

# HemaTechnologies

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## ASSAY SHEET

### ESR CONTROL

MANUFACTURER R&D SYSTEMS, Inc.  
MATERIAL SEDRite™ Plus - Lot # SR-071  
EXPIRATION DATE 05 January 2012

		LEVEL I Lot No. <b>SR 071-1</b>		LEVEL II Lot No. <b>SR 071-2</b>	
METHOD	UNITS	MEAN	RANGE	MEAN	RANGE
<b>ESR STAT PLUS</b>	mm/hr	13	5 - 21	96	58 - 134

Note: 1. Follow the enclosed R & D Systems instructions for use.  
2. Assay values provided by HemaTechnologies.

# SEDRite Plus

## HEMATOLOGY CONTROLS

### CONTROL

**LOT** SR071



2012-01-05

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

		<b>LEVEL 1</b>	<b>LOT</b> SR071-1	<b>LEVEL 2</b>	<b>LOT</b> SR071-2
METHOD	Units	Mean	Range	Mean	Range
Diesse Mini-Ves	mm/hr	10	1 - 19	70	40 - 100
Diesse Ves-Matic 10/Easy	mm/hr	12	2 - 22	70	40 - 100
Diesse Ves-Matic 20	mm/hr	14	2 - 26	62	32 - 92
Excyte™ 10/M	mm/hr	10	1 - 19	60	30 - 90
Excyte 40	mm/hr	10	1 - 19	65	35 - 95
Westergren, saline diluted	mm/hr	9	1 - 17	45	20 - 70
Westergren, sodium citrate diluted	mm/hr	9	1 - 17	45	20 - 70
Westergren, undiluted *	mm/hr	9	1 - 17	40	15 - 65
STARRSED	mm/hr	9	1 - 17	55	30 - 80
Wintrobe	mm/hr	9	1 - 17	35	15 - 55

\* 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

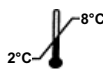
SEDRite Plus is intended for *in vitro* diagnostic use only by trained personnel.



### 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 be similar in appearance to fresh whole blood. In unmixed tubes/vials, the supernatant may appear cloudy and reddish; this is normal and does not indicate deterioration. Other discoloration, very dark red supernatant or unacceptable results may indicate deterioration. **Do not use the product if deterioration is suspected.**