

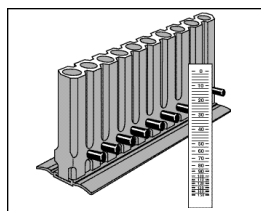
Seditainer* Evacuated Blood Collection Tube For Erythrocyte Sedimentation Rate Determination

Black Cap. Labelled Tubes
Reorder No. **366065** (U.S.A. Only)

Black Cap. Labelled Tubes
Reorder No. **366674** (Not available in U.S.A.)

Black Stopper. Labelled Tubes
Reorder No. **606666** (Not available in U.S.A.)

FOR IN VITRO DIAGNOSTIC USE.



SEDITAINER Stand
Reorder No. **366016**

INTENDED USE

The SEDITAINER Erythrocyte Sedimentation Rate (ESR) System is for collection of blood specimens for the measurement of ESR within the blood collection tube, using the SEDITAINER ESR Stand.

SUMMARY AND PRINCIPLES OF SYSTEM

The SEDITAINER Tube provides a means of collecting and testing blood in a closed evacuated system. The tube contains 1.25 mL of 0.105 Molar (M) buffered sodium citrate solution, giving a 4:1 blood to additive ratio when the evacuated tube is correctly filled to its 5 mL draw volume. The SEDITAINER Tube provides a means to measure the ESR (mm/h) without the need to access or transfer the specimen. The filled tube has a 100 mm column height and the ESR is read from a scale on the SEDITAINER Stand. The scale was determined using a mathematical algorithm that relates the distance the erythrocytes have fallen to a value that would be obtained by using the Classic Westergren Method (Berg, 1985).

The use of a 100 mm column results in a measured value that differs from the Westergren method. The general relationship is non-linear. A mathematical approximation of this relationship was determined using the results of evaluations across the full range of ESR values. This mathematical approximation is described by the following equation:

$$y = 0.87x - 0.0027x^2$$

Where: x = Westergren Value
y = SEDITAINER Value

and was used to design the scale on the SEDITAINER Stand to approximate the Westergren ESR.

PRINCIPLES OF THE ESR

Erythrocytes sediment when anticoagulated blood is allowed to sit undisturbed. Sedimentation occurs in three stages during the 1 h test. During the first 10 minutes rouleaux form, with slow sedimentation. For the next 40 minutes cells settle rapidly, with most of the settling occurring during this period. Finally, during the last 10 minutes, packing occurs. If tubes are allowed to sit undisturbed for more than 1 h, additional settling may occur.

COMPONENTS OF SYSTEM

The SEDITAINER Tube is a sterile glass evacuated tube measuring 120 mm long by 10.25 mm wide, with a black rubber stopper. The stopper is covered by a plastic shield that assists in the proper placement of the SEDITAINER Tube in the standard size (13 and 16 mm) needle holder. The tube contains 1.25 mL of a 0.105 M solution of buffered sodium citrate and has a vacuum level to draw 5.0 mL of blood. Only the interior of the tube is sterile. (See "Summary and Principles of System" section.)

PRODUCT USE PRECAUTIONS:

CAUTION:

1. All glass has the potential for breakage; take precautionary measures during handling.
2. Handle all biologic samples and blood collection "sharps" (lancets, needles, luer adapters, and blood collection sets) according to the policies and procedures of your facility.
3. Obtain appropriate medical attention in the event of any exposure to biologic samples (for example, through a puncture injury), since this may transmit viral hepatitis, HIV (AIDS), or other infectious disease.
4. Utilize any built-in used needle protector, if the blood collection device provides one. Becton Dickinson does not recommend resheilding used needles. However, the policies and procedures of your facility may differ and must always be followed.
5. Discard all blood collection "sharps" in biohazard containers approved for their disposal.
6. Transferring a sample from a syringe to a tube is not recommended. Additional manipulation of sharps increases the potential for needlestick injury. In addition, depressing the syringe plunger during transfer can create a positive pressure, forcefully displacing the stopper and sample and causing a potential blood exposure. Using a syringe for blood transfer may also cause over or underfilling of tubes, resulting in an incorrect blood-to-additive ratio and potentially incorrect analytic results. Tubes with draw volume smaller than apparent dimensions may not fill to their stated volume when filled from a syringe. The laboratory should be consulted regarding the use of these samples.
7. If blood is collected through an intravenous (I.V.) line, ensure that line has been cleared of I.V. solution before beginning to fill blood collection tubes. This is critical to avoid erroneous laboratory data from I.V. fluid contamination.
8. Store unused inventory as indicated on carton and case before use.
9. Use tube before expiration date shown on carton, case and tube labels.

10. Take precautions to prevent possible backflow of additive from the tube during blood drawing. (See "Prevention of Backflow" section.)

11. **DO NOT REMOVE THE TUBE CLOSURE UNDER ANY CIRCUMSTANCES.**

SPECIMEN COLLECTION AND PROCESSING

Required Equipment Not Provided for Specimen Collection:

1. Practice Universal Precautions, using gloves and appropriate apparel for protection from exposure to bloodborne pathogens.
2. Any VACUTAINER® Brand Needle Holder of the standard size may be used.
3. Alcohol swab for cleansing site.
4. Dry sterile gauze.
5. Tourniquet.
6. Needle disposal container for used needle or needle/holder combination.

Required Equipment Not Provided for Specimen Processing:

1. Gloves and other personal protective equipment as necessary for protection from exposure to bloodborne pathogens.
2. SEDITAINER Stand.

Preparation for Specimen Collection:

Be sure the following materials are readily accessible before performing venipuncture:

1. See required equipment above.
2. All necessary tubes, identified for size, draw, and additive.
3. Labels for positive patient's identification of samples.

Recommended Order of Draw:

1. Tubes for sterile samples
2. Tubes without additives
3. Tubes for coagulation studies
4. Tubes with additives (e.g., heparin, EDTA)

SST® Tubes, VACUTAINER® Clot Activator Tubes, and VACUTAINER® PLUS Tubes are considered additive tubes. SEDITAINER Tubes may be drawn after coagulation tubes or included with other additive tubes.

Prevention of Backflow:

Since some evacuated blood collection tubes contain chemical additives, it is important to avoid possible backflow from the tube, with the possibility of adverse patient reactions. To guard against backflow, observe the following precautions:

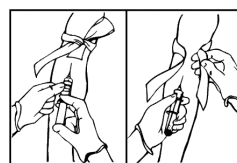
1. Place patient's arm in a downward position.
2. Hold tube with the stopper uppermost.
3. Release tourniquet as soon as blood starts to flow into tube.
4. Make sure tube contents do not touch stopper or end of the needle during venipuncture.

Venipuncture Technique and Specimen Collection:

General Instructions

WEAR GLOVES DURING VENIPUNCTURE AND WHEN HANDLING BLOOD COLLECTION TUBES TO MINIMIZE EXPOSURE HAZARD.

1. Select tube or tubes appropriate for required specimen. For sterile collections, see the specific instructions noted in the collection device product circular.
2. Assemble needle in holder. Be sure needle is firmly seated to ensure needle does not unthread during use. If drawing sterile specimen, use a sterile holder.
3. Gently tap tubes containing additives to dislodge any material that may be adhering to the stopper.
4. Place tube into holder. Do not puncture stopper.
5. Select site for venipuncture.
6. Apply tourniquet. Prepare venipuncture site with an appropriate antiseptic. DO NOT PALPATE VENIPUNCTURE AREA AFTER CLEANSING.



7. Place patient's arm in a downward position.
8. Remove needle shield. Perform venipuncture WITH ARM DOWNWARD AND TUBE STOPPER UPPERMOST.
9. Push tube onto needle, puncturing stopper diaphragm. Center tubes in holder when penetrating the stopper to prevent sidewall penetration and resultant premature vacuum loss.

10. REMOVE TOURNIQUET AS SOON AS BLOOD APPEARS IN TUBE. DO NOT ALLOW CONTENTS OF TUBE TO CONTACT THE STOPPER OR END OF THE NEEDLE DURING PROCEDURE.

Note: Blood may occasionally leak from the needle sleeve. Practice Universal Precautions to minimize exposure hazard.

If no blood flows into tube or if blood ceases to flow before an adequate specimen is collected, the following steps are suggested to complete satisfactory collection:

- Push tube forward until tube stopper has been penetrated. If necessary, hold in place to ensure complete vacuum draw.
 - Confirm correct position of needle cannula in vein.
 - If the multiple sample needle is used, remove tube and place new tube onto the holder.
 - If second tube does not draw, remove needle and discard. Repeat procedure from Step 1.
- When first tube has filled to its stated volume and blood flow ceases, remove it from holder.
 - Place succeeding tubes in holder, puncturing diaphragm to begin flow. Draw tubes without additives before tubes with additives. See Recommended Order of Draw.
 - While each successive tube is filling, turn the filled tube upside-down and return it to upright position. This is one complete inversion.
For proper additive performance, SEDITAINER Tubes must be inverted and returned to upright 8 - 10 times. If other tubes are collected during the same venipuncture, refer to appropriate product circular for handling instructions.
 - As soon as blood stops flowing in the last tube, remove needle from vein, applying pressure to puncture site with dry sterile swab until bleeding stops.
 - Once clotting has occurred, apply bandage if desired.
 - After venipuncture, the top of the stopper may contain residual blood. Take proper precautions when handling tubes to avoid contact with this blood. Any needle holder that becomes contaminated with blood is considered hazardous and should be decontaminated with bleach or disposed of.
 - Dispose of the used needle using an appropriate disposal device. DO NOT RESHIELD. Reshielding of needles increases the risk of needlestick injury and blood exposure.

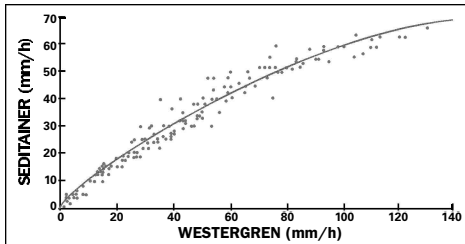
PERFORMANCE OF THE SEDITAINER ESR

- Collect venous blood into SEDITAINER Tube.
- Just before performing the test, invert the tube 8 - 10 times to mix thoroughly. Use of a rotating mixer is recommended.
- Place SEDITAINER Tube in SEDITAINER Stand. Align 0 mark at top of scale with the bottom of the meniscus of the blood at the blood-air interface.
- Place rack on table or counter where it will not be moved or disturbed for the duration of the test. Stand must be level.
- Set timer for 60 minutes.
- When timer indicates, read level of interface between the settled erythrocytes and the supernatant plasma from scale on SEDITAINER Stand.

RESULTS

ANALYTIC EQUIVALENCE

Studies have been performed showing the analytic equivalence of the results provided by the SEDITAINER Tube and Stand to that of the Classic Westergren Method. Using the median Seditainer values for each 5 mm/h Classic Westergren interval, for 300 patients in the range of 0-130 mm/h, parabolic regression determined the relation of the Seditainer ESR System to Classic Westergren to be $y = 0.87x - 0.0027x^2$, where x = Classic Westergren Value (mm/h) and y = Seditainer Value for corresponding Westergren Value. Using this equation for the 300 patients, a correlation coefficient of 0.998 was determined.¹ The following diagram demonstrates this relation: Data are available upon request.



It is the laboratory's ultimate responsibility to verify that a change from one tube type to another does not significantly affect analytic results obtained from patient samples.

CONVERSION SCALE

The conversion scale becomes highly compressed above Westergren values of 100 mm and ESR readings above this level should be repeated using the Classic Westergren Method if precise values are required.

LIMITATIONS OF SYSTEM

The ESR is a non-specific test. No specific diagnostic information is produced by this test. Elevations result from a multitude of conditions from pregnancy to malignancy.

The quantity of blood drawn varies with altitude, ambient temperature, barometric pressure, tube age, venous pressure, and filling technique. Store samples at room temperature before testing. Test should be performed within 6 hours of collection.

Possible Sources of Error

Incorrect additive to blood ratio will affect results. Tubes should be filled to the stated volume. Failure to mix sample thoroughly by inverting 8 - 10 times, may result in erroneous results

Hemolysis, resulting in decreased red cell concentration, may affect ESR. The stand must be level. An angle change of as little as 3° from vertical may increase ESR by as much as 30%. The surface on which the stand is placed must not vibrate, as this accelerates sedimentation.

TECHNICAL SERVICE

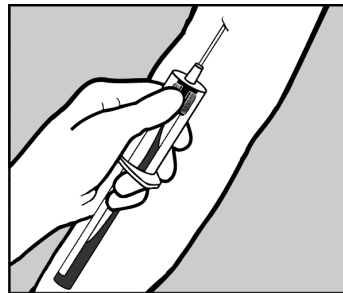
Technical Service may be reached at 800-631-0174. You may write to Becton Dickinson VACUTAINER Systems for information at:

Technical Service
Becton Dickinson VACUTAINER Systems
1 Becton Drive, Franklin Lakes, NJ 07417-1885

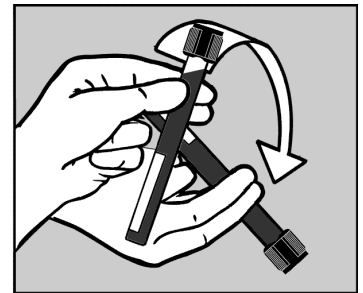
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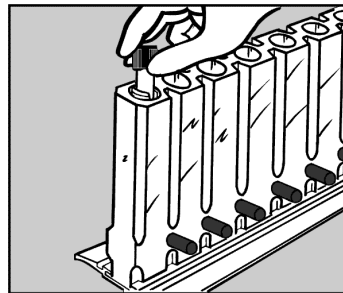
PROCEDURE THE SEDITAINER* ESR SYSTEM



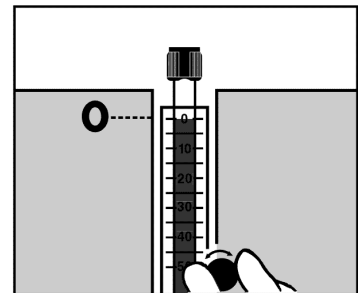
1. Collect blood, using accepted venipuncture technique.



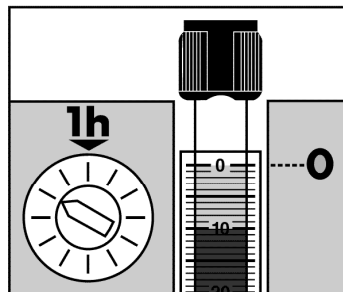
2. Gently invert SEDITAINER Tube at least 8 - 10 times.
3. Repeat before inserting Tube into Stand.



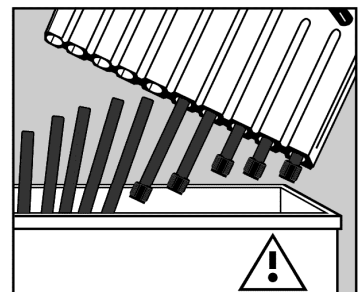
4. Insert SEDITAINER Tube into Stand.



5. Align zero level of scale to bottom of meniscus.



6. Set timer and read erythrocyte level after 1 hour.



7. Discard SEDITAINER Tubes without opening.

*SEDITAINER, VACUTAINER, SST, and PLUS are trademarks of Becton Dickinson and Company.
SEDITAINER Stand Reorder Number 366016 - U.S. Pat. No. 4,801,428.

