iSED® Family of Analyzers Correlation Protocol

For miniiSED®, iSED, iSED ELITE, and iSED PRO Analyzers

Correlation studies (or method comparisons) are performed as part of method validations to assess whether two analytical methods are comparable. Samples are analyzed using the current method (reference method) and the new (test) method. Statistical analysis is used to determine agreement.

Precision and Carry Over studies should also be completed during method validation.

SAMPLE REQUIREMENTS

- At least 60 samples with a value distribution between 15 to 105 mm/hr[1]
    - At least 40% of the samples should be abnormal with results over 35 mm/hr
- Samples should be from both males and female subjects
- Samples must be collected in EDTA anticoagulant 13 x 75 mm capped sample tube (lavender top)
    - There must be enough sample volume to run on the test method and reference method (the iSED family of analyzers requires approximately 500 ul minimum volume)
- Samples must be free of clots and not hemolyzed or lipemic upon visual inspection
- Samples must be processed within four (4) hours from venipuncture and kept at room temperature
- HCT and MCV data must be collected for each sample to assist data analysis
    - ESR results are affected by anemia, so it is recommended to use samples with HCT results within the reference range if possible

For all analyzers: ***In some instances, particularly for low volume laboratories, it may be difficult to meet the sample requirements. The chances of a failed correlation are increased if sample requirements are not met. If a correlation is not passing and the sample set is too small, it will be necessary to continue testing more samples.***

For miniiSED correlations only: ***Patient samples must be well mixed prior to testing. If automated mixing is not enabled on the miniiSED analyzer (please reference Automated Onboard Mixing Protocol for miniiSED, Document # 1017-28-007), samples must be mixed by mechanical rocker for a minimum of three (3) minutes before testing. Hand mixing is not sufficient. Testing must occur immediately after mixing to ensure accuracy of the results.***

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INSTRUMENTS AND MATERIALS

- Current erythrocyte sedimentation rate (ESR) analyzer/method
- miniiSED, iSED, iSED ELITE, *or* iSED PRO Analyzer
- SEDiTROL® ESR Controls: Level 1 & Level 2
- HCT and MCV results for each sample
- iSED Family of Analyzers Correlation Worksheet, Document # 100-23-011
- Precision Test Protocol, Document # 100-07-013
- Carry Over Protocol, Document # 100-07-012
- An automated mixing platform

RUNNING QUALITY CONTROLS

SEDiTROL Quality Controls Level 1 & 2 should be run on the miniiSED, iSED, iSED ELITE, or iSED PRO analyzer each day of correlation testing. Quality Control protocols for the reference method should be adhered to during correlation testing.

The SEDiTROL Quality Control material must be thoroughly mixed to ensure accurate results. It is recommended to mix the controls on a mechanical rocker or rotator for 25 minutes prior to the first use of a new vial and then for five (5) minutes on each subsequent use. Hand mixing is not sufficient.

1. Mix SEDiTROL Levels 1 & 2 on an automated mixing platform for the appropriate amount of time (refer to SEDiTROL Instructions for Use, Document # 315-09-011).
2. Run controls on miniiSED, iSED, iSED ELITE, or iSED PRO according to the analyzer-specific Instructions for Use (refer to Table 1).
3. Record results on Correlation Worksheet
4. Repeat steps 1-3 each day of correlation testing.

The testing order of SEDiTROL Levels 1 & 2 should be alternated to ensure uniform usage.

Table 1: Instructions for Use

miniiSED Operator's Manual	1017-09-001
iSED Operator's Manual (serial #s <5000)	112-09-043
iSED (serial #s >5000) / iSED ELITE Operator's Manual	222-09-007
iSED PRO Operator's Manual	120-09-007

RUNNING SAMPLES

It is recommended that samples be tested first on the test method (miniiSED, iSED, iSED ELITE, or iSED PRO) followed by the reference method. Samples should be run on both methods within 60 minutes of each other.

1. Run samples on miniiSED, iSED, iSED ELITE, or iSED PRO according to the analyzer-specific Instructions for Use (refer to Table 1).
2. Run sample on the reference method.
3. Record results on the Correlation Worksheet.
4. Record HCT and MCV results for the sample on the Correlation Worksheet.
5. Repeat steps 1-4 for all samples.

DATA ANALYSIS

Complete the Correlation Worksheet and return to ALCOR® Scientific at: techservice@alcorscientific.com

ALCOR Scientific Technical Support will use statistical software to perform the regression analysis.

A correlation can be considered passing and the methods equivalent if the following conditions are met[1]:

1	The 95% confidence interval for b (slope) contains the value 1
2	The 95% confidence interval for a (intercept) contains the value 0
3	The Cusum test value P is >0.05

Complete Precision and Carry Over Protocols along with worksheets as part of method validation and to assist in correlation data analysis.

REFERENCES

1. CLSI. Procedures for the Erythrocyte Sedimentation Rate Test; Approved Standard—Fifth Edition CLSI document H02-A5. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.