Monosed® ESR Vacuum Tubes

REF **PRD-PRV11B-50**
PRD-PRV11V-H12

CE For *in vitro* diagnostic use

Intended Use

ESR Tubes are single use devices intended to be used as whole blood sample tubes for the quantitative determination of Erythrocyte Sedimentation Rate (ESR) using ELITechGroup ESR analyzers. These devices are to be used by trained medical personnel only. The ESR Tubes are intended for IN VITRO DIAGNOSTIC USE ONLY (IVD).

Device Summary

It is well established that patients affected by various diseases (e.g. tuberculosis, malignancies, rheumatic fever, rheumatoid arthritis, multiple myeloma and acute inflammation) have a raised ESR[1-5], due mainly to alterations in some plasma and erythrocyte factors causing the formation of erythrocyte rouleaux [6-8].

The Monosed ESR Vacuum Tubes are evacuated glass tubes, with a butyl rubber stopper that ensures vacuum is maintained. Each tube contains buffered 3.2% sodium citrate solution (0.109 M) as an anticoagulant. The volume of anticoagulant, along with the draw volume ensures the correct ratio of whole blood to anticoagulant (4 part to 1 part volume/volume). One tube is required for each sample determination.

Monosed ESR Vacuum Tubes, when used in conjunction with applicable ELITechGroup ESR instruments, give a result which is comparable to a one hour Westergren ESR result.

Description

REF **PRD-PRV11B-50 Monosed ESR Vacuum Tubes**: Kit includes 50 irradiated ESR vacuum tubes with a butyl-rubber stopper. The tubes contain 0.32 mL of 3.2% buffered sodium citrate solution (0.109 M) and are ready for use. The tubes should be used at an altitude of 0-500m above sea level.

REF **PRD-PRV11V-H12 Monosed ESR Vacuum Tubes (High Altitude)**: Kit includes 50 irradiated ESR vacuum tubes with a butyl-rubber stopper. The tubes contain 0.32 mL of 3.2% buffered sodium citrate solution (0.109 M) and are ready for use. The tubes should be used at an altitude of 1000-1500m above sea level.

⚠ Warnings and Precautions

Handle and dispose of Monosed ESR Vacuum Tubes and all human blood products as though capable of transmitting infectious agents. Dispose Monosed ESR Vacuum Tubes in a safe manner in accordance with local/national regulations.

Use the Centers for Disease Control and Prevention (CDC) recommended universal precautions[9] for handling tubes and specimens. Do not pipette by mouth; do not eat, drink, smoke or apply cosmetics in areas where specimens are handled. Clean up spills immediately with a 0.5% sodium hypochlorite solution.

Tube Preparation

The Monosed ESR Vacuum Tubes are supplied ready to use. No preparation is necessary.

Tube Storage and Stability

Monosed ESR Vacuum Tubes should be stored at 4 to 25 °C. Do not freeze. When stored properly, Monosed ESR Vacuum Tubes can be used up to the expiration date.

Specimen Collection

Whole blood specimen collection should only be carried out by trained medical personnel.

Specimen collection may be carried out using venipuncture technique[10].

⚠ **Warning**: If blood collection utilizes a butterfly system, the Monosed ESR Vacuum Tube must not be the first tube in the collection order. The dead volume of the butterfly device must be filled with blood prior to collection using the Monosed ESR vacuum Tube.

Monosed ESR Vacuum Tubes contain the proper volume of sodium citrate to dilute whole blood 4:1 as required. It is possible to collect the whole blood sample in an EDTA tube and transfer the sample to a Monosed ESR Vacuum Tube to perform ESR analysis. Whole blood transferred from an EDTA tube does not affect the ESR measurement when diluted properly in sodium citrate. The primary tube should be mixed thoroughly, taking care to resuspend the sample completely prior to transferring. It is best to transfer the sample using the vacuum method in order to avoid contamination of the sample itself and ensure the correct blood volume. If transferring with a pipette, transfer 1.28 mL of whole blood, or midway between the two lines. The tube should be filled to at least the minimum line and not more than the maximum line on the tube.

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Specimen Storage and Stability

In accordance with the recommendations of the Clinical & Laboratory Standards Institute (CLSI), blood samples collected and stored in a Monosed ESR Vacuum Tube should be tested within 4 hours if left at room temperature (18 to 25 °C)[11]. The specimen may be kept refrigerated (2 to 8 °C) for up to 12 hours but must be brought to room temperature and mixed thoroughly prior to analysis.

Blood used for ESR testing and stored in an EDTA tube is stable for up to 24 hours if refrigerated[12] but must be brought to room temperature and mixed thoroughly prior to analysis.

Interfering Substances

The following external factors can alter the ESR value after blood collection and should be avoided: improper dilution ratio, bubbles, foam, grossly hemolyzed samples, sudden agitation, temperature outside recommended analyzer operating conditions of 15 to 32 °C, direct sunlight, and lipemic samples. As with all ESR analyzers, abnormally high or low hematocrits, along with other hemoglobinopathies, may affect results.

Materials Provided

Monosed ESR Vacuum Tubes, Qty 50 tubes

REF

PRD-PRV11B-50

PRD-PRV11V-H12 (High Altitude)

Materials Required but Not Provided

1. Venipuncture Kit
2. Analyzer - one of the following ELITechGroup ESR Analyzers:

   REF

   Microsed-System® - PRD-MSS-EL-08TKNE

   Mix-Rate® - X20 PRD-X20-EL-08TKN

   Monitor-20 - PRD-MVP-EL-08TKN

   Monitor-100 - PRD-MVS-EL-08TKN
3. Accu-Sed® Plus ESR Controls

   REF

   Accu-Sed® Plus Normal / Abnormal ESR Controls DS-71006

Calibration

Calibration is not required.

Limitations

Monosed ESR Vacuum Tubes are single use only. Refer to the Interfering Substances section for possible sources of interference.

REFERENCES

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2. Ansell B., Bywaters E.G.L. "The unexplained high erythrocyte sedimentation rate." Br Med J 1: 372 (1958).
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4. Coburn A.F., Kapp E.M. "Observations on the development of the high blood sedimentation rate in rheumatic carditis." J Clin Invest 15: 715 (1936).
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6. Gilligan D.R., Ernstene A.C., "The relationship between the erythrocyte sedimentation rate and the fibrogen content of plasma." Am J Med Sci 187: 552 (1934).
7. Lucia S.P. et al. "The relation between the suspension stability of erythrocytes and various constituents of pathologic human blood." Am J Med Sci 192: 179 (1936).
8. Jeannet M. "Mecanismes de la vitesse de sedimentation erythrocytaire." Schweiz Med Wochenschr 94: 465 (1964).
9. U.S. Department of Health and Human Services. "Recommendation for Prevention of HIV Transmission in Health Care Settings." MMW Report, Aug 21, 1987, Vol. 36, No. 2S.
10. CLSI. "Procedure for the Collection of Diagnostic Blood Specimens by Venipuncture." Approved Standard 5th Edition: Vol. 23 No. 32, Villanova, PA (2003).
11. CLSI. "Procedures for the Erythrocyte Sedimentation Rate Test; Approved Standard – Fifth Edition." H02-A5, Vol. 31 No. 11.
12. Greer, John P., MD., et al. Wintrobe Clinical Hematology. 11th ed. Vol. 1, pp. 4. Philadelphia: Lippincott Williams & Wilkins (2004).

GLOSSARY OF SYMBOLS

	Manufacturer	LOT	Batch code/ Lot number	IVD	*In vitro* diagnostic medical device
CONT	Contents		Caution		Consult instructions for use
REF	Catalogue Number		Temperature Limit		Do not reuse
	This way up		Use by / Expiration date		Fragile
CE	European Conformity	IRRADIATED	Irradiated	EC REP	European Authorized rep
	Importer of Medical Devices				

In the European Union by:

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