

SEDITROL® ESR QUALITY CONTROL

EXCLUSIVELY FOR *iSED*®

DSC06
6 x 4.5 mL

Level 1 **C136**
Lot # **36** Level 2 **C236**

Expiration Date
23-MAY-2021

IVD
For In Vitro Diagnostics Use Only

INTENDED USE:


ALCOR Scientific Inc. Seditrol® ESR Quality Controls are intended for use exclusively on *iSED*®, as a QC tool in order to monitor the precision of ESR laboratory testing procedures.

REAGENT:

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

PROCEDURE:

Product should be treated the same as patient specimens and run in accordance with the instructions from the operator's manual.

1. Touch the 'Add Sample' icon, , on menu screen.
2. Insert one (1) tube of Seditrol® Level 1, in the empty sample position presented by the instrument, making sure to orient the barcode label facing right, toward the internal barcode reader. If the barcode is not immediately recognized, rotate the tube slightly until a beep is heard. The beep indicates the instrument has successfully read the barcode.
3. The instrument will present the next open position.
4. Repeat step 2 using one (1) tube of Seditrol® Level 2.
5. Read the control results printed by *iSED*®.

LIMITATIONS:

1. Product should not be used past expiration date
2. 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.

STORAGE & STABILITY:

Product will be stable to expiration date when stored unopened at 18° to 30° C. Once opened product is stable for 31 days at room temp (18° to 30° C) when tightly capped. **DO NOT FREEZE OR EXPOSE TO EXCESSIVE HEAT**

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 Mfg 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.

| ERYTHROCYTE SEDIMENTATION RATE | | | | | | |
|--------------------------------|------------------|-------|---------|-------|---------|-------|
| | Type | Units | LEVEL 1 | | LEVEL 2 | |
| | | | Mean | Range | Mean | Range |
| <i>iSED</i> ® | Glass or Plastic | mm/hr | 8 | ± 6 | 63 | ± 26 |
| Westergren (Modified) | Plastic | mm/hr | 4 | ± 2 | 47 | ± 18 |

For additional literature or questions regarding the information above please free to contact our technical support department. Company representatives are available to assist you Monday through Friday from 8.30am to 5pm Eastern Time and they can be reached by calling 1.800.495.5270.

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