POLYMEDCO

For IN VITRO Diagnostic Use.

SED - CHEK® 2

Hematology Erythrocyte Sedimentation Rate Control for **Automated and Manual ESR Systems**

ESR-2CTA	Abnormal	6 x 8 mL
ESR-2CTN	Normal	6 x 8 mL
ESR-2CT	Abnormal	3 x 8 mL
	Normal	3 x 8 mL

Store at 18°- 30°C
Do not refrigerate

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

POLYMEDCO, INC. Cortlandt Manor, NY 10567

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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 vial 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 vials and tubes to light. Vials 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 vial and utilize a new vial. If difficulties persist, contact POLYMEDCO Technical Service at (800) 431-2123 for further assistance and/or instructions.

Printed 07/2012 • 20755-01

PROCEDURE

SED-CHEK® 2 is tested according to the directions provided by the manufacturer of the ESR method and is treated in the same manner as patient samples (i.e. Do Not Void Diluent From Tube).

1. Invert the vial until packed cells have been resuspended. Continue mixing for 30 seconds. Avoid foaming. DO NOT VORTEX.
2. Follow the manufacturer's directions for filling sample tubes. If performing the modified Westergren procedure, be sure to mix SED-CHEK® 2 and **Diluent** by inversion.
3. After each use, clean the threads of the cap and vial with an absorbent material and recap immediately. Avoid prolonged exposure of opened vials to light and excessive heat. Vials should be kept tightly closed after use to avoid evaporation. Store at room temperature 18°-30°C (See Storage and Stability).

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 is provided separately on a data sheet generated by multiple analysts' testing over several days using automated and manual ESR methods. 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

SED-CHEK® 2 may not be assayed for all available ESR methods. Refer to the expected range of the data sheet 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 now 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-2CT	SED-CHEK® 2 ESR Bi-level (3 x 8 mL each level)	48 mL	6 x 8 mL
ESR-2CTN	SED-CHEK® 2 ESR Normal	48 mL	6 x 8 mL
ESR-2CTA	SED-CHEK® 2 ESR Abnormal	48 mL	6 x 8 mL

Manufactured for POLYMEDCO, INC.

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