R&D systems
a bio-techne brand

Günter Keul GmbH

SEDRite Plus

HEMATOLOGY CONTROLS

CONTROL

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

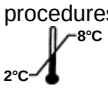
SEDRite Plus is intended for ***in vitro*** **diagnostic use** only by trained personnel.

WARNING:

POTENTIAL BIOHAZARDOUS MATERIAL. 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 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.keul.de

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 Plus upright at 2 - 8° C (35 - 46° F) when not in use**. Protect tubes/vials from overheating and freezing**. Unopened tube/vials are stable through the expiration date. Opened tube/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 tubes/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 Plus thoroughly at all mixing steps.

1. Remove tubes/vials from the refrigerator and allow to warm to room temperature **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:
   a) If tube/vial has been opened for sampling, clean residual material from the cap and tube rim with a lint-free tissue. Replace the cap tightly.
   b) 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 technical assistance or additional information, please call your dealer or local distributor. If there is no, you may call Bio-techne® Technical Service at 33 (0)2 99 35 19 36.

QUALITY CONTROL PROGRAM

For information on the Inter-Laboratory Quality Control Program, please call Bio-techne® CBC-Monitor Service at 33 (0)2 99 35 19 36.

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EC REP

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IS0SR00-V10 11/2020 *

CE IVD

** Updated room temperature : 20 - 25 °C instead of 15 - 30 °C*

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SEDRite Plus

CONTROL

ASSAY VALUES AND EXPECTED RANGES
VALEURS CIBLES ET INTERVALLES DE VARIATIONS

QCP Data Months : **July, August, September**
Mois de Contrôle : **Juillet, Août, Septembre**

LOT **SR0725E**

2025-10-05

Methods & Instruments / Méthodes & Instruments	CONTROL 1 LOT SR0725E-1 ESR/V.S. mm/h 1st Hour/1ere Heure				CONTROL 2 LOT SR0725E-2 ESR/V.S. mm/h 1st Hour/1ere Heure			
	Mean Moyenne	Range Variation			Mean Moyenne	Range Variation		
TECHNIQUE MANUELLE: Méthode WESTERGREN dilué dans du citrate de sodium / **MANUAL METHOD:** WESTERGREN sodium citrate diluted : Tubes Seditainer / Seditainer Tubes Pipettes Sediplast & Takives & Sedivac & Sedirate/ Sediplast & Takives & Sedivac & Sedirate pipettes	**10**	1	-	19	**36**	11	-	61
TECHNIQUE MANUELLE: Méthode WESTERGREN non dilué* / **MANUAL METHOD: WESTERGREN** undiluted* Pipettes Sediplast & Takives & Sedivac & Sedirate / Sediplast & Takives & Sedivac & Sedirate pipettes	**9**	1	-	17	**28**	8	-	48
TECHNIQUE MANUELLE: Méthode WINTROBE / **MANUAL METHOD:** WINTROBE	**10**	1	-	19	**28**	8	-	48
STARRSED	**10**	1	-	19	**42**	17	-	67
HORIBA Auto Compact Starrsed & Starrsed Inversa 24M/ST (1) (2) **ROCHE** InteRRliner / Starliner (1) **SYSMEX** Starrsed Interrliner XN (1)	**9**	1	-	19	**27**	11	-	43
LS DIAG SRA 48LS (1) **DIESSE/MENARINI** Mini-Ves	**10**	1	-	19	**64**	24	-	104
DIESSE/MENARINI Ves-Matic 10 / Easy	**10**	1	-	19	**64**	24	-	104
DIESSE/MENARINI Ves-Matic 20	**10**	1	-	19	**64**	24	-	104
DIESSE/MENARINI Ves-Matic 30 (1)	**12**	1	-	22	**64**	27	-	101
DIESSE/MENARINI Ves-Matic Cube 30 (1) Patient Mode with automatic correction for temperature Mode Patient avec correction automatique de la température	**12**	1	-	22	**37**	11	-	63
DIESSE/MENARINI CUBE 30 Touch & Ves-Matic 5 (1) Quality Mode with automatic correction for temperature Module Qualité avec correction automatique de la température	**9**	1	-	17	**22**	8	-	36
DIESSE/MENARINI Ves-Matic Cube 80 & Ves-Matic Cube 200 (1) Quality Mode with automatic correction for temperature Module Qualité avec correction automatique de la température	**8**	1	-	15	**27**	7	-	47
CLINICAL DATA Excyte 10 / M	**10**	1	-	19	**54**	14	-	94
CLINICAL DATA Excyte 40	**10**	1	-	19	**58**	18	-	98
TERUMO Monitor J (1)	**10**	1	-	19	**62**	31	-	93
BIOCADE BiocaVS12 & BiocaVS40 (1) **ELECTALAB** MicroSed,Monitor20 & 20E & 100 (1) **ELITECH** MIXRATE 10 & MIXRATE 20 & MIXRATE 100 (1) **TERUMO** Monitor V10 & V20 & V100 (1) / **KIMASED** AUTO 16 / 20 / 60 (1) **TECHNIQUE BIOLOGIQUE** MicroSed,Monitor20 & 100 (1) **GREINER/SAYAG** SRS-20, SRS-100, SRT & SRTX (1) **BIOCODE HYCEL** LENA & ERILINE & THERMA NE & BIOSTATIC (1)	**8**	1	-	15	**47**	23	-	71
BECTON DICKINSON SEDIsystem Gen.II V.3.xx & Sedi-15 (1)	**17**	3	-	31	**77**	38	-	116
VGA/EUROTEC VT-25, VT-50 & VT-100 (1) Méthode I.C.S.H. non dilué / I.C.S.H. undiluted method *	**6**	1	-	11	**23**	8	-	38
VGA/EUROTEC VT-72 (1) Méthode I.C.S.H. non dilué / I.C.S.H. undiluted method *	**6**	1	-	11	**18**	5	-	31
BERKHUN SDM-60 / Other Instruments / Autres Appareils (1) **SARSTEDT** SediPlus S 100 & S 200 (1) & S 1000 & S 2000 Système de mesure VS **S-Sedivette & S-Monovette / S-Sedivette & S-Monovette** ESR System (1) **VGA/EUROTEC** VT-25, VT-50, VT-72 & VT-100 (1) Méthode diluée solution saline ou citrate / Saline or sodium citrate diluted method	**8**	1	-	15	**44**	13	-	75

(1) Assay values provided by Bio-techne®, France. (1) Valeurs fournies par Bio-techne®, France.

(2) Assay values obtained in 1 hour with correction for temperature. (2) Valeurs obtenues en 1 heure avec correction de la température

*Test is considered undiluted if no fluid is introduced to specimen during any step of testing process. Le test est considéré comme non dilué si aucun liquide n'est introduit dans l'échantillon avant la mesure.

EC REP

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IVD CE