

Excyte® PLASTIC ESR VACUUM TUBES

REF EP-10605, EP-10605-H1

For *in vitro* diagnostic use

Intended Use

Excyte Plastic ESR Vacuum Tubes are for the quantitative determination of erythrocyte sedimentation rate (ESR) of whole blood using any of the following Excyte analyzers: Excyte Mini, Excyte M, Excyte 20 or Excyte 40.

Summary And Principle of Method

It is well established that patients affected by various diseases (e.g. tuberculosis, malignancies, rheumatic fever, rheumatoid arthritis, multiple myeloma, acute inflammation, etc.) have a raised ESR^{1,5}, due mainly to alterations in some plasma and erythrocyte factors causing the formation of erythrocyte rouleaux⁶⁻⁸.

The Excyte Mini, M, 20 and 40 random access ESR analyzers are automated instruments controlled by a microprocessor and exclusively employed for the analysis of ESR. Excyte analyzers can be used for random and continuous loading of samples while following the sedimentation of each sample independently. Whole blood is collected in 120 mm long plastic tubes containing 0.34 mL sodium citrate (0.109 mol). One tube is required for each determination.

A well-mixed sample is placed in an individual channel in the Excyte instrument where a photoelectric cell passes up the outside of each tube to record the height of the column of red cells at which light transmission occurs at 950 nm (infrared). After 30 minutes of sedimentation, the new level at which light passes through the column is recorded and the decrease in height is corrected mathematically to give a result which is comparable to a 1 hour Westergren ESR.

Reagents

REF EP-10605: 50 vacuum tubes per box. Sterilized plastic tubes with a butyl-rubber stopper. The tubes contain 0.34 mL sodium citrate (0.109 mol) and are ready for use

REF EP-10605-H1: 50 vacuum tubes per box. Sterilized plastic tubes with a butyl-rubber stopper. The tubes contain 0.34 mL sodium citrate (0.109 mol) and are ready for use at altitudes of 800 – 1300 meters.

Warnings and Precautions

For *in vitro* diagnostic use

Handle and dispose of Excyte Plastic ESR Vacuum Tubes and all human blood products as though capable of transmitting infectious agents. Use the Centers for Disease Control (CDC) recommended universal precautions⁹ for handling reagents and specimens. Do not pipette by mouth; do not eat, drink, smoke or apply cosmetics in areas where specimens are handled. Clean up spills immediately with a 0.5% sodium hypochlorite solution.

Reagent Preparation

The Excyte ESR tubes are supplied ready to use. No preparation is necessary.

Reagent Storage and Stability

Tubes should be stored at 4 to 25 °C. Do not freeze. When stored properly, tubes can be used up to the expiration date.

Specimen Collection

1. Apply the tourniquet.
2. Disinfect the venipuncture site.
3. Apply a sterile needle to the draw vacuum device.
4. Perform venipuncture with patient's arm in a downward position and the tube in an upward position.
5. The stopper should not be removed to add anything to the sample.
6. To avoid coagulation, mix the blood immediately with the sodium citrate solution by turning upside down several times.

Note: If blood collection utilizes a butterfly system, the Excyte ESR tube must not be the first tube in the collection order. The dead volume of the butterfly device must be filled with blood prior to collection using the Excyte ESR tube.

Specimen Storage and Stability

In accordance with the recommendations of the International Committee for Standardization in Hematology (ICSH), blood samples collected in this manner and stored in an Excyte tube should be tested within 4 hours if left at room temperature (18 to 25 °C)¹¹. The specimen may be kept refrigerated (2 to 8 °C) for up to 12 hours, but must be brought to room temperature and mixed thoroughly prior to analysis.

Blood used for ESR testing and stored in an EDTA tube is stable for up to 24 hours if refrigerated¹², but must be brought to room temperature and mixed thoroughly prior to analysis.

Interfering Substances

The following external factors can alter the ESR value after blood collection and should be avoided: improper dilution ratio, bubbles, foam, grossly hemolyzed samples, sudden agitation, temperature outside recommended operating conditions of 15 to 32 °C, direct sunlight, and lipemic samples. As with all ESR analyzers, abnormally high or low hematocrits, along with other hemoglobinopathies, may affect results.

Materials Provided

Excyte Plastic ESR Vacuum Tubes, catalog nos. EP-10605 or EP-10605-H1

Materials Required But Not Provided

1. Analyzer - one of the following Excyte ESR analyzers:
 - Excyte Mini, catalog no. EP-10610 automated ESR analyzer with 10 positions
 - Excyte M, catalog no. EP-10614 automated ESR analyzer with 10 positions and on board mixing
 - Excyte 20, catalog no. EP-10618 automated ESR analyzer with 20 positions and on board mixing
 - Excyte 40, catalog no. EP-10616 automated ESR analyzer with 40 positions
2. Controls - Accu-Sed® Plus Normal Control, catalog no. DS-71002; Accu-Sed® Plus Abnormal Control, catalog no. DS-71003; Accu-Sed® Plus Control Set, 5 vials normal, 5 vials abnormal, catalog no. DS-71005A.
4. Mixer - Optional Excyte Duo-Mixer, catalog no. EX-10573
5. Printer - Optional Excyte Printer, catalog no. EX-13886
6. Barcode Scanner - Optional Excyte Barcode Scanner, catalog no. EX-10551

Procedure

Before performing the ESR determination, carefully read the instructions contained in the instrument manual.

After blood is drawn and the Excyte Plastic ESR Vacuum Tube is filled with 1.36 mL of blood, mix the sample immediately with the sodium citrate. Immediately prior to analysis, the sample should be mixed thoroughly as described below.

1. Program the instrument according to the instructions in the Operator's Manual¹³⁻¹⁶.
2. Draw the blood as directed under "Specimen Collection".
3. Tube should be filled to at least the minimum line and not more than the maximum line on the tube. If too little sample is present (below the minimum mark - SAMPLE LOW), the sample will be rejected by the instrument without being analyzed.
4. Mix the blood with the sodium citrate solution by turning upside down at least 10 times, before placing the tube in the instrument, or use an automatic rotating mixer with a RPM value of 15 - 20.
5. Insert the tube containing a well mixed patient sample into any open channel and record the position number.

6. At the end of the cycle, the result is shown on the display, according to the order of the numbered positions. If the optional ExcYTE printer is connected, the result will print at the end of 30 minutes.
7. Once the measurement is complete and the value has been recorded or printed, remove the tube.
8. The instrument is now ready to perform a new cycle.

Note: If the stopper is removed and reinserted, the seal will be weakened and the stopper could slowly separate from the tube, which could result in a spill inside the analyzer, causing damage and contamination.

Calibration

Calibration is not required.

Quality Control

ELITechGroup recommends running two levels of controls (normal and abnormal) each day of use. The recommended controls are the Accu-Sed Plus Normal and Abnormal ESR Controls. Refer to Accu-Sed Plus package insert¹⁷ for further instruction including expected values. Refer to the ExcYTE Mini, M, 20 or 40 Operator's Manual for specific quality control instructions.

Calculations

All calculations are performed by the instrument.

Limitations

For single use only. Refer to the Interfering Substances section for possible sources of interference.

Usable Range

The usable range of ESR on the ExcYTE Mini, ExcYTE M, ExcYTE 20 and ExcYTE 40 is 1-140 mm/hr. When a sample has a value >140 mm/hr, this message is displayed or printed: ">140" and should be reported as such. Do not dilute the sample.

Reference Values-Normal ESR Values¹⁸

Male 0-15 mm/hr
Female 0-20 mm/hr

Use this range as only a guide. Each laboratory should establish its own reference range.

SPECIFIC PERFORMANCE

Patient Correlation

We compared blood samples from patients with ESR's ranging from 1 to 124 mm/hr on the ExcYTE Mini, ExcYTE M, ExcYTE 20 and ExcYTE 40 automated ESR analyzers and Westergren (modified) method. Results were compared by least squares regression and the following statistics were obtained:

ExcYTE Mini/Modified Westergren: $R = 0.993, n = 61, Y = 0.983x - 0.38$
ExcYTE M/Modified Westergren: $R = 0.990, n = 40, Y = 0.929x - 0.68$
ExcYTE 20/Modified Westergren: $R = 0.988, n = 66, Y = 0.850x - 1.692$
ExcYTE 40/Modified Westergren: $R = 0.988, n = 55, Y = 0.961x - 0.559$

Precision Data

Accu-Sed Plus controls (normal and abnormal) were prepared and run in triplicate over multiple days using the ExcYTE Mini, ExcYTE M, ExcYTE 20 and ExcYTE 40 automated ESR analyzers.

Precision of ExcYTE Recoveries in mm/hr

ExcYTE Mini	Within Run				Total		
	mean	1SD	%CV	n	mean	1SD	%CV
Normal	7.4	0.5	7.4%	45	7.2	0.6	7.9%
Abnormal	60.0	2.2	3.7%	45	67.6	6.0	8.9%

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ExcYTE M	Within Run				Total		
	mean	1SD	%CV	n	mean	1SD	%CV
Normal	10.2	0.4	4.4%	45	10.0	0.8	8.2%
Abnormal	65.2	1.3	2.0%	45	73.1	6.8	9.3%

ExcYTE 20	Within Run				Total		
	mean	1SD	%CV	n	mean	1SD	%CV
Normal	7.2	0.4	6.2%	45	8.5	1.1	12.9%
Abnormal	59.8	0.8	1.4%	45	72.7	6.6	9.1%

ExcYTE 40	Within Run				Total		
	mean	1SD	%CV	n	mean	1SD	%CV
Normal	10.4	0.9	8.6%	45	9.8	1.1	11.6%
Abnormal	73.4	2.7	3.7%	45	80.7	6.8	8.4%

References

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14. ExcYTE M Automated ESR Operator's Manual, Vital Diagnostics, L7067, current rev.
15. ExcYTE 40 Automated ESR Operator's Manual, Vital Diagnostics, L7069, current rev.
16. ExcYTE 20 Automated ESR Operator's Manual, ELITechGroup B.V., L7188, current rev.
17. Accu-Sed Plus Package Insert, ELITechGroup Inc., 55-0524, current rev.
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GLOSSARY OF SYMBOLS

	Manufacturer		Batch code / Lot number		In vitro diagnostic medical device
	Contents		Caution		Consult instructions for use
	Catalogue number		Temperature limit		Do not reuse
	This way up		Use by / Expiration date		Fragile
	European Conformity		Sterilized by irradiation		