Positioning to Win: miniiSED vs. Manual Westergren Method

Manual Westergren Method Manufacturers:

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

Profile of a Westergren user

- **Location**
  - Primary: hospitals, rheumatology clinics, and other stand-alone labs
  - Secondary: Physician Office Labs (POL), mainly because many of these are CLIA Waived labs that are not certified to use our analyzers at this time. There is a huge opportunity in POLs due to the sheer number of them. Good prospecting is needed to find the ones that are CLIA Moderately Complex certified.

- **Volume**
  - Medium to small sample volumes, 1-20 samples / day
  - Since the Westergren method is the oldest method still in the market, ANY sized lab could still be running this method.
  - Higher volume labs are great candidates for the iSED and would see big benefits from our technology.

- **Reimbursement**
  - Accustomed to higher reimbursement rate (~$4.00) vs. semi-automated and automated methods (~$2.00) in US, making it less desirable for them to switch to an alternative method. Reimbursement OUS varies depending on the market ($0.20 -$2.00).
  - Reimbursement is especially of interest to the POL. Most hospital and stand-alone labs will not be as sensitive to this issue, but it may come up.

- **Staff/Skill Level**
  - All hospitals and labs designated as CLIA Moderately Complex will have qualified staff capable of performing all types of testing. Technologists in hospital and stand-alone labs have many competing priorities and due to a reduction in number and skilled technologists to hire, will see value in investing in automation to overcome skilled labor shortages.
  - Skill level in the POL or clinic may be lower, e.g., they are not a Medical Technologist (MT) or Medical Laboratory Technician (MLT) and may have limited experience running analyzers or performing more complex testing.

- **Economic/Financial**
  - Hospitals and stand-alone labs understand the benefits of automation and are willing to invest in automated technologies. Their purchasing process could

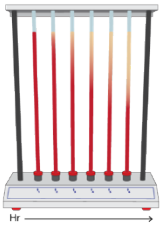
require capital expense approval for purchases and often choose placement type options to overcome an outlay of capital.
    - POLs are much more cost conscious and will see not only an increase in the cost of automating but will also experience a reduction in reimbursement. Creative startup programs to transition them away from manual methods will be key for this market segment.

- **The ideal Westergren customer profile to switch to the miniiSED**
    - Labs running 5-20 samples/day will see significant benefits from reduction of hands-on time for sample handling and processing, TAT to result, and biohazard safety.
    - 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.

- **Workflow**
    - General steps for both workflows
        - **Setup-**Upon receipt of the sample(s), the user would either manually mix or put on a mechanical rocker. Once mixed, samples are decapped and pipetted into the Westergren reservoir or tube, the column is inserted into the reservoir, and the device is placed into the rack designed to hold the tubes upright and stable for the testing period.
        - **Test-**This needs to be in an area free from vibrations, such as a centrifuge, and in a controlled temperature environment. The user sets the timer for 60 minutes and resumes other activities. When the timer goes off each tube is read and results are recorded. If another sample comes in during this time, they follow the same process and a second timer would be running. The user would need to multitask to manage these concurrent runs with different timers.
        - **Read/Report-** When the timer goes off the user must stop the task they are doing to read, record and report the test result. Recording the test result could mean entering the result into the LIS, as in a hospital or stand-alone lab, or into the electronic patient record, as in a POL.
        - **QC-**Should be run daily before testing patient samples and requires the full 60 minutes just like running patient samples. Depending on lab operations there are two QC scenarios: the QC might be run concurrently with the first batch of samples, with assumptions that the QC results will be valid and the patient test results in that run will also be valid, or the QC might be run before any patient samples are tested. In this scenario, the patient samples would need to wait the full 60 minutes to be tested until the QC is completed and considered valid.
    - Workflow #1 – Tests are run in batches. Samples are accumulated as they come into the lab until enough have come in to run a batch of 8-10 samples, enough to fill a rack. This is done to allow the user to set up several samples at once in the rack with a single timer. The user then goes about other tasks for the 60-minute test period and completes the process as described above.
    - Workflow #2 –If the daily volume is low or they do not get samples every day, tests are run as they arrive in the lab. For this scenario they may not run QC until

a sample is received, and then they would use one of the two scenarios described above.

Comparison of miniiSED and Westergren

	miniiSED 	Westergren Method 	WINNING METHOD
Testing methodology	Photometric Rheology DIRECT measurement of RBC aggregation	Gravimetric INDIRECT measurement of RBC sedimentation	miniiSED
Total Minimum Volume	Up to 500 µL (varies by tube type)	1 -2 mL	miniiSED
Testing Volume	100 µL	1 -2 mL	miniiSED
Throughput Max tests/hour	180 samples/hour	Samples / hour limited by the number of tubes and racks available	miniiSED
Time to result / Analysis time	15 seconds Note: to ensure accurate results, samples must be mixed for at least 3 minutes on a mechanical rocker prior to testing	60 minutes	miniiSED
Random access-always ready to accept samples	Yes	Yes, but depends on the number of racks because racks hold up to 10 samples at a time.	miniiSED
Loading samples	Insert primary EDTA tube, one tube at a time every 15-20 seconds	Pipet and rack up to 10 samples in a batch	miniiSED
Mixing on Board	No 3 minutes (minimum) mixing manually or on a mechanical rocker	No	SAME
Printer	Optional	No	miniiSED
Interface Capability	Yes; uni-directional	No	miniiSED
Sample Tube Requirements	13X75 EDTA with pierceable cap Compatible: BD MAP, BD Vacutainer, Greiner miniCollect, Sarstedt S-Monovette	Any tube with K2 or K3 EDTA	miniiSED
Quality Control	Human-based, bi-level 60-day open vial stability 18-month shelf life RT storage Online QC program	Purchase controls of their choice with varying specifications; 60 minutes to run	miniiSED
Temperature Control	Yes	No	miniiSED
Automated Washing	Yes automatic wash after 15 min or initiated by user	N/A	miniiSED
Barcode reader	Yes, internal	No	miniiSED
Hands-on time / Process Steps	4 steps: mix sample for a minimum of 3 minutes manually or on a mechanical rocker, insert the tube into the sample port, remove the tube from the sample port, record result or send to LIS Hands-On Time: ~20-30 seconds	9 steps: mix sample for a minimum of 3 minutes, decap, pipet/transfer, recap, insert Westergren tube, set in rack, set timer, return in 60 minutes, read result, record result Hands-On Time: 10-15 minutes depending on speed and skill of user	miniiSED
Cost / Reimbursement	$1-$2 / test $3,150 (US), if not under the placement program Controls: $600 / quarter Accessories: $65 / quarter Reimbursement: ~$2.20 / test (US)	Tubes ~$0.10 Racks can cost $80-$200 (reusable) Controls Reimbursement: ~$4.00 / test (US)	Westergren

References are listed at the end of the Guide

Summary of comparison

Key reasons to choose the miniiSED:

- **Accurate results**
  - Results using the Westergren method are influenced by the HCT and MCV, which can give an inaccurate result. It is also affected by external factors such as vibrations from a centrifuge and temperature of the lab.
  - The miniiSED uses photometric measurement of red blood cell aggregation, which is not affected by the hematocrit (HCT) or mean corpuscular volume (MCV) of the sample; vibrations do not affect the result and the temperature is controlled.

- **Reduced hands-on time**
  - The Westergren method takes between 5-10 minutes of hands-on time: manual or sample mixing on a rocker, decap the sample, pipet into the Westergren tube, recap the sample, rack the tube, and set a timer; after 60 minutes the user returns to visually read and record (write or type) the results in the patient record.
  - The miniiSED requires either manual or mechanical mixing for at least 3 minutes on a rocker prior to insertion into the analyzer, then removal of the sample after test completion (15 seconds analysis time). There is no decapping/recapping of samples or pipetting of blood. Results may be recorded manually or transmitted via an LIS.

- **Reduced time to result (TAT)**
  - Westergren takes 5-10 minutes of hands-on time plus 60 minutes of test time per sample.
  - The miniiSED time to result is 15 seconds. Results may be manually recorded, printed or transmitted via LIS.

- **Reduced sample volume and risk of QNS**
  - The Westergren method requires up to 2 MILLILITERS (mL) of sample, increasing the chance of quantity not sufficient (QNS) and sample re-draw from the patient. This volume can be prohibitive to testing pediatrics or small sample volumes.
  - 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, which is 1/10th to 1/20th the amount of sample needed for Westergren.

- **Increased user safety**
  - Samples must be decapped, pipetted into the Westergren tubes, recapped, and then properly disposed after testing. The Westergren Method creates a lot of user biohazard exposure via aerosols and potential contact with blood during these steps.
  - The miniiSED is a closed system. The capped EDTA tube is placed directly into the analyzer where a needle pierces the cap and takes the sample directly from the primary EDTA tube inside the analyzer. The operator is not exposed to the sample or the needle through this process. Waste is captured in the self-contained, biohazard container or is disposed directly into a drain.

Manual Westergren wins over miniiSED ONLY on price and reimbursement:

- Price
  - The average selling price for Westergren ranges from $150 to $250 (including rack and tubes) and varies by market. The cost per test is ~$0.10 to $0.50 / test; racks are reusable. Other supplies needed would be Controls (which could be expensive- ask what the customer is paying for QC) and pipets for sample transfer.
  - In the US, the average selling price for automated ESR is $.75-$2.00, dependent on volume. Seditrol® costs ~$2,400 / year; miniiWASH®, miniiWASTE® and paper would average about ~$260/year.
- Reimbursement
  - Labs receive about $4 / test (US) compared to automated methods at ~$2.20 / test (US). Often labs are not willing to switch to an alternate method because they will pay a higher price per test AND receive lower reimbursement, which impacts profitability.
  - This is especially important to know when speaking with POLs who have more visibility to these financials. Hospitals and stand-alone labs are more concerned with labor costs, productivity, and overall cost of operation so this will be less of an objection from them.

Common customer objections to switching:

- Volume is too low to justify investing in automation
  - Make it as easy as possible for the customer to switch. Take advantage of a placement program where the analyzer is acquired via purchase of test cards and no capital outlay is required. Explore the possibility of a Starter Kit that includes controls and accessories to minimize the cost of switching.
- Reimbursement is lower and price is higher
  - This is a difficult combination and a true objection as the lab receives a higher reimbursement rate of ~$4 / test for Westergren Method compared to ~$2.20 / test for automated ESR. What they do not see is the cost of their labor and other non-tangibles that consume this additional reimbursement.
  - You must sell the value of automation to get them to switch. Use the “miniiSED wins over Manual Westergren Method” to overcome these reimbursement and price issues. The benefits of reduced hands-on time (labor), reduced TAT (physician satisfaction, reduced overtime and meeting lab TAT goals), reduced errors (cost of errors and lab reputation), and increased safety (employee health and satisfaction) are not quantifiable but have value to the lab and to the user.

SPIN Questions to Identify and Address Pain Points:

Pain Point #1: Westergren method impacts result TAT.

Situation questions:

1) How many sed rates do you run daily?

- If the end user is running more than 20 sed rates / day, having a manual process is not efficient for the lab and is very time consuming. The following P, I and N questions will be even magnified the more samples they test manually.

2) How do you run your sed rates each day?
   - Batch?
   - Upon arrival?
   - Do you receive orders for STAT sed rate? How many STAT samples do you receive?
3) How do you run your QC?
   - Most labs run patient samples after QC has finished. This means they are waiting over an hour before patient samples can be tested.
   - Some labs will run QC along with their first batch of samples. There is some risk that those sample results are invalid if the QC fails.
   - Some labs do not run QC at all. These will be tough to convert due to the cost and process of running QC which is not familiar to them.

Problem questions:

1) If they are batching: How many batches do you run per day? How many do you wait to batch?
   - Most labs batch samples, potentially holding up all results until they receive sufficient samples to run a full rack of Westergren tubes (~10).
   - With the miniiSED, you can run sed rate as soon as samples come into the lab and results are in 15 seconds.
2) Do you hold up your testing until after QC is run?
   - The miniiSED QC takes 9 minutes to complete, and since Seditrol® does not have to be refrigerated the end user can run QC immediately at the beginning of the shift.
3) How do you handle STAT samples?

Implication questions:

1) How does waiting to batch samples impact your overall TAT? Do you ever get calls from (nurses, doctors, ER) looking for the results? How do you explain to them that it takes 1 hour to do this test?
2) What happens if your QC fails? What do you do? If you ran it with your samples, do you report the results or wait and run another QC run before you report the results?
3) What happens when a sed rate comes in right before the end of the shift or the workday? Do you have to stay and work OT? What if it is a STAT?
   - Labs do not like paying overtime (OT) and managers can allow only a certain number of OT hours per week. If they have a miniiSED, this would minimize the possibility of having OT and employee stress is reduced.

Needs payoff:

1) Would it improve employee satisfaction and help your budget to have an analyzer that can test samples upon arrival, with a 15 second time to result?

2) What if you had an analyzer that allowed you to test every sample as soon as it arrives, in under a minute?
3) Would the ability to perform STAT sed rates eliminate overtime for late sed rates?
4) Would having an analyzer that takes less than 1-minute hands-on time and results in 15 seconds be beneficial to your workflow?

Pain Point #2: Westergren requires significant sample volume that can lead to QNS and sample redraws.

Situation questions:

1) What sample volume does your Westergren method require?
2) What types of sample tubes do you receive for sed rate testing?
3) How often do you have sed rate ordered on pediatric samples?
    - Some labs might send these samples out since they usually have a volume too low for Westergren and could be performed on a method that requires less volume
4) What percentage of your Hematology samples also have sed rates ordered on them? Do you run sed rates on your Hematology samples or are they separate samples?

Problem questions:

1) How often do you receive samples that have insufficient volume to run the Westergren Method?
    - Some samples might have too low volume to run Westergren and the lab will request a patient re-draw, which can upset the patient and labs want to avoid this at all costs.
2) How do you handle QNS samples? Do you request a new sample?
    - Most patient blood samples have multiple tests requested and labs need to be conservative on how much sample they use per test to prevent depleting the sample. Since the Westergren method requires a large sample volume the risk of QNS is greater.
3) How do you handle pediatric samples? Do you ever need to send samples out to a reference lab? What is the TAT for samples sent to a reference lab for testing and how does that impact your TAT?
    - If they cannot run on their method they could send to a reference lab that is using a method that requires lower volume (e.g. iSED!). Send outs increase their cost and TAT.
4) How often do you have to repeat a sed rate?

Implication questions:

1) What happens when you are unable to report a result due to QNS?
    - Nurses and physicians are calling the lab for the results-some are quite vocal and complain to the pathologist when results are not provided as expected.

- This could cause a delay in diagnosis, treatment, discharge from the hospital or release from the doctor's office if the patient is waiting for their lab results.

2) What is the impact of redraws on your patients, especially pediatrics?
   - Cost of employee (time, labor) and the supplies (tubes, needles, etc.) to do the redraw.
   - Turnaround time-labs have overall metrics to hit TAT goals; sed rate is one of the biggest offenders to hitting this metric. If they don't "get it right the first time" and have to do a redraw, the TAT will significantly be impacted.
   - Patient (or in the case of pediatrics, the parent) satisfaction-hospitals have become increasingly aware of the amount of blood they draw and have worked to minimize that by using methods that reduce the amount of blood needed. Parents get especially emotional about repeated blood draws on their children.
3) How does sending samples to a reference lab impact your budget and TAT?
   - Labs are very conscious of the cost of sending tests out and will want to avoid this. In addition, sed rates already take an hour, so sending out will not be something they want to do.

Needs payoff:

1) Would it reduce the number of QNS samples to have an analyzer that 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).
   - The miniiSED would prevent QNS issues and can test pediatric samples directly from the BD MAP tube. No need to send the sample out or request a re-draw.
2) Would you be interested in a testing method that eliminates QNS, redraws and potential send outs?
3) What if I could offer you an automated analyzer that eliminates QNS and improves your TAT, with no capital outlay?
   - Understand the customer's financial situation and offer a placement promotion when needed. If necessary, a Starter Kit might also help for low volume customers.

Pain Point #3: Westergren introduces a safety risk to the user from biohazard exposure and increased risk for human errors.

Accidents, especially needle/sharp punctures or skin/eye exposure to blood, are expensive events in the lab due to the subsequent procedures that must be followed to document and follow up on these incidents, not to mention they are physically and emotionally stressful on the exposed person who now has the added concern that they may have been exposed to an infectious disease. These events are required to be reported through worker's compensation and entail sending the exposed person to the Emergency Room where they must be treated, especially for any puncture wounds, but also baseline tested for infectious diseases such as HIV and Hepatitis. If not already vaccinated, the exposed person will receive prophylactic injections for Hepatitis. A case is created and filed with the laboratory or hospital safety manager or OSHA manager, and additional testing follow up must be performed to ensure no infectious disease has developed.

Situation questions:

1) What is your process setting up Westergren?
    - Tubes are either mixed by hand or placed on a rocker before setting up the test. Then there are 3 main biohazard exposures the user will encounter:
        - Decapping the sample. Removal of a cap requires a twist and pull sideways motion, potentially sending aerosols toward the user's face.
        - Pipetting or pouring the sample into the Westergren reservoir.
        - Inserting the Westergren tube into the reservoir. The user twists the tube, so the diluted blood fills up to the zero mark at the top of the tube. If the end user twists too hard, blood could come shooting out the top of the tube. Most users will wear a face shield (Personal Protection Equipment, PPE) to prevent blood from potentially squirting into the face or onto the lab bench.
        - A potential 4th exposure could be that if blood does exit the top of the tube or there is a spill during decapping or pipetting, it must be cleaned up using good laboratory practices with disinfectant and disposable materials thrown into a biohazard receptacle.
2) Do you perform the transfer from the primary EDTA tube to the dilution tube on the bench top or under a hood?
    - Most users will wear a face shield when setting up Westergren, to prevent any blood from accidentally splashing on the face, in addition to gloves and lab coat (standard PPE).
    - Laboratorians are trained to treat all blood as potentially infectious, assuming it could contain bloodborne pathogens like HIV, hepatitis B and hepatitis C.
    - Transfer of sample from the primary tube increases the biohazard exposure risk to the user and increases the risk of human error, from loss of traceability to the primary tube, and potential labeling errors of the secondary Westergren tube which must be properly labeled with patient identification.

Problem questions:

1) How often are you exposed directly to blood when setting up Westergren?
    - When decapping, does blood ever spray or aerosol from the tube?
    - Have you ever pushed the Westergren tube too hard into the reservoir and had blood spray from the top?
    - Have you spilled any blood while pipetting or transferring patient sample into the Westergren tube?
    - The miniiSED requires no sample decapping, no pipetting or transfer of sample, no exposure to blood from the sample or from the waste, which is self-contained in the miniiWASTE container.
2) How much waste does your lab produce from setting up Westergren? How many biohazard bins/sharp containers do you go through a week? What is your current hazardous waste disposal cost and how much of that waste is from Westergren?
    - Waste management is expensive for labs because it is potentially biohazardous material and must be properly disposed in red biohazard containers. These

containers are picked up by a bio-waste company for proper disposal and the lab is charged per container of waste.
    - The waste produced from Westergren is the depleted EDTA tube, dilution tube, transfer pipettes, and Westergren tube. Westergren tubes are very long and can quickly fill up a sharps/biohazard container. It also depends on their volume on how quickly the biohazard bins are filled.
    - The cost of this disposal is probably more visible to the POL and labs outside a hospital. Disposal of sharp containers and hazardous waste bins can be costly depending on the lab's volume. If the lab generates 4-8 boxes of waste a month, disposal costs can range from $150-$400 per month.
    - The miniiSED produces minimal waste and is collected in a 250mL waste container that can be dumped down a dirty sink drain (depends on the lab waste protocol) or disposed in a waste container.
3) How do you label your Westergren samples in the rack? Do you hand write, use barcodes or tags? How do you maintain traceability between the secondary label and the primary sample tube?
    - When transferring from a patient sample to another tube, it must be labeled with proper patient information-this is called "positive sample id" or "traceability". The patient information can be stored in a barcode, where the end user scans the barcode for proper tube identification. The use of a barcode is the least error-prone method because handwriting patient information can introduce transcription error and illegible handwriting, but smaller labs, including physician office labs, may not have electronic ways to label their samples and rely on handwritten identification. Loss of traceability and recording errors damage the reputation of the lab and requires a re-draw and retest of all samples in question, that is, if it is discovered. In many cases it is not even detected, and results are recorded incorrectly with no indication that there is anything amiss.

Implication questions:

1) Biohazard exposure
    - What do you do when you have aerosol exposure from decapping?
    - What happens if a Westergren tube breaks in the process of setting up?
        - Sample would be lost when this happens and could cause a re-draw request if no sample is left in the EDTA tube. As previously discussed, labs do not want to request re-draws.
        - Ask if there has been any injury from breaking a Westergren tube.
2) Cost of biohazard waste
    - How does the quantity of biohazard waste impact your budget?
    - Are these costs rising? Is there anything you can to do reduce them?
    - What happens if your volume grows, as you probably have seen during the pandemic?
3) Loss of traceability/transcription errors
    - What happens if there is loss of traceability with the primary sample tube ID?
    - How do you know if there has been a transcription error with the patient ID or result reading?
    - What happens if you do not catch the mistake?

- If you do find an error, do you have to request a re-draw and perform the test again?
    - The lab will have to perform the test again in the case of a sample swap. If the transcription error can't be resolved, the test will have to be performed again. If there is not enough sample, a re-draw might be requested, which labs want to avoid.

Needs payoff:

1) Would your operators feel better about using an analyzer that is a closed system, with no exposure to blood, and features that increase user safety?
    - The miniiSED samples directly from the primary EDTA tube, requiring no decapping, sample pipetting or manual tube transfers, and captures waste in a self-contained biohazard container for increased user safety.
2) Would it benefit your budget if you had an analyzer that produced minimal waste?
    - Waste consists of the self-contained miniiWASTE container that can be poured down the drain (dependent on lab procedures) or discarded in a biohazard container.
3) Would it be beneficial to your lab to have an analyzer that has an on-board barcode scanner for accurate patient identification and connects to your LIS for easy and accurate transfer of patient results?
    - The miniiSED has an on-board barcode scanner and connects to the laboratory information system (LIS). This helps eliminate the risk of human errors from transcribing results and sample swaps.

Pain Point #4: Westergren results are influenced by HCT, MCV, temperature, and vibrations.

Situation questions:

1) Where do you have your Westergren setup station?
    - Westergren cannot be exposed to sunlight or next to any equipment that can cause the lab bench to vibrate, such as a centrifuge. Labs will have a corner where only Westergren is setup. If the lab is too cold or too warm, this has the potential to falsely increase or decrease ESR results.
2) Do you monitor temperature in your lab?
3) What percentage of your ESR samples have hematology testing too? How often do you have the HCT and MCV results on ESR samples?

Problem questions:

1) What do you do if the lab temperature is above or below room temperature? Do you still run Westergren?
2) Do you receive many samples with a high or low HCT or MCV?
    - High or low HCT or MCV can produce falsely increased or falsely decreased ESR results. Inaccurate results will be reported with no correction is made for high/low HCT or MCV results.

Implication questions:

1) What happens to samples with a high or low HCT or MCV? Do you still run them on Westergren?
    - Labs will run the Westergren and the physician (doctor ordering the test) will take into consideration the CBC result to determine if the sample had a high or low HCT or MCV. Most end users will not know if a sample has a high/low HCT or MCV unless they purposely review the Hematology results. Some labs will utilize a correction protocol for these abnormal results, but others will not, reporting inaccurate results.
2) What happens if an inaccurate result is reported out?
    - In most cases there is no knowledge that the result was affected by high/low HCT or MCV, temperature or vibration. But if it is discovered, hospitals and labs can be sued for malpractice if inaccurate results are reported out to physicians. Not only legal issues could result but can lead to loss of reputation for the lab, impact to diagnosis or treatment, and ultimately patient distress and dissatisfaction.

Needs payoff:

1) Would it be beneficial to have an analyzer that is not impacted by HCT, MCV, temperature or vibrations?
    - The miniiSED provides accurate results by measuring RBC aggregation vs. sedimentation, like the Westergren, which is not affected by temperature, vibration, or abnormal HCT or MCV results.