

SEDITROL® Erythrocyte Sedimentation Rate Control

Levels 1 and 2

Exclusively for ALCOR® 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	C1					
	Level 2	C2					
				EXP	DD-MM-YYYY		IVD

INTENDED USE

ALCOR Scientific Inc. Seditrol® ESR Control is intended for use as a quality control to monitor the precision of the erythrocyte sedimentation rate (ESR) on the ALCOR 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.

REAGENT

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

STORAGE & STABILITY

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

***Note: The 60 days stability has been validated for use on the iSED® and the miniSED® only and has not been validated for any other method or usage. For all other 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 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 analyzers and are specific to this product and lot. The tests listed were performed by using manufacturer's supported reagents and a representative sampling of this 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 reagents. It is recommended that each laboratory establish its own means and acceptable ranges and use those 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.

PROCEDURE

Prior to first use of the Seditrol Level 1 and Level 2 Control, place the tubes on a mechanical rocker or rotator for 25 minutes. Ensure that the cells have been thoroughly resuspended before placing the control tubes onto the ALCOR ESR analyzer. The analyzer will draw an additional 20µL of sample from the first run to prime the analyzer following a wash cycle. To ensure the volumes for Level 1 and Level 2 remain as consistent as possible it is recommended to alternate the order controls are run each day.

Product should be treated the same as a patient specimen and run in accordance with the instructions from the analyzer Operator's Manual or Instructions For Use.

1. Place the 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 ALCOR ESR analyzer. Avoid foaming.
2. Insert one (1) tube of Seditrol Level 1 or Level 2 in accordance with the instructions in the analyzer Operator's Manual, ensuring that the barcode is read and recognized by the analyzer. Controls can be run in any order. Alternating which control is run first will optimize the quantity of control material usage. The barcode must be scanned in order to process Seditrol correctly. Manual entry of the barcode ID will not suffice.
3. Repeat step 2 using one (1) tube of Seditrol Level 2 or Level 1. Controls can be run in any order. Alternating which control is run second will optimize the quantity of 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

	Type	Units	LEVEL 1		LEVEL 2	
			Mean	Range	Mean	Range
ERYTHROCYTE SEDIMENTATION RATE						
iSED®	Glass or Plastic	mm/hr		±		±
miniiSED®	Glass or Plastic	mm/hr		±		±
Westergren (Modified)	Plastic	mm/hr		±		±

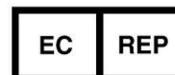
For additional literature, languages, or questions regarding the information above please contact our technical support department. Company representatives are available to assist you Monday through Friday from 8:30am to 5:00pm Eastern Time and they can be reached by calling 1.800.495.5270 (US only) or + 1.401.737.3774.

If you require emergency technical assistance, please take advantage of our voice mail which will be routinely consulted by our service engineers.



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