7. Position the SediRedi™ test unit on the SediStand™ vertical rack (REF: RT-40113) at room temperature and start a timer for precisely 60 minutes. Ensure the rack and unit remain vertical, away from vibrations, drafts, or direct sunlight as it may affect the result of the test.
8. After 60 minutes, read the SediRedi™ results directly from the numerical scale imprinted on the pipette and record it.
9. Dispose of the entire test unit following all applicable biohazard and infectious waste regulations.

ADULT REFERENCE RANGES (TYPICAL RANGES)

- Male under 50: 0–15 mm/hour
- Male over 50: 0–20 mm/hour
- Female under 50: 0–20 mm/hour
- Female over 50: 0–30 mm/hour

PRODUCT DISPOSAL

Dispose of used test tubes, pipettes, and blood samples in a puncture-resistant biohazard container in accordance with local, state, and federal regulations for biological waste and infectious waste regulations.

REFERENCES

1. Tishkowski K, Gupta V. Erythrocyte Sedimentation Rate. [Updated 2023 Apr 23]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-.; https://www.ncbi.nlm.nih.gov/books/NBK557485/
2. Reference method for the erythrocyte sedimentation rate (ESR) test on human blood. Br J Haematol. 1973 May;24(5):671-3.
3. International Council for Standardization in Haematology (ICSH). (1993). "ICSH recommendations for measurement of erythrocyte sedimentation rate." Journal of Clinical Pathology, 46(3), 198–203.
4. CLSI. Procedures for the Erythrocyte Sedimentation Rate Test; Approved Standard—Fifth Edition. CLSI document H02-A5. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

SYMBOLS

IVD For In Vitro Diagnostic Use	25°C (77°F) 4°C (39°F) Temperature Limitation	LOT Batch Code	Use by:
Do not Re-Use	Σ 100 Containts sufficient for 100 determinations	REF Catalog Number	Keep away from sunlight
Keep away from rain	Consult Instructions for Use	Rx Professional Use Only	

DISTRIBUTED BY:
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RED TUNICA

SEDiREDi™

Autozero Westergren ESR System

REF RT- 20130

For Rx Professional Use Only | For In-Vitro Diagnostic Use Only | Single Use Only

INTENDED USE

RedTunica™ SediRedi™ - Autozero Westergren ESR System is a quantitative, non-specific, erythrocyte sedimentation rate (ESR) test device that aids in the detection of inflammation or abnormality in the body from whole human blood specimens. The test is intended for use by healthcare and/or clinical laboratory professionals.

SUMMARY AND EXPLANATION OF THE TEST

RedTunica™ SediRedi™ - Autozero Westergren ESR System is a blood test that can reveal inflammatory activity in the body. A sedimentation rate test is not a stand-alone diagnostic tool, but it can help diagnose or monitor the progression of an inflammatory disease. On its own, it cannot determine the problem that is causing inflammation in the body, so it is a complement to other blood tests, such as a C-reactive protein tests.

RedTunica™ SediRedi™ - Autozero Westergren ESR System follows the recommendations of the Westergren method, commonly referred to as the "Sed Rate" test, is a widely used, non-specific laboratory test that measures the rate at which red blood cells (erythrocytes) fall in a Westergren tube over a period of one hour. This test serves as an indirect indicator of inflammation, infection, or other pathological conditions in the body.[1]

In the Westergren method, originally described by Alf Westergren in the 1920s, a sample of anticoagulated whole blood (typically mixed with sodium citrate) is placed in a vertical, calibrated tube with a length of 200 mm and an internal diameter of 2.55 mm. The tube is left undisturbed at room temperature, and the distance that the erythrocytes fall in one hour is measured in millimeters (mm/h). The result, known as the sedimentation rate, reflects how quickly the red blood cells settle to the bottom of the tube. Reference ranges in adults vary by age and sex, but generally, values are higher in females and increase with age (e.g., 0–15 mm/h for male and 0–20 mm/h for female under 50).

The International Committee for Standardization in Haematology (ICSH) adopted the Westergren method as the gold standard for ESR measurement in 1973.[2] Even after the advent of automated machines used to analyze the ESR, the Westergren method was still confirmed as the gold standard in 2011 by both the ICSH and the Clinical and Laboratory Standards Institute (CLSI).[3]

PRECAUTIONS

- For In-Vitro diagnostic use only.
- For Single Use. Do not re-use.
- All patient samples should be treated as potentially infectious and handled according to standard precautions.
- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- Do not use any test component after the expiration date which is printed on the outer packaging.
- The Occupational Safety and Health Administration (OSHA) and Good Laboratory Practice recommend the use of personal protection equipment (PPE) – such as protective eyewear, shields, gloves, lab coats and footwear when working with or near potentially hazardous materials.
- EDTA tube (Lavender Top) is recommended for sedimentation rate testing procedures because EDTA has the least effect on erythrocyte morphology. EDTA tube may also be used for CBCs and differentials.
- Allow refrigerated blood to warm to room temperature before testing.
- Test blood stored at 18 - 25°C within 4 hours.
- Blood refrigerated at 4°C should be tested within 6 hours.
- All results must be interpreted together with other clinical information available to the physician.

LIMITATIONS

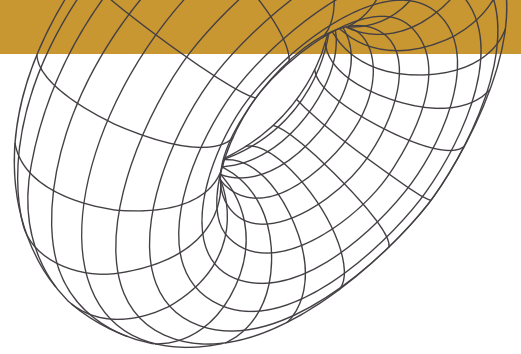
- All operators should follow the instructions for use with attention to step-by-step instructions for each sample tested, to ensure consistency of the test.
- For best results, use fresh whole blood human samples.
- The Westergren ESR method test uses a 3.8% buffered trisodium citrate solution (1 part citrate to 4 parts EDTA whole blood) as an anticoagulant. Inadequate mixing of these anticoagulants may disrupt the required ratio, potentially affecting the sedimentation rate and leading to inaccurate ESR results.[4]
- Failure to fill the tube to the designated "Fill Line" with blood can alter the 1:4 citrate-to-blood ratio, which may interfere with the accuracy of the ESR reading as measured on the pipette's numerical scale.
- The Erythrocyte Sedimentation Rate (ESR) Westergren Method is a sensitive but non-specific test influenced by various physiological, pathological, and technical factors.
- Interfering factors that can affect the accuracy and reliability of ESR results may include, but not limited to, age, sex, pregnancy, menstruation, anemia, plasma protein disease, sickle cell disease, hypofibrinogenemia, anticoagulant issues, tube positioning, temperature, time delay, vibrations, medications and substances such as aspirin, NSAID, oral contraceptives, corticosteroids. This is not a comprehensive list of interfering factors that can affect the ESR results.
- See ICSH guidelines or standard hematology texts (e.g., Dacie and Lewis Practical Haematology) for factors affecting ESR results.

REAGENTS AND MATERIALS

- 100 Disposable Pipettes
- 100 Vials Prefilled with 0.25mL of 3.8% Trisodium Citrate Diluent
- 1 Instructions for Use

Required but not provided

- Timer
- Vertical Rack Stand
- Blood Sample Collection Tube
- Personal Protection Equipment (PPE)



STORAGE AND STABILITY

- The test kit should be stored at 4 - 25°C
- The freshly collected whole blood sample specimen is recommended to be processed no later than 4 hours.
- If testing is delayed between 4 and 12 hours, store the sample at 4°C and return it to room temperature before proceeding.
- Allow refrigerated blood to warm to room temperature before testing.

TEST PROCEDURE

1. Take one (1) SediRedi™ vial and one (1) SediRedi™ pipette out of the packaging.
2. Gently tap the base of the SediRedi™ vial on the lab bench two or three times to ensure the citrate settles at the bottom of the vial.
3. Add 1mL of thoroughly mixed EDTA-treated blood up to the marked fill line on the SediRedi™ vial using one of the methods below:

    a. Remove the stopper and insert the blood using a transfer pipette or pour the blood directly from the collection tube. Place the stopper back into the vial.

    OR

    b. Place a piercing funnel (REF: RT-40114) into the stopper to hold it open, then use a transfer pipette or pour the blood directly from the collection tube. Afterward, remove and discard the funnel appropriately.

IMPORTANT: Blood must reach the fill line on the SediRedi™ vial for accurate results and to avoid bubbles.

4. Carefully invert the vial at least six (6) times to fully mix the blood with the citrate. Then, lightly tap the bottom of the SediRedi™ vial on the bench to settle the diluted sample at the base.
5. With one hand holding the SediRedi™ pipette at the 150mm mark and the other holding the SediRedi™ vial, firmly push the blue rubber plunger firmly through the SediRedi™ vial's pierceable stopper until it stops.
6. Hold the vial in a totally upright position and apply steady, gentle pressure downward to insert the pipette fully to the bottom. The blood will rise into the pipette automatically and stop at the zero mark.

NOTE: A self-sealing barrier at the zero mark prevents blood or aerosols from passing through. Any overflow will flow over the plunger and stays safely within the vial.