



## iSED<sup>®</sup> Family of Analyzers Precision Protocol

For miniSED<sup>®</sup>, iSED, iSED ELITE, and iSED PRO Analyzers

The assessment of precision is part of the process of validating a method to confirm that it is suitable for use. Precision is the closeness of agreement between independent results of measurements obtained under specified conditions; it is solely related to the random error of measurements and has no relation to trueness/accuracy.

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

### SAMPLE REQUIREMENTS

- One sample from each quartile of the erythrocyte sedimentation rate (ESR) analytical range<sup>1</sup> as per Table 1:

**Table 1: Sample Requirements**

Quartile (ESR Value)	Number of Samples Needed	Minimum Volume Required
1-30 mm/hr	1	1.5 mL
31-60 mm/hr	1	1.5 mL
61-90 mm/hr	1	1.5 mL
>90 mm/hr	1	1.5 mL

- Samples must be whole blood collected in EDTA anticoagulant 13 x 75 mm sample tubes (lavender top) with a pierceable cap with at least 1.5 mL volume
- Samples must be free of clots and not hemolyzed or lipemic upon visual inspection
- Samples must be processed within four hours from venipuncture and kept at room temperature

If samples in Table 1 are difficult to obtain, the alternative quartiles in Table 2 may be considered:

**Table 2: Alternative Sample Requirements**

Quartile (ESR Value)	Number of Samples Needed	Minimum Volume Required
10-20 mm/hr	1	1.5 mL
21-40 mm/hr	1	1.5 mL
41-60 mm/hr	1	1.5 mL
61-105 mm/hr	1	1.5 mL

### INSTRUMENTS AND MATERIALS

- Samples as defined in the Sample Requirements section
- miniSED, iSED, iSED ELITE, or iSED PRO Analyzer
- iSED Family of Analyzers Precision Worksheet, Document # 100-23-013
- Computer with Microsoft Excel<sup>®</sup>

- **For miniiSED users only:** Mechanical rocker (if not using onboarding mixing feature)

## TESTING PROCEDURE

Ten replicates of each sample should be run.

1. Run sample on miniiSED, iSED, iSED ELITE, or iSED PRO according to the analyzer-specific Instructions for Use (refer to Table 3).
2. Record results on the Precision Worksheet.
3. Let sample sit idle for 5 minutes before retesting the sample.
4. Run nine more replicates of the same sample by repeating steps 1 to 3 nine more times.  
**Note:** All runs of a specific sample should be completed in one shift/within eight hours.
5. Repeat steps 1-4 for the remaining three samples.
6. Proceed to data analysis.

**Table 3: Instructions for Use**

<b>miniiSED Operator’s Manual</b>	1017-09-001
<b>iSED Operator’s Manual (serial #s &lt;5000)</b>	112-09-043
<b>iSED (serial #s &gt;5000) / iSED ELITE Operator’s Manual</b>	222-09-007
<b>iSED PRO Operator’s Manual</b>	120-09-007

## DATA ANALYSIS

1. For each sample, evaluate the series mean, standard deviation, and CV% of the 10 replicates.
2. Acceptable criteria for precision testing is as follows:

<b>ESR Result</b>	<b>Acceptable CV%</b>
Values 1-30 mm/hr	Less than 15%
Values 31-60 mm/hr	Less than 15%
Values 61-90 mm/hr	Less than 15%
Values >90 mm/hr	Less than 15%

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

Contact ALCOR Scientific Technical Support at [techservice@alcorscientific.com](mailto:techservice@alcorscientific.com) for support with this Precision Protocol or 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.