



POLYMEDCO

For IN VITRO Diagnostic Use.

SED - CHEK[®] 2

Hematology Erythrocyte
Sedimentation Rate Control
for **StaRRsed ESR Systems**

Store at 18° - 30°C
Do not refrigerate

Caution: Contains human source material. Handle as potentially infectious. See insert for details.



ESR-2SSA
6 x 5 mL (Abnormal)

Lot # 11201231A
Exp. 30 JUN 2024

POLYMEDCO, INC. Cortlandt Manor, NY 10567

20979-01

INTENDED USE

SED-CHEK[®] 2 is a whole blood reference control material designed to monitor patient ESR procedures. SED-CHEK[®] 2 helps to monitor technique as well as environmental, physical and mechanical factors such as room temperature, tube position and vibration.

SUMMARY AND PRINCIPLE

Good laboratory practices require that stable reference materials be used to verify the accuracy and precision of testing equipment and procedures. SED-CHEK[®] 2 may be used as one would use whole blood in sedimentation rate procedures.

REAGENTS

SED-CHEK[®] 2 is an in vitro diagnostic control composed of stabilized human red cells suspended in a buffered, bacteriostatic and fungistatic fluid.

WARNINGS AND PRECAUTIONS

Warning: Potentially Biohazardous Material

Because no test method can offer complete assurance that HIV, HBsAg, or other infectious agents are absent, it is recommended that human blood based products be handled with the same precautions used for any potentially biohazardous patient specimens.

Each donor unit used in preparation of SED-CHEK[®] 2 has been tested and found to be non-reactive for antibodies to Human Immunodeficiency Virus (HIV), Hepatitis B Surface Antigen (HBsAg) and Hepatitis C Virus (HCV).

SED-CHEK[®] 2 is intended solely for in vitro diagnostic use for the purpose described on the labeling. POLYMEDCO shall not be liable for any claimed damages arising from other usage.

STORAGE AND STABILITY

Upon receipt, store SED-CHEK[®] 2 at 18°-30°C (64°-86°F). Do not refrigerate. Unopened, this product is stable until the expiration on the tube label. Once the control is open, SED-CHEK[®] 2 is stable for 31 days at room temperature, 18°-30°C (64°-86°F). Avoid prolonged exposure of opened tubes to light. Tubes should be kept tightly closed after use to avoid evaporation. **DO NOT FREEZE. DO NOT EXPOSE TO EXCESSIVE HEAT.**

If results vary outside the specified assay ranges, discard the tube and utilize a new tube. If difficulties persist, contact POLYMEDCO Technical Service at (800) 431-2123 for further assistance and/or instructions.

PROCEDURE

SED-CHEK® 2 is tested according to the directions provided by the instrument manufacturer and is treated in the same manner as patient samples.

1. Invert the tube until packed cells have been resuspended. Continue mixing for 30 seconds. Avoid foaming. DO NOT VORTEX.
2. Follow the manufacturer's directions for loading tubes into the analyzer.
3. After each use, store at room temperature 18°-30°C. (See Storage and Stability). Avoid prolonged exposure to light and excessive heat.

NOTE: To ensure consistent and reproducible results, the control material must be thoroughly mixed and handled in the same manner each time.

EXPECTED VALUES

An expected range generated by multiple analysts' testing over several days, is provided below under expected ranges. Variation in inter-lab results will be greater than the precision for any one laboratory's procedure. Results depend on differences in equipment, reagents, supplies, and techniques.

Therefore, a lab should establish its own acceptable ranges. If the controls fail to perform consistently within acceptable ranges, patient results should be considered invalid. Contact POLYMEDCO Technical Service for assistance.

LIMITATIONS OF THE PROCEDURE

Refer to the expected range below to verify applicability to your lab's procedure. If your method is not referenced, please contact POLYMEDCO for more information and details. SED-CHEK® 2 is not designed to be used as a control for any hematology procedures other than erythrocyte sedimentation rate.

QUALITY CONTROL PROGRAM

A Quality Control Program is available to all customers at no additional charge.

BIBLIOGRAPHY

1. Wintrobe, M.: Clinical Hematology, Lea and Febiger, Philadelphia, pp. 314-322, 1956.
2. Miale, J.; Laboratory Medicine Hematology, The C. V. Mosby Company, St. Louis, pp. 469-475, 1972.
3. Koepke, Bull, Gilmer and Goldblatt: Hematology in Quality Assurance Practices for Health Laboratories, Interdisciplinary Books: American Public Health Assn., 1978.

ORDERING INFORMATION

Product Number	Product Description	Vol.	Product Packaging
ESR-2SSN	SED-CHEK® 2 ESR Normal	30 mL	6 x 5 mL
ESR-2SSA	SED-CHEK® 2 ESR Abnormal	30 mL	6 x 5 mL

Expected Ranges:

Method	Level 1 - Normal 11201231N	Level 2 - Abnormal 11201231A
StaRRsed®	1 - 12 mm/hr	31 - 46 mm/hr

Sed-Chek 2 is a registered trademark of POLYMEDCO, INC.
StaRRsed is a registered trademark of R&R Mechatronics BV



510 Furnace Dock Road, Cortlandt Manor, NY 10567
(800) 431-2123 (914) 739-5400 FAX (914) 739-5890



Obelis s.a. (O.E.A.R.C.)
Bd Général Wahis 53
1030 Brussels, Belgium

Tel: +(32) 2 732-59-54 Fax: +(32) 2 732-60-03