iSED Methodology Comparison and Positioning

iSED Features and Benefits

Feature	Benefit
Results in 20 seconds	Fast TAT and delivery of patient results
Direct measurement of red blood cell aggregation by photometric rheology	Accurate and reliable results unaffected by external factors such as temperature, vibrations, pipetting errors, and sample variables such as hematocrit (HCT) and mean corpuscular volume (MCV)
Fully automated with onboard barcode reader, sample mixing, direct tube sampling, results printed or transmitted to LIS	Minimal hands-on time, reduced biohazard exposure and opportunity for operator error
Primary tube sampling	No need to transfer sample into other tubes; no biohazard exposure; minimal skill required
Small footprint	High productivity using minimal bench space
Test credits never expire	Protected investment regardless of test volume
Human based controls with 18-month shelf life, no refrigeration, 60-day open vial stability	Reliable, consistent QC product that behaves like a patient sample and ensures the quality of the results; long stability enables full usage of the product and return on investment
100µL sample volume	Fewer Quantity Not Sufficient (QNS) issues and redraws, ideal for pediatric and low volume samples
Throughput 180 samples per hour	Increased workflow efficiency and productivity
Random access, continuous loading	Increased lab efficiency and ease of use
Quality Assurance Programs	Ensure accurate results with online, real time QC peer review and proficiency testing programs
Routine Maintenance: <1 minute Periodic Maintenance/Deep Clean: ~7 minutes every 30 days or 1000 samples	Minimal hands-on time for maintenance enables operator to do other high value tasks
Touch screen Graphical User Interface (GUI)	Easy to read and use LCD screen

Traditional Westergren Method

ESR testing using the Westergren method is gravity-based and has some critical and well known technical, operational and safety limitations.

Key limitations of the Westergren Method:

Westergren Method	iSED Benefit
Influenced by the Hematocrit (HCT) and Mean Corpuscular Volume (MCV) of the sample, which could lead to inaccurate results	iSED technology measures RBC aggregation using a photometric reading cell, which is not affected by HCT and MCV of the sample, to provide accurate results
Manual process prone to human errors in pipetting sample and reading the result on the tube	Requires no manual sample pipetting; result is interpreted by the analyzer and printed after each sample-minimal skill is required; results can be automatically transmitted to the LIS eliminating human transcription errors
Increased risk of biohazardous exposure to bloodborne pathogens via aerosols from decapping and pipetting into tubes	Direct sampling from the primary EDTA tube; no sample decapping or transfer required
Time intensive process – 60-minute test time	Fast TAT: 20 second test time
Result affected by external factors such as temperature and vibrations	iSED is temperature controlled and vibrations, such as from a centrifuge, do not affect the result
Sample not mixed sufficiently	iSED automatically mixes samples for 3 minutes ensuring sample integrity and reliable results
Requires large sample volume up to 2.0 milliliters (mL), which can increase the chance of QNS and make it difficult to test pediatrics or low volume samples	iSED requires only 100 microliters (µL) of sample, ideal for pediatric and low volume samples; reduced risk of QNS and redraws
Daily Quality Control is time intensive and takes 60 minutes before samples can be run	iSED runs controls the same as patient samples and takes ~15 minutes including onboard mixing and analysis time

Common objections to switching:

- Lab runs too few sed rates / day to justify the capital cost
    - Take advantage of a placement program where no capital cost is required, just the purchase of test cards that never expire.
    - Explore the possibility of a Starter Kit to minimize the cost of switching.
- Lab receives a higher reimbursement rate (about $4 / test in US; check your local market rates OUS) for sed rates on Westergren method since the cost per test is lower compared to automated sed rates ($2.20 / test)
    - Discuss workflow advantages and saved tech time – it takes 5-10 minutes to set up a Westergren plus the 60-minute time to result, then read and record the result vs. a single step to load the tube and walk away. If the iSED is connected to the LIS, the tech only needs to return to collect and store the tested samples.
- Lab runs between 10-25 sed rates per day, but no available capital to purchase a new analyzer
    - Discuss workflow advantages and saved tech time. It takes 5-10 minutes to set up a Westergren plus the 60-minute time to result, then return to read and record the result vs. a single step to load the tube and walk away, allowing techs to move on to other tasks without interruption to read a Westergren result.

- Take advantage of a placement program if capital is not available.

Manufacturers of Westergren tubes:

- Polymedco – Sediplast Westergren tubes
- DWK Life Sciences - Kimble Westergren ESR Tube
- Wyeth Holdings/Pfizer - Dispette pipette
- Globe Scientific Sedi-Rate
- BD - ESR Seditainer

Semi-Automated Methods

Semi-automated methods are based on the Westergren Method. Some are referred to as Modified Westergren, however, only part of the process is automated such as a digital result reader, automated mixing, and shorter time to result. All semi-automated analyzers require the user to transfer sample from the primary EDTA tube to a separate ESR tube (manufactured by the same company as the analyzer) and inserting that tube into the analyzer. This requires the end user to mix the primary EDTA tube prior to transferring sample to the ESR tube, which may or may not auto mix again, depending on the method used.

Key limitations of semi-automated methods:

Semi-automated Method	iSED Benefit
Influenced by Hematocrit (HCT) and Mean Corpuscular Volume (MCV) of the sample, which could lead to inaccurate results	iSED technology measures RBC aggregation using a photometric reading cell, which is not affected by HCT and MCV of the sample to provide accurate results
Manual sample transfer to special ESR tube (additional consumables), which is prone to human pipetting errors and increased risk of exposure to bloodborne pathogens	iSED does not require additional ESR tubes and samples directly from the primary EDTA tube with no sample transferring required
Time intensive process – 20-60 minutes to result	Time to result 20 seconds for each sample for quick turnaround time
Difficult to quality control multiple channels in one analyzer leading to discrepant results and lower throughput due to closing discrepant channels	iSED quality control (Seditrol®) is run through the same single photometer that reads patient results, ensuring consistent, accurate results
Manual maintenance, which requires more hands-on time	iSED self-cleans after being idle for 15 minutes; additional deep cleaning, initiated by the operator, is automated
Requires 1-2 milliliters (mL) sample volume, increasing the chance of QNS issues and re-draws	Minimum sample volume required is up to 500 µL: 100 µL for testing + dead volume (which varies by sample tube type), decreasing QNS issues and re-draws
Throughput of 20-80 samples an hour with sample position range of 3-40 channels. The channels can be taken offline with this method, reducing capacity.	Throughput of 180 samples / hour with 20 sample positions and a single photometer that is never offline, guaranteeing 100% capacity and throughput.

Common objections to switching:

- No available capital to purchase a new analyzer or analyzer is too expensive
  - Do a cost analysis and find out where there may be opportunity for savings

    - Take advantage of a placement program
    - Explore the possibility of a Starter Kit to minimize the cost of switching.
- Understaffed – no time to switch to a new analyzer at this time
    - Focus on minimal install time and support – quick and easy installation and startup; analyzers are easy to use ("plug and play"), user training is on-demand at the user's pace, correlation data is calculated by ALCOR and provided to enable fast time to implementation
- We like our current analyzer – if not broken, why fix it?
    - If the customer has limited experience with other methods, they "don't know what they don't know". Offer to do a demonstration to show how fast and easy the system is to operate. Their techs will love it!
    - Discuss workflow and safety advantages – less hands-on time, 20 second time to result allowing techs to quickly process these tests and move on to other high value tasks; upgrade to a fully automated analyzer vs. semi-automated where the process still requires several manual steps such as decapping the sample, pipetting and/or sample transfer to an ESR tube (biohazard exposure) and manual recording of results.

Manufacturers of semi-automated methods:

- Alifax – Roller 20MC (requires manual sampling of uncapped tubes)
- Diesse (Streck US) – Ves-matic Easy, Ves-matic 20, Ves-matic 30
- Polymedco – Sedimat 15, ESR Auto Plus (discontinued), Sediten ESR Reader
- EliTech Group – Excyte Mini, Excyte 20, Excyte M, Excyte 40
- HemaTechnologies – ESR Stat plus, ESR Stat 6
- RR Mechatronics – Starrsed ST

Competitor Comparison-Semi-Automated Methods

Analyzer	iSED	Ves-matic 20	Ves-matic 30	ESR Stat +	Sedimat 15	ESR Auto+	Excyte Mini	Excyte 20	Excyte M	Excyte 40	Starrsed ST	Roller 20MC
Manufacturer	ALCOR Scientific	Diesse (Streck)	Diesse (Streck)	Hema Technologies	Polymedco	Streck	ELITech Group	ELITech Group	ELITech Group	ELITech Group	RR Mechatronics	AliFax
Country of Origin	USA	Italy	Italy	USA	Italy	USA	USA	USA	USA	USA	Netherlands	Italy
Methodology	Photometric Rheololgy	Sedimen-tation	Sedimen-tation	Sedimen-tation	Sedimen-tation	Sedimen-tation	Sedimen-tation	Sedimen-tation	Sedimen-tation	Sedimen-tation	Sedimen-tation	Photometric Rheololgy
Sample Handling												
Auto Mixing	Yes	Yes	Yes	No	No	No	No	Yes	Yes	No	No	No
Sample Volume	100 µL	1 mL	1.5 mL	25 µL	1.6 mL	1.2 mL	1.2 mL	1.2 mL	1.2 mL	1.2 mL	1.2 mL	30 µL
Total Minimum Volume	Up to 500 µL	1 mL	1.5 mL	n/a	n/a	n/a	n/a	n/a	n/a	n/a	2 mL	100 µL
Sample Positions	20	20	30	3	8	10	10	20	10	40	24	-
Barcode Scanner	Internal	External	Internal	No	No	Yes	Optional	Yes	No	Optional	Yes	Optional
EDTA Primary Tube	Yes	No	Yes	No	No	No	No	No	No	No	Yes	Yes
Batch/ Continuous-Feed	Continuous	Batch	Batch	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Manual
Random Access	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
Performance												
Max Tests/hr	180	40	60	20	32	20	20	40	20	80	24 or 36 (30 min)	-
Time to 1st Result	3 min 20 sec	24 mins	33 mins	5 mins	15 mins	30 mins	30 mins	30 mins	30 mins	30 mins	30-60 mins	4 min
Data Interface												
LIS Interface	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Printer	Internal	Internal	Internal	External	External	Internal	External	Internal	External	External	External	Internal
Consumables												
Test Counter	Test Card	Test Card	Test Card	Test Card	Test Card	Test Card	Test Card	Test Counter	Test Card	Test Card	Test Card	Test Card
Quality Control												
Material	Human-based	Human-based	Human-based	Human-based	Human-based	Human-based	Human-based	Human-based	Human-based	Human-based	Human-based	Latex
Level	Bi-level	Bi-Level	Bi-Level	-	Bi-Level	Bi-Level	Bi-Level	Bi-Level	Bi-Level	Bi-Level	Bi-Level	Tri-level
Refrigeration	No	optional	optional	-	No	No	No	No	No	No	No	Yes
Shelf Life	18 months	12 months	12 months	-	18 months	18 months	18 months	18 months	18 months	18 months	18 months	6 months
Open vial stability	60 days RT	7 days RT 95 days 2-8°	7 days RT 95 days 2-8°	-	31 days	31 days	31 days	31 days	31 days	31 days	31 days	42 days 2-8°
Runs per tube/vial	28	Unlimited	Unlimited	-	-	-	-	-	-	-	3	30- 6
Maintenance											–	
Auto Self Clean	Yes	No	No	No	No	No	No	No	No	No	Yes	No

Automated Methods

Automated methods can be modified Westergren methods, use photometric rheology (ALCOR and Alifax analyzers), and optical infrared. An analyzer is considered fully automated if the entire sampling process is automated, meaning the analyzer draws directly from the primary EDTA tube with no sample transfer, results are automatically printed or transmitted via direct connection to the Laboratory Information System (LIS), and could have automatic mixing and automated maintenance. Some automated systems, like the Alifax Jo-Plus, Starrsed Interrliner and Diesse Ves-matic Cube Track, can be integrated into Laboratory Automation Systems (LAS), where samples are automatically placed in a rack by a robotic arm and automatically transported to the appropriate analyzer based on the tests ordered in the LIS.

Key differences between iSED and other automated systems

Other automated systems	iSED Benefit
If not using photometric rheology, results are influenced by the HCT and MCV, which could lead to inaccurate results	iSED technology measures RBC aggregation using a photometric reading cell, which is not affected by HCT and MCV of the sample to provide accurate results
Maximum throughput is between 20-190 samples per hour	iSED has a throughput of 180 samples/ hour
Time to first result ranges between 5-60 minutes Mixing time ranges 5-26 minutes Analysis time ranges from 19-38 seconds	Time to first result is 3-minute automated mixing time and then 20 seconds for each result for quick turnaround time
Some have an external hand-held barcode scanner, where the user must manually scan tubes and verify that the tubes are loaded in the correct order (batch sampling)	iSED has continuous loading of samples and an internal barcode reader for quick and accurate patient identification
Require 175µL – 2mL of sample and 500-1.4mL dead volume EXCEPT for the Roller 10PN which requires only 30µL of sample	Minimum sample volume required is up to 500 µL: 100 µL for testing + dead volume (which varies by sample tube type), decreasing QNS issues and re-draws
Some have manual mixing by inverting the EDTA tube by hand or placing on a rocker	Automated mixing for 3 minutes to ensure sample is adequately mixed for accurate results
Most LIS (laboratory information system) interfaces are uni-directional unless the analyzer can do a host query (bi-directional) like Diesse Ves-matic Cube 200, 80, Cube Track, Ves-matic 5 and all Alifax analyzers.	The iSED LIS interface is uni-directional for quick and accurate transmission of results; since ESR is the only test performed on this analyzer, it will analyze and transmit the results on all samples

Common objections to switching:

- No available capital to purchase a new analyzer.
    - Do a cost analysis and find out where there may be opportunity for savings.
    - Take advantage of a placement program; explore the possibility of a Starter Kit to minimize the cost of switching.

- The iSED is not a rack-based system and we cannot load CBC racks directly on the analyzer. We don't want to change our current workflow.
    - 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. Each lab is different so ask **S**ituation questions to find out the percentage of ESR ordered on the Hematology samples. If the end user removes samples without ESR, then they are manually sorting and re-racking the samples, adding hands-on time and potential for error by removing samples that require ESR testing which would increase their TAT. Plant these seeds of doubt in the end user's mind.
- The iSED cannot connect to a laboratory automation system. We like not having to sort samples by hand and manually load sed rate samples one at a time.
    - 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 the iSED as a backup if their system is down. Ask questions to understand their workflow.
- The iSED throughput is comparable to our current analyzer; we don't see the need to change.
    - Discuss how they are running QC and maintenance. The iSED is fully automated and requires less hands-on time, which could be a plus for the lab.
- Our current system can host query (bi-directional) so we can load all samples onto the analyzer and the analyzer knows to test only samples with ESR. The iSED does not have that feature.
    - Ask questions about their workflow. If they are presorting samples anyway, the iSED would be a great alternative. The iSED could be a backup if their system goes down or offline for maintenance.
    - Since the iSED performs only ESR and samples with ESR tests ordered are loaded by the operator, a uni-directional interface allows for all the operational benefits of the iSED to be realized.

Manufacturers of automated systems:

- Alifax – Roller 20LC, Roller 20PN, Roller 10PN, Test 1, Jo-plus
- Diesse (Streck in US) – Mini-Cube, Cube 30 touch, Ves-matic Cube 80, Ves-matic Cube 200, Ves-matic Cube Track, Ves Matic 5
- RR Mechatronics –Starrsed RS, Starrsed TL

Competitor Comparison-Automated Methods

Analyzer	iSED	Test 1	Roller 20 PN	Roller 20 LC	Roller 10 PN	Jo- Plus	MINI-CUBE	Cube 30 Touch	Ves-matic Cube 80	Ves-matic Cube 200	Starrsed RS
Manufacturer	ALCOR Scientific	Alifax	Alifax	Alifax	Alifax	Alifax	Diesse (Streck)	Diesse (Streck)	Diesse (Streck)	Diesse (Streck)	RR Mechatronics
Country of Origin	USA	Italy	Italy	Italy	Italy	Italy	Italy	Italy	Italy	Italy	Netherlands
Methodology	Photometric Rheololgy	Photometric Rheololgy	Photometric Rheololgy	Photometric Rheololgy	Photometric Rheololgy	Photometric Rheololgy	Optical Infrared	Optical Infrared	Optical Infrared	Optical Infrared	Sedimentation
Sample Handling											
Auto Mixing	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes
Sample Volume	100 µL	175 µL	175 µL	175 µL	30 µL	175 µL	2-4 mL	1.5 – 4 mL	1.5 mL	1.5 mL	1.4 mL
Total Minimum Volume	Up to 500 µL	800 µL	800 µL	800 µL	100 µL	n/a	2 mL	1.5 mL	1.5 mL	1.5 mL	1.4 mL
Sample Positions	20	60	20	18	10	Auto loading	10	10	56	50	84
Barcode Scanner	Internal	Internal	Optional	Optional	Optional	Internal	Yes	Optional	Yes	Yes	Yes
EDTA Primary Tube	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes
Batch/ Continuous-Feed	Continuous	Batch	Batch	Batch	Manual	Auto loading	N/A	N/A	Both	Both	Continuous
Random Access	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No
Performance											
Throughput Max Tests/hr	180	150	120	100	-	120	20	20	90	190	75-135 (30 min)
Time to 1st Result	3 min 20 sec	5 min	5 min	5 min	4 min	30 sec	30 mins	30 mins	26 mins	22 mins	30-60 mins
Data Interface											
LIS Interface	Uni-directional	Bi-directional	Bi-directional	Bi-directional	Bi-directional	Bi-directional	Yes	Yes	Bi-directional	Bi-directional	Bi-directional
Printer	Internal	Internal	Internal	Internal	Internal	n/a	Internal	External	Internal	Internal	External
Consumables											
Test Counter	Test Card	Test Card	Test Card	Test Card	Test Card	Test Card	Test Card	Test Card	Test Card	Test Card	Test Card
Quality Control											
Material	Human-based	Latex	Latex	Latex	Latex	Latex	Human-based	Human-based	Human-based	Human-based	Human-based
Level	Bi-level	Tri-level	Tri-level	Tri-level	Tri-level	Tri-level	Bi-Level	Bi-Level	Bi-Level	Bi-Level	Bi-Level
Refrigeration	No	Yes	Yes	Yes	Yes	Yes	optional	optional	optional	optional	No
Shelf Life	18 months	6 months	6 months	6 months	6 months	6 months	12 months	12 months	12 months	12 months	18 months
Open vial stability	60 days RT	42 days 2-8°	42 days 2-8°	42 days 2-8°	42 days 2-8°	42 days	7 days RT 95 days 2-8°	7 days RT 95 days 2-8°	7 days RT 95 days 2-8°	7 days RT 95 days 2-8°	31 days
Runs per tube/vial	28	30- 6	30- 6	30- 6	30- 6	30- 6	-	-	-	-	3
Maintenance											
Auto Self Clean	Yes	No	No	No	No	No	N/A	N/A	N/A	N/A	Yes

Quick Response Guides for iSED and miniiSED

Instructions: If you are positioning both analyzers, copy and paste the below, then add the Specific Features for each analyzer.

Key Features of BOTH the iSED and miniiSED:

- Photometric Rheology directly measures RBC aggregation using the same photocell in both analyzers. Due to this technology, ESR is not impacted by HCT, MCV, lab temperature or vibrations.
- Primary tube sampling: 13X75mm EDTA tubes, including BD MAPP and Greiner MiniCollect pediatric tubes.
- 100µL testing volume, ideal for pediatrics and low volume samples.
- Throughput: up to 180 samples/hour; random access, continuous loading.
- Internal barcode reader: positive sample ID and sample traceability.
- Same Test Cards are used for both analyzers; Test Credits never expire.
- Results: printed and/or transmitted directly to LIS, stored onboard for easy retrieval.
- Maintenance: fully automated.
- Quality Control: Seditrol® is human based, 18-month shelf life, 60 days open vial stability, ROOM TEMPERATURE storage; QAP program is included.

Specific Features of the iSED

- Medium to high volume labs: 25-100 samples/day.
- Sample capacity: 20 samples.
- Mixing: automated onboard, 3 minutes/sample.
- TAT: 20 seconds.
- Printer: integrated onboard.

Click Here for a demonstration of the iSED

Specific Features of the miniiSED

- Small volume labs: <25 samples/day.
- Sample capacity: 1 sample.
- Mixing: manual or mechanical rocker.
- TAT: 15 seconds.
- Printer: optional.

Click Here for a demonstration of the miniiSED

Instructions: If you are positioning iSED OR miniiSED alone, copy and paste one of the below.

Key Features of the iSED:

- Medium to high volume labs: 25-100 samples/day.
- Photometric Rheology directly measures RBC aggregation using the same photocell in both analyzers. Due to this technology, ESR is not impacted by HCT, MCV, lab temperature or vibrations.
- Sample capacity: 20 samples.
- Primary tube sampling: 13X75mm EDTA tubes, including BD MAPP and Greiner MiniCollect pediatric tubes.
- Mixing: automated onboard, 3 minutes/sample.
- TAT: 20 seconds.
- 100µL testing volume, ideal for pediatrics and low volume samples.

- Throughput: up to 180 samples/hour; random access, continuous loading.
- Internal barcode reader: positive sample ID and sample traceability.
- Results: printed and/or transmitted directly to LIS, stored onboard for easy retrieval.
- Maintenance: fully automated.
- Seditrol® QC: human based, 18-month shelf life, 60 days open vial stability, ROOM TEMPERATURE storage; QAP program is included.

Click Here for a demonstration of the iSED

Key Features of the miniiSED:

- Small volume labs: <25 samples/day.
- Photometric Rheology directly measures RBC aggregation. Due to this technology, ESR is not impacted by HCT, MCV, lab temperature or vibrations.
- Sample capacity: 1 sample.
- Primary tube sampling: 13X75mm EDTA tubes, including BD MAPP and Greiner MiniCollect pediatric tubes.
- Mixing: manually or mechanical rocker.
- TAT: 15 seconds.
- 100µL testing volume, ideal for pediatrics and low volume samples.
- Throughput: up to 180 samples/hour; random access, continuous loading.
- Internal barcode reader: positive sample ID and sample traceability.
- Results: printed and/or transmitted directly to LIS, stored onboard for easy retrieval.
- Maintenance: fully automated.
- Seditrol® QC: human based, 18-month shelf life, 60 days open vial stability, ROOM TEMPERATURE storage; QAP program is included.

Click Here for a demonstration of the miniiSED