

Sediplast® Autozero Westergren ESR System Instructions for Use

Note: Complete instructions for use are printed on the inside of the carton

Intended Use

The Sediplast® ESR system is used for the determination of Erythrocyte Sedimentation Rates (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 1.0 ml of anticoagulated (EDTA recommended) 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 diluent) 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 potentially hazardous materials.

Specimen Preparation and Storage

No component preparation is required when using vials with diluent. For those customers using vials without diluent, a 4:1 dilution ratio 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.

Blood at room temperature (15-25) °C: test should be set up within 4 hours

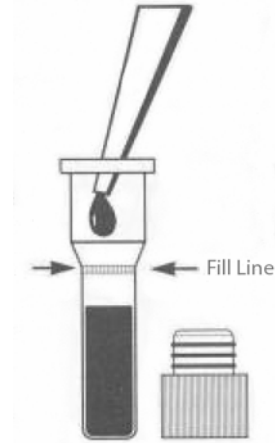
Refrigerated blood: must first be brought to room temperature and thoroughly mixed before testing
Blood kept at 4°C: test should be set up within 12 hours

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

Procedure

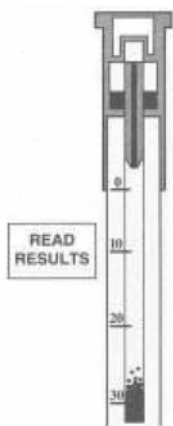
1. Assemble and check for integrity of supplies. Remove the pink stopper on the prefilled vial (0.2 ml of 3.8% Sodium Citrate is used as diluent). Using a transfer pipette, fill the vial to the **BOTTOM** of the indicated fill line, with 0.8 ml of blood to make the required 4:1 dilution ratio. The Sediplast®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



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 rate in millimeters.



9. Dispose of properly after use.
10. Remove gloves and wash hands in accordance with established procedures.

Specifications

Dimension of Sediplast Pipette (Tube):
 Overall Length 200 mm
 Graduated 0 -150 mm
 Bore Size (I.D.) 2.55 mm
 Uniformity of Bore ± 0.05 mm

Product Number

| | |
|---|-------------------------|
| <u>With (Sodium Citrate) Diluent</u> | <u>Unit</u> |
| S-1000 | Pkg/1000 |
| S-100 | Pkg/100 |
| <u>Without Diluent</u> | <u>Unit</u> |
| S-1001 | Pkg/1000 |
| S-101 | Pkg/100 |
| <u>Sediplast Rack</u> | <u>Unit</u> |
| S-1040 Disposable | Each |
| S-104B | Case of 12 (Disposable) |
| S-1045 Acrylic | Each |
| <u>Leveling Plate</u> | <u>Unit</u> |
| S-1035 (Large) | Each |
| S-1030 (Small) | Each |

Manufactured by:



LP ITALIANA SPA

Via C. Reale, 15/4 - 20157 Milano (Italy)
 Tel. +39 02 3933 061 - Fax +39 02 3931 3484
 info@lpitaliana.com – www.lpitaliana.com

Distributed by:



POLYMEDCO, INC.

510 Furnace Dock Road
 Cortlandt Manor, NY, 10567
 Tel. 800-431-2123 or 914-739-5400
 Fax 914-739-5890
 info@polymedco.com – www.polymedco.com

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