



ESR

Control

For use in the quality control of the erythrocyte sedimentation rate (ESR) test

USES

ESR Control is designed to be used in the quality control of the erythrocyte sedimentation rate measurement in automated analyzers.

Consult the value assigned on the labels of both levels, since it is lot-specific.

PROVIDED REAGENTS

Control Level 1: buffered stabilized suspension of human erythrocytes at normal or close to normal levels, with appropriate preservatives.

Control Level 2: buffered stabilized suspension of human erythrocytes at pathological levels, with appropriate preservatives.

INSTRUCTIONS FOR USE

Control Level 1 and 2: ready to use.

WARNINGS

The Controls are for "in vitro" diagnostic use.

ESR Control has been prepared from non-reactive material for Hepatitis B surface antigen (HBsAg), antibodies to Hepatitis C virus (HCV) and antibodies to the human immunodeficiency virus (HIV). Nonetheless, the controls and samples should be handled as capable of transmitting infection.

Use the reagents according to the working procedures for clinical laboratories.

All reagents and samples should be discarded according to the local regulations in force.

STABILITY AND STORAGE INSTRUCTIONS

ESR Control is stable at room temperature (18-30°C) until the expiration date indicated on the box. Do not freeze or expose to high temperatures.

Once opened, it is stable for 31 days at room temperature (18-30°C), keeping the vials tightly closed. Avoid prolonged exposure of open vials to light. The vials should be kept tightly closed after use to avoid evaporation.

PROCEDURE

The Controls must be used in the same way as an unknown sample, according to the instructions of the instrument or kit.

- 1- This product must be prepared with a new tube each time.
- 2- Rotate the vial between the palms of the hands in a horizontal and inverted position for 20 to 30 seconds.

Occasionally invert the vial. Mix without shaking. Avoid foaming.

3- Repeat step 2 until a complete suspension is obtained. Long-term stored vials require more extensive mixing.

4- Gently invert the vial 10-12 times.

5- Make sure the content of the vial is completely in suspension. If not, repeat steps 3 to 5 until full suspension is achieved.

6- Follow the manufacturer's instructions for filling the sample tubes. The classical Westergren procedure does not require predilution of the control material. Cover immediately and run as a control.

7- After each use, clean any residual material from the vial threads and the inner cap. Store as described in STABILITY AND STORAGE INSTRUCTIONS.

EXPECTED RESULTS

Values are assigned on instruments properly maintained and calibrated by the manufacturer.

The average values of each laboratory must be within the corresponding acceptable range, but may deviate from the indicated values throughout the shelf life of the product.

Variations over time and between laboratories may be due to differences in laboratory technique, instrument calibration method, and reagents. It is recommended that each laboratory establish its own acceptable values and ranges and use those provided as guidelines only.

PROCEDURE LIMITATIONS

- Do not use after the expiration date.
- This product is not designed to be used as a standard.
- An unusual appearance of the reagent may be observed. If the values obtained are not within the expected ranges, repeat the analysis with a new reagent vial.

WIENER LAB PROVIDES

- 2 x 9 ml: 1 x 9 ml Level 1 + 1 x 9 ml Level 2 (Cat. N° 1937601)

Symbols

The following symbols are used in the packaging for Wiener lab. diagnostic reagent kits.



This product fulfills the requirements of the European Directive 98/79 EC for "in vitro" diagnostic medical devices



Authorized representative in the European Community



"In vitro" diagnostic medical device



Contains sufficient for <n> tests



Use by



Temperature limitation (store at)



Do not freeze



Biological risks



Volume after reconstitution



Contents



Batch code



Manufactured by:



Harmful



Corrosive / Caustic



Irritant



Consult instructions for use



Calibrator



Control



Positive Control



Negative Control



Catalog number

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Wiener lab.

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