

September 9, 2025

Technical Bulletin 1013

Extended Sample Stability for iSED® Family of Analyzers

Products Impacted:	Product	Part Number
	iSED PRO Series S	112-00120-SYS
	iSED (serial numbers >5000)	112-00101
	iSED ELITE	112-00222
	miniiSED®	112-01017

Attention

All users of iSED PRO Series S, iSED (serial numbers >5000), iSED ELITE, and miniiSED

Introduction

Erythrocyte sedimentation rate (ESR) test methods have traditionally had a sample stability window of 4 hours when samples are stored at room temperature and 24 hours when samples are refrigerated. iSED analyzers use novel photometric rheology technology to assess red blood cell aggregation – which represents the first step of red blood cell sedimentation – rather than sedimentation after 60 minutes. The difference in methodology results in significantly longer sample stability windows. Longer stability windows allow for more flexible workflows and help prevent sample degradation when samples are traveling long distances or delayed in testing. ALCOR Scientific has validated new sample stability claims for the iSED family of analyzers (see above for affected devices).

New Sample Stability Claims

ALCOR Scientific has validated room temperature (18-25°C) sample stability up to **28 hours** and refrigerated (4-8°C) sample stability up to **48 hours**. The following Instructions for Use have been updated with the new stability claims:

Document	Document Number
iSED PRO Instructions for Use	120-09-007
iSED (serial numbers >5000) and iSED ELITE Instructions for Use	222-09-007
miniiSED Instructions for Use	1017-09-001



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The Sample Stability sections in the above Instructions for Use now contain the following data:

Refrigerated Samples

Fresh EDTA-anticoagulated samples spanning the dynamic range of the assay were identified by doing a baseline test on iSED ELITE*. These samples were then stored at 4-8°C and analyzed at multiple time points. Testing was performed November 2024 - April 2025. The 48 hour results were plotted as a function of the baseline results and analyzed by Passing-Bablok regression. Fifty-two samples were tested. The regression statistics of the 48-hour vs. baseline comparison were: slope = 0.94 with a 95% confidence interval of 0.85 to 1.03, intercept = 1.32 with 95% confidence interval of -1.54 to 3.46 and a Spearman correlation coefficient of 0.95. The slope and intercept confidence intervals including 1.00 and 0.00, respectively and a correlation coefficient ≥ 0.90 demonstrates statistically significant identity between baseline and 48 hours when samples are stored at 4-8°C, thus supporting a refrigerated stability claim of 48 hours.

Room Temperature Samples

Fresh EDTA-anticoagulated samples spanning the dynamic range of the assay were identified by doing a baseline test on iSED ELITE*. These samples were then stored at room temperature and analyzed at multiple time points. Testing was performed November 2024 - April 2025. The 28 hour results were plotted as a function of the baseline results and analyzed by Passing-Bablok regression. Fifty-one samples were tested. The regression statistics of the 28 hour vs baseline comparison were: slope = 0.93 with a 95% confidence interval of 0.84 to 1.05, intercept = 1.52 with confidence interval of -2.80 to 3.97 and a Spearman correlation coefficient of 0.90. The slope and intercept confidence intervals including 1.00 and 0.00, respectively and a correlation coefficient ≥ 0.90 demonstrates statistically significant identity between baseline and 28 hours when samples are stored at 18-25°C, thus supporting a room temperature stability claim of 28 hours.

*The iSED family of analyzers, including miniiSED, iSED, iSED ELITE, and iSED PRO, use a common analytical unit for generating ESR results. Since the underlying technology is common and all analyzers are calibrated to a common Reference Unit, sample stability is the same across the analyzers.

Please note: New sample stability claims for iSED analyzers with serial numbers <5000 have not been validated at this time.

Actions Required

1. Contact ALCOR Scientific Technical Support at techservice@alcorscientific or your authorized representative for the latest version of your analyzer's specific Instructions for Use.
2. ALCOR Scientific recommends updating laboratory protocols and procedures with the updated sample stability claims, if desired. If validation of these updated claims is necessary, please be sure to follow any relevant operating procedures or local and regional guidelines to implement this change.
3. File this Technical Bulletin as part of your Quality System, as required.

For additional information on this Technical Bulletin, please contact ALCOR Scientific Technical Service at techservice@alcorscientific.com or 401-737-3774.



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