##### Principle

The basic principle of the erythrocyte sedimentation rate (ESR) test is that anticoagulated blood is placed in a vertical column that remains undisturbed for a specified amount of time. At the conclusion of the test, the distance the red cells have settled is measured in mm per hour (Westergren method).

The MINI-CUBE is an automated ESR analyzer incorporating new technology that accurately and precisely measures the sedimentation rate of erythrocytes in standard 13 x 75 mm K2EDTA blood collection tubes with Hemogard™ or conventional stoppers, or K2EDTA Microtainer® tubes (BD). The results are recorded as mm per hour in only 20 minutes. The instrument compensates for temperatures above 18 °C according to Manley’s Nomogram and offers the ability to adjust for patient Hematocrit values <40%.

Red cell sedimentation is accelerated by an increase in the plasma concentration of “acute phase proteins,” which are increased in acute tissue damage, chronic inflammation, chronic infection, and pregnancy. The ESR reflects both the increase in certain accelerating proteins, such as fibrinogen and gamma globulins, and the decrease in retarding proteins, such as albumin. Conditions that promote the formation of rouleaux produce an elevated ESR result.

**Specimen Collection and Handling**

##### Specimen Collection

13 x 75 mm standard K2EDTA blood collection tubes; Acceptable sample volume: 2.0 mL – 4.0 mL

BD Microtainer K2EDTA blood collection tubes; Minimum sample volume: 500 µL

Refer to CLSI guidelines for EDTA tube stability.

**NOTE:** The MINI-CUBE can accept EDTA sample tubes with a maximum of **one** secondary patient label adhered as close to the lavender cap as possible and with a label-free gap on one side of the tube.

**Specimen:** The specimen of choice is whole blood anticoagulated with EDTA.

1. Optimal draw is a tube drawn to capacity. You need at least 2.0 ml of sample per test.
2. Specimens must not be clotted (fibrin strands, clots), grossly hemolyzed, or drawn above (proximal) an IV sight.

**Patient Preparation:** No special patient preparation is required

**Handling Conditions:**

1. Samples must be properly labeled.
2. All specimens will be checked visually for clots.
3. Samples can be run within 4 hours if stored at room temperature (15-30°C)
4. All specimens failing to meet these requirements must be recollected. All recollections must be documented in the Laboratory LIS system.

**Note: All patient specimens should be treated as infectious body substances. Follow Body Substances isolation precautions.**

**Loading a Transponder**

1. From the HOME screen, select the SETTINGS icon.
2. Navigate to page 2 in SETTINGS and select REFILL to load more tests on the MINI-CUBE.
3. A window reading “Insert CHECK DEVICE and press CHECK key” will open.
4. Gently lay the instrument down with the display screen facing up and insert the transponder tube with the cap to the left.
5. Place the instrument upright, press CHECK and follow the instructions on the screen.
6. The number of remaining tests will update in the upper left corner of the screen.

**Quality Control**

Two levels of control material will be performed once per day. Results will be documented into the Laboratory LIS System via the HEMO QC worksheet.

**Controls:** ESR-Chex Plus is an assayed bi-level control for evaluating the accuracy and precision of automated and manual Erythrocyte Sedimentation Rate (ESR) methods.

**Registering a New QC Lot**

Only one control lot may be registered in the QC file at a time. Registering a new control lot will delete the registration of the previous lot. Control data from the previous lot will be saved in the QC Archive.

1. From the HOME screen, select the SETTINGS icon.
2. Navigate to page 2 in SETTINGS and Select QC to open the QC SETTINGS screen.
3. Scan the barcode on each level of ESR-Chex Plus to auto-populate the barcode, lot number, expiration date and control range fields. Alternatively, manually enter the information listed on the control assay into these fields.
4. Press the RETURN arrow on the lower left corner of the screen to exit QC SETTINGS.
5. Press YES to save the new settings, or NO to discard the new settings.

**Handling Conditions:** ESR-Chex Plus is stable through the manufacture expiration date when stored at 2-10°C. After bringing to room temperature, ESR-Chex Plus is stable throughout the open-vial dating, as indicated on the assay sheet, when stored at 18°C to 30°C. Open-vial stability is defined as the maximum number of continuous days a vial can be brought to room temperature and mixed for analysis. Working vials are to be stored at room temperature, and may not be returned to refrigerated temperature.

**Indications of Product Deterioration:** Discoloration of the product may be caused by overheating or freezing during shipping or storage. Gross hemolysis (darkly colored supernatant) may be indicative of product deterioration. However, moderately colored supernatant is normal and should not be confused with deterioration of the product.

**Mixing and Handling Instructions:**

1. Remove from refrigerator and allow to equilibrate to room temperature (15-20 minutes)
2. To mix:
3. Vortex unopened vials for up to 60 seconds to resuspend product prior to first time use.
4. Hold the vial vertically and roll between the palms of hands for 15-20 seconds.
5. Continue to mix by holding the ends between the thumb and finger, rapidly inverting the vial 20 times end-over-end.
6. Examine the bottom of the vial to ensure that the product is completely resuspended and repeat steps 2b-2c if necessary.
7. Analyze the samples immediately after mixing. If mixed vials sit for more than 1 minute before analysis, remix the vials by inverting 8-10 times.
8. Working vials stored at room temperature (18°C to 30°C) should not require additional vortexing. Mix working vials by following steps 2b-2e and repeat as necessary to ensure the cells are completely resuspended.

**Running QC Samples**

1. From the HOME screen, select the START icon.
2. Scan the barcode on the vial from the registered lot of ESR-Chex Plus.
3. A window titled “Inserted QC Code” that contains the registered QC lot data will open.
4. Press YES to run the tube as a QC sample, or NO to run the tube as a patient sample.
5. Insert the QC vial into any available well with the label gap facing the dot on the right side of the well.
6. The control result and the expected range will automatically print when the test is complete. If the result is outside the expected range, the result on the MINI-CUBE screen will be highlighted in red. If the result is within the expected range, the result on the MINI-CUBE screen will be highlighted in green.

**Viewing QC Results**

The QC Archive stores up to 5,000 QC results per level. Lot-specific statistical reports can be generated from these archive files. When the QC Archive reaches capacity, the oldest value will be deleted and the newest value will be added.

1. From the HOME screen, select the ARCHIVE icon.
2. From the ARCHIVE menu, select the QC icon to view all available QC data in the archive list.
3. To reprint QC results:
	1. Select an individual result in the QC Archive list.
	2. Press the DOWNLOAD icon and select PRINT to reprint the individual result, or PRINT LIST to print the entire QC archive.
4. To view details for an individual QC result:
	1. Press and hold an individual result in the QC Archive list.
	2. Press the CHART icon to view the Levey-Jennings chart and statistical data about the entire lot.
	3. Press the DOWNLOAD icon to reprint the result.
5. To view details for a specific QC lot:
	1. Select an individual QC result from the desired lot in the QC Archive list.
	2. Press the CHART icon to view the Levey-Jennings chart and statistical data about the entire lot.
	3. From the Levey-Jennings Chart, press the DOWNLOAD icon to print the collection of data in the chart.
6. To delete a QC result:
	1. Select an individual result in the QC Archive list.
	2. Press the DOWNLOAD icon and select DELETE to permanently remove an individual QC result. **NOTE:** QC results must be deleted individually.

**Running Patient Samples**

The mixing procedure is critical for accurate results. Before starting a test, EDTA patient samples must be prepared as follows:

1. Ensure that the sample is at room temperature for 15 minutes prior to analysis.
2. Immediately before starting the analysis, **gently** and completely invert the EDTA tube end-over-end 10 to 12 times to resuspend the sample. Do not shake or agitate the sample vigorously, as this could cause bubbling or hemolysis.
3. Examine the sample to ensure bubbling is not present at the meniscus as this could interfere with the sample reading.

**Entering a Sample ID Code**

Scanning a Sample ID:

1. From the START screen, scan the patient barcode with the barcode scanner.
2. A window titled “New Sample” will open with the barcode information displayed in the Sample ID field.
3. Insert the well-mixed patient sample into any available well with the label gap facing the dot on the right side of the well.
4. A full-color image of the tube containing a barcode image will appear on the screen and testing will automatically initiate.

Manually Entering a Sample ID:

1. From the START screen, insert the well-mixed patient sample into any available well with the label gap facing the dot on the right side of the well.
2. A full-color image of the tube without a barcode image will appear on the screen and testing will automatically initiate.
3. Press the tube image on the screen. A window titled “Position” will open.
4. Press the “Sample ID” field to open a keyboard and manually enter the patient ID.
5. Press the ENTER arrow to close the keyboard.
6. Press OK to close the “Position” window.
7. A barcode image will appear on the tube indicating that it contains a Sample ID.

**Result Reporting**

It is good laboratory practice to visually correlate the level of sedimentation in the sample tube to the printed result. The MINI-CUBE automatically prints the result on the printer and data output port and displays an image of the sample tested on the screen.

Results will be entered manually into the Laboratory LIS System. Results will also be recorded on the Miscellaneous Hematology Log sheet.

**Reportable Range:**

13 x 75 mm EDTA tubes (2.0 mL – 4.0 mL ): 0 – 140 mm/hr

Samples with a result greater than 140 mm/hr should be reported as “>140 mm/hr.”

BD Microtainer EDTA tubes (500 µL): 0 – 60 mm/hr

Samples with a result greater than 60 mm/hr should be reported as “>60 mm/hr.”

* If the result is below the normal threshold programmed in the SETTINGS menu, the result on the MINI-CUBE screen will be highlighted in green. If the result is equal to or higher than the normal threshold, the result on the MINI-CUBE screen will be highlighted in red.
* Samples run in BD Microtainer tubes will display an image of a small tube on the screen and “PEDIATRIC” will be indicated on the sample printout. In the RESULTS Archive, a subscript “P” will be displayed immediately to the right of the ESR result.

The RESULTS Archive stores up to 5,000 patient results. When the RESULTS Archive reaches capacity, the oldest value will be deleted and the newest value will be added.

**Limitations of the Procedure**

See the MINI-CUBE User Manual for guidance on abnormal samples (icteric, lipemic, etc.).

The clinical significance of an ESR result obtained from an abnormal sample, including but not limited to icteric, lipemic, cold agglutins, anemic conditions, low hemoglobin concentrations, hemolysis, or any other pathological condition that interferes or prevents a clear red blood cell to plasma interface, should be determined by the clinician ordering the test. Manual and automated ESR measurements in samples without a clear interface are subject to a high degree of variability. In the MINI-CUBE, the sample may go undetected or yield variable results. Visually inspect the sample at the conclusion of the test to confirm the presence of a clear interface.

**Preventive Maintenance**

**NOTE:** Always turn off the MINI-CUBE and disconnect it from the power source before performing any type of maintenance. Do not open or remove the MINI-CUBE cover.

1. Regularly verify that the print head on the MINI-CUBE printer is free from dust.
2. Regularly clean the instrument using a soft, damp cloth or paper.
3. In the event of biological material leakage, wipe the outer surface of the instrument with 70% isopropyl alcohol and immediately contact Streck Technical Services at 800-843-0912 or technicalservices@streck.com for further instruction.

**References**

1. MINI-CUBE User Manual, [www.Streck.com](http://www.Streck.com)
2. ESR-Chex Plus Package Insert, Streck 06-2018
3. Clinical and Laboratory Standards Institute, H02, Procedures for the erythrocyte sedimentation rate test. Approved Standard – Fifth Edition.