

Status **Pending** PolicyStat ID **16880447**



Origination	N/A
Last Approved	N/A
Effective	Upon Approval
Last Revised	N/A
Next Review	2 years after approval

Owner	Carolyn Webb: Heme Technical Specialist
Area	Hematology
Applicability	Community Physician

## ESR on EXCYTE Mini

### Intended Use

The EXCYTE Mini is a random access, in-vitro diagnostic analyzer used for the quantitative determination of the erythrocyte sedimentation rate (ESR) using whole blood in ECXYTE ESR tubes. The EXCYTE Mini ESR compares favorably to the modified Westergren method.

### Principle

Ten pairs of infrared sensors vertically monitor and measure the sample tubes in 60 second cycles. The measurement of light transmittance is performed in 0.2 mm increments. Newly inserted samples are detected on each cycle provided the sample tubes contain the recommended volume. At the first rising (when the instrument has ensured that the meniscus is clearly distinct), the software recognizes any positions occupied by samples containing the right level of blood. The level of the sample collection just inserted is checked and analysis begins. The computer records the "zero" time for each sample, and all the following readings, until 30 minutes have elapsed. During this phase the instrument monitors the presence of the sample.

### Scope

This procedure applies to the following locations as of the date indicated:

- CP Laboratories
  - Drexel Town Square Health Center
  - Mequon Health Center
  - Moorland Reserve Health Center
  - North Hills Health Center - October 2024
  - Tosa Health Center
  - Town Hall Health Center

- West Bend Health Center
- Community Hospitals
  - Froedtert Menomonee Falls Hospital
  - Froedtert West Bend Hospital

## Sample Type and Stability

A lavender EDTA tube with a minimum of 1 mL of blood is required for ESR testing. EDTA specimens are stable for 8 hours at RT and 24 hours if refrigerated. Blood must be brought to room temperature and mixed thoroughly prior to analysis.

ESR tubes: specially designed non-vacuum ESR measurement tubes supplied by ELITechGroup must be used to ensure accurate ESR measurement by the EXCYTE Mini. EXCYTE glass non-vacuum tubes contain 0.28 mL of sodium citrate. Specimens are stable in ESR tube for 4 hours at RT and 12 hours if refrigerated. ESR tube time must not exceed the original specimen stability time.

## Supplies and Controls

EXCYTE Mini ESR analyzer	
EXCYTE M Glass non-vacuum ESR tubes (50/package)	(EX-50100)
Accu-Sed ESR Sed Rate Controls (Normal/Abnormal 5x2x8.5mL)	(DS-71005A)
EXCYTE Printer	
EXCYTE Thermal Paper (3 rolls/pack) - Thermal paper used for Clinitek analyzer may be substituted.	(EX-13888)
EXCYTE barcode scanner	
Thin Transfer Pipets	

## Instrument Placement

The EXCYTE Mini should NOT be placed near centrifuges, oscillating agitators or other vibrating instruments which might cause movement of the bench. The bench must be flat and level. Direct light on the instrument and sudden changes in temperature should be avoided. Keep a free area of at least 15 cm around the instrument to allow the instrument to cool. The power supply cable and power switch must be accessible at all times.

## Calibration

Each instrument is pre-calibrated by the manufacturer, and it does not require a user re-calibration. The calibration of each instrument is traceable from the serial number of the instrument.

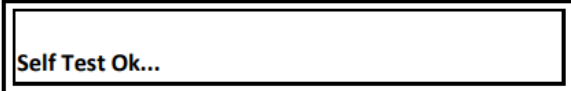
## Maintenance

The EXCYTE Mini does not require special maintenance, due to the simplicity of the instrument and the component parts. The most sensitive parts are the infrared sensors inside the instrument.

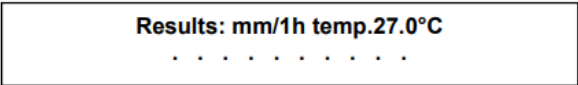
# Daily:

1. Start of day:
  1. Remove dust cover.
  2. Turn on the Excyte Mini using the switch situated at the rear side of the instrument. Each time the Excyte Mini is switched on, it performs an electronic initialization and self-test to check for proper operation.

Once the self-test has successfully finished, the following appears:



The instrument is now ready for analysis, and the display will show a screen similar to the following:



2. End of day:
  1. power down the analyzer by toggling the power switch located on the back of the device to the off position.
  2. Cover analyzer with dust cover

# Monthly:

1. Dust can be removed using an ordinary vacuum cleaner
2. Clean the instrument externally once a month with a disinfectant solution (e.g. 70% isopropyl alcohol) to reduce the microbial contamination.

# Cautions:

When not in use, the analyzer must be covered with the dust cover to protect the test tube positioning plate (reading plate) from dust.

The entry of liquids or solid material into the channels can cause considerable damage to the instrument, so use caution when cleaning.

# Quality Control Procedure

## Requirement:

Two levels of quality control material are run each day of patient testing. Beaker ESR QC labels automatically generate each morning.

## Materials:

QC material is ACCU-SED PLUS normal and abnormal levels.

## Stability:

Opened vial stability is 31 days at room temp and protected from light.

## QC Procedure

1. Thoroughly mix the QC material by hand or using tube rocker. Invert the control vial until the packed cells have been suspended. Continue mixing for an additional 30 seconds. Avoid foaming. Do not vortex.
2. Using the glass non-vacuum EXCYTE tubes, fill tube so the specimen meniscus is between the two black lines.
3. Label using Beaker QC labels prior to insertion into the EXCYTE.
4. Mix the ESR tube by inversion 10 times.
5. Scan the QC barcode and place the tube in an open slot.
  - a. ESR tube must be inserted within 15 seconds after scanning the barcode. The instrument will detect the tube insertion position and will display the position and ID on the screen for 2 seconds.
6. Repeat steps 1-5 with second level of control material.
7. After each use, wipe the threads of the control cap and vial with an absorbent material and recap immediately.
8. After 30 minutes, results will print. Manually enter results into LIS.
9. If QC is unacceptable, repeat test ensuring that the control material is thorough mixed. If still unacceptable try a new vial of control material and additional troubleshooting steps as needed. Acceptable QC results must be obtained before testing patient samples.
  - a. 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.

## Additional Quality Assurance Practices

1. Expected control ranges are provided by ELITech for multiple ESR methods. During new control lot evaluation, use the expected range provided for Excyte Mini. Evaluating data should fall within the assayed ranges.
2. Each laboratory will establish its own mean and standard deviation for each lot of ESR Control by running evaluating lot in parallel with active lot of control. The lab mean should fall within the expected range. The lab limits (target mean and SD) should be set when the control lot is activated. Subsequent results should fall within the laboratory's acceptable ranges..
3. Laboratory QC data is submitted monthly for peer group comparison to [www.elitechgroup.com/vqc](http://www.elitechgroup.com/vqc).

## Procedure-Patient Sample

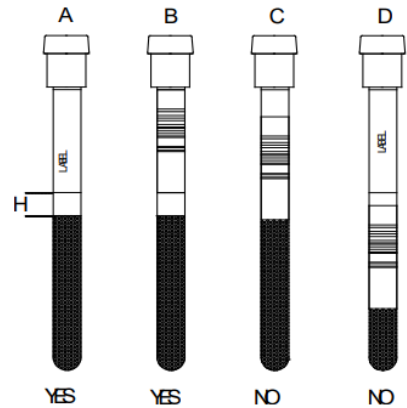
1. Perform maintenance and QC prior to patient testing.
2. Mix the EDTA tube thoroughly, then promptly transfer approximately 1.0 mL of the EDTA sample into the glass non-vacuum ESR tube. Meniscus of sample should be between lines indicated on the

ESR tube.

3. Place sample label on ESR tube above the top black line.
  - a. The label must be positioned correctly and completely adhered to the test tube surface. If not, label fragments fall into the test tube channel and obstruct a correct reading function during analysis.

### 7.3 TUBE LABELING

Identify the sample by writing on the original test tube label or by applying a barcode label. Follow the scheme to carry out this action correctly. In Figure A, the tube has the correct blood level and the original label on which to write the patient code or any other relevant data if the barcode label is absent. The part marked "H" shows the transparent zone that must be absolutely free and clear to allow the infrared rays to recognize the end of the blood column. Figure B shows the correct position for the label. Figures C and D illustrate how erroneous applications of the labels obstruct the reading and analysis.



4. Mix the ESR tube by inversion 10 times.
5. Scan the barcode and place the tube in an open slot.
  - a. ESR tube must be inserted within 15 seconds after scanning the barcode. The instrument will detect the tube insertion position and will display the position and ID on the screen for 2 seconds.
6. After 30 minutes, results will be printed automatically and will also show up on the EXCYTE Mini display.
7. Enter results into the LIS using Accession Result Entry.
8. Remove the tubes after the results have been recorded. "." Will appear, indicating that this channel position is free for introduction of another tube.
  - a. Remove tubes carefully, maintaining tubes in vertical position, in order to avoid breaking tubes.
  - b. If the tube is removed before the end of the analysis, the instrument prints "rem" (removed) error
9. Discard tubes in biohazard sharps container.

## Reference Ranges:

Male:	0-50 yrs = 0-15 mm/hr
	>50 yrs = 0-20 mm/hr
Female:	0-15 yrs = 0-20 mm/hr
	>50 yrs = 0-30 mm/hr

Results >140 should be repeated (if no previous results or previous results are different). If duplicated,

results may be reported as >140

## Limitations:

The following external factors can alter the ESR value after blood collection:

- Dilution ratio
- Bubbles
- Strongly hemolyzed samples
- Sudden agitation
- Improper mixing
- Temperature
- Time after sample-taking\*
  - \* EDTA sample is acceptable for 8 hours at room temperature or 24 hours refrigerated. Sample in ESR Tube is stable for 4 hours at room temperature (not exceeding original 8 hour room temperature) or 12 hours refrigerated.
- Direct sunlight
- Foam
- Lipemic samples
- Tube inclination
- As with all ESR analyzers, abnormally high or low hematocrits, along with other hemoglobinopathies, may affect results.

## Troubleshooting:

See troubleshooting guide on page 19 of the attached EXCYTE Mini User's Manual.

In the rare case that an Excyte Mini malfunctions, please call Technical Support at 1-800-453-2725 or email [service.ebs@elitechgroup.com](mailto:service.ebs@elitechgroup.com). Service can be made by authorized ELITechGroup Inc. personnel only. Work performed by unauthorized personnel invalidates the warranty.

## Reference:

EXCYTE Mini User's Manual. ELITechGroup Inc. 370 West 1700 South Logan, UT 84321 United States. 12/1/2022

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## Attachments

[Excyte Control IFU Example.pdf](#)

[Excyte ESR Verification Summary.docx](#)

[Excyte Mini User's Manual.pdf](#)

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[Excyte Selftest OK.png](#)

[Excyte tube labeling.png](#)

[Excyte-Glass-Tubes IFU.pdf](#)

## Approval Signatures

Step Description	Approver	Date
CP Lab Managers/ Director	Emery Smith: Lab Manager	Pending
CP Lab Managers/ Director	Tina Bognar: CP Director	Pending
CP Lab Managers/ Director	Karen Kunding: Lab Manager	Pending
CP Lab Managers/ Director	Mary M Cypert: Lab Manager	10/2024
Technical Specialists	Colleen Turtenwald: Technical Specialist	10/2024
Technical Specialists	Carolyn Webb: Heme Technical Specialist	10/2024
Policy Owner	Carolyn Webb: Heme Technical Specialist	10/2024

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## Applicability

Community Physician

## Standards

No standards are associated with this document