


SEDiTROL® Erythrocyte Sedimentation Rate Control

Levels 1 and 2

Quality Control for the iSED® Family of ESR Analyzers

REF	DSC01	Level 1 (Normal), 1 x 4.0 mL			
		Level 2 (Abnormal), 1 x 4.0 mL			
	DSC06	Level 1 (Normal), 3 x 4.0 mL			
		Level 2 (Abnormal), 3 x 4.0 mL			
LOT	Level 1	C148		EXP	22-02-2027
	Level 2	C248			

INTENDED USE

SEDiTROL Erythrocyte Sedimentation Rate (ESR) Control is intended for use as a quality control to monitor the precision of ESR on the miniSED®, iSED, iSED ELITE, and iSED PRO ESR Analyzers.

SUMMARY AND PRINCIPLE

The use of quality control material is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. Two levels of control are available to allow performance monitoring within the clinical range.

MATERIAL

This product is composed of stabilized human red cells suspended in a buffered fluid and preservative.

STORAGE & STABILITY

This product will be stable until the expiration date when stored unopened at room temperature (18° to 30°C). Once in use, the product is stable for 60 days at room temperature (18° to 30°C) when it remains tightly capped and is only used with the iSED family of ESR analyzers. Avoid prolonged exposure of opened vials to light. For optimal performance, do not refrigerate. Inspect product for deterioration (see Limitation 3) and mix well before use (see Procedure for mixing instructions).

Note: The 60 days stability has been validated for use with iSED, iSED ELITE, iSED PRO and miniSED® only and has not been validated for any other method or usage. For all other ESR methods, the product is stable for 31 days at room temperature (18° – 30° C) when tightly capped.

DO NOT FREEZE OR EXPOSE TO EXCESSIVE HEAT

STORE UPRIGHT. MIX WELL BEFORE ANALYSIS.

LIMITATIONS

1. This product should not be used past the expiration date.
2. This product is not intended for use as a standard.
3. Inability to obtain expected values may indicate product deterioration. Discoloration of the product may be caused by excessive heat or cold during shipping or storage. Atypical physical appearance, such as the presence of large particulates, may be observed with this product. If the recovered values are not within the expected ranges, retest with a new vial of this product. If the same result is obtained, contact ALCOR® Scientific Technical Support.

ASSIGNMENT OF VALUES

The mean values printed in this insert were derived from replicate testing and are specific to this product and lot. Individual lab means should fall within corresponding acceptable ranges; however, lab means may vary from the listed values during the life of the product. Variations over time and between labs may be caused by differences in lab practices, instrumentation calibration, and consumables. It is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as a guide.



WARNING

Biological source material. Treat as potentially infectious.

Each human whole blood donor unit used to manufacture this control was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen, antibody to Hepatitis C and antibody to HIV-1/HIV-2. This product may also contain other human source material for which there are no approved tests. In accordance with good lab practice, all human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

Serious incident reporting.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the EU Member State or the Regulatory Authority in which the user and/or patient is established.

PROCEDURE

Prior to the **first use** of the SEDIROL Level 1 and Level 2 Controls, place the tubes on a mechanical rocker or rotator for 25 minutes. Ensure that the cells have been thoroughly resuspended before placing the tubes onto the iSED, iSED ELITE, iSED PRO, or miniiSED ESR analyzer. The analyzers aspirate 100µl of SEDIROL Control for analysis. If the control is being run directly after a wash cycle, the analyzer will draw an additional 20µL of sample from the first run to prime. To ensure the volumes for SEDIROL Level 1 and Level 2 remain as consistent as possible, it is recommended to alternate the order controls are run each time they are run.

Product should be run in accordance with the instructions from the appropriate Operator's Manual: iSED Operator's Manual (112-09-043), iSED/iSED ELITE Operator's Manual (222-09-007), iSED PRO Operator's Manual (120-09-007), or miniiSED Operator's Manual (1017-09-001).

1. Place the SEDIROL Control tubes on a mechanical rocker or rotator for 5 minutes and ensure that all cells have been thoroughly resuspended before placing the control tubes onto the ESR analyzer. Avoid foaming.
2. Insert one (1) tube of SEDIROL Level 1 or Level 2 in accordance with the instructions in the Operator's Manual, ensuring that the barcode is read and recognized by the analyzer. Controls can be run in any order. Alternating which Level of SEDIROL is run first will optimize control material usage. The barcode must be scanned in order to process SEDIROL correctly. Manual entry of the barcode ID will not suffice.
3. Repeat step 2 using the other tube of SEDIROL. Controls can be run in any order. Alternating which control is run second will optimize control material usage.
4. After each use, wipe any residual material from the exterior of the cap. Store as described in the Storage and Stability Section.

METHOD

	Units	LEVEL 1		LEVEL 2	
		Mean	Range	Mean	Range
ERYTHROCYTE SEDIMENTATION RATE					
iSED/iSED ELITE	mm/hr	6	± 5	70	± 28
miniiSED	mm/hr	6	± 5	70	± 28
iSED PRO	mm/hr	6	± 5	70	± 28
Westergren	mm/hr	10	± 7	66	± 26

For additional information or questions regarding the information, above please contact ALCOR[®] Scientific Technical Support at techsupport@alcorscientific.com or 1.800.495.5270 (US only) / + 1.401.737.3774.



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