Sediplast® Autozero Westergren ESR System

Intended Use

The Sediplast ESR system is for the determination of Erythrocyte Sedimentation Rate (ESR) in whole blood.

Summary

The ESR is a non-specific test which indicates the presence of inflammation in the body. The test is used as an initial screening tool and also as a follow-up test to monitor the effects of therapy and the progression or regression of disease.

Principle

A pipette (tube) is filled with 0.8 ml of anticoagulated blood (total blood column 200 mm) and allowed to stand for a period of one hour. After one hour, a reading is taken at the plasma meniscus. This reading represents the distance in mm from the zero mark on the tube and is equal to the Erythrocyte Sedimentation Rate.

Components Provided

1) Fixed bore pipettes, with a self-zeroing cap, a reservoir for excess blood and a cap with a labyrinth path ending with a vented bore to allow the escape of the air.
2) Vials (which may or may not contain anticoagulant) and stopper caps with a predetermined fracture diaphragm at the bottom.

General guidelines The Sediplast® system is intended for professional use only. All patient samples should be treated as potentially infectious and handled according to standard precautions.

The Occupational Safety and Health Administration (OSHA) and Good Laboratory Practice recommend use of personal protection equipment (PPE) - such as protective eyewear, shields, gloves, lab coats and footwear - when working with or near potential hazardous materials.

Preparation No component preparation is required. For those customers using vials without diluent, a 4:1 dilution of the whole blood is required.
This is accomplished, for example, by mixing 0.8 ml of blood and 0.2 ml of 3.8% Sodium Citrate (or saline) in a clean disposable tube.

INSTRUCTIONS FOR USE

Assemble and check for integrity of supplies.

1 Remove the pink stopper on the prefilled vial (0.2 ml of 3.8% Sodium Citrate is used as diluent).
Using a transfer pipette, fill the vial to the BOTTOM of the indicated fill line, with 0.8 ml of blood to make the required 4:1 dilution ratio.
The *Sediplast*® system is available with and without diluent.

2 Replace pink pierceable stopper and gently invert several times to obtain homogeneous mixing.

3 Place vial in its rack on a level counter surface free from vibration.

4 The diaphragm of the pink stopper is calibrated to break under the light pressure made by inserting the pipette.

5 Carefully insert the pipette through the pierceable stopper and gently push downwards until the pipette comes into contact with the blood sample. Next, while holding the middle of the pipette, gently twist the pipette and push downwards until the pipette rests on the BOTTOM of the vial.
DO NOT USE EXCESSIVE FORCE AND DO NOT HOLD OR BLOCK THE TOP OF THE PIPETTE

6 The pipette will autozero the blood and any REASONABLE excess will flow into the reservoir compartment.

7 To ensure proper results, it is essential that the pipette makes FIRM contact with the bottom of the vial.

8 Let sample stand for exactly one hour and then read the numerical results of the erythrocyte sedimentation in millimeters

9 Dispose of properly after use.

10 Remove gloves and wash hands in accordance with established procedures.

General guidelines

11 *Testing Timetable*
Blood at room temperature (15-25)°C: test should be set up within 4 hours
Refrigerated blood: must first be brought to room temperature and thoroughly mixed before testing
Blood kept at 4°C: test should be set up within 12 hours
Normal Values
Male: (under 50) 0-15 mm/hr – (over 50) 0-20 mm/hr
Female:(under 50) 0-20mm/hr – (over 50) 0-30mm/hr

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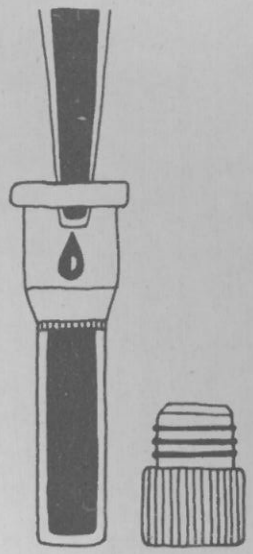

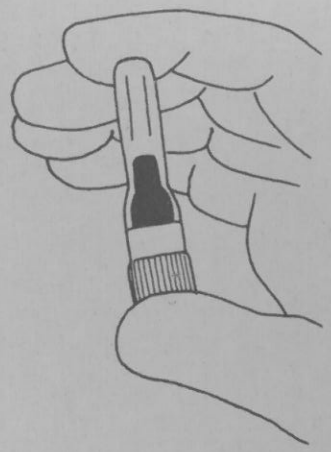

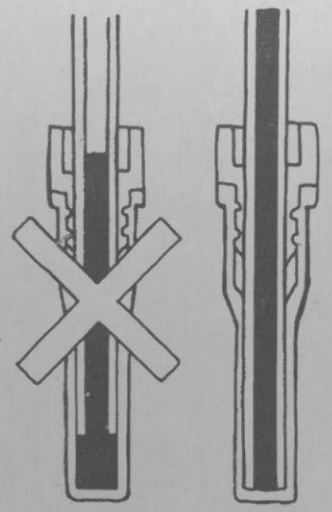

FILLING INSTRUCTIONS

1) Remove the pink stopper on the prefilled vial (0.2 ml of 3.8% sodium citrate is used as diluent). Using a transfer pipette, fill the vial to the bottom of the indicated fill line with 0,8 ml of blood to make required 4:1 dilution.
   ***Sediplast*®** system can be delivered also without diluent.
2) Replace pierceable stopper and gently invert several times to mix.
3) Place vial in its rack on a level surface. Carefully insert the pipette through the pierceable stopper until the pipette comes in contact with the bottom of the vial.
   The diaphragm of the pink stopper is calibrated to break under the light pressure made by inserting the pipette.
   The pipette will autozero the blood and any excess will flow into the reservoir compartment.
4) To ensure proper results, it is essential that the pipette makes **FIRM** contact with the bottom of the vial.
   Let sample stand for exactly one hour and then read the numerical results of the erythrocyte sedimentation in millimeters.
   Dispose of properly after use.

INSTRUCTIONS DE REMPLISSAGE

1) Enlever le bouchon rose du tube à essai avec 0,2 ml de citrate de sodium 3,8%. Remplir avec une pasteur pipette le tube jusqu'au cran de graduation avec 0,8 ml de sang pour avoir le correct rapport de diluition de 4:1.
   Le système ***Sediplast*®** est également livrable sans anticoagulant.
2) Boucher le tube à essai et mélanger doucement 5/6 fois.
3) Mettre le tube dans le portoir et introduire à travers le bouchon perforable la pipette. La membrane du bouchon est calibrée pour être facilement perforée avec une légère pression pendant l'introduction de la pipette même.
   Un dispositif automatique arrête la colonne de sang au **"0"** et permet à l'excédent de rentrer dans le réservoir à travers un petit trou parfaitement calibré.
4) Il est absolument indispensable que la pipette touche complètement le fond du tube à essai. Laisser reposer le prélèvement dans le support et après 1 heure exacte relever les résultats de la vitesse de sedimentation. Jeter l'ensemble dans un récipient à déchets speciaux.

INSTRUCCIONES DE LLENADO

1) Retirar el tapón rosa del tubo con 0,2 ml de sodio citrato al 3,8%. Usando una pipeta o directamente de la jeringa, llenar el tubo hasta el tope graduado con 0,8 ml de sangre, para obtener la dilución requerida de 4:1.
   El sistema ***Sediplast*®** puede suministrarse también sin anticoagulante.
2) Poner nuevamente el tapón y agitar 5 o 6 veces para obtener una mezcla correcta.
3) Situar el tubo en el rack. Cuidadosamente introducir la pipeta a través del tapón perforable. La membrana del tapón está calibrada de modo que permite una fácil perforación con una ligera presión durante la inserción de la pipeta.
   Un dispositivo automático especial posiciona la columna al nivel **"cero"** y cualquier exceso de sangre fluirá a un compartimento superior de reserva.
4) Para obtener resultados absolutamente correctos, es indispensable que la pipeta esté en contacto firmemente con el fondo del tubo. Dejar la muestra en posición vertical exactamente una hora y entonces lea los resultados numéricos de la V.S.G.
   Desechar pipeta y tubo después de su uso.

ISTRUZIONI DI RIEMPIMENTO

1) Togliere il tappo dalla provetta già pronta con 0,2 ml di sodio citrato al 3,8%. Dosare fino alla tacca di graduazione 0,8 ml di sangue, così da ottenere il giusto rapporto di diluizione di 4:1, usando una pipetta, o direttamente dalla siringa di prelievo.
   Il sistema ***Sediplast*®** può essere fornito anche senza anticoagulante.
2) Tappare nuovamente la provetta e miscelare 5 o 6 volte per dolce capovolgimento.
3) Porre la provetta nel portaprovette ed inserire la pipetta attraverso il tappo perforabile. La membrana del tappo è calibrata in modo da essere facilmente perforata con una leggera pressione durante l'inserimento della pipetta stessa.
   Uno speciale azzeratore automatico interrompe comunque la colonna di sangue allo **"0"** e fa confluire quello in eccesso in un compartimento superiore.
4) Per ottenere risultati assolutamente corretti, è indispensabile che la pipetta tocchi completamente sul fondo della provetta. Lasciare il campione in posizione verticale per un'ora esatta e quindi leggere il risultato della VES.
   Gettare in apposito contenitore dopo l'uso.