Positioning to Win: miniiSED vs. ELITech Excyte Mini and Excyte 20

Profile of an Excyte Mini and Excyte 20 user

- **Location**
  - Primary: hospitals, rheumatology clinics, and other stand-alone labs
  - Secondary: CLIA Moderately Complex physician office labs (POLs)

- **Volume**
  - Small to medium sample volumes, 1-20 samples/day
  - miniiSED is a great option for this segment; higher volume labs are great candidates for the iSED and many of the following positioning points will apply to it too.

- **The ideal Excyte Mini and Excyte 20 customer profile to switch to the miniiSED**
  - Labs running 5-20 samples/day,100-400 samples/month will see significant benefits from reduction of hands-on time for sample handling and processing, TAT to result, biohazard safety and overall workflow and efficiency improvement from the fully automated features.
  - Labs that do not have the capital budget to purchase a miniiSED could take advantage of a placement program, aiding in the transition from a financial perspective.
  - Labs that use either the evacuated glass or plastic black top tubes or the non-evacuated plastic red top tubes will benefit from using the miniiSED. The non-evacuated red top tubes require manual sample transfer from the EDTA tube and contain sodium citrate for diluting the blood. Between 1-1.2mL of blood is transferred to the ESR tube prior to loading on the Excyte Mini or Excyte 20.

- **Workflow**
  - **Sample collection-**Excyte Mini/Excyte 20 use ESR tubes that contain sodium citrate (vs. EDTA) to dilute and/or anti-coagulate the blood prior to testing on the analyzer. There are three types of ESR tubes, which are separate consumables that must be purchased:
    - Evacuated ESR tubes (glass or plastic, black top tubes) draw 1mL or 1.36mL (respectively). These would be used by a phlebotomist to collect the sample directly into the tube, however, most labs do not want to add a specific tube that the phlebotomist has to remember to draw. Unlike the routine purple top tube (EDTA) used in Hematology and on most ESR systems, this tube cannot be used for any other test and adds an additional expense to the lab budget. In addition, there are blood draw reduction initiatives in many hospitals where they are looking for ways to reduce the amount of blood drawn from their patients. The stability of blood in the vacuum tubes is only 12 hours refrigerated (EDTA tubes stability is 24 hours refrigerated).
    - Non-evacuated ESR tube (plastic red top). These tubes are not vacuum tubes that can be used for blood collection and require the sample to be pipetted into them. The phlebotomist would collect a regular EDTA purple top tube and bring it back to the lab. After mixing, the user would manually

transfer 1-1.2mL of blood to the non-evacuated red top ESR tube. This sample transfer and testing would likely happen after any other testing is completed, such as a CBC performed in Hematology or a Hemoglobin A1C (HbA1C) usually done in Clinical Chemistry.

- **Sample mixing-**Excyte 20 has automated mixing for 5 minutes while the Excyte Mini requires manual mixing of a minimum of 10 inversions prior to testing. ELITech offers the Excyte Duo Mix designed to hold up to 40 samples with interchangeable racks that can accommodate many different types of tubes in addition to their proprietary tubes.
- **Technology-**Excyte Mini and Excyte 20 use optical infrared LED technology to scan along the tube to measure the red blood cells settling in the tube (sedimentation), which is the same gravity-based method as the Westergren. After mixing (either manual or automated) and 30 minutes testing time, the result is displayed on the screen, and printed and/or transmitted via the uni-directional LIS. Both the Excyte Mini and Excyte 20 have a 30-minute analysis time.

Both systems are based on the Westergren method and experience many of the limitations of that procedure, such as large sample volume needs (minimum 1 and 1.2 mL), longer TAT (30 minutes), additional hands-on time, and they are essentially batch analyzers.

Comparison of miniiSED and Excyte Mini/Excyte 20

	miniiSED 	Excyte Mini 	Excyte 20 	WINNING ANALYZER
Testing methodology	Photometric Rheology RBC aggregation	Optical infrared LED photoelectric cell RBC sedimentation	Optical infrared LED photoelectric cell RBC sedimentation	**miniiSED**
Minimum Volume	Up to 500 µL (varies by tube type)	1 mL or 1.36 mL (dependent on tube type)	1 mL or 1.36 mL (dependent on tube type)	**miniiSED**
Testing Volume	100 µL	1-1.36 mL	1-1.36 mL	**miniiSED**
Time to first result / Analysis time	15 seconds after 3 minutes of Manual mixing or mechanical rocker	10-12 inversions + 30 minutes / 30 minutes (optimal result time) 10 minute-pre-indication; 15-min option	35 minutes 30 minutes (optimal result time) 10 minute-pre-indication; 15-min option	**miniiSED**
Random access-always ready to accept samples	Yes	No	No	**miniiSED**
Loading samples	One sample at a time	One sample at a time, batch	One sample at a time, batch	Same
# of Positions	1	10	20	Excyte
Throughput Max tests/hour	180 samples/hr	Up to 40 samples/hour	Up to 80 samples/hour	**miniiSED**
Mixing on Board	No Manual mixing by hand or 3minutes on a mechanical rocker	No Manual mixing, 10-12 inversions	Yes 5 minute mixing cycle	Excyte 20
Size-foot print (in / cm)	9.5 x 7.1 x 10.4 in 24.1 x 18.0 x 26.4 cm	6 x 8 x 4 in 15.2 x 20.3 x 10.2 cm	8.5 x 13.5 x 10.5 in 21.59 x 34.29 x 26.67 cm	Excyte Mini
Automated Washing	Yes automatic wash after 15 min or initiated by user	No maintenance between samples since cap is not pierced and blood is not drawn into analyzer	No maintenance between samples since cap is not pierced and blood is not drawn into analyzer	Excyte
Barcode Reader	Yes-Internal	Optional-External	Yes-On side of analyzer	**miniiSED**
Printer	Optional-External	Optional-External	Yes-Internal	Excyte 20
Interface Capability	Yes Uni-directional	Yes Uni-directional	Yes Uni-directional	Same
Quality Control	Human-based, bi-level 60-day open vial stability 18-month shelf life RT storage Online QC program	Human-based, bi-level 31-day open vial stability 18-month shelf life RT storage Online QC program	Human-based, bi-levels 31-day open vial stability 18-month shelf life RT storage Online QC program	**miniiSED**
Sample Tube Requirements	13X75 EDTA/ pierceable cap BD MAP, BD Vacutainer, Greiner miniCollect, Sarstedt S-Monovette	Excyte ESR tubes	Excyte ESR tubes	**miniiSED**
Sample Stability	4 hours at RT 24 hours at +4°C	4 hours at RT 24 hours at 2-8°C Vacuum tubes-12 hours at 2-8°C	4 hours at RT 24 hours at 2-8°C Vacuum tubes-12 hours at 2-8°C	**miniiSED**
Temperature Control	Yes	No applies temperature correction to results	No applies temperature correction to results	**miniiSED**

References are listed at the end of the Guide

Summary of comparison

Key reasons to choose the miniiSED:

- **Sample requirements**
  - Excyte Mini/Excyte 20 require a minimum 1mL of sample. This large sample requirement could lead to a rejection of the sample due to QNS and/or a sample re-draw to have the minimum amount of sample needed to produce a result. This is not ideal for pediatric samples, which typically contain between 400-500µL of sample, or for low volume samples that do not contain enough to meet this minimum. Drawing 1mL of blood from a pediatric patient is a significant amount and therefore, not routinely done.
  - The miniiSED minimum sample required is up to 500 µL, which includes only 100µL 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. BD MAP and Greiner MiniCollect tubes are validated to place directly on the analyzer, enabling primary tube sampling for pediatrics with ½ the amount of blood required, including dead volume.

- **Tube requirements**
  - Excyte Mini/Excyte 20 require special Excyte ESR tubes to perform the testing. There are 3 different tube types:
    - (1) Evacuated plastic and (2) evacuated glass black top tubes-these contain pre-measured sodium citrate anticoagulant and can be used to draw blood directly from the patient. Using these tubes is not the desired or most common scenario for several reasons
      - Training/Potential for Error-labs that use the vacuum Excyte ESR tubes, which are only for ESR, must train their phlebotomists to draw this tube, creating potential for error in knowing to draw this tube when ESR is ordered.
      - Blood volume-use of these tubes increases the amount of blood drawn from the patient, which is in addition to drawing the standard EDTA tube, and others, for other routine tests. Not only is this tube extra blood, but it cannot be used for any other test, nor is any of the sample actually used for ESR, because the sedimentation is read from the tube itself. What a waste of patient blood!
      - Increased cost-doctors will order multiple tests on their patients for which one EDTA tube can be used (HbA1C, CBC, DIFF, ESR, etc.) making it more cost-effective vs. paying for a special ESR tube that cannot be used for any other test.
    - (3) Non-evacuated plastic red top tubes that are used when samples are drawn in other tubes, such as EDTA/purple top tubes, and require pipetting of the sample into these tubes. This is the most common scenario, but still a poor choice for several reasons
      - Sample traceability-the original tube has the patient identification in a barcode label that is placed directly on the tube. When the sample is transferred to a secondary tube, in this case the plastic red top tube, this connection to the patient ID is lost, leading to loss of traceability and potential errors in result reporting.

        - Sample volume-these tubes require 1mL of sample to be pipetted into the tube to perform the test. This does not lend itself to accommodate pediatric or low volume samples and would lead to QNS and sample redraw.
        - Increased cost-these tubes are an extra expense on top of the blood collection tubes.
    - Pediatric sample tubes cannot be run on Excyte analyzers directly and would require two 500µL tubes to be drawn and combined by pipetting into the non-evacuated ESR tube for testing. As described in the Sample Requirements above, there is risk of QNS if there is not 1mL of sample in the combined volume to run the test. With pediatric or low volume sample situations the lab could send out to a reference lab, which impacts the lab budget, increases TAT, and increases the amount of blood drawn from the patient.
    - miniiSED has no special tube requirements. It samples directly from the primary EDTA tube, including micro-collection devices that are used for pediatrics, and ESR testing can be performed on the same sample that other tests are being done. This provides better utilization of the patient sample, is more cost effective, and ensures positive patient ID and traceability to the result.

- **Sample handling**
    - Excyte Mini and Excyte 20 utilize ONLY special tubes for testing. In the most common scenario, the sample is manually transferred by pipetting the blood from the EDTA tube into the non-evacuated red top tubes. This causes biohazard risk to the user from aerosols and loss of sample due to spills during the pipetting process.
    - miniiSED samples directly from the primary EDTA tube, eliminating exposure risk to the user.

- **Internal barcode reader**
    - Positive sample identification and traceability of the result to the patient ID is important to prevent reporting the wrong results on a patient that could lead to poor treatment decisions and unnecessary medical care. Excyte Mini has an external barcode scanner that introduces the risk of swapping samples while loading. Excyte 20 claims to have an internal barcode reader, however, it is located on the side of the sample loading area, which means that a sample can easily be scanned there, but an unscanned sample could easily be loaded instead. Mis-identified samples with incorrect reporting of results is a common human error in systems that do not have full traceability and positive sample ID.
    - In addition, for each of these analyzers, if the non-evacuated red top tube is being used, which is the most common scenario, the barcode label needs to be applied to this secondary tube for scanning, introducing a loss of traceability to the sample ID even before it is scanned.
    - miniiSED has an internal barcode reader for positive patient identification and full sample and result traceability directly from the primary tube. The barcode reader does not require meticulous placement of the barcode label, minimizing hands-on time for sample management.

- **Methodology**
    - Excyte Mini and Excyte 20 use optical infrared technology to scan the tube. They use a gravity-based methodology, just like the Westergren method, in which the

measurement is based on sedimentation of the aggregated red blood cells. This has the same limitations as the Westergren including effects from HCT, MCV, mixing, temperature, and vibrations, therefore the Excyte Mini and Excyte 20 sedimentation rate results have the potential to be less accurate due to these variables.
    - miniiSED uses photometric rheology to measure the intensity of red blood cell aggregation, which occurs in the first phase of the sedimentation process. The miniiSED is not impacted by environmental factors, such as temperature and vibrations, or sample variables such as HCT and MCV, and measures red blood cell aggregation via a direct measurement of aggregation in the photometric reading cell.

- **Time to result**
    - Excyte Mini and Excyte 20 state that they can perform a complete sed rate test in as little as 15 minutes with optional pre-indication in 10 minutes, which is a +/- preliminary indicator that the results might be abnormal. The full analysis time for optimal results is **30 minutes**, leading to a longer turnaround time and impact to lab workflow. Excyte 20 time to first result is a total of 35 minutes (5-minute mixing time and 30-minute analysis time), and the Excyte Mini requires 10-12 mixing inversions prior to the 30-minute testing time.
    - miniiSED time to first result is **15 seconds** after mixing for a minimum of 3 minutes manually or on a mechanical rocker.

Common objections to switching:

- We are happy with our current analyzer; if it's not broken, why fix it?
    - "Happy" is relative. If they have not used anything else, they may not realize that there is a better way. Ask about sample requirements, tube requirements, throughput and time to result, and sample traceability, plus the limitations of the sedimentation methodology in general, as described below in the SPIN questions.
- We are swamped right now and switching analyzers isn't a priority.
    - (US only) This is a great opportunity to highlight our ALCOR iLEARN platform. iLEARN is a learning platform where the end user has access to OnDemand operational training to be up and running at their own pace. Once they have completed training, they can begin correlation and we crunch the numbers for them.
    - In general, if we can make it simple for the customer to switch through installation, training and correlation support, they will see big benefits once implementation is completed.
- Excyte is less expensive.
    - Do a cost analysis to understand which tubes they are using as that is an incremental expense vs. the miniiSED, which does not require any special tubes to perform ESR.
    - Use the SPIN questions below to establish value in the mind of the customer around their pain points of sample volume, sample tube requirements, sample traceability, hands-on time, methodology limitations and turnaround time.

SPIN Questions to Identify and Address Pain Points:

Pain Point #1: Samples require minimum of 1-1.2 mL sample volume and special ESR tubes.

Situation questions:

1) Do you use vacuum Excyte ESR tubes or non-vacuum? A mix of both?
2) Do you run into any QNS issues with your Excyte analyzer?
3) How many pediatric or low volume samples do you receive?

Problem questions:

1) If using the evacuated (black top) tubes, how do you train your phlebotomists to know to draw this tube for ESR? Do you keep both types of tubes on hand in case the black top tube is not collected?
2) What do you do with pediatric samples? Do you require 2 micro-collection containers to be drawn then combine them for testing? Are you able to run them on your current analyzer or do you have to send them out to a reference lab?

Sending samples out to a reference lab costs money and increases TAT.

3) How do you handle QNS samples? Do you have to request a re-draw of the sample?

Doctors do not like requesting the patient to come back to draw another sample, especially for pediatric patients.

Implication questions:

1) If using the evacuated (black top) tubes, what happens if the phlebotomist doesn't draw the tube when ESR is requested? What else are you using these samples for? Isn't this a waste of patient sample if you can only use it for ESR? How does this fit in with your hospital's blood utilization initiatives? (they are trying to REDUCE the amount of blood drawn and will select methods/analyzers that utilize lower amounts of blood for this reason).
2) If using the non-evacuated red top tubes, how much time and expertise does it take your techs to manually pipet samples from the EDTA tubes into the ESR tubes? Can all of your employees run this test or do you have requirements that certain techs are allowed to do it because of the sample handling procedures? How do you handle biohazard exposure during pipetting of these samples? 1mL is a lot of sample to waste for one test. Once pipetted, can/do you use the sample for any other tests?
3) What happens when you do not have enough sample volume to meet the 1mL requirement? What do you do about pediatric or low volume samples? Do you have a backup analyzer or send out process for these samples?

Needs payoff:

1) How would it impact your lab to have an analyzer that requires no special tubes for collection or testing, samples directly from the primary EDTA tube, requires only 100 µL of sample and provides results in 15 seconds?
2) Would you see benefits to your sample management and workflow to have an analyzer that can run pediatric samples directly from a single micro-collection device?

miniiSED can run on BD MAP tubes and Greiner MiniCollect tubes with minimum sample requirement up to 500 µL, which includes only 100µL 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.

Pain Point #2: External barcode reader

Situation questions:

1) Do you have an Excyte Mini or Excyte 20? How many samples with ESR tests ordered do you run per day?
2) Do you use the evacuated black top tubes or the non-evacuated red top tubes with your Excyte ESR analyzer?

Problem questions:

1) How do you label a secondary (daughter) tube when a sample has to be transferred into the non-evacuated red top tube?
2) How do you ensure sample traceability in an analyzer that has an external barcode reader? How would you know if there is a loss of traceability?
3) Does the barcode scanner on the Excyte 20 ever have difficulty scanning the barcode labels?

This question is for users with an Excyte 20 that often has issues not scanning the barcode label.

4) Do your techs ever have distractions when manually scanning samples that could cause a sample to be disconnected from its results?

External barcode readers increase the risk of scanning one sample but loading a different one instead on the analyzer.

Implication questions:

1) What happens if there is a sample swap and the wrong patient result is reported? What is the follow up required when you find out that this happened?
2) How do you ensure that you have sample traceability, especially when labeling and transferring sample to secondary tubes?

The best way to ensure traceability and positive sample ID is to place the tube directly into a closed system (e.g. our sample port), the barcode is read, the sample is identified and tested, the results are reported, and the sample is removed. There is no interruption in this cycle that could cause a mismatch of results with the patient ID.

Needs payoff:

1) Would it be reassuring to have an analyzer that scans the barcode as it is being inserted into the analyzer, ensuring positive patient identification?

Pain Point #3: Methodology and TAT

Situation questions:

1) How many sed rates do you do per day? How much time do your techs spend labeling and pipetting samples for ESR testing?
2) Do you run ESR on Excyte as they come into the lab or do you wait to batch?
3) Does the temperature of the lab ever fluctuate outside of normal parameters?
4) Is your ESR testing being performed near a centrifuge?
5) Is your analyzer connected to your LIS or do you manually report results?

Problem questions:

1) Do you cross reference and correct your ESR results for Hematocrit (HCT) or Mean Corpuscular Volume (MCV)?
2) Do you ever receive calls asking for ESR results on samples that have not yet started or are still waiting to read and report?

Implication questions:

1) What do you do if a patient has an abnormal HCT or MCV? What do you do if the temperature of the lab is higher or lower than normal? Would you know?
2) What happens if you need to repeat tests but you do not have enough sample?
3) How do you respond to calls asking for results that you have not started or that have not completed a run? How does managing these calls impact your workflow?

Needs payoff:

1) How would it impact your lab to have an analyzer where the results are not impacted by HCT or MCV, temperature or vibration?
2) Would it improve your efficiency and turnaround time to be able to run ESR tests as they come into the lab (i.e. no batching) and report results in 15 seconds vs. 30 minutes?

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").

miniiSED vs. Excyte Mini

(copy and paste the following in your email)
Key differences vs. your current system and reasons to choose miniiSED for (Lab/Hospital Name) laboratory

- **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.
- **Time to result:** quick TAT is 15 seconds
- **Efficiency:** no special or proprietary tubes are needed! Standard 13X75 EDTA tubes, including BD MAP and Greiner MiniCollect, can be loaded directly on the analyzer for primary tube sampling, reducing or eliminating hands-on time transferring samples to required special tubes.

- **Reduced biohazard risk:** samples directly from the primary EDTA tube via a pierceable cap, eliminating risk of biohazard exposure due to decapping and sample transfer.
- **Traceability:** has an internal barcode reader for positive patient identification and sample traceability, ensuring that the sample result is connected to the correct patient ID.
- **Accuracy:** technology is not impacted by environmental and sample variables such as HCT, MCV, temperature and vibrations, ensuring accurate patient results and reduced potential for errors.