to 12 samples per hour.
+ Compatible with standard 13 x 75 mm EDTA tubes and 500 µL BD Microtainer and BD Microtainer MAP EDTA tubes.
+ Excellent correlation to the Modified Westergren method.
+ User-friendly touchscreen interface.
+ External barcode scanner and printer.
+ QC and patient archives store 5,000 results per file.

20–minute run time

Clear results in 20 minutes

12 samples/hr

Insert tubes

Internal scanning and mixing

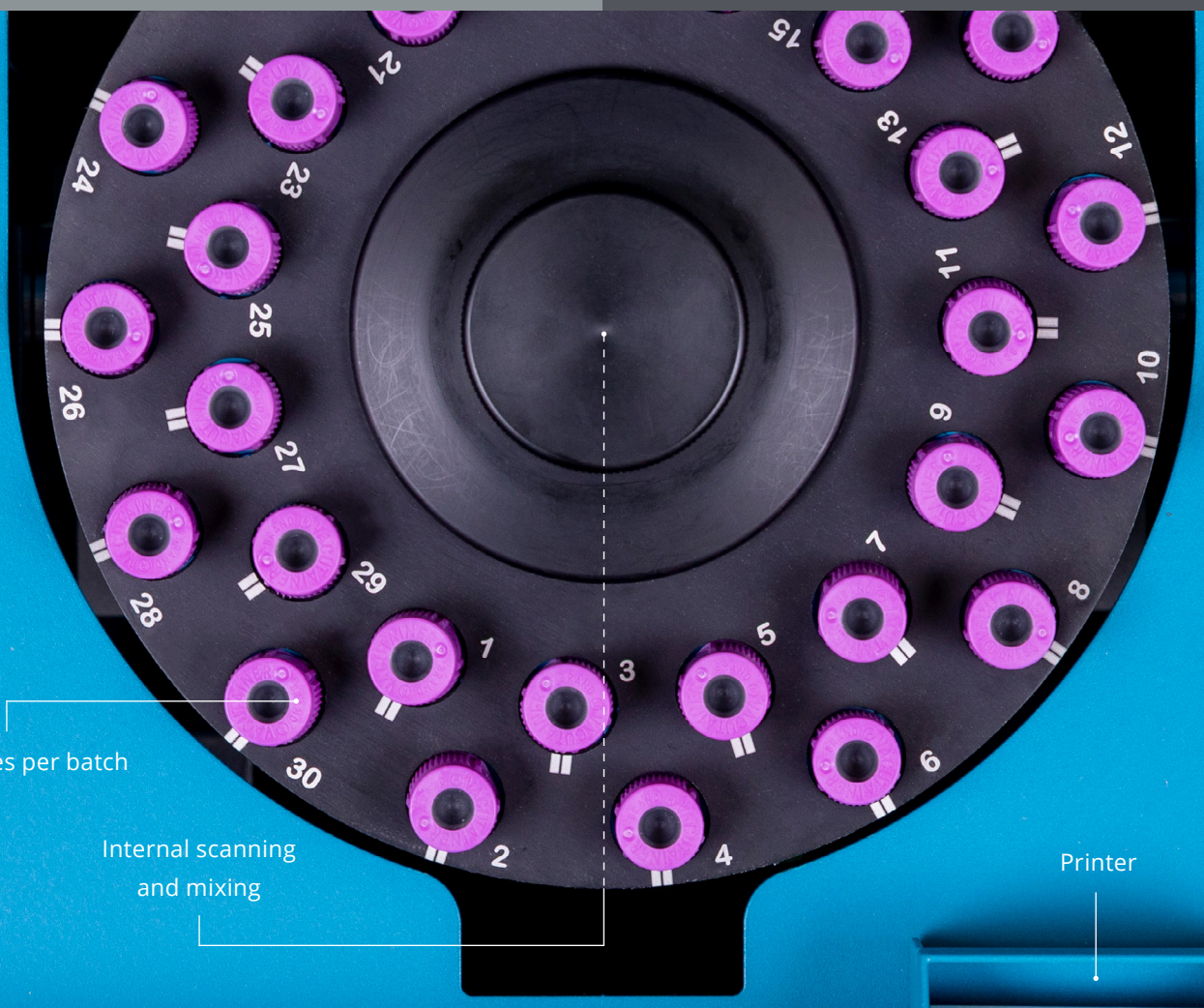
Diesse CUBE 30 Touch

+ Clear results in 20 minutes – test up to 90 samples per hour.
+ Compatible with standard 13 x 75 mm EDTA tubes.
+ Excellent correlation to the Modified Westergren method.
+ User-friendly touchscreen interface.
+ Internal barcode scanner and printer.
+ QC and patient archives store 5,000 results per file.

20–minute run time

20–minute run time

90 samples/hr



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Diesse MINI-CUBE Correlation Study

This study was conducted to verify correlation of the automated Diesse MINI-CUBE system to the Modified Westergren benchmark method and the Streck ESR-Auto Plus® automated method. The MINI-CUBE provides excellent correlation to Modified Westergren in standard 13 x 75 mm EDTA tubes. The system also provides flexibility to run 500 µL samples in BD Microtainer and BD Microtainer MAP tubes.

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 saline 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. A number of automated systems are available for ESR testing, but most pose some inconveniences for the clinical laboratory. A separate ESR tube is often needed, which does not eliminate the risk of exposure of lab personnel to potentially infectious material.

The MINI-CUBE system simplifies the testing procedure while maintaining excellent correlation to the Modified Westergren method. The MINI-CUBE performs a direct measurement of samples collected in standard 13 x 75 mm K_2 or K_3EDTA tubes, thereby eliminating the need for a separate ESR collection tube and potentially biased results due to improper sodium chloride dilutions, as well as reducing exposure to biological hazards. The instrument offers an archive for patient and QC results, LIS compatibility, a

barcode scanner for positive patient identification and an optional Bluetooth printer.[3]

To accommodate variability in blood collection tube configurations and patient sample volumes, the MINI-CUBE is compatible with standard 13 x 75 mm K_2 or K_3EDTA tubes with Hemogard or conventional stoppers and a sample volume of 2.0 mL to 4.0 mL. The MINI-CUBE is also compatible with standard BD Microtainer K_2EDTA tubes and BD Microtainer MAP K_2EDTA tubes with a sample volume of 500 µL. Correlation data is outlined in the Results section.

Methods

Sample Collection

Blood from donors was collected into one standard 13 x 75 mm, 4.0 mL K_2EDTA tube and one standard 10.0 mL K_2EDTA tube. Samples collected in EDTA tubes were mixed immediately after collection by completely inverting the tubes 8 to 10 times. All samples were tested within 4 hours of collection.

Sample Preparation for Modified Westergren

Blood samples collected in standard 10.0 mL K_2EDTA tubes were inverted 8 to 10 times allowing the air bubble to reach the end of the tube with each inversion. Using a transfer pipette, aliquots of

Diesse MINI-CUBE Correlation Study

1.0 mL of blood were added to the fill line of a Dispette 2 reservoir, capped and mixed by manual inversion 8 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 pipette 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 Diesse MINI-CUBE

4.0 mL sample volume: Blood samples collected in standard 13 x 75 mm, 4.0 mL draw volume K_2EDTA tubes were inverted 8 to 10 times allowing the air bubble to reach the end of the tube with each inversion.

2.0 mL and 3.0 mL sample volume: Blood samples collected in standard 10.0 mL K_2EDTA tubes were inverted 8 to 10 times allowing the air bubble to reach the end of the tube with each inversion. Using a pipette, aliquots of 2.0 mL or 3.0 mL of blood were added to standard 13 x 75 mm K_2EDTA tubes, capped and mixed by manual inversion 8 to 10 times allowing the air bubble to reach the end of the tube with each inversion.

500 µL sample volume: Blood samples collected in standard 10.0 mL K_2EDTA tubes were inverted 8 to 10 times allowing the air bubble to reach the end of the tube with each inversion. Using a pipette, aliquots of 500 µL of blood were added to standard BD Microtainer K_2EDTA tubes or BD Microtainer MAP K_2EDTA tubes, capped and mixed by manual inversion 8 to 10 times allowing the air bubble to reach the end of the tube with each inversion.

Care was taken during sample mixing to avoid the formation of bubbles, which could interfere with sample results. Identification numbers assigned to each donor were entered into the MINI-CUBE systems. When prompted, the tubes were inserted into a free position in the MINI-CUBE to initiate testing. Results in mm/hr automatically printed at the conclusion of the measurement.

Sample Preparation for Streck ESR-Auto Plus

Blood samples collected in standard 10.0 mL K_2EDTA tubes were inverted 8 to 10 times allowing the air bubble to reach the end of the tube with each inversion. Using a transfer pipette, the sample was added to the fill line of a Streck ESR-Vacuum Tube, capped and mixed by manual inversion 8 to 10 times allowing the air bubble to reach the end of the tube with each inversion.[4] Identification numbers assigned to each donor were entered into the ESR-Auto Plus instrument. When prompted, the tubes were inserted into a free position in the ESR-Auto Plus to initiate testing. Results in mm/hr automatically printed at the conclusion of the 30-minute measurement.

Results

Table 1 summarizes the correlation data obtained from samples collected in 13 x 75 mm K_2EDTA tubes (4.0 mL) for analysis on the MINI-CUBE and samples with aliquots transferred into 13 x 75 mm K_2EDTA tubes (2.0 mL and 3.0 mL) and BD Microtainer tubes (500 µL) for analysis on the MINI-CUBE; Dispette tubes for analysis on the Dispette 2 method; and Streck ESR-Vacuum Tubes for analysis on the ESR-Auto Plus.

Table 1

Diesse MINI-CUBE Whole Blood Correlation

		Study 1		Study 2*		Study 3*	
Diesse MINI-CUBE	**Method 2**	**Correlation**		**Correlation**		**Correlation**	
4.0 mL BD 13 x 75 mm K_2EDTA	Dispette 2	96.7%	n = 50	91.6%	n = 50	93.8%	n = 48
3.0 mL BD 13 x 75 mm K_2EDTA	Dispette 2	—	—	—	—	94.8%	n = 48
2.0 mL BD 13 x 75 mm K_2EDTA	Dispette 2	93.5%	n = 20	—	—	92.3%	n = 48
500 µL BD Microtainer K_2EDTA	Dispette 2	82.2%	n = 50	89.5%	n = 50	84.3%	n = 48
500 µL BD Microtainer MAP K_2EDTA	Dispette 2	n/a	n/a	80.1%	n = 50	79.5%	n = 48
4.0 mL BD 13 x 75 mm K_2EDTA	ESR-Auto Plus	93.9	n = 50	88.3%	n = 50	—	—

**Study 2 and Study 3 contain software updates to improve the BD Microtainer correlation and add BD Microtainer MAP tube compatibility.*

Diesse MINI-CUBE Correlation Study

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. Care was taken during sample mixing to avoid the formation of bubbles, which could interfere with the sample results. Both manual and automated ESR methods are subject to a high degree of variability in samples that lack a clear erythrocyte to plasma interface. Testing should commence within four hours of collection if specimen was 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 bloodwork findings that may be present.[5] Although there is an enormous body of literature concerning the ESR, an elevated value remains a non-specific finding. The FDA continues to classify all automated ESR systems, such as the MINI-CUBE, as class 1, 510(k) exempt medical devices.[6]

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.[7]

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.[8] Automated instruments such as the MINI-CUBE improve the practicality of the original Westergren method. The Diesse MINI-CUBE further reduces the potential biohazard, shortens the turnaround time, and provides excellent correlation to the Modified Westergren benchmark method.

References:

1. International Committee for Standardization in Haematology. Reference method for the sedimentation (ESR) test on human blood. BR J Haematol 1973; 24:671-673.
2. Clinical and Laboratory Standards Institute, H02. Procedures for the erythrocyte sedimentation rate test. Approved Standard.
3. Diesse MINI-CUBE User Manual.
4. ESR-Auto Plus Operator Manual.
5. American College of Rheumatology, www.rheumatology.org.
6. FDA, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm?GMPPart=864#start.
7. Westgard JO, Westgard SA. Basic Quality Management Systems 2014. Defining Statistical QC Procedures 171-188.
8. The Clinical Laboratory Improvement Amendment. Individualized Quality Control Plan alternate QC policy, http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html.

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Diesse CUBE 30 Touch – Excellent Correlation to Modified Westergren

The Diesse CUBE 30 Touch reduces the potential biohazard, shortens the turn-around time, and provides excellent correlation to the Modified Westergren benchmark method.

Abstract

This study was conducted to verify correlation of the automated Diesse CUBE 30 Touch system to the Modified Westergren benchmark method and the Diesse MINI-CUBE and Streck ESR-Auto Plus® automated methods. Three CUBE 30 Touch systems were evaluated against the manual Fisherbrand Dispette 2, the Diesse MINI-CUBE and the Streck ESR-Auto Plus. In summary, the data collected indicates the CUBE 30 Touch system meets or exceeds a 94% correlation to the Modified Westergren method for 4.0 mL CUBE 30 Touch samples.

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 saline 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. A number of automated systems are available for ESR testing, but most pose some inconveniences for the clinical laboratory. A separate ESR tube is often needed, which does not eliminate the risk of exposure of lab personnel to potentially infectious material.

The CUBE 30 Touch system simplifies the testing procedure while maintaining excellent correlation to the Modified Westergren method. The CUBE 30 Touch performs a direct measurement of samples collected in standard 13 x 75 mm K_2 or K_3 EDTA tubes, thereby eliminating the need for a separate ESR collection tube and potentially biased results due to improper sodium chloride dilutions, as well as reducing exposure to biological hazards. The instrument offers an internal mixing function for batch sample preparation, a data archive for patient and QC results, LIS compatibility, an internal barcode scanner for positive patient identification and an internal printer.[3]

To accommodate variability in patient sample volumes, the CUBE 30 Touch system is compatible with standard 13 x 75 mm K_2 or K_3EDTA blood collection tubes with a sample volume of 1.5 mL to 4.0 mL. Correlation data is outlined in the Results section.

Methods

Sample Collection

Blood from 50 donors was collected into three standard 13 x 75 mm, 4.0 mL K_2EDTA tubes. Samples collected in EDTA tubes were mixed immediately after collection by completely inverting the tubes six to eight times. All samples were tested within 4 hours of collection.

Diesse CUBE 30 Touch – Excellent Correlation to Modified Westergren

Sample Preparation for Modified Westergren

Blood samples collected in standard 4.0 mL K_2EDTA tubes were inverted six to eight times allowing the air bubble to reach the end of the tube with each inversion. Using a transfer pipette, 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 pipette 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 Diesse CUBE 30 Touch

4.0 mL sample volume: Blood samples collected in standard 13 x 75 mm, 4.0 mL draw volume K_2EDTA tubes were inverted six to eight times allowing the air bubble to reach the end of the tube with each inversion.

Identification numbers assigned to each donor were entered into the CUBE 30 Touch systems. When prompted, the tubes were inserted into a free position in the CUBE 30 Touch to initiate testing. Results in mm/hr automatically printed at the conclusion of the 20-minute measurement.

Sample Preparation for Diesse MINI-CUBE

4.0 mL sample volume: Blood samples collected in standard 13 x 75 mm, 4.0 mL draw volume K_2EDTA tubes were inverted six to eight times allowing the air bubble to reach the end of the tube with each inversion.

Care was taken during sample mixing to avoid the formation of bubbles, which could interfere with sample results. Identification numbers assigned to each donor were entered into the MINI-CUBE systems. When prompted, the tubes were inserted into a free position in the MINI-CUBE to initiate testing. Results in mm/hr automatically printed at the conclusion of the 20-minute measurement.

Sample Preparation for Streck ESR-Auto Plus

Blood samples collected in standard 4.0 mL K_2EDTA tubes were inverted six to eight times allowing the air bubble to reach the end of the tube with each inversion. Using a transfer pipette, the sample was added to the fill line of a Streck ESR-Vacuum Tube, capped and mixed by manual inversion eight to 10 times allowing the air bubble to reach the end of the tube with each inversion.[4] Identification numbers assigned to each donor were entered into the ESR-Auto Plus instrument. When prompted, the tubes were inserted into a free position in the ESR-Auto Plus to initiate testing. Results in mm/hr automatically printed at the conclusion of the 30-minute measurement.

Results

Table 1 summarizes the correlation data obtained from samples collected in 13 x 75 mm K_2EDTA tubes (4.0 mL) and analyzed on the Diesse CUBE 30 Touch and Diesse MINI-CUBE; Dispette tubes for analysis on the Dispette 2 method; and Streck ESR-Vacuum Tubes for analysis on the ESR-Auto Plus.

Table 1

Diesse CUBE 30 Touch Whole Blood Correlation

Method	Correlation	Sample Size
Diesse CUBE 30 Touch (4.0 mL*) vs. Dispette 2	94.39%	n = 50
Diesse CUBE 30 Touch (4.0 mL*) vs. MINI-CUBE (4.0 mL*)	96.66%	n = 50
Diesse CUBE 30 Touch (4.0 mL*) vs. ESR-Auto Plus	89.30%	n = 50

**CUBE 30 Touch and MINI-CUBE samples prepared in standard 13 x 75 mm K_2EDTA tubes.*

Discussion

ESR results obtained from specimens collected by direct patient draw or transferred from a K_2EDTA tube are equivalent on the automated methods in this study. 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. Care was taken during sample mixing to avoid the formation of bubbles, which could interfere with the sample results. Both manual and automated ESR methods are subject to a high degree of variability in samples that lack a clear erythrocyte to plasma interface. Testing should commence within four hours of collection if specimen was 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.

Diesse CUBE 30 Touch – Excellent Correlation to Modified Westergren

When samples are added to a cycle by the random access feature, the Diesse Cube 30 Touch employs a carousel that introduces slight lateral movement to the samples in order to scan the sample barcodes. While ESR testing traditionally requires samples to remain undisturbed, the ESR results obtained in this study indicate no appreciable difference or adverse effects as a result of the slight carousel movement.

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 bloodwork findings that may be present.[5] Although there is an enormous body of literature concerning the ESR, an elevated value remains a non-specific finding. The FDA continues to classify all automated ESR systems, such as the CUBE 30 Touch, as class 1, 510(k) exempt medical devices.[6]

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References

1. International Committee for Standardization in Haematology. Reference method for the sedimentation (ESR) test on human blood. BR J Haematol 1973; 24:671-673.
2. Clinical and Laboratory Standards Institute, H02-A5. Procedures for the erythrocyte sedimentation rate test. Approved Standard-Fifth Edition.
3. Diesse CUBE 30 Touch User Manual.
4. ESR-Auto Plus Operator Manual.
5. American College of Rheumatology, www.rheumatology.org.
6. FDA, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm?GMPPart=864#start.
7. Westgard J.O., Westgard S.A. Basic Quality Management Systems 2014. Defining Statistical QC Procedures 171-188.
8. The Clinical Laboratory Improvement Amendment. Individualized Quality Control Plan alternate QC policy, http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html.

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Diesse MINI-CUBE Precision

Overview

This document provides the results of the evaluation of precision of the Diesse MINI-CUBE instrument performed by Diesse Diagnostica Senese, SpA, March 2016.

Quality Control Material

ESR-Chex Level 1 (Normal) Lot 5159 Exp. Date 2016-06
ESR-Chex Level 2 (Abnormal) Lot 5159 Exp. Date 2016-06

MINI-CUBE Instruments

Instrument A Serial 1039200026 Software Version 0.64
Instrument B Serial 1039200027 Software Version 0.64
Instrument C Serial 1039200029 Software Version 0.64

Statistical Calculation of Precision

Intra-assay precision:

For each sample, the Mean (M) and Standard Deviation (SD) of the replicates are calculated. The Intra-assay Variation Coefficient (CV%) is calculated using the following formula: CV% = (SD/M)*100.

Inter-assay precision:

For each sample, the total Mean and SD from all the results obtained over the 5 days of the experiment are computed and Inter-assay CV% is calculated.

Inter-instrument precision:

For each sample, the total Mean and SD from all the results obtained over the 5 days of the experiment performed on 3 different instruments are computed and Inter-instrument CV% is calculated.

Acceptance criteria:

CV% ≤ 15%

Results

Intra-assay precision:

Means of 4 replicates of each QC blood sample tested on one instrument by a single operator during 1 working day.

	ESR Value (mm/h)	
	Streck ESR-Chex	
Replicate	Normal	Abnormal
1	11	52
2	11	47
3	11	50
4	11	64
Mean	11	53
SD	0.00	7.46
CV%	-	14.1

Table 1: Intra-assay precision

Inter-assay precision:

Means of 20 replicates of each QC blood sample tested on one instrument by a single operator during 5 working days.

	ESR Value (mm/h)				
	Streck ESR-Chex				
Replicate	Day 1	Day 2	Day 3	Day 4	Day 5
1	11	11	12	11	13
2	11	11	11	11	13
3	11	11	11	11	13
4	11	10	10	10	14

Mean	11
SD	1.09
CV%	9.9

Table 2a. Inter-assay precision, Normal Level

	ESR Value (mm/h)				
	Streck ESR-Chex				
Replicate	Day 1	Day 2	Day 3	Day 4	Day 5
1	52	51	53	50	51
2	47	47	49	47	50
3	50	65	65	63	67
4	64	50	53	48	52

Mean	54
SD	6.84
CV%	12.7

Table 2b. Inter-assay precision, Abnormal Level

Diesse MINI-CUBE Precision

Inter-instrument precision:

Means of 60 replicates of each QC blood sample tested on 3 instruments by a single operator during 5 working days.

		ESR Value (mm/h)				
		Streck ESR-Chex				
Instrument	Replicate	Day 1	Day 2	Day 3	Day 4	Day 5
Instrument A	1	11	11	12	11	13
	2	11	11	11	11	13
	3	11	11	11	11	13
	4	11	10	10	10	14
Instrument B	1	10	11	10	10	10
	2	10	11	11	11	11
	3	10	10	11	11	10
	4	9	11	11	9	11
Instrument C	1	10	11	10	11	11
	2	10	10	11	11	11
	3	11	10	11	11	11
	4	10	11	11	11	10

Mean	11
SD	0.88
CV%	8.0

Table 3a. Inter-instrument precision, Normal Level

		ESR Value (mm/h)				
		Streck ESR-Chex				
Instrument	Replicate	Day 1	Day 2	Day 3	Day 4	Day 5
Instrument A	1	52	51	53	50	51
	2	47	47	49	47	50
	3	50	65	65	63	67
	4	64	50	53	48	52
Instrument B	1	50	52	51	49	49
	2	47	49	48	46	46
	3	65	65	65	48	62
	4	50	50	52	63	48
Instrument C	1	55	53	56	54	50
	2	50	50	53	52	48
	3	66	65	72	68	63
	4	51	50	55	54	49

Mean	54
SD	6.93
CV%	12.8

Table 3b. Inter-instrument precision, Abnormal Level

Conclusion

All the values obtained during the precision evaluation experiment fall within the expected range and confirm the precision and repeatability of the MINI-CUBE instrument.

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Diesse CUBE 30 Touch Precision

All the values obtained during the precision evaluation experiment fall within the expected range and confirm the precision and repeatability of the CUBE 30 Touch instrument.

Overview

This document provides the results of the evaluation of precision of the Diesse CUBE 30 Touch instrument performed by Streck, Inc., April 2018.

Quality Control Material

ESR-Chex Plus Level 1	Lot 403	Exp. Date 2019-01
ESR-Chex Plus Level 2	Lot 403	Exp. Date 2019-01

Instruments

CUBE 30 Touch Serial 1039500112 Software Version 1.0

Statistical Calculation of Precision

Intra-assay precision:
For each sample, the Mean (M) and Standard Deviation (SD) of the replicates are calculated. The Intra-assay Variation Coefficient (CV%) is calculated using the following formula: CV% = (SD/M)*100.

Acceptance criteria:
CV% ≤ 15%

Data

ESR-Chex Plus Data
ESR-Chex Plus data was collected in each sample position on a single instrument by a single operator during 3 working days spanning the open-vial stability period of the control.

	ESR Value (mm/h) Level 1, Lot 403			ESR Value (mm/h) Level 2, Lot 403		
Position	Day 1	Day 5	Day 7	Day 1	Day 5	Day 7
1	1	1	1	47	47	51
2	1	1	6	47	47	49
3	2	1	2	47	47	49
4	1	2	4	49	47	47
5	1	1	1	49	47	49
6	1	1	1	47	47	47
7	2	1	4	47	49	49
8	3	5	1	47	47	49
9	1	2	4	47	49	47
10	4	5	1	49	47	47
11	2	2	2	49	47	47
12	1	1	1	49	47	47
13	2	1	1	49	47	49
14	2	4	3	49	47	47
15	1	2	3	49	47	49
16	3	1	2	49	47	47
17	2	2	1	47	47	49
18	2	1	2	47	45	45
19	2	2	1	49	49	47
20	3	1	4	47	47	49
21	1	1	3	49	49	47
22	1	2	1	47	47	47
23	2	2	3	47	47	49
24	2	1	1	47	47	49
25	1	2	1	49	49	51
26	2	2	2	49	49	51
27	1	1	1	49	49	49
28	1	1	1	47	47	49
29	3	2	2	49	49	51
30	4	4	2	47	47	49

Table 1: ESR-Chex Plus Data Table, lot 403

Diesse CUBE 30 Touch Precision

Results

Intra-assay precision (Repeatability):
Means of 30 replicates of each QC blood sample tested on one instrument by a single operator during 1 working day.

	ESR Value (mm/h) Level 1, Lot 403	ESR Value (mm/h) Level 2, Lot 403
Mean	2	48
SD	1.3	1.3
CV%	–*	2.6%

Table 2: Intra-assay precision, Repeatability

Intra-assay precision (Within-lab):
Means of 90 replicates of each QC blood sample tested on one instrument by a single operator during 3 working days spanning the open-vial stability of the control.

	ESR Value (mm/h) Level 1, Lot 403	ESR Value (mm/h) Level 2, Lot 403
Mean	2	48
SD	1.8	1.4
CV%	–*	2.9%

Table 3: Intra-assay precision, Within-lab

**When the mean value is close to zero, the coefficient of variation will approach infinity and is sensitive to small changes in the mean. Therefore, CV% is not reported for this value.*

Conclusion

All the values obtained during the precision evaluation experiment fall within the expected range and confirm the precision and repeatability of the CUBE 30 Touch instrument.

Featured products

Hear from reviewers using the Diesse MINI-CUBE from Streck to ensure true ESR measurements:

★★★★★

"Love it! Very easy to use. Simple to order. No worry with checking inventory."

Doug Mueller,
Mason District Hospital

★★★★★

"Sed rates are no longer a hassle! MINI-CUBE is very easy to use, even allowing us to use pediatric bullets."

Ashley Robinson,
HCA Houston Healthcare

★★★★★

"This analyzer is great. Easy to use. The tech support and all those at Streck have been very helpful."

Celinda Holik,
St. Mary's Healthcare

★★★★★

"The Diesse MINI-CUBE is very effective in achieving high-quality and reproducible results. It is very easy to use and set up. This analyzer makes running ESR very easy, quick, and reliable."

Fridai O'Brien,
Fort Duchesne Health Center

★★★★★

"The analyzer is compact with good reportability to laboratory information systems, no transferring of specimen or quality control material, and no daily calibration."

Karen Faller,
Door County Medical Center

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Diesse MINI-CUBE from Streck

Diesse CUBE 30 Touch from Streck