

Positioning to Win: iSED vs. Alifax Test 1

Profile of a Test 1 user

- **Location**
 - Ideal customers are hospitals, rheumatology clinics, emergency departments, blood banks, and stand-alone diagnostic laboratories.
- **Volume**
 - Medium to mega sample volumes. Many of these labs are highly automated with Lab Automation Systems (LAS) that are custom designed to manage a multidisciplinary lab workflow including Clinical Chemistry (CC) and Immunoassay (IA) (these 2 disciplines make up >85% of the lab sample and total test volume), Hematology (often called HEMO or HEMA) (which may or may not include ESR), Coagulation (COAG), and Urinalysis (UA).
- **The ideal Test 1 customer profile to switch to the iSED**
 - Approximate monthly ESR sample volume of 400-1300 samples/month or 20-50 samples/day. This volume is manageable for end users to insert tubes one a time on the iSED vs the Test 1 that loads samples with racks. If they are doing >1300/month, position iSED as an excellent backup.
 - Very large labs, like commercial reference labs, might be more difficult to meet their workflow needs with the iSED given the large volume. In this scenario, an iSED backup might be a good solution for end users with >1300 samples/month. Please make note of this type of customer as a prospect for new analyzers in development.
 - Best Fit in any of the automation scenarios: Volumes 400-1300/month
 - Test 1 is not connected to a track (operates stand-alone)
 - Test 1 is not integrated with a Hematology analyzer
 - Test 1 does not accommodate the Hematology analyzer racks (samples would be sorted and re-racked for the Test 1-additional hands-on time/manual labor/opportunity for error)
 - Hands-on time to create wash tubes and daily maintenance cycle time is a minimum 55% less with iSED, and if the wash cycle fails, the iSED will automatically try 3 times before giving an error, where the Test 1 the process must be repeated. Wash tubes for the Test 1 can only be used up to 5 times before discarding.
 - Labs that did not include the Test 1 on the automation track since scanning for ESR tests would slow down the whole automation line because the barcode reader must scan every tube. Some labs prefer not to slow down the line and perform ESR offline (not using the automation track).

- **Workflow**

Take the time to understand the end user workflow and how the iSED can maximize/improve their workflow goals. There are several different workflow scenarios for these labs. In some labs, Hematology may be part of a core lab multidisciplinary line or it could have its own dedicated Hematology Workcell configuration. Here are some example workflow configurations that will help you understand where a customer's pain points might be as you are prospecting and probing:

- **Workflow type #1-Multidisciplinary Total Lab Automation (TLA)**

- Pre-Analytical: All samples are loaded on the automation system via Bulk Loader Module, regardless of sample type or type of test ordered, the sorting is done automatically, and centrifugation (if the sample requires it) is done either offline or via an integrated centrifuge module. The sample is picked up by a robotic arm, the barcode is read, and the test order is retrieved from the LIS via a bi-directional interface. The sample is scheduled for routing to an analyzer that is connected to the track and that meets the testing criteria for the ordered tests; samples may go to multiple locations for testing on different analyzers. Samples may be decapped (for centrifuged serum and plasma samples) or will remain capped (as in ESR, Hematology and Coagulation testing where whole blood samples are used) before being sent to their respective analyzers on a conveyor track.
 - Analytical: Once scheduled for testing, robotics place samples into carriers, or “pucks”, that are circulating on the track and are transported to the analyzers. When samples arrive at their testing analyzer, additional processing may need to be done, e.g., sample mixing would be needed at the analyzer for Hematology and for ESR. Since high volume Hematology analyzers manage samples in racks of 10-12, samples are removed from the “puck” by a robotic arm and placed into a rack at the analyzer. This is an additional step that further complicates the automation of Hematology and ESR on an automation track. Testing is performed and results are transmitted back to the LIS. In this environment, auto-verification is usually enabled, where normal results are passed through and reported automatically without review by the operator, based on established review criteria enabled by the software. Abnormal results are flagged for review prior to release.
 - Post-Analytical: Samples are routed to be racked and stored for a designated period, based on specific lab criteria, before being discarded. Some TLA systems have automated retrieval of samples-if they do not have this, staff spends a lot of their time looking for samples manually. Samples retrieved for retesting are checked for criteria for retesting, either by the automation software or by the staff, to ensure the sample is still valid/stable for that specific test. An ESR sample pulled for retest must meet the “<4 hours at RT and <24 hours refrigerated” criteria. In addition, some TLA systems have the capability to automatically discard samples per the lab storage criteria, otherwise the staff is responsible to track and manage sample storage.
- **Workflow type #2-Dedicated Workcell**
 - Automation is divided into separate areas with specific testing disciplines in “islands”. For example, a CC and IA workcell is designed to manage the highest volume testing areas of the lab, and since the sample types are similar (serum, plasma) with the same pre-analytical treatment (centrifugation, decapping), this configuration is very efficient.
 - A Hematology dedicated workcell is also efficient as these samples require the same pre-analytical processing (capped, mixed whole blood) and could be sorted into analyzer specific racks by an automated sorter or by staff before being taken to the workcell where the analyzers are co-located in a cluster to maximize accessibility to the entire workflow.
 - **Workflow type #3**
 - Very small lab space with limited automation but enough volume to need the Test 1.
 - Samples are hand sorted into racks by staff and taken to their respective analyzers for testing.
 - Depending on their workflow, the racks could be loaded with

- only Hematology samples (no other tests ordered),
 - mixed Hematology and ESR samples,
 - only ESR samples.
- For samples that have Hematology and ESR or ESR only ordered on them and depending on the HEMA system in use,
 - racks loaded with samples that were tested on a HEMA analyzer are loaded directly on the Test 1 for ESR testing; the Test 1 will scan the barcode and run ESR only when ordered and skip samples when it is not
 - racks pre-sorted with ESR only samples are loaded directly on the Test 1 for ESR testing

Comparison of iSED and Test 1

	 iSED	 Test 1	WINNING ANALYZER
Testing methodology	Photometric Rheology RBC aggregation	Photometric Rheology RBC aggregation	SAME
Minimum Volume	Up to 500 µL (varies by tube type)	800µL/1mL	iSED
Testing Volume	100 µL	175 µL	iSED
Time to First Result / Analysis Time	3 minutes 20 seconds / 20 seconds	5 minutes / 20 seconds	iSED
Random access-always ready to accept samples	YES- can stop the run to load a new sample	NO- loaded in racks Only if the previous run finished	iSED
Loading samples	One at a time, able to prioritize STAT samples	In racks -12 samples/rack up to 40-60 samples at once, more difficult to prioritize STAT samples once samples are loaded	Test 1
# of Positions	20	40-60	Test 1
Throughput Max tests/hour	180 Samples/hour	150 Samples/hour	iSED
Mixing on Board	Yes-Mixing on board by complete inversion of sample (360° rotation)	Yes-Mixing on board by complete inversion of sample (360° rotation)	SAME
Size-foot print (in / cm)	13 x 11 x 14 5.1cm x 4.3cm x 5.5cm	20.0 x 22.0 x 23.6 49 x 54 x 60	iSED
Automated Washing	Yes iWASH onboard After 15 min idle-automatic and/or initiated by user	No 2 wash tubes made by user, placed in positions 19, 20; replaced after 5 uses ; wash user programmed 30-180 minutes after last sample	iSED
Barcode Reader	Yes-Internal	Yes-Internal	SAME
Printer	Internal	Internal	SAME
Interface Capability	Yes Uni-directional	Yes Bi-directional	Test 1
Quality Control	Human-based, bi-level 60-day open vial stability 18-month shelf life RT storage Online QC Program	Latex Controls, tri-level 42-day open vial stability 6-months shelf life 2-8° storage Online QC Program	iSED
QAP Program	Online	Not Offered	iSED
Sample Tube Requirements	13X75 EDTA/ pierceable cap BD MAP, BD Vacutainer, Greiner miniCollect, Sarstedt S-Monovette	13X75 EDTA pierceable cap Compatible: Pediatric, BD MAP, BD Vacutainer, Greiner miniCollect, Sarstedt S-Monovette	SAME
Sample Stability	4 hours at RT 24 hours at +4°C	24 hours at +4°C	iSED
Temperature Control	YES	YES	SAME

Summary of comparison

Key reasons to choose the iSED:

- **Quality control**
 - Seditrol is human-based material, which means it is more like real patient samples rather than Alifax's latex controls which are not human-based. Seditrol has a 60-day open vial stability vs. Alifax controls with only 42-day open vial stability. Latex controls are not real blood, but still need to be refrigerated, which should raise doubt about the stability of the material, compared to our Seditrol, which is real blood and stable for 60 days at room temperature. This can plant a seed of doubt into the customer's mind about how stable latex controls really are if they need to be refrigerated and the material is not even real blood.

- **Maintenance**
 - Daily maintenance on the iSED is automatic and self-cleans if idle for 15 minutes so it is always clean and ready for new samples. Test 1 does not have automatic maintenance. Instead the end user must create two tubes with 3mL distilled water to be run 30-180 minutes after the last sample was run and depends on the sample volume of the lab. If running 24 hours, have the potential to run maintenance 8 times a day if not continuously running samples. Regardless of sample volume, maintenance on the Test 1 is performed at the end of day using 2 tubes of distilled water.

- **Sample requirements**
 - The iSED minimum sample required is up to 500 μ L, which includes only 100 μ L for testing + dead volume (varies by tube type-refer to the ALCOR Tube Compatibility Chart) in the currently validated sample tubes, making it ideal for low volume and pediatric samples. Test 1 requires 175 μ L of sample and 800 μ L dead volume (almost twice as much), which could lead to QNS, re-draw and not ideal for pediatric samples.

- **Random access**
 - The iSED can accept samples at any time if a position is open and STAT samples can be easily prioritized vs. the Test 1 where it cannot be stopped once the system has started.

Test 1 wins over iSED:

- **Loading samples** – The Test 1 is a rack-based system that can load up to 12 racks and can hold 40-60 samples at once, depending on the type of racks used and the model of the Test 1. The iSED can load one sample at a time for up to 20 samples but loading samples into racks is more desirable to the end user because racks of samples that were run on their Hematology analyzer are already loaded and ready to place directly on the Test 1. (another point might be that if the system scans the barcode and looks for an ESR order and only runs the ESR samples, then it is doing the sorting for them. If it doesn't do that, the user will have to remove non-ESR samples from the rack and "re-rack" them. Having "pre-racked" samples and using them directly from the Hematology system is a big benefit for the customer)

iSED at par with Test 1:

- **Throughput** – The iSED has a throughput of 180 samples/hour if the end user inserts samples continuously. The Test 1 has a throughput of 150 samples/ hour, but the end user can load samples in a rack at once and walk away, eliminating the need to continuously insert the samples. It depends on the workflow of the laboratory to know which workflow is more desirable. For high volume labs, the rack-based system is more desirable since it reduces hands on time.

Common objections to switching:

- The Test 1 is a rack-based system, where we can load samples directly from our CBC analyzer to the Test 1, it scans the tubes and tests only samples with ESR requested.
 - Do you insert the CBC rack immediately or do you pull the samples that do not have ESR?
 - Approximately 1 out of 10 CBC samples will have ESR requested, which means potentially 9 samples for every rack or 109 samples per session are stuck on the analyzer for an hour that do not need ESR, which could potentially increase TAT. If the end user pulls samples without ESR, then what is the point of having racks. Plant a seed of doubt in the end user's mind.
- The Test 1 is a rack-based system and samples are pre-loaded on a rack all at once; we can walk away for an hour to do other tasks, whereas the iSED you must manually load each sample individually and it can hold only 20 samples at one time.
 - How many samples do you receive in an hour?
 - Test 1 is a batch system and if samples are coming in throughout the day it might be faster to put them on an analyzer and run when you receive them or have an offline backup, such as the iSED.

SPIN Questions to Identify and Address Pain Points:

Pain Point #1: Samples without sed rate are held up on Test 1

Situation questions:

- 1) Do you load racks directly from a hematology analyzer to the Test 1 or do you only insert samples that have sed rate?
 - If the end user puts all samples on the Test 1, whether they have sed rate ordered or not, those samples will be held up until all samples have been processed.
- 2) Are you using a hematology track system? Is your sed rate managed on the automation track?
 - If the end user does not have ESR testing on the automation track, then the iSED could be a better fit for their workflow or as a backup to the Test 1 if is down.

Problem questions:

- 1) How many samples do you receive in an hour? How often do you load 4-5 racks at one time?
 - If the end user is only loading a few ESR samples at one time, then having a batch system might not be best for their workflow and an iSED might be faster.

- 2) How long are samples without sed rate held up on the Test 1? What do you do if one of the samples is a STAT sample?
 - If samples from the CBC analyzer are not sorted based on ordered sed rate then samples without sed rate will be loaded on Test 1 and it takes an hour to run a full session. This means samples without sed rate are held up from further testing on the track system.

Implication questions:

- 1) What happens when you just start a run and another sample comes in? What if it is a STAT?
- 2) How often does your track go down? How often does your Test 1 go down? What happens when your track or Test 1 is down? How does that impact your TAT?

Needs payoff:

- 1) Would it improve your TAT for you to have an offline backup analyzer for the times when the Test 1 is down?
- 2) Would it improve your workflow for you to have a random-access analyzer?
- 3) Would it be better for your workflow if you had an analyzer that can accept sed rate samples anytime instead of holding up non sed rate samples?

Pain Point #2: No automated maintenance and frequent QC purchases.

Situation questions:

- 1) How often do you perform daily maintenance?
 - End users must perform a daily wash before running QC, after instrument is idle for up to an hour and at the end of the work shift.
- 2) How often do you run the bleach procedure? (is there a recommendation in their user manual?)
- 3) How many uses do you get from the wash tubes?
 - Each wash tube has about 5 uses before it needs to be discarded.
- 4) How frequently do you run controls?
- 5) How often do you need to order them?

Problem questions:

- 1) How long is your system down during maintenance?
 - The more hands-on time spent performing maintenance, the less time the user spends running samples or performing high value tasks in the lab, such as generating results. Maintenance is considered a low value task in the lab, and the lab is already challenged with staffing qualified technologists to do the work. The lab has invested in automation to cover this labor shortage and having this valuable resource doing maintenance is not a good ROI for their people. Maintenance can be a big pain point for them and for us to try to relieve.
- 2) How long does it take to run controls?
 - End users get 6 or 30 draws out of each Alifax QC tube, depending on the kit purchased. Maintenance is done before QC samples are run on the Test 1 and a wash afterwards if samples are not added immediately, increasing hands-on time.

Implication questions:

- 1) What happens if the Test 1 is undergoing maintenance? (this happens a minimum of 2 times per day for 3-4 minutes)
- 2) What is your monthly QC cost and how quickly do you run through a kit?
 - Alifax QC kits cost between \$48 (6 test kit) and \$181 (30 test kit). Depending on how frequently the lab runs QC, especially if they are open 24/7, they would run through QC quickly.

Needs payoff:

- 1) Would it improve your workflow and TAT, and reduce hands-on time to have an analyzer that has automated maintenance?
 - Our analyzers automatically wash after being idle for 15 minutes with no intervention or preparation of cleaning materials. Deep wash is performed every 31 days or 1,000 samples, which is less frequently than Test 1 that requires a bleach clean every week for over 60 samples a day or every 2 weeks if less than 60 samples. The iSED requires the operator to insert a single pre-made bleach tube and takes less than 6 minutes for the cleaning cycle, which is easier than creating 3 tubes (two DI and 1 bleach) for Test 1.
- 2) What if I could impact your (budget, workflow, productivity) by \$X or X% (calculate this based on their answer to previous S, P and I questions). Would you see value in switching if I could save you X time/money?
 - Depending on the answers you are given to the S, P, and I questions above, calculate how much they are spending on controls and/or the amount of time they spend performing maintenance. If techs are spending time performing maintenance vs. running patient samples, that is not a good ROI for the end user.

Quick Response Guides for Competitors

Instructions: After a conversation with the prospect you can follow up with a summary of competitive advantages of our analyzers. These key differences are targeted specifically to the competitor. It is best to leave the competitor name out of the communication (called “current system”).

iSED vs. Test 1

(copy and paste the following in your email)

Key differences vs. your current system and reasons to choose miniSED for (Lab/Hospital Name) laboratory

- **Quality Control:** Seditrol® is human whole blood that performs like patient samples, is stored at RT, and has open vial stability of 60 days; 1-month and 3-month kit sizes are available; a wash is NOT required before or after running controls, eliminating additional maintenance procedures required due to the latex-based material.
- **Maintenance:** automatically self-cleans after being idle for 15 minutes with no additional wash tubes, no hands-on time or user intervention; Deep Clean is run on demand after 1000 samples or every 30 days.

- **Sample requirements:** requires only 100µL of sample for testing, and a total minimum sample volume up to 500µL (includes dead volume), reducing potential for QNS and re-draws, ideal for pediatric or low volume samples.
- **Random access:** load samples any time a position is open; the run can be stopped at any time making it easy to prioritize STATs