

Erythrocyte Sedimentation Rate Control
for Starrsed ESR Analyzers

2023-02-22 18°C 30°C



LOT **QCA9FDAA29**



	Mean value	Range
Starrsed, temp. corrected to 18°C	41	±10

Reference method	Mean value	Range
Starrsed, not corrected (at 24°C)	48	±10
Dispette 2, not corrected (at 23°C)	51	±10
Polymedco Sediplast, not corrected (at 23°C)	59	±10
Westergren, manual, glass, dilution, temp.corr. to 18°C	50	±10
Westergren, manual, glass, dilution, not corr. (at 23°C)	56	±10

Version: QCA9FDAA29 2021-11

INTENDED USE

Starrsed Control is an in-vitro diagnostic quality control material to monitor the accuracy and precision of Erythrocyte Sedimentation Rate (ESR) instruments and procedures.

SUMMARY AND PRINCIPLE

Good laboratory practice requires that stable reference material is used to verify the accuracy and 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.

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 to 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 to 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 to the instructions for loading patient samples (see instruments "Instructions For Use").

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 Assay mean value. The assayed mean values, expected ranges and reference values are derived from validation measurements on multiple instruments at different sites. All these values are mentioned on the product insert (the assayed mean value encoded in the tubes barcode) and are lot-specific.

The assayed mean values and expected ranges are derived from multiple analyses at different sites and on multiple instruments. The values, provided on the package insert and encoded in the tubes barcode, are specific for this lot of product. The lab should establish its own acceptable ranges. Whenever the Controls fail to perform consistently within the acceptable ranges, patient results should be considered invalid. Contact your Starrsed instrument provider for assistance.

If results vary outside the specified assay ranges, discard the tube and utilize a new tube. 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

Product no.	Product description	Tube vol.	Product packaging
QRR 049001	Starrsed Control, level N	4.6 ml	6 x 4.6 ml
QRR 049002	Starrsed Control, level A	4.6 ml	6 x 4.6 ml

RR Mechatronics sales@rrmechatronics.com	
De Corantijn 13 1689AN Zwaag, The Netherlands Tel: +31 229 291 129	20 Altieri Way. Unit#4 Warwick, RI 02886, USA Tel: +1 888 431-6101

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This package insert in other languages:

https://www.rrmechatronics.com/product/consumables/Starrsed_Control/package-inserts

ENGLISH

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