

# Excyte® ESR Vacuum and Non-Vacuum Tubes

REF EX-50205  
EX-50100

 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<sup>1-5</sup>, due mainly to alterations in some plasma and erythrocyte factors causing the formation of erythrocyte rouleaux<sup>6-8</sup>.

The Excyte ESR Tubes are available in both vacuum and non-vacuum glass tubes, with a butyl rubber stopper. For the Excyte ESR Vacuum Tubes, the butyl rubber stopper ensures the vacuum is maintained. Each tube type 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 Tubes, when used in conjunction with Excyte ESR instruments, give a result which is comparable to a one hour Westergren ESR result.

## Description

REF **EX-50205 Excyte ESR Vacuum Tubes:** Kit includes 50 irradiated ESR vacuum tubes with a butyl-rubber stopper. The tube contains 0.28 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 **EX-50100 Excyte ESR Non-Vacuum Tubes:** Kit includes 50 irradiated ESR non-vacuum tubes with a butyl-rubber stopper. The tubes contain 0.28 mL of 3.2% buffered sodium citrate and are ready for use.

## Warnings and Precautions

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

Use the Centers for Disease Control and Prevention (CDC) recommended universal precautions<sup>9</sup> 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 Tubes are supplied ready to use. No preparation is necessary.


## Tube Storage and Stability

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

## Specimen Collection

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

### Excyte ESR Vacuum Tubes (EX-50205)

 Specimen collection may be carried out using venipuncture technique<sup>10</sup>. After blood is drawn and the Excyte ESR Vacuum Tube is filled with 1.0 mL of blood, mix the sample immediately with the sodium citrate. Tube should be filled to at least the minimum line and not more than the maximum line on the tube. **Warning:** If blood collection utilizes a butterfly system, the Excyte 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 Excyte ESR Vacuum Tube.

### Excyte ESR Non-Vacuum Tubes (EX-50100)

Whole blood specimen should be collected in an EDTA tube according to accepted clinical protocol<sup>11</sup>. Sample should be mixed well prior to transferring 1.0 mL to the Excyte ESR tube. Meniscus of sample should be between lines indicated on the ESR tube.

Excyte ESR 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 Tube to perform ESR analysis. The primary tube should be mixed thoroughly, taking care to resuspend the sample completely prior to transferring.



## 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)<sup>11</sup>. 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<sup>12</sup> 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



Excyte ESR Tubes, Qty 50 tubes



EX-50205

EX-50100

## Materials Required But Not Provided

- Venipuncture Kit
- Analyzer - one of the following Excyte ESR Analyzers:
  -  Excyte Mini - EX-10310
  - Excyte 10 - EX-10312
  - Excyte M - EX-10314
  - Excyte 20 - EX-10318
  - Excyte 40 - EX-10316
- Accu-Sed® Plus ESR Controls
  -  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 tubes are single use only. Refer to the Interfering Substances section for possible sources of interference.

## REFERENCES

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- Greer, John P., MD., et al. Wintrobe Clinical Hematology. 11th ed. Vol. 1, pp. 4. Philadelphia: Lippincott Williams & Wilkins (2004).

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## GLOSSARY OF SYMBOLS

	Manufacturer		Batch code/ Lot number		In vitro diagnostic medical device
	Contents		Caution		Consult instructions for use
	Catalogue Number		Temperature Limit		Do not reuse
	This way up		Use by / Expiration date		Fragile
	European Conformity		Irradiated		European Authorized rep