Excyte® ESR Tubes

Intended Use
Excyte ESR Tubes are for the quantitative determination of the erythrocyte sedimentation rate (ESR) of whole blood using the following Vital Diagnostics® ESR analyzers as mentioned on page 2.

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 and acute inflammation) have a raised ESR, due mainly to alterations in some plasma and erythrocyte factors causing the formation of erythrocyte rouleaux.

The Vital Diagnostics ESR system is comprised of a whole blood collection tube and an ESR analyzer. The analyzers (listed in the Intended Use Section of this package insert) are automated instruments, controlled by a microprocessor and exclusively employed for the analysis of ESR. The analyzers can be used for random and continuous loading of samples while following the sedimentation of each sample independently.

Whole blood is collected in the 120mm Excyte ESR tube containing 0.28mL of 3.2% sodium citrate. One tube is required for each determination.

The Excyte ESR tube, containing whole blood and mixed well (refer to Procedure Section of this package insert), is placed in an individual collection tube and an ESR analyzer. Once the presence of a tube is detected by the instrument, a photoelectric cell passes up 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
Composition
EX-50205: 50 vacuum tubes per box.
Irradiated glass tubes with a butyl-rubber stopper. The tube contains 0.28mL, 3.2% sodium citrate and is ready for use.

EX-50100: 50 non-vacuum tubes per box.
Irradiated glass tubes with a butyl-rubber stopper. The tube contains 0.28mL, 3.2% sodium citrate and is ready for use.

Warnings And Precautions
For in vitro diagnostic use.

Handle and dispose of all human source materials as though capable of transmitting infectious agents using the universal precautions recommended by the Centers for Disease Control and Prevention (CDC). 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.

Insert the tube gently into the analyzer to prevent breakage.

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

Reagent Preparation
The Excyte ESR Tubes are supplied ready to use.

For single use only.

Reagent Storage And Stability
Store the Excyte ESR tubes 4 to 25 °C. When stored correctly, tubes can be used up to the expiration date printed on the label.

Specimen
Collection
For vacuum tubes (EX-50205)
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. Do not remove stopper 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.

For non-vacuum tubes (EX-50100)
1. Collect the whole blood specimen in an EDTA tube according to accepted clinical protocol.
2. Mix blood well prior to transferring to the Excyte ESR tube.
Specimen Storage and Stability

In accordance with the recommendations of the International Committee for the 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)\(^2\). Within the 4 hours it is possible to analyze the same sample twice, after a mixing step of at least 10 minutes.

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 refrigerated\(^3\), but must be brought to room temperature and mixed thoroughly prior to analysis.

Procedure

Materials Provided

Excyte ESR Tubes, Product Numbers: EX-50205 or EX-50100

Materials required but not provided

1. Analyzer:

<table>
<thead>
<tr>
<th>Product</th>
<th>Product Number (North America)</th>
<th>Sample Positions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excyte 10</td>
<td>EX-10312</td>
<td>10</td>
</tr>
<tr>
<td>Excyte Mini</td>
<td>EX-10310</td>
<td>10</td>
</tr>
<tr>
<td>Micrød-R</td>
<td>N/A</td>
<td>10</td>
</tr>
<tr>
<td>Excyte M</td>
<td>EX-10314</td>
<td>10</td>
</tr>
<tr>
<td>Excyte M Scan</td>
<td>EX-10414</td>
<td>10</td>
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<td>Excyte 20</td>
<td>EX-10318</td>
<td>20</td>
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<tr>
<td>Excyte 40</td>
<td>EX-10316</td>
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2. Accu-Sed® Plus ESR Controls

<table>
<thead>
<tr>
<th>Product</th>
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<th>Configuration</th>
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</thead>
<tbody>
<tr>
<td>Normal</td>
<td>DS-71002</td>
<td>5 x 8.5mL</td>
</tr>
<tr>
<td>Abnormal</td>
<td>DS-71003</td>
<td>5 x 8.5mL</td>
</tr>
<tr>
<td>Combined</td>
<td>DS-71005A</td>
<td>5 x 8.5 mL (Normal)()</td>
</tr>
<tr>
<td>Combined</td>
<td>N/A</td>
<td>2 x 8.5 mL (Normal)()</td>
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</table>

3. Duo-Mix

<table>
<thead>
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<th>Product Number (North America)</th>
<th>Configuration</th>
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<tr>
<td>EX-10573</td>
<td>40 pos. for 8-10mm tubes</td>
</tr>
<tr>
<td>EX-10577</td>
<td>40 pos. for 13mm tubes</td>
</tr>
<tr>
<td>EX-10578</td>
<td>20 pos. for 8-10mm tubes &amp; 20 pos. for 13mm tubes</td>
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</tbody>
</table>

4. Excyte Printer, Optional, Product Numbers:

- EX-13886 (North America)

5. Excyte Barcode Scanner, Optional, Product Numbers:

- EX-10551 (North America)
Calibration
Calibration is not required.

Quality Control
Vital Diagnostics recommends running two levels of controls (normal and abnormal) each day of use. The recommended controls are the Accu-Sed Plus ESR controls. Refer to the Accu-Sed Plus package insert for further instructions, including expected values. Refer to the instrument operator’s / user’s manual for specific quality control instructions.

Calculations
All calculations are performed by the instrument.

Limitations
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.

Limits and Ranges
Useable Range
The usable range of ESR on the Vital Diagnostics ESR instruments 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 Values
Male 0-15 mm/hr
Female 0-20 mm/hr
This range should serve as a guide only. Each laboratory should establish its own reference range.

References

Accu-Sed, Excyte and Vital Diagnostics are US registered trademarks of ELITechGroup.

Glossary of Symbols

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