SEDRite Plus

HEMATOLOGY CONTROLS

CONTROL

LOT SR0725

2026-01-05

QC DATA MONTHS: JUL, AUG, SEP, OCT, NOV, DEC

		LEVEL 1 LOT SR0725-1				LEVEL 2 LOT SR0725-2			
METHOD	Units	Mean	Range			Mean	Range		
Diesse Mini-Ves	mm/hr	10	1	-	19	64	24	-	104
Diesse Ves-Matic 10/Easy	mm/hr	10	1	-	19	64	24	-	104
Diesse Ves-Matic 20	mm/hr	10	1	-	19	64	24	-	104
Excyte™ 10/M	mm/hr	10	1	-	19	54	14	-	94
Excyte 40	mm/hr	10	1	-	19	58	18	-	98
Westergren, sodium citrate diluted	mm/hr	10	1	-	19	36	11	-	61
Westergren, undiluted *	mm/hr	9	1	-	17	28	8	-	48
STARRSED	mm/hr	10	1	-	19	42	17	-	67
Wintrobe	mm/hr	10	1	-	19	28	8	-	48

* Test is considered undiluted if no fluid is introduced to specimen during any step of testing process.

INTENDED USE

SEDRite Plus is a control designed to monitor erythrocyte sedimentation rate (ESR) values obtained from manual and automated ESR methods. Please refer to the assay table for specific methods.

SUMMARY AND PRINCIPLE

It is an established laboratory practice to use a stable control to monitor the performance of diagnostic tests. This control is composed of stable materials that provide a means of monitoring the performance of manual and automated ESR methods. It is sampled in the same manner as an EDTA anti-coagulated patient specimen.

REAGENTS

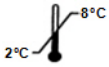
SEDRite Plus is an *in vitro* diagnostic reagent composed of mammalian erythrocytes suspended in a plasma-like fluid with preservatives.

PRECAUTION

SEDRite Plus is intended for ***in vitro*** **diagnostic use** only by trained personnel.

WARNING:

POTENTIAL BIOHAZARDOUS MATERIAL. Wear protective laboratory gloves and other blood barrier protection when handling this control. Human Blood components were not used in the manufacture of this control. However, this control does contain components from non-human sources and may transmit infectious disease. When handling or disposing of product, follow precautions for patient specimens as specified in the OSHA Bloodborne Pathogen Rule (OSHA 29 CFR Part 1910.1030) or other equivalent biosafety procedures.



STABILITY AND STORAGE

Store SEDRite Plus upright at 2 - 8° C (35 - 46° F) when not in use. **Protect tubes/vials from overheating and freezing.** Unopened vials are stable through the expiration date. Opened tubes/vials are stable for 30 days, provided they are handled properly.

INDICATIONS OF DETERIORATION

After mixing, product should not be similar in appearance to fresh whole blood. In unmixed vials the supernatant fluid is expected to be of dark color. Unacceptable results may indicate deterioration**. Do not use the product if deterioration is suspected.**

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INSTRUCTIONS FOR USE

CAUTION: It is critically important to mix SEDRite Plus thoroughly at all mixing steps.

1. Remove tubes/vials from the refrigerator and allow to warm to 20 - 25°C (68 - 77°F) for 15 minutes before mixing.
2. To mix, hold a tube/vial horizontally between the palms of the hands. **Do not pre-mix on a mechanical mixer**.
   a) Roll the tube/vial back and forth for 30 - 60 seconds; occasionally invert the tube/vial. Mix **vigorously**, but do not shake.
   b) Continue to mix in this manner until the red cells are completely suspended. Tubes/vials stored for a long time may require extra mixing.
   c) Gently invert the tube/vial 10 times immediately before sampling.
3. Analyze the sample as instructed by the instrument manufacturer's instructions for your instrument/equipment.
   a) For automated methods, do not remove the diluent from test reservoirs before using this control.
   b) For manual methods, if you normally dilute patient samples, also dilute the control.
4. After sampling:
   c) If tube/vial has been open for sampling, clean residual material from the cap and tube rim with a lint-free tissue. Replace the cap tightly.
   d) Return tubes/vials to refrigerator within 30 minutes of use.

EXPECTED RESULTS

Verify that the lot number on the tube/vial matches the lot number on the table of assay values. Assay values are determined on well-maintained, properly calibrated instruments using the instrument manufacturer's recommended reagents. Reagent differences, maintenance, operating technique, and calibration may contribute to inter-laboratory variation.

PERFORMANCE CHARACTERISTICS

Assigned values are presented as a Mean and Range. The Mean is derived from replicate testing on instruments operated and maintained according to the manufacturer's instructions. The Range is an estimate of variation between laboratories and also takes into account inherent imprecision of the method and expected biological variability of the control material.

Assay values on a new lot of control should be confirmed before the new lot is put into routine use. Test the new lot when the instrument is in good working order and quality control results on the old lot are acceptable. The laboratory's recovered mean should be within the assay range.

For greater control sensitivity each laboratory should establish its own mean and acceptable range and periodically reevaluate the mean. The laboratory range may include values outside of the assay range. The user may establish assay values not listed on the Assay Sheet, if the control is suitable for the method.

LIMITATIONS

The performance of this product is assured only if it is properly stored and used as described in this insert. Incomplete mixing of a tube/vial prior to use invalidates both the sample withdrawn and any remaining material in the tube/vial.

TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

For assistance in resolving control recovery problems, please call Technical Service at (800) 523-3395. For additional information on R&D Systems, Inc. hematology controls and calibrators, or to place an order, call Customer Service at (800) 428-4246.

QUALITY CONTROL PROGRAM

For information on CBC-Monitor, our Inter-Laboratory Quality Control Program, call (800) 523-3395 ext. 4435.

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EC REP

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IVD

CE

Rx Only