iSED®

Erythrocyte Sedimentation Rate

FAQ's

Cat.112-00101

ALCOR SCIENTIFIC

General Product Information

1. **What is the test time after mixing?**
   20 seconds for blood samples and control solutions.

2. **How much sample is used in testing?**
   100 microliters for blood and controls (500 microliters of dead volume is required in a standard EDTA tube).

3. **What is the minimum sample volume?**
   500 microliters in standard EDTA tubes. 250 microliters in BD Microtainer MAP tubes.

4. **What size EDTA tubes are required?**
   13X75 mm or 13X72 mm with pierceable caps BD Microtainer MAP tubes are also an acceptable sample type.

5. **How long is the mix time?**
   iSED mixes samples for 3 minutes (180 rotations) before testing as recommended in the CLSI guidelines.

6. **How many samples can run at the same time?**
   iSED has a 20-position sample wheel with continuous feed that accommodates single or multiple samples in whatever order they are received. An open position is always available.

7. **What is the linear range? How does it compare to the competition?**
   iSED range is 0 to 130. Semi-automated systems range 0 to 140.

   NOTE: The difference in ranges to the competition is clinically insignificant. Patient treatment is no different if test result is 130 or 140.

8. **If new samples are placed after testing has started for initial samples does the mix or test time change for the samples that are already in progress?**
   No. *iSED* is intuitive and continues testing for samples that are in process. All samples only go through a 3 minute mix and 20 second test time.

9. **What type of service is provided if the analyzer goes down?**
   If an analyzer goes down there are 3 phases to the troubleshooting process.
   1. Customer can review *iSED* screen warnings/error messages and refer to the Operator's Manual for some solutions.
   2. Customer can call ALCOR customer service to troubleshoot over the phone and they will be instructed on to how access the settings screen if needed.
   3. A replacement may be sent to the customer if customer service is unable to resolve issues via the phone.

10. **How are patient ID's entered?**
    Patient ID's can be read by the internal barcode reader or entered manually through the touch screen keypad or assigned by *iSED* with an 8 digit ID.

11. **Is *iSED* LIS compatible?**
    Yes, *iSED* is LIS compatible.

Technology:

12. **What type of technology does *iSED* use?**
    iSED uses advanced Rheology Technology. It captures the impact of the most critical phase of the early-phase in the phenomenon of RBC sedimentation, the so-called Rouleaux formation. This is the critical phase of ESR because the size of the red blood cell aggregates is directly proportional to the ESR values which increase according to the presence and intensity of inflammation. The technical innovation of the *iSED* consists of measuring **directly** the aggregation of the red blood cells while the traditional ESR methodologies measure **indirectly** the aggregation of the red blood cells**.**

After measuring the aggregation directly, the *iSED* produces ESR results in mm/hr. Utilizing EDTA blood from the primary tube, results are reported within seconds. The *iSED* is less affected by variables commonly associated with traditional ESR testing, the most important of which is the **hematocrit.** This explains the differences sometimes observed during a comparison with Westergren or modified Westergren methodology.

13. How does *iSED* ensure the sample is mixed well?

iSED has a 3 minute mix cycle as required by CLSI and a unique patented technology that gives an ultrasonic pulse to break apart the blood cells before testing after the sample is mixed.

- **a.** *iSED* aspirates the sample and places it in a temperature controlled reading cell where it receives an ultrasonic burst to ensure a "perfect" disaggregation of the red blood cells. Then the *iSED* measures the aggregation of the cells by taking 500 reading of the complete aggregation reaction profile.
- **b.** *iSED* measures the first portion of what the Westergren method measures and this is the cause of the final Westergren result.
- **c.** The algorithm extrapolates what is going to happen in 60 minutes like Westergren.

14. Do external factors affect *iSED* results?

No. *iSED* ESR results are unaffected by the variables commonly associated with traditional ESR testing such as mixing, temperature, vibration, and operator variability. However, you should not place the *iSED* on a bench next to a centrifuge.

15. Are *iSED* results affected by the Hematocrit?

No The method used by the iSED for determining sed rate is much less affected by hematocrit than traditional ESR methods. It measures sed rate independent of both hematocrit and MCV (mean corpuscular volume).

16. Are iSED results affected by lipemia, hemolysis, or other conditions of the patient?

Extreme lipemia changes the viscosity of the sample, interfering with the measurement. The iSED will give an error message if it detects this change. Hemolysis disrupts the RBC's since the iSED detects RBC aggregation, if hemolysis has occurred to such a degree that aggregation of RBC's has been reduced, it will affect the results. Sickle Cell anemia and multiple myeloma are two conditions that are incompatible with an accurate ESR result on iSED, or Westergren method. ESR results are not accurate in patients with multiple myeloma, regardless of what method is used.

Myeloma affects iSED and the relative ESR measurement, because multiple myeloma is not detected by RBC aggregation. ESR is increased in case of multiple myeloma, but is not related to an inflammatory condition, as the sedimentation is increased due to a calcium crystal formation that happen in the 30/40 min of the sedimentation process. So, to be clear, this is not a downfall of iSED, but rather laboratorians should be aware of the interference myeloma has on any ESR measurement.

17. How does the iSED handle a specimen that may contain a clot?

The system is designed to be unaffected by micro clots. Because the iSED uses a differential measurement system a static clot does not interfere with the final measurement, as this shows no variation in the detected reaction. The iSED has a needle designed to prevent clots with interfering dimensions from being aspirated into the hydraulic circuit and the reading cell. If a clot prevents the sample aspiration, the iSED will retry the aspiration process 3 times before it gives you an error code "unable to withdraw" and ejects the sample. After this error, a washing procedure is performed to remove potential clots, and even in this case, up to 3 attempts are performed in case of a failure to remove the clot on the previous wash cycle, before giving an error code. Lastly, there is a simple bleaching procedure available to clean the line if the automatic wash is not able to clear the instrument.

Calibration

18. How is the device calibrated?

Every time the analyzer performs a wash cycle it checks the photometer light levels to see if the values are the same to ensure that the device is reading properly. If the values are different the analyzer self- compensates. If the analyzer is unable to self- correct the system will give a warning indicating that the wash is NOT OK.

19. Is an external calibrator required?

No and external calibrator is not required.

20. **For laboratories using LIS and do not require printed results, can the printing feature be 'Turned Off'?**
    There is no way to turn off the printing feature at this time. To resolve this issue simply remove the paper from the printer.

21. **What happens if a sample is entered but does not have a recognizable barcode or the Patient ID hasn't been manually entered?**
    iSED will automatically assign an 8 digit identification number based on the sample position number, test in session, and session of day.

22. **How many times can an EDTA tube be pierced without degrading the performance?**
    An EDTA tube can be pierced ten times.

23. **Does *iSED* work with pediatric tubes?**
    iSED works with the BD Microtainer line (product ref. # 363706). Other pediatric tubes are extremely difficult to mix and cannot be used.

Accessories

24. **What is a Test Card?**
    A Test Card is a small card (looks like a credit card) containing a certain number of tests. Once inputted into *iSED*, the tests will be loaded and available test units will show on screen.

    NOTE: This works similar to minutes on a prepaid phone card.

25. **How are they packaged?**
    They are made containing tests in quantities of 500;1,000; 2,000; 5,000; 10,000; or 20,000 tests.

26. **Are quality control tests counted as a test?**
    Yes, the quality control tests are processed and counted as normal samples.

27. **How do operators know how many tests are loaded?**
    iSED has a built-in test counter. The number of remaining tests can be found on line 2 of the display.

28. **Do I have to use the thermal paper that comes with the *iSED*?**
    Yes, unauthorized use of the optional thermal paper will cancel the One (1) Year Warranty.

29. **How many rolls of printer paper come in the package?**
    3 rolls 57mmm x 25 mm. Reorder # DS-05233.

30. **What volume of iWash is in the bottle?**
    500 mL/bottle

31. **How many bottles come in a pack?**
    4 bottles / pack (reorder # 112-12-001)

32. **How many wash cycles can be ran with each bottle of iWash?**
    Approximately 150 wash cycles per bottle. The system uses approximately 3 ml per wash cycle.

33. **What is the composition of the iWash?**
    The iWash is Type 1 Ultra-Pure water which is ion free, bacteria free, and organic free. Type 1 Ultra-Pure water meets and exceeds Clinical Laboratory Reagent Water specifications.

34. **What is the shelf life of the iWash?**
    We are currently in the midst of a stability study of the iWASH. We've determined stability for 6 months from date of manufacture (as of October, 2014), but we hope to extend this to at least 12 months at the conclusion of the study.

35. How often is a wash cycle?
A wash cycle is run after fifteen (15) minutes of non-use or On-Demand. A wash cycle should always be run prior to turning off the instrument.

36. Is a wash cycle ran or required after every test?
No. The first 90 microliters of the blood sample is used to remove carry over from the prior sample. The next 10 microliters of blood is used for testing.

Blood Sample Handling

37. How soon must the test be performed after the blood sample is drawn?
According to CLSI guideline; blood drawn from the patient directly into EDTA tube is stable to test within 6 hours from venipuncture (4hrs per page 18 of the CLSI Guidelines HO2-A5) and up to 24 hours, if refrigerated (per page 4 of the CLSI guidelines HO2-A5).

38. Do blood samples need to be brought to room temperature before use?
Yes. This usually takes about 15 minutes. Please check with your specific laboratory's standard operating procedures for blood sample handling.

Seditrol® Quality Controls

39. What controls does the *iSED* use?
Seditrol QC are human-based whole blood quality controls.

40. How are the controls packaged?
Each package include six (6) 4.5mL tubes – 3 normal (white top) and 3 abnormal (blue top) reorder # DSC 06.

41. How many times per day should QC be run?
Alcor recommends at least once per day, however, it is up to each individual lab to determine how many times per day QC should be run. Please check with your specific laboratory's standard operating procedures for quality controls.

42. Does the Seditrol QC need to be refrigerated?
No. The QC can be kept at room temperature (18° to 30° C), even after piercing.

43. What is the open vial stability of Seditrol QC?
The open vial stability of Seditrol Quality Control is 31 days.

44. What is unopened shelf life of Seditrol QC?
The unopened shelf life of Seditrol QC is 18 months from the date of manufacture.

45. What is the test time for controls?
The test time for Seditrol is 20 seconds after a 5 minute mix cycle.

46. How many times can Seditrol QC tube be pierced without degrading the performance?
Seditrol QC can be pierced up to 40 times without degrading the performance.

47. Does *iSED* know if the control test performed is in range?
No, the user must compare results to the Seditrol package insert

48. Does *iSED* know when controls have expired?
No, the user must compare results to the Seditrol package insert

49. How many QC tests can be performed with one control solution kit?
A control kit comes with 6 vials of control (3 high / 3 low)

- If a lab is running QC once per day = 3 month supply
- If a lab is running QC twice per day = 1 1/2 month supply
- If a lab is running QC three times per day = 1 month supply

50. How many reading sensors does *iSED* have to QC?
iSED has one reading sensor to QC.

51. Does *iSED* have a real time, on-line QA program?
Yes. The *iSED* system includes a real time, on-line QA program that requires a password for access that labs can access for Levy Jennings reports and to see how their QC results compare to their peer group.

Correlation Studies

52. How well does the *iSED* correlate to the Westergren method?
iSED has been shown to have a 95% or better correlation to the Westergren method.

Needle Replacement

53. When should the sample needle be replaced?
It is recommended that the sample needle be replaced after 30,000 piercings. Contact Technical Support for instructions on replacing the needle.