



iSED[®] SAMPLE PROCESSING

Analyzer Operator Training

SAMPLE REQUIREMENTS



Sample Volume

The total sample volume required to perform ESR on the iSED is as follows:

- Routine tubes: approximately 500 μL
- Pediatric tubes: approximately 350 μL
- **For all samples aspirated volume is only 100 μL**



Sample Type

- Whole blood in a capped 13 x 75 mm tube with **K3-EDTA or K2 EDTA** anti-coagulant (*lavender top tube*).
- Sample tube should be gently mixed at collection to avoid clots and other aggregates (DO NOT MIX VIGOROUSLY).



Sample Temperature and Stability

- Samples are stable for up to 28 hours at room temperature or 48 hours refrigerated.
- Sample must be brought to room temperature for at least 15 minutes if refrigerated.

Please contact your local distributor for a full list of compatible tubes with known dead volumes.

CONSUMABLES

Test Card

A Test Card is a smart card which contains a **pre-determined quantity of Test Credits**. Test Cards do not expire and are available in various denominations to satisfy all testing volumes.

iWASH®

The iWASH wash solution is required to ensure optimal analyzer performance.

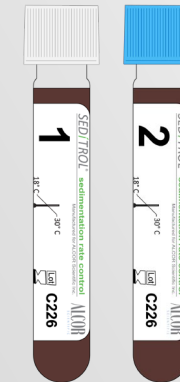
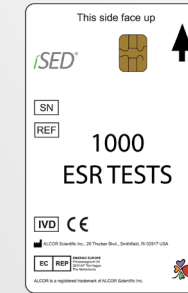
SEDiTROL® Quality Control, Levels 1&2

The SEDIROL Quality Controls are required as the external controls for the analyzer.

deepCLEAN® Cleaning Solution (optional)

The deepCLEAN Cleaning Solution is used for the Deep Cleaning procedure, which is important for proper functioning of the analyzer.

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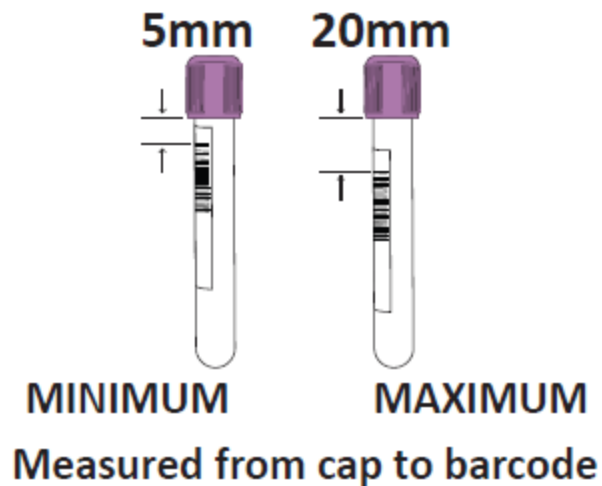
CONTINUOUS OPERATION MODE

It is recommended that the instrument **remains on and ready for use**. Should the instrument need to be powered off for any reason, run a wash cycle prior to powering off the unit.

The instrument is programmed to perform a self-cleaning wash after being idle for 15 minutes following the last sample tested. The process takes approximately one (1) minute and utilizes approximately 4.5 mL of iWASH for each wash cycle. Once completed, testing can resume as normal.

PATIENT IDENTIFICATION

Patient samples are read and identified by the internal barcode reader as they are loaded into the instrument. All common laboratory barcodes are supported, including Code 39, UPC and Code 93 formats.




When patient identification cannot be read by the internal barcode reader, or if there is no barcode present, the operator may enter patient data manually.

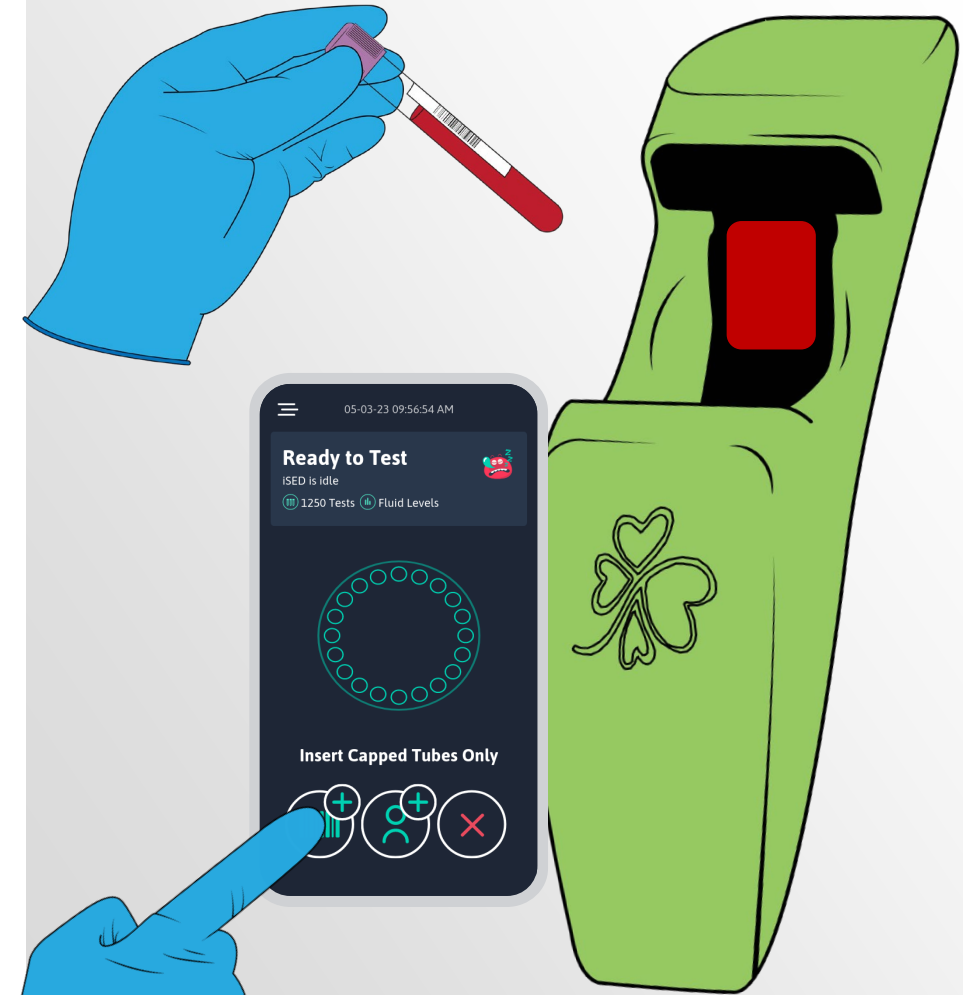
PROCESSING BARCODED SAMPLES

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To process barcoded samples:


1. Touch the  icon.
2. The sample wheel rotates to the next open slot position within the sample loading port. Insert the barcoded tube with the barcode oriented **to the right**. A red light will illuminate, and a distinctive beep will sound when the barcode is successfully recognized.
3. Repeat step 2 until all samples have been loaded and/or all positions in the sample wheel are occupied.
4. Sample processing will begin automatically.

There is a five (5) second window to load additional samples. If this window is missed and more samples need to be tested, simply restart the process.

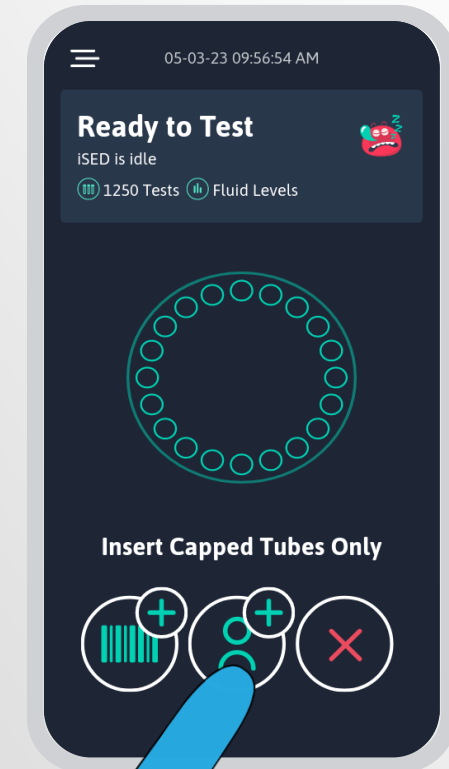


PROCESSING NON-BARCODED SAMPLES

To process non-barcoded samples:

1. Touch the  icon.
2. The sample wheel rotates to the next open slot position within the sample loading port. The instrument will prompt the operator to enter patient identification data manually using the alphanumeric keyboard. Patient info must be recorded in one (1) or more of the following data fields:
 - Alphanumeric ID
 - Patient's first name
 - Patient's surname
3. Insert the tube.
4. Repeat steps 2-3 until all samples have been loaded and/or all positions in the sample wheel are occupied.
5. Sample processing will begin automatically.

There is a ten (10) second window to load additional samples. If this window is missed and more samples need to be tested, simply restart the process.



REFERENCE VALUES

The reference values shown are averages found in men and women. An increase in these values can be a sign of multiple different health issues that should be diagnosed by a physician or qualified individual.

The ranges provided are for reference only.

All laboratories should follow their own protocol for establishing reference ranges.

ESR Reference Values (mm/hr)*	
Males < 50 yrs old	<15
Males > 50 yrs old	<20
Females < 50 yrs old	<20
Females > 50 yrs old	<30

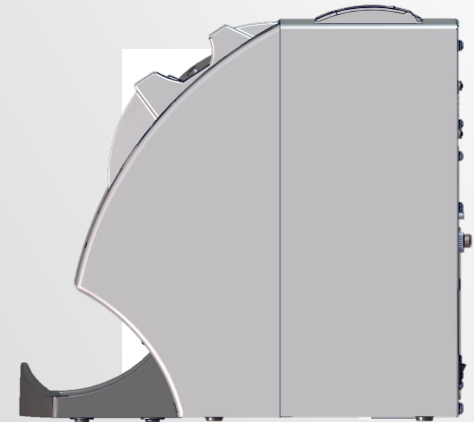
*Keohane EM, Otto CN, Walenga JM. Rodak's Hematology: Clinical Principles and Applications Sixth Edition. Elsevier; 2019.

SAMPLE ANALYSIS OVERVIEW

The following will occur once samples have been loaded:

- All samples are automatically mixed on the sample wheel for a minimum of three (3) minutes (180 inversions) before testing.
- The analyzer will pierce the tube to withdraw sample.
- Light transmission through the sample will be analyzed (to measure red blood cell aggregation) in a flow cell.
- Time to result after mixing is approximately 20 seconds.
- The sample is automatically ejected after processing.

- The analyzer has a 20-position sample wheel.
- The continuous feed feature accommodates samples in “random access” mode (if there is space available in the sample wheel).
- The analyzer result range is 1 to 130 mm/hr.



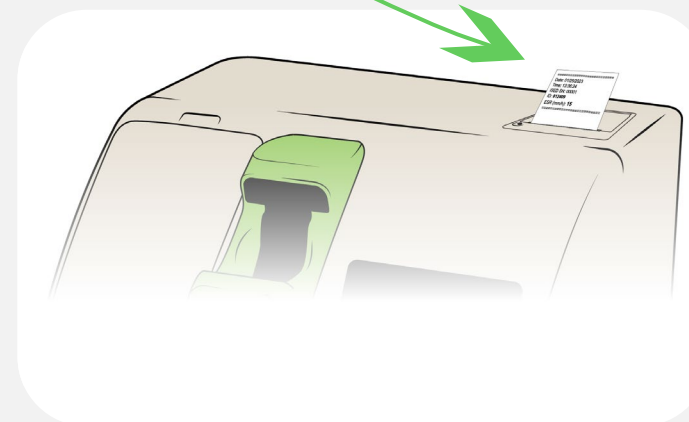
RESULT PRINTOUTS

Results Format

Results are shown on screen after analysis and printed by the internal printer. If the instrument is unable to analyze the sample and report results, the printout will replace the 'ESR (mm/h):' field with an error message.

Date: 03/25/2013
Time: 13:36:24
iSED Sn: 00001
ID: **812409**
ESR (mm/h): **15**

Date of measurement
Timestamp of measurement
Instrument serial number
Barcoded or Manual sample
identification Format of ESR
result reported

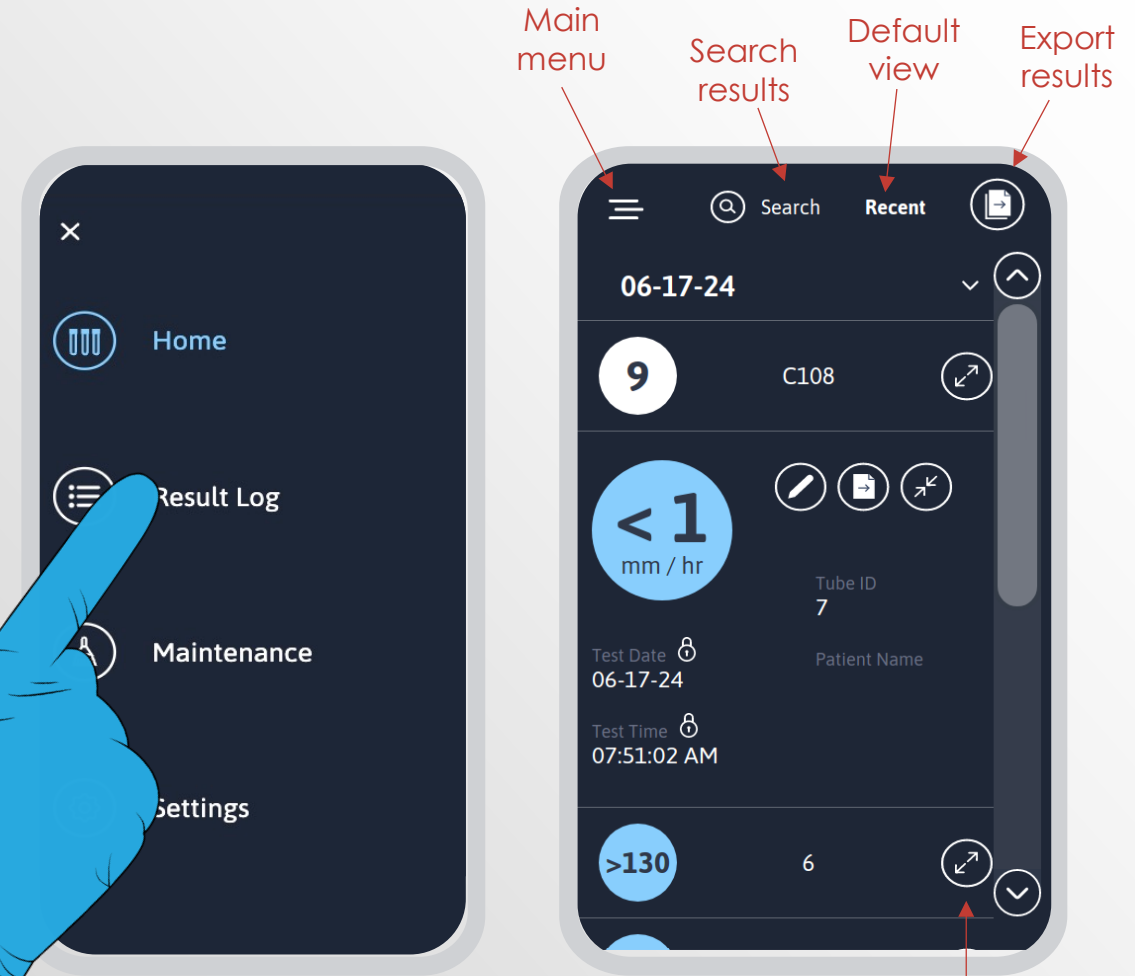


RESULTS INFORMATION

- Results can be accessed after analysis from the Result Log.
- Results are displayed with most recent test results first.
- The blue circle represents a patient result.
- A white circle represents a SEDIROL Control or Proficiency Test result.
- Results can be searched for by date, name, patient number, etc.
- Results can be exported by selecting the “Papers” icon in the upper right.
- Results can be expanded for more information by selecting the “Expand” icon in the bottom right.



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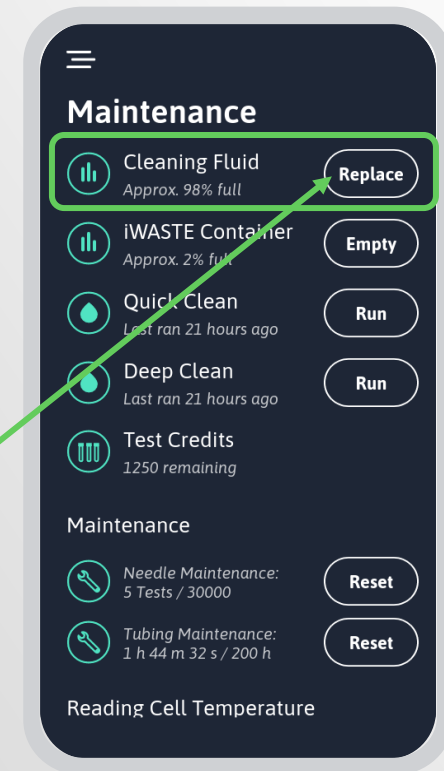


Expand results

ROUTINE WASH CYCLES

The iWASH, Wash Solution is **required** to ensure analyzer performance. A **quick clean or wash cycle** is run 15 minutes after the last sample or can be performed on-demand as needed.

1. The analyzer utilizes ~4.5mL of iWASH per wash cycle and takes approximately 1 (one) minute.
2. Wash cycles are not required to be run after each test.
3. It is recommended the analyzer be left on at all times. Should the analyzer need to be powered off, a wash cycle should be run prior to powering off.
4. Instructions for replacing the iWASH bottle can be found in the iSED Operator's Manual. In the Maintenance sub-menu, the Cleaning Fluid "Replace" button must be selected to reset the counter to 100% full.
5. The use of any other product could affect the performance of the instrument and void the warranty.



CLEANING FLUID & WASTE CONTAINER

The fluid levels status indicator on the Home Screen will alert the operator to any issues with wash or waste bottles.

1. The fluid level indicators are based on cycle counts, not direct fill volume measurements.
2. The status of the iWASH (Wash Fluid) and iWASTE® (iWASTE Container) bottles can also be viewed in the Maintenance Menu.
3. If the iWASH bottle is empty or the iWASTE bottle is full, an error message will appear on the screen and must be resolved before testing can continue.

When a bottle is changed, remember to select Replace in the Maintenance Menu.



THANK YOU!



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