



SEDITROL® ESR QUALITY CONTROL

DSC04 4 x 9 mL

Lot # **34**

Level 1 **C134**

Level 2 **C234**

Expiration Date

21-SEP-2020

IVD

For In vitro Diagnostics Use Only

INTENDED USE:

ALCOR Scientific Inc. ESR controls are intended for use as a QC tool 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.

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

PROCEDURE:

Product should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument.

1. Product must be used with a fresh sample tube each time.
2. Invert Control vial until packed cells have been re-suspended, approximately 30 sec. Place vial on tube rocker for additional four minutes. Avoid foaming. **DO NOT VORTEX.**
3. Remove vial from rocker and **WITHOUT DELAY**, fill sample tubes according to manufacturer's directions.
4. Place sample tube on rocker for two minutes immediately preceding testing.
5. After each use, wipe residual materials from threads of Controls vial and inside cap. Replace cap tightly and store as described in the Storage and Stability Section.
6. Dispose of sample tubes. **DO NOT reuse.**

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.

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 as only 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.

SEDITROL® SEDIMENTATION RATE CONTROL

METHOD						
	Type	Units	LEVEL 1		LEVEL 2	
			Mean	Range	Mean	Range
ERYTHROCYTE SEDIMENTATION RATE						
Becton Dickinson Seditanier (366065)	Glass	mm/hr	6	± 5	72	± 12
Diesse Mini-Cube (1)	Plastic	mm/hr	13	± 5	92	± 25
Diesse MiniVes (Europe)	Plastic	mm/hr	15	± 5	92	± 25
Diesse Ves-matic 10 (1)	Plastic	mm/hr	9	± 5	84	± 25
Diesse Ves-matic 20 / 20 Plus New	Plastic	mm/hr	10	±10	96	± 13
Diesse Ves-matic 20 / 20 Plus New (1)	Plastic	mm/hr	9	± 5	97	± 25
Diesse Ves-matic 30 / 30 Plus (1)	Plastic	mm/hr	11	± 5	103	± 25
Diesse Ves-matic 60 / 60 Plus (1)	Plastic	mm/hr	13	± 5	97	± 25
Diesse Ves-matic Cube 30	Plastic	mm/hr	9	± 5	99	± 25
Diesse Ves-matic Cube 30 Touch (1), Diesse	Plastic	mm/hr	6	± 5	107	± 25
Diesse Ves-matic Cube 80 / 200	Plastic	mm/hr	6	± 5	81	± 25
Diesse Ves-matic Easy	Plastic	mm/hr	8	± 5	75	± 24
Diesse Ves-matic Easy (Europe)	Plastic	mm/hr	11	± 5	87	± 25
Dispette 2	Plastic	mm/hr	4	± 4	53	± 14
Kimble-Chase Disposable Westergren Tubes(2)	Glass	mm/hr	4	± 4	55	± 15
Polymedco Sedimat 60	Plastic	mm/hr	4	± 4	49	± 10
Polymedco Sediplast	Plastic	mm/hr	4	± 4	52	± 15
Sarstedt S-Sedivette	Plastic	mm/hr	7	± 5	76	± 14
Streck ESR Auto-Plus	Glass	mm/hr	10	± 7	74	± 18
Vital Diagnostics Excyte 20 (1)	Glass	mm/hr	7	± 6	75	± 12
Vital Diagnostics Excyte 40 (1)	Glass	mm/hr	6	± 6	80	± 12
Vital Diagnostics Excyte M/10 (1)	Glass	mm/hr	7	± 6	82	± 12
Vital Diagnostics Excyte Mini (1)	Glass	mm/hr	6	± 6	77	± 12
Vital Diagnostics MICROsed systems (1)	Glass	mm/hr	7	± 4	78	± 18
Vital Diagnostics Monitor Series (1)	Glass	mm/hr	5	± 4	86	± 18
Westergren (Modified)	Plastic	mm/hr	5	± 5	52	± 10
Wintrobe	Glass	mm/hr	4	± 4	42	± 15

(1) TEMPERATURE CORRECTION: Means and Expected Ranges are corrected to 18°C in accordance with the Manley table.

(2) METHOD VARIATION: Tubes do not contain Sodium Citrate (Diluent).

For additional literature or questions regarding the information above please free to contact our technical service department. Company representatives are available to assist you Monday through Friday from 8.30 am to 5 pm Eastern Standard 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.



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