



iSED® Family of Analyzers Carryover Protocol

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

The purpose of carryover testing is to demonstrate that the sequence of testing does not affect the measured values on the miniiSED, iSED, iSED ELITE, or iSED PRO analyzers.

Correlation and Precision studies should also be completed during method validation.

SAMPLE REQUIREMENTS

- One sample from each of the erythrocyte sedimentation rate (ESR) analytical ranges as per Table 1:

Table 1: Sample Requirements

ESR Range	Number of Samples Needed	Minimum Volume Required
Low Range: 5-15 mm/hr	1	2.5 mL
High Range: >55 mm/hr	1	2.5 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 2.5 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 if stored at room temperature or processed within 24 hours if stored refrigerated

INSTRUMENTS AND MATERIALS

- Samples as defined in the Sample Requirements section
- Four plain (no anticoagulant) 13 x 75 mm sample collection tubes with pierceable caps
- 1 mL standard transfer pipettes
- miniiSED, iSED, iSED ELITE, or iSED PRO Analyzer
- iSED Family of Analyzers Carryover Worksheet, Document # 100-23-012
- Computer with Microsoft Excel®
- Mechanical rocker

SAMPLE PREPARATION

1. Mix the samples (as defined in Table 1) on a mechanical rocker for at least three minutes.
2. Remove the caps/stoppers from two plain sample collection tubes.
3. Using the transfer pipette, transfer 1 mL of the high ESR result sample to each empty tube and replace the tube stoppers.
4. Mark the plain tubes with the values a1 and a2.
5. Close the primary sample tube with high ESR result.
6. Discard the transfer pipette.

7. Remove the caps/stoppers from the other two empty sample collection tubes.
8. Using the transfer pipette, transfer 1 mL of the low ESR result sample to each empty tube and replace the tube stoppers.
9. Mark the plain tubes with the values b1 and b2.
10. Close the primary sample tube with low ESR result.
11. Discard the transfer pipette.

TESTING PROCEDURE

1. Run sample a1 on miniSED, iSED, iSED ELITE, or iSED PRO according to the analyzer-specific Instructions for Use (refer to Table 2).

Table 2: Instructions for Use

miniSED 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

2. Run sample a2.
3. Run sample b1.
4. Run sample b2.
5. Repeat steps 1-4 two times for a total of three runs as per Table 3:

Table 3: Test Runs

	Run 1	Run 2	Run 3
Test sequence 1	a1	a1	a1
Test sequence 2	a2	a2	a2
Test sequence 3	b1	b1	b1
Test sequence 3	b2	b2	b2

6. Record all results on the Carryover Worksheet.
7. Proceed to data analysis.

DATA ANALYSIS

1. The Carryover Worksheet from ALCOR® Scientific will automatically calculate carryover.
2. To calculate the % carryover manually, use the following formula where k is the carryover result expressed in a percentage:

$$k = \frac{b1-b2}{a1-b2} * 100\%$$

3. Acceptable criteria for carryover testing is <10%.

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 for support with this Carryover Protocol or data analysis.