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iSED® PRO SAMPLE PROCESSING

Operator Training

SAMPLE REQUIREMENTS

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Sample Volume

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

- Routine tubes: approximately 500 µL
- Pediatric tubes: approximately 350 µL
- For all sample's, aspirated volume is only 100 µl
  - **Note:** Although infrequent, <50 µL of sample may be needed for priming the system in addition to the 100 µl aspirated sample volume.

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 28 hours when stored at room temperature and 48 hours when stored refrigerated.
- Sample must be brought to room temperature for at least fifteen minutes if refrigerated.

Sample Rack

- Sample must be loaded onto the iSED PRO analyzer via a hematology rack, but the rack does not need to be full in order to be loaded onto the analyzer, nor does every sample require an ESR test for the rack to be processed.

US customers, please contact ALCOR® Scientific Technical Support for a full list of compatible tubes with known dead volumes.

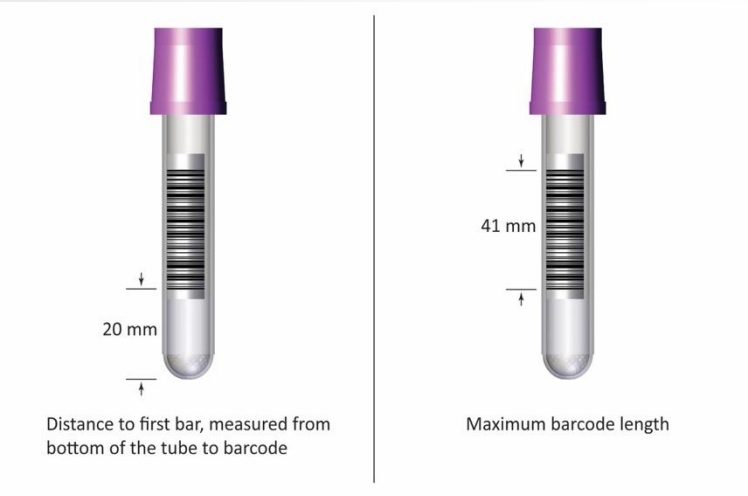
Customers outside of the US, please contact your local distributor for this list.

PATIENT IDENTIFICATION

Barcoded Tubes:

1. Once samples are loaded into the analyzer, a robotic arm picks up each sample tube to scan the barcode and places the sample tube into the Mixing Wheel if an ESR test has been requested.
2. All common laboratory barcodes are supported, including Code 128, Code 39, UPC, and Code 93 formats.
3. Barcode labels need to be placed in a vertical position on the tube.

Non-Barcoded Tubes: For instances when sample identification cannot be read by the internal barcode reader, or if there is no barcode present, the instrument will process samples according to the selected workflow mode.



Note: iSED PRO accepts racks with any number of tubes properly loaded into the rack. The analyzer does not require pre-alignment of the tubes' barcode labels prior to loading into the analyzer.

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, you must run a wash cycle prior to powering off the unit.

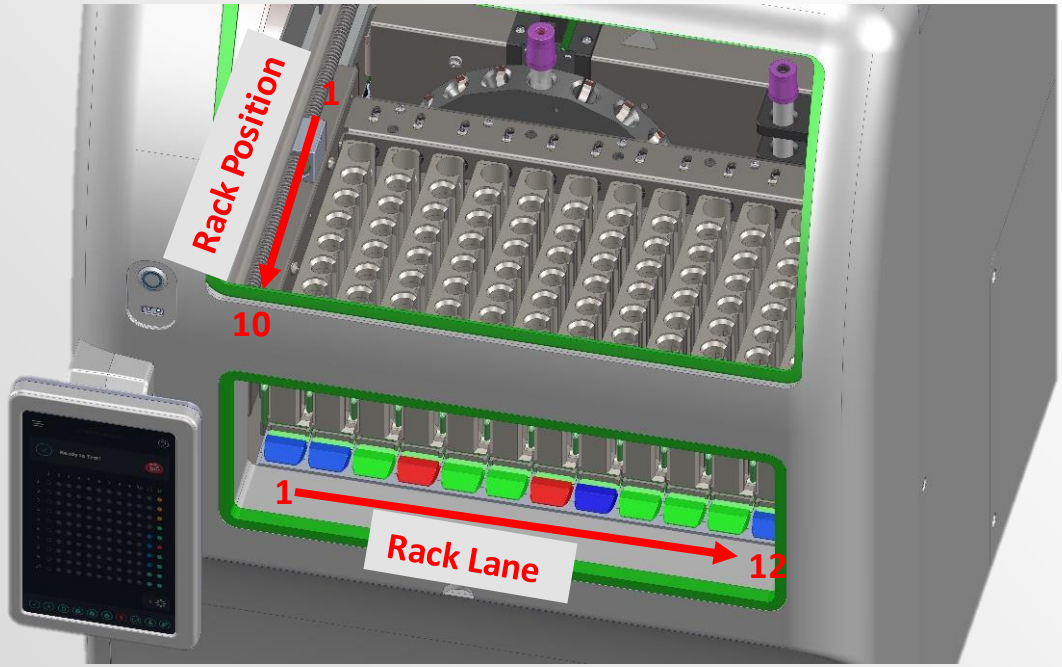
The iSED PRO is programmed to perform a self-cleaning wash after being idle for 15 minutes following the last sample tested. The process takes approximately one (1) minute and utilizes approximately 5 mL of iWASH® PRO for each wash cycle.

TERMINOLOGY

Rack Lane: This is a position on the analyzer that accepts hematology racks.

Rack Position: The individual sample tube's specific position within the hematology rack.

Tube Slot: The individual sample tube's position on the iSED PRO internal Mixing Wheel prior to measurement.



BASIC WORKFLOW

iSED PRO operates via the insertion of hematology racks into any unoccupied Rack Lane located through the front Rack Port opening. Rack Lane status is indicated by a status light at the front of the lane.

To start processing a sample rack:

1. Insert rack into available Rack Lane indicated by **green** status light.
2. Slide rack completely into the lane until a click latch locks the rack in place. Lane status light will change from **green** to **blue**.
3. At this point, the operator can walk away while the analyzer processes the rack. iSED PRO will begin to build out a work queue by picking up each tube and scanning the barcode ID, handling the sample according to the laboratory-chosen workflow mode.
4. If no tube is present in a Rack Position, iSED PRO will skip to the next rack position.

Green: Lane is unoccupied and ready to accept a new rack.

Blue: Lane is occupied. The rack that is inserted is queued for processing.

Flashing Blue: Lane is occupied, and the inserted rack is currently being processed.

Red: This lane has an error and cannot be used at the moment.

STAT TESTING

iSED PRO allows STAT testing prioritization for **whole racks** of samples. To initiate a STAT test:

1. Insert the hematology rack containing sample(s) requiring STAT priority.
2. If the analyzer is not already processing samples (idle), then the rack will immediately be at the top of the priority queue for measurement. If the analyzer is already processing samples, press the STAT icon on the Home Screen to bring up the STAT screen.
3. On the STAT screen, select the Rack Lane currently holding the hematology rack containing STAT tubes, and press Confirm.
4. You will be asked to confirm this decision again on the next screen.

Note: By marking a rack as STAT priority, iSED PRO will stop processing new samples in non-STAT lanes and begins picking up samples in the STAT rack. All samples in the STAT rack will be marked as STAT samples.

SAMPLE ANALYSIS OVERVIEW

The following will occur once samples have been loaded:

- A robotic arm removes the sample tube from the hematology rack, scans the barcode, and places the tube in the analyzer's Mixing Wheel for mixing if an ESR test is indicated.
- After appropriate sample mixing, the sample is analyzed, an ESR result is generated, and the sample is returned to its position in the hematology rack.
- Light transmission through the sample is analyzed to rapidly generate a result, and results are reported in mm/hr.
- Time to result after mixing is approximately 20 seconds.

- iSED PRO Series is compatible with common hematology racks (Sysmex, Mindray, Etc).
- iSED PRO accepts racks with any number of tubes properly loaded into the rack.
- The analyzer does not require pre-alignment of the tubes' barcode labels prior to loading into the analyzer.

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.

RESULTS INFORMATION

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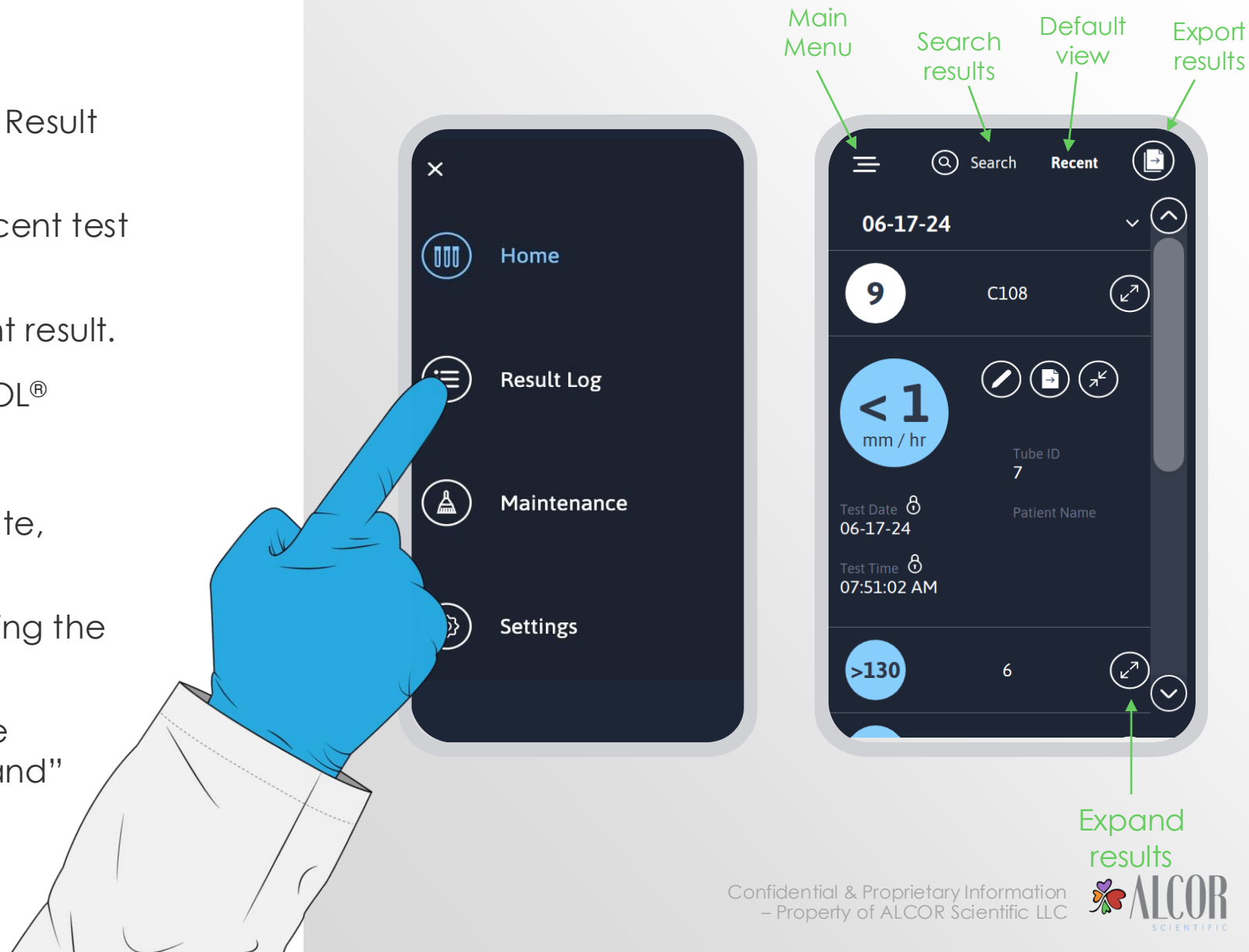
- Results can be accessed from the Result Log.
- Results are displayed with most recent test results first.
- The blue circle represents a patient result.
- A white circle represents a SEDiTROL®
- Control or Proficiency Test result.
- Results can be searched for by date, name, patient number, etc.
- 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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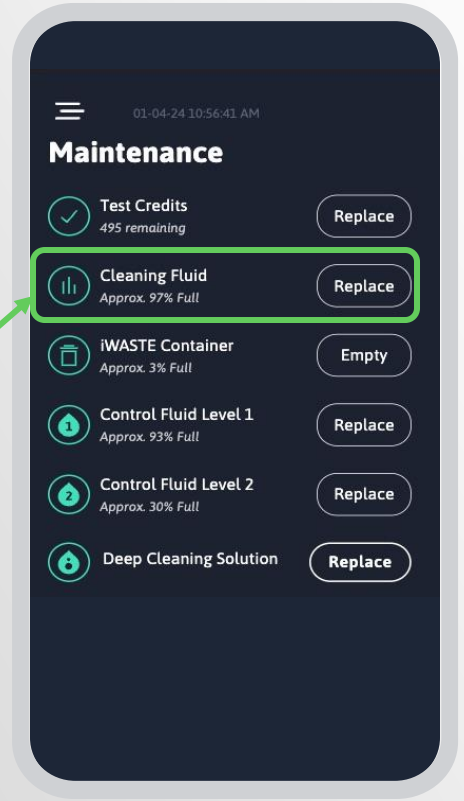
ROUTINE WASH CYCLES

The iWASH® PRO Wash Fluid 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.

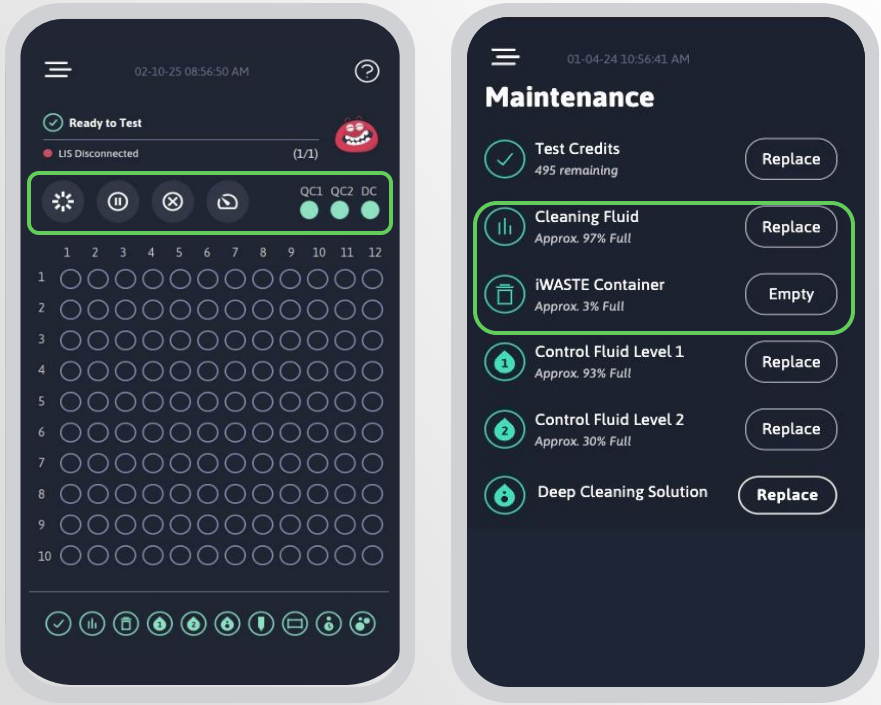
1. The analyzer utilizes 4.5 mL of iWASH PRO Wash Fluid per wash cycle and takes approximately 1 (one) minute.
2. It is recommended the analyzer be left on at all times. Should the analyzer need to be powered off, a wash cycle should be run prior to powering off.
3. Instructions for replacing the iWASH PRO bottle can be found in the iSED PRO Instructions for Use. In the Maintenance Menu, the Cleaning Fluid "Replace" button must be selected to reset the counter to 100% full.
4. The use of any other product could affect the performance of the instrument and void the warranty.



CLEANING FLUID & WASTE CONTAINER

An error message on the Home Screen's Status Banner accompanied by an alarm will alert the operator to any issues with the cleaning fluid or waste container.

1. The fluid level indicators are based on cycle counts.
2. The status of the iWASH PRO Cleaning Fluid and iWASTE PRO Waste Container can also be viewed in the Maintenance menu.
3. If the iWASH PRO bottle is empty or the iWASTE PRO 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 or Emptied in the Maintenance Menu. This will reset the counters.

THANK YOU!

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