

	iSED/iSED ELITE	ALIFAX Roller Series		ALIFAX Test 1	ALIFAX Test 1 2.0
		Roller 20PN	Roller 20MC		
<b>Methodology</b>	Photometric rheology (measures RBC aggregation)	Capillary photometry (measures RBC aggregation)	Capillary photometry (measures RBC aggregation)	Capillary photometry (measures RBC aggregation)	Capillary photometry (measures RBC aggregation)
<b>Sample Probe</b>	Internal	Internal and external (2 measurement units)	Internal and external (2 measurement units)	Internal	Internal and external (2 measurement units)
<b>Sample Volume</b>	<b>Aspirated Volume:</b> 100 µL <b>Minimum Test Volume:</b> 500 µL EDTA whole blood	<b>Aspirated Volume:</b> 175 µL (+ 232 µL sample priming) <b>Minimum Test Volume:</b> 800 µL	<b>Aspirated Volume:</b> 30 µL (+ 50 µL sample priming) <b>Minimum Test Volume:</b> 100 µL	<b>Aspirated Volume:</b> 175 µL (+ 232 µL sample priming) <b>Minimum Test Volume:</b> 800 µL <b>Pediatric Dead Volume:</b> 500 µL	<b>Aspirated Volume:</b> 175 µL (+ 232 µL sample priming) <b>Minimum Test Volume:</b> 800 µL <b>External Sampling Aspirated Volume:</b> 30 µL <b>External Sampling Volume:</b> 300µL
<b>Sample Tube Requirements</b>	13x75 mm EDTA tubes with pierceable caps, BD Microtainer <sup>®</sup> MAP tubes (refer to iSED <sup>®</sup> Analyzers Tube Compatibility Chart)	Test-tubes 13x75 mm (0,512 x 2,953 inches) like BD Vacutainer <sup>®</sup> or BD Microtainer <sup>®</sup> or Greiner Bio-one	Test-tubes 13x75 mm (0,512 x 2,953 inches) like BD Vacutainer <sup>®</sup> or BD Microtainer <sup>®</sup> or Greiner Bio-one	Test-tubes 13x75 mm (0,512 x 2,953 inches) like BD Vacutainer <sup>®</sup> or BD Microtainer <sup>®</sup> or Greiner Bio-one	<ul style="list-style-type: none"> <li>Greiner Bio-one Vacuette<sup>®</sup> / BD Vacutainer<sup>®</sup> (13x75) / KIMA Vacutest<sup>®</sup> (13x75 mm) or similar tubes, with a capacity of 3 ml, diameter 13 mm and height in the range [75-83 mm] including cap</li> <li>Sarstedt or Sarstedt Monovette<sup>®</sup> (11x66 mm)</li> <li>BD Microtainer MAP<sup>®</sup> (13x75 mm)</li> <li>Sarstedt S-Monovette<sup>®</sup> EDTA, Tapval<sup>®</sup> pediatric tube, BD Vacutainer<sup>®</sup> pediatric tube, only for external sampling system</li> </ul>
<b>Sample Stability</b>	4 hr at room temperature; 24 hrs at 2-8°C	4 hr at room temperature; 24 hrs at 2-8°C	4 hr at room temperature; 24 hrs at 2-8°C	It would be better to test the sample within 4-6 hours from venepuncture or within 24 hours if kept at +4/+8 °C (+39 / +46 °F)	It would be better to test the sample within 4-6 hours from venepuncture or within 24 hours if kept at +4/+8 °C (+39 / +46 °F)
<b>Throughput</b>	20 sample capacity, 180 samples per hour	20 sample capacity, 120 samples per hour	1 sample capacity	40-60 sample capacity, 150 tests per hour	<ul style="list-style-type: none"> <li>40-60 sample capacity, 195 samples per hour</li> <li>TLA: 180 samples per hour</li> </ul>
<b>Time to First Result</b>	3 minute mix + 20 seconds; subsequent results available within 20 seconds	5 minute mix + 30 seconds	4 minute mix + 18 seconds	5 minute mix + 20 seconds	<ul style="list-style-type: none"> <li>5 minute mix + 18.5 seconds</li> <li>External sample 18.5 seconds (after mixing manually)</li> </ul>
<b>Workflow</b>	<ul style="list-style-type: none"> <li>Random access</li> <li>Continuous sample loading, can prioritize STATs</li> <li>Onboard mixing</li> <li>Internal sample barcode reader</li> <li>No barcode placement restrictions</li> <li>Can use sample tube for other hematology tests</li> <li>Minimal biohazard risk</li> </ul>	<ul style="list-style-type: none"> <li>Rack based</li> <li>Batch testing</li> <li>Manual barcode entry</li> <li>Optional external sample barcode reader</li> <li>Minimal biohazard risk</li> <li>Optional external sampling</li> </ul>	<ul style="list-style-type: none"> <li>One sample at a time, manual loading</li> <li>Optional external barcode reader</li> <li>Minimal biohazard risk</li> <li>Optional external sampling</li> </ul>	<ul style="list-style-type: none"> <li>Not random access</li> <li>Internal sample barcode reader</li> </ul>	<ul style="list-style-type: none"> <li>Random access with use of external probe</li> <li>External sampling unit allows for STAT capability</li> <li>Internal sample barcode reader</li> <li>Internal and external probes must be quality controlled</li> <li>Two versions “desk model” or “track model”</li> <li>Internal and external patient sampling</li> </ul>
<b>Interface Capability</b>	Yes, Uni-directional	Yes, Bi-directional	Yes, Bi-directional	Yes, Bi-directional	Yes, Bi-directional
<b>Quality Control</b>	<b>SEDiTROL<sup>®</sup> ESR Control</b> <ul style="list-style-type: none"> <li>Human whole blood matrix (Mimics patients)</li> <li>Open Vial Stability: 60 days at room temperature</li> <li>Shelf life: 18 months</li> <li>Online QC program</li> </ul>	<b>ALIFAX Latex Control</b> <ul style="list-style-type: none"> <li>Latex matrix</li> <li>Open Vial Stability: 42 days at 2-8°C</li> <li>Internal and external probes must be quality controlled</li> </ul>	<b>ALIFAX Latex Control</b> <ul style="list-style-type: none"> <li>Latex matrix</li> <li>Open Vial Stability: 42 days at 2-8°C</li> <li>Internal and external probes must be quality controlled</li> </ul>	<b>ALIFAX Latex Control</b> <ul style="list-style-type: none"> <li>Latex matrix</li> <li>Open Vial Stability: 42 days at 2-8°C</li> </ul>	<b>ALIFAX Latex Control</b> <ul style="list-style-type: none"> <li>Latex matrix</li> <li>Open Vial Stability: 42 days @ 2-8°C</li> <li>Internal and external probes must be quality controlled</li> </ul>
<b>Routine Maintenance</b>	<ul style="list-style-type: none"> <li>No operator initiated daily maintenance</li> <li>Automatic washing 1x after 15 minutes idle</li> <li>Deep clean after 30 days or 1000 tests</li> <li>No special cleaning required when running QC material</li> </ul>	<ul style="list-style-type: none"> <li>Required operator initiated daily maintenance</li> <li>Washing not automatic, user initiated</li> <li>3 wash/bleach cycles before QC, shutdown</li> <li>Frequent replacement of tubing, needles</li> </ul>	<ul style="list-style-type: none"> <li>Required operator initiated daily maintenance</li> <li>Washing not automatic, user initiated</li> <li>3 wash/bleach cycles before QC, shutdown</li> <li>Frequent replacement of tubing, needles</li> </ul>	<ul style="list-style-type: none"> <li>Required operator performed daily maintenance required</li> <li>Washing not automatic, user initiated</li> <li>3 wash/bleach cycles before QC, shutdown</li> <li>Frequent replacement of tubing, needles</li> </ul>	<ul style="list-style-type: none"> <li>Automatic and manual washing</li> <li>3 wash/bleach cycles before QC, shutdown</li> <li>Frequent replacement of tubing, needles</li> </ul>
<b>Required Accessories</b>	<ul style="list-style-type: none"> <li>Test cards</li> <li>iWash Solution</li> <li>iWaste bottles</li> <li>No per-test reagents/disposables required</li> </ul>	<ul style="list-style-type: none"> <li>Smart card</li> <li>Wash tank</li> <li>Waste tank</li> <li>Sample racks</li> </ul>	<ul style="list-style-type: none"> <li>Smart card</li> <li>Wash tank</li> <li>Waste tank</li> <li>Sample racks</li> </ul>	<ul style="list-style-type: none"> <li>Smart card</li> <li>Wash tank</li> <li>Waste tank</li> <li>Sample racks</li> </ul>	<ul style="list-style-type: none"> <li>Smart card</li> <li>Wash tank</li> <li>Waste tank</li> <li>Sample racks</li> </ul>

# WHY CHOOSE THE ISED/ISED ELITE?



## More Efficient QC Workflow

- SEDiROL® ESR Controls are **made from human blood** while ALIFAX controls are suspensions of latex particles. SEDiROL Controls allow the iSED analyzers to measure aggregation, while ALIFAX controls only allow the analyzer to measure turbidity.
- iSED analyzers only have one analytical unit while some ALIFAX analyzers have 2 analytical units that require separate QC procedures.
- **No special operator initiated cleaning** is needed before or after running the SEDiROL® ESR Controls. SEDiROL controls are simply loaded into the iSED analyzers like patient samples. Controls need to be processed according to a special procedure on the ALIFAX analyzers. The latex matrix of the ALIFAX QC material causes buildup in the system, requiring the need for extensive washing to be performed before and after a QC run. This requires hands-on time and disrupts the normal workflow.
- SEDiROL® ESR Controls have a **60-day open vial stability** and can be conveniently **stored at room temperature**. ALIFAX controls have 42-day open vial stability and must be stored at 2-8°C.



## Less Maintenance:

- There **is less required maintenance** with the iSED analyzers. There is no required daily maintenance, and iSED analyzers **automatically self-clean** so they are always clean and ready for samples.
- The ALIFAX systems require more extensive maintenance. Some ALIFAX analyzers have external probes/circuits which essentially doubles the maintenance required.



## Smaller Sample:

- The iSED systems requires the **smallest routine test volume** (up to 500 µL depending on the tube brand being used). Only 100 µL is aspirated for testing which allows for the more sample to be leftover for other hematology tests.
- The ALIFAX ESR analyzers require 800 µL test volume for routine testing with 175 µL of sample being aspirated. The priming volumes for the ALIFAX systems can also require >50 µL in addition to the test volume.



## Reduced Risk of Biohazard Exposure:

- iSED analyzers pose a **lower risk of biohazard exposure** because tubes remain capped and aspiration is performed internally.
- The ALIFAX analyzers' external probe/circuit requires that tubes be uncapped in order to be aspirated for analysis, **potentially exposing the operator to biohazardous material**.
- The maintenance/cleaning procedures for the ALIFAX analyzers' external probe also introduce the risk of biohazard exposure during routine maintenance since the probe may contain biohazardous material.

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**Approved By:**

[\(CO-3639\) Alternate ESR Comparison sheet for both OUS and US team.](#)

**Description**

Release Alternate ESR Comparison Sheet for both OUS and US team.

**Justification**

Need to release Alternate ESR Comparison Sheet for both US and OUS teams.

<b>Assigned To:</b>	<b>Initiated By:</b>	<b>Priority:</b>	<b>Impact:</b>
Belinda Fralick	Belinda Fralick	High	Minor

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**Version History:**

<b>Author</b>	<b>Effective Date</b>	<b>CO#</b>	<b>Ver.</b>	<b>Status</b>
Belinda Fralick	April 4, 2024 10:56 AM EDT	<u><a href="#">CO-3639</a></u>	0	Published