

**INTENDED PURPOSE**

In-vitro diagnostic quality control material to monitor the precision of Starrsed Erythrocyte Sedimentation Rate (ESR) instruments and procedures.

**SUMMARY AND PRINCIPLE**

Good laboratory practice requires that stable reference material is used to verify the precision of testing equipment and procedures. Starrsed Control is used as one would use a whole blood patient specimen in sedimentation rate procedures. Two levels of control are used to monitor within the normal and abnormal clinical range.

**REAGENTS**

Starrsed Control is composed of stabilized human red cells suspended in a buffered, preservative fluid.

**WARNING AND PRECAUTIONS**

Contains human source material. Handle as potentially infectious.

Each donor unit used in preparation of Starrsed Control has been tested and found non-reactive for antibodies to Human Immunodeficiency Virus (HIV-1/HIV-2), Hepatitis B Surface Antigen (HBsAg) and antibodies to Hepatitis C (HCV).

No test method can assure complete absence of infectious agents. Therefore Starrsed Control should be handled with the same precautions used with patient specimens.

This product should be disposed of as medical waste.

Any serious incident that has occurred in relation to this product must be reported to the distributor and/or manufacturer and the competent local authorities.

**LIMITATIONS**

Starrsed Control is to be used for Erythrocyte Sedimentation Rate testing only and shall not be used to control any other hematology procedure.

Starrsed Control shall not be used as a standard.

Starrsed Control should not be used past the expiration date.

RR Mechatronics as supplier of the Starrsed Control shall not be liable for any claimed damages arising from other than intended usage.

**STORAGE AND STABILITY**

Store Starrsed Control at 18°-30°C (64°-86°F).

DO NOT FREEZE. DO NOT EXPOSE TO EXCESSIVE HEAT.

STORE THE TUBES UPRIGHT WITH THE CAP ON TOP.

Unopened, this product is stable until the expiration date (see tube label and insert), typically 540 days after production. Once the tube has been used (cap has been punctured or cap was removed) the product remains stable for 31 days at room temperature 18°-30°C (64°-86°F). Avoid prolonged exposure of tubes to light. Tubes should remain 'closed' at all times after each use.

**PROCEDURE**

Starrsed Control is provided in ready-to-use sample tubes and is used in the same manner as patient samples. Starrsed Control is to be used for the Westergren method with dilution only as prescribed by the "ICSH review of the measurement of the ESR" (2011) and the "CLSI Procedures for the ESR Test; Approved standard; H02-A5" (2011).

1. Rub the Starrsed Control tube between hands until packed cells have been completely re-suspended. (See also video instruction) <https://portal.rrmechatronics.com/whatiseqas/>



2. Place tube for at least 15 minutes on a roller mixer or rotator mixer for thoroughly mixing. Avoid foaming. DO NOT VORTEX.

NOTE: To ensure consistent and reproducible results, the Control material must be thoroughly mixed and handled in the same manner each time.

3. Load or draw the sample immediately after mixing.

*Starrsed ESR analyzer in EDTA mode:* Load the Starrsed Control tube directly into the analyzer according the instructions for loading patient samples (see instruments "Instructions For Use").

*Starrsed ESR analyzer in Citrate mode:* Immediately after re-suspending, transfer the necessary amount of material into a pre-citrated tube according instructions of the tube manufacturer. Close the tube with the mixture and invert at least 12 times, then load the sample into the analyzer according the instructions for loading patient samples (see instruments "Instructions For Use")

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4. After each use, restore tube as described in section STORAGE AND STABILITY.

Note:

Interrliner, Starrsed ST, Starrsed RS: the contents of one tube is sufficient for three Control samples.

Starrsed TL: the contents of one tube is sufficient for two Control samples.

Do not mix residual material with material from other tubes. Do not re-use empty tubes.

**EXPECTED VALUE RANGE**

Starrsed Control is assayed for the Starrsed ESR analyzers. The software always calculates a temperature corrected result because only temperature corrected results can be compared with the assayed mean value. The assayed mean value is derived from validation measurements on multiple instruments at different sites. The assayed mean value is encoded in the tubes barcode and is lot-specific.

Individual laboratory means should fall within the lot specific acceptable range; however, laboratory means may vary from the listed values during the life of this product. Variations between laboratories may be caused by differences in instrument condition and procedures. It is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as guides. Whenever the Controls fail to perform consistently within the acceptable ranges according local quality procedures, patient results should be considered invalid. If results vary outside the specified assay ranges, check instrument and followed procedures. If difficulties persist, contact your supplier for further assistance and/or instructions.

**QUALITY CONTROL PROGRAM**

A Quality Control Program is incorporated in the application software of all Starrsed analyzers. For more information contact your Starrsed instrument provider.

**ORDERING INFORMATION**

A0026578 Starrsed Control, level A, Tube vol 4.6 ml, Product packaging 6 x 4.6 ml

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