SEDRite III

HEMATOLOGY CONTROLS

CONTROL

LOT SED0717

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

2018-01-05

		LEVEL 1 LOT SED0717-1			LEVEL 2 LOT SED0717-2		
METHOD	Units	Mean	Range		Mean	Range	
Sedimat® 15	mm/hr	6	1	- 11	57	27	- 87

INTENDED USE

SEDRite III is a control designed to monitor erythrocyte sedimentation rate (ESR) values obtained from 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 automated ESR methods. It is sampled in the same manner as an EDTA anti-coagulated patient specimen.

REAGENTS

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

PRECAUTION

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

WARNING:

POTENTIAL BIOHAZARDOUS MATERIAL For *in vitro* diagnostic use. Each human donor/unit used in the preparation of this product has been tested, and yielded non-reactive / negative results for all conditions referenced in 21 CFR 610.40 (a) (b), as required by the FDA. Testing was conducted using FDA-licensed tests. Additional details can be found at: http://www.rndheme.com/TechnicalInformation.aspx.
No test method can offer complete assurance that infectious agents are absent; therefore this material should be handled as potentially infectious. When handling or disposing of vials follow precautions for patient specimens as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

STABILITY AND STORAGE

Store SEDRite III 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.**

INSTRUCTIONS FOR USE

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

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

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EXPECTED RESULTS

Verify that the lot number on the tube 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.

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 prior to use invalidates both the sample withdrawn and any remaining material in the tube.

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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