

MONOSED VACUUM TUBES

REF PRD-PRV11B-50

CONT 50 test tubes

For *in vitro* diagnostic use

INTENDED USE

These devices are exclusively used for venous blood collection for the determination of the Erythrocyte Sedimentation Rate (ESR). These devices must be used together with Vital Diagnostics ESR Automated Analyzer and with Vital Diagnostics Reading Scale for ESR determination to obtain the ESR value. These devices must be used by professional users only. These devices are intended for IN VITRO DIAGNOSTIC USE ONLY (IVD).

IMPROPER USE

Are considered improper uses:

1. Stopper removal
2. Device re-use
3. The use of these tubes with instruments different from Vital Diagnostics ones
4. Perform the venipuncture without following these instructions
5. The use of a butterfly needle to collect the blood(*)
6. Blood drawing when the tube is in downward position
7. The use after the expiry date
8. Every use different from those specified as INTENDED USE, are considered improper.

(*) If blood collection utilizes a butterfly system, the MONOSED 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 tube.

PRODUCT DESCRIPTION

These devices are evacuated glass tubes, where the vacuum is assured by a butylic rubber stopper. Each tube contains a buffered sodium citrate solution (3.2%) as anticoagulant. The volume of anticoagulant added, assures the correct ratio blood:citrate (4 part to 1 part volume/volume).

Tube	Drawing *	Diameter
PRD-PRV11B-50	1,28 mL	8 mm

* Approximate drawing at the level of the sea +/- 250 m, when storage and operating conditions are assured (T 20 - 25°C)

OPERATING CONDITIONS

In order to obtain a proper filling of the tube:

1. Tubes must have a temperature between 20°C and 25°C.
2. If not differently stated during the manufacturing process, a proper filling of the tubes is guaranteed only when the collection is performed at 0 +/- 250 meters above the level of the sea.
3. Do not overheat tubes prior to collect the blood

TUBES STORAGE

1. Store empty tubes at 4 to 25°C
2. Do not store tubes containing blood at or below 0°C to avoid breakage of tubes and/or hemolysis of the sample.
3. In case test is performed within 4 hours, store tubes containing blood at 4 - 25°C
4. Store tubes containing blood at 4 - 8°C in case test is performed within a period from 4 to 8 hours after sampling. Samples for measurements need to be at room temperature.
5. Tubes must be at room temperature before collecting blood

SPECIMEN COLLECTION

Read carefully before performing the venipuncture

REQUIRED BUT NOT PROVIDED EQUIPMENT

1. Gloves, eyes protection and other personal protective equipment
2. Needle
3. Needle holders (BD Vacutainer, Terumo, Greiner Bio-one

etc...)

4. Dry sterile gauze
5. Tourniquet

CAUTIONS

In order to avoid operator contamination, the operator, prior to perform the venipuncture and during samples handling, has to wear gloves, eyes protection and other personal equipment.

VENIPUNCTURE TECHNIQUE

1. Assemble the needle together with the holder
2. Select the site for the venipuncture on patient's arm
3. Apply tourniquet, sterilize the selected site with a gauze
4. Place the patient's arm in a downward position
5. Remove the needle shield and perform the venipuncture
6. Center the tube in the holder and firmly push the tube on the holder in order to penetrate the tube's stopper.
7. Remove the tourniquet as soon as the blood flows into the tube
8. When the blood flow ceases, remove the tube from the holder
9. When the last tube has been filled, remove the needle from the vein applying pressure to the puncture site with a dry sterile swab until bleeding stops

PREVENTION OF BACKFLOW

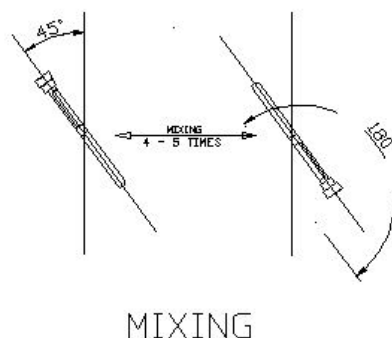
Since evacuated tubes contains anticoagulant solutions, it is important to avoid any possible backflow from the tube. To avoid it follow these steps:

1. Place patient's arm in a downward position
2. Remove the tourniquet as soon as the flow of blood starts
3. **AVOID ANY CONTACT BETWEEN THE NEEDLE AND THE ANTICOAGULANT DURING VENIPUNCTURE**



MIXING PROCEDURE

To obtain a proper sample mixing, perform 4 - 5 complete inversions of the tube, before insert the tube into the analyzer or use an automatic agitator. Do not shake the sample because this could cause sample's hemolysis or foam production.



DEVICES DISPOSAL

Dispose of devices as HAZARDOUS MATERIALS since they contains biological materials. Follow local regulations to do it properly.

QUALITY CONTROL















Vital Diagnostics recommends running two levels of controls (normal and abnormal) each day of use. The recommended controls are the Accu-Sed Plus ESR controls. Refer to the Accu-Sed Plus package insert for further instructions, including expected values. Refer to the instrument operator's / user's manual for specific quality control instructions.

LIMITATIONS

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.

GLOSSARY OF SYMBOLS

	Manufacturer		Batch code / Lot number
	<i>In vitro</i> diagnostic medical device		Contents
	Caution		Consult instructions for use
	Catalog number		Temperature limit
	Do not reuse		This way up
	Use by / Expiration date		Fragile
	European Conformity		β-ray irradiation treated to reduce the potential of microbial growth.