Excyte® ESR Vacuum Tube

REF **EP-10605**
EP-10605-H1

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, acute inflammation, etc.) 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 Excyte ESR Vacuum Tubes are evacuated plastic 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.

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

Description

REF **EP-10605 - Excyte ESR Vacuum Tube**: Kit includes 50 sterilized ESR vacuum tubes with a butyl-rubber stopper. The tubes contain 0.34 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 **EP-10605-H1 - Excyte ESR Vacuum Tube (High Altitude)**: Kit includes 50 sterilized ESR vacuum tubes with a butyl-rubber stopper. The tubes contain 0.34 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 800-1300m above sea level.

⚠ Warnings and Precautions

Handle and dispose of Excyte ESR Vacuum Tubes and all human blood products as though capable of transmitting infectious agents. Dispose of Excyte 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 Excyte ESR Vacuum Tubes are supplied ready to use. No preparation is necessary.

Tube Storage and Stability

Excyte ESR Vacuum Tubes should be stored at 4 to 25 °C. Do not freeze. When stored properly, Excyte 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 Excyte ESR Vacuum Tubes 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 Excyte ESR Vacuum Tubes.

Excyte 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 an Excyte 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 1.36 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 an Excyte 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 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

Excyte ESR Vacuum Tubes, Qty 50 tubes

REF

EP-10605

EP-10605-H1 (High Altitude)

Materials Required but Not Provided

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

   REF

   Excyte Mini - EP-10610

   Excyte M - EP-10614

   Excyte 20 - EP-10618

   Excyte 40 - EP-10616

3. Accu-Sed® Plus ESR Controls

   REF

   Accu-Sed® Plus Normal ESR Control DS-71002

   Accu-Sed® Plus Abnormal ESR Control DS-71003

   Accu-Sed® Plus Normal / Abnormal ESR Control Set DS-71005A

Calibration

Calibration is not required.

Limitations

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

References

1. Peyman M.A. "The effect of malignant disease on the erythrocyte sedimentation rate." Br J Cancer 16: 56 (1962).
2. Ansell B., Bywaters E.G.L. "The unexplained high erythrocyte sedimentation rate." Br Med J 1: 372 (1958).
3. Boyd R.V., Holfbrand B.I. "Erythrocyte sedimentation rate in Elderly Hospital Inpatients." Br Md J 1: 901 (1966).
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).
5. Wintrobe M.M. "The erythrocyte sedimentation test." Int Clin 46th Ser 2: 34 (1936) (bibliography).
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	STERILE R	Sterilized by irradiation	EC REP	European Authorized rep

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