Accu-Sed® Plus
Abnormal ESR Control, 5x8.5 mL

REF **DS-71003** CE For *in vitro* diagnostic use, for professional use only

INTENDED USE

Accu-Sed Plus ESR Controls are whole blood reference control materials designed to monitor patient erythrocyte sedimentation rate (ESR) procedures. Accu-Sed Plus ESR Controls help to monitor technique as well as environmental, physical and mechanical factors such as room temperature, tube position and vibration.

SUMMARY

Good laboratory practices require the use of stable reference materials to verify the accuracy and precision of testing equipment and procedures. Accu-Sed Plus ESR Controls may be used in sedimentation rate procedures as one would use anticoagulated whole blood.

REAGENTS

COMPOSITION

Accu-Sed Abnormal Controls contain human red blood cells, preservatives, and stabilizers.

WARNINGS AND PRECAUTIONS

- The Accu-Sed ESR Controls are for professional *in vitro* diagnostic use only.
- CAUTION: Handle Accu-Sed Plus ESR Controls and all human blood products as though capable of transmitting infectious agents. Use the Centers for Disease Control and Prevention (CDC) recommended universal precautions[1] for handling Accu-Sed Plus ESR Controls and human specimens. Do not pipette by mouth; do not eat or drink or apply cosmetics in areas where specimens are being handled. Clean up spills immediately with a 0.5% sodium hypochlorite solution. Dispose of controls as though they contain infectious agents.
- For more information, Safety Data Sheet (SDS) is available on request for professional user.

PREPARATION

Accu-Sed Plus ESR Controls are supplied ready to use. No reconstitution is necessary.

STORAGE AND STABILITY

- **IMPORTANT! –** Accu-Sed Plus Abnormal ESR Controls must remain upright during storage. Failure to do so may adversely affect product performance.
- Do not use Accu-Sed Plus Abnormal ESR Controls beyond their expiration dates. Do not freeze. Do not expose to excessive heat.

Stability	Storage	Claim
Unopened:	18 to 30 °C, protect from light	To expiration
Open Vial:	18 to 30 °C, protect from light	31 days

SOLUTION DETERIORATION

If control results fall outside the specified assay ranges, discard the vial and use a new one. If the problem persists, contact ELITech at (800) 453-2725.

DAMAGED PACKAGING

Do not use the solution if the packaging is damaged as this might have an effect on product performance (leakages, pierced/punctured bottle or cap, etc.).

WASTE MANAGEMENT

Disposal of all waste material should be in accordance with local and legal requirements.

PROCEDURE

MATERIALS PROVIDED

5 x 8.5 mL Accu-Sed Plus Abnormal ESR Control L2

MATERIALS REQUIRED BUT NOT PROVIDED

- ESR Analyzer
- ESR Sample Collection Tubes
- Do not use materials that are not required as indicated above

INSTALLATION AND USE

Accu-Sed Plus Controls are analyzed according to the directions provided with the instrument and in the same manner as patient samples.

1. This product must be prepared with a fresh tube each time.
2. Invert the control vial until the packed cells have been suspended. Continue mixing for an additional 30 seconds. Avoid foaming. Do not vortex.
3. Follow the manufacturer's directions for filling the sample tubes. The classical Westergren procedure does not require predilution of the control material.
4. After each use, clean the threads of the cap and vial with an absorbent material and recap immediately.
5. Store opened vials at room temperature. Avoid prolonged exposure of the opened vials to light. Vials should be tightly closed after use to prevent evaporation.
6. Dispose of the used sample tube with control material. Do not reuse.

LIMITATIONS

Accu-Sed Plus ESR Controls are assayed only for the ESR methods listed under Expected Results. Use Accu-Sed Plus ESR Controls only for ESR procedures. Do not use these controls with any other hematology procedure.

EXPECTED VALUES

Expected control ranges are provided for the ESR methods listed in the assay table. These ranges are based on data generated by a single laboratory. Variation in interlaboratory results will be greater than the imprecision from any single laboratory. Results can also vary depending on differences in equipment, reagents, temperature, supplies and techniques.

Each laboratory should establish its own intralaboratory mean and standard deviation for each lot of ESR Control according to its own established procedures. Subsequent results should fall within the control ranges established from these statistical parameters.

QUALITY CONTROL PROGRAM

Navigate to www.elitechgroup.com/vqc for information on ELITechGroup's online, real time Quality Assurance Program.

GLOSSARY OF SYMBOLS

	Manufacturer	LOT	Batch code / Lot number	IVD	*In vitro* diagnostic medical device
CONT	Contents	CE	European Conformity		Consult instructions for use
REF	Catalogue Number		Temperature Limitation		Use by / Expiration date
	Biohazard Risk		This Way Up	EC REP	European Authorized Rep
CONTROL	Control	L2	Abnormal Control		Keep away from sunlight

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ASSAY TABLE

Kit Base Lot Number	Abnormal Control
LOT 225100	LOT 225110 2023-07-06

Diluted Westergren Methods	Units	Mean	Range
Excyte® 10/M/Mini	mm/hr	67	49 – 85
Excyte® 20	mm/hr	66	48 – 84
Excyte® 40	mm/hr	73	55 – 91
Monitor Family	mm/hr	65	47 – 83
MixRate Family	mm/hr	61	43 – 79
BD Sedi Family	mm/hr	46	36 – 56
Greiner Bio-One Sed-Rate Screener Family	mm/hr	60	42 – 78
Polymedco Sediplast™	mm/hr	43	28 – 58
Dispette™ 2	mm/hr	48	33 – 63

INSTRUMENT ID CODES AND BARCODES

Instrument	Abnormal QC ID Code / Barcode	
Excyte® 20	225266090	225266090
Excyte® 40	225273096	225273096
Monitor Family	225265097	225265097
MixRate Family	225261093	225261093
BD Sedi Family	225246052	225246052
Greiner Bio-One Sed-Rate Screener Family	225260092	225260092

* ESR values corrected on temperature of 18°C, in accordance with Manley Table.

REFERENCES

1. U. S. Department of Health and Human Services: Recommendation for Prevention of HIV Transmission in Health Care Settings. MMW Report, Aug 21, 1987, Vol. 36, No. 2S.

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