



Abbott

i-STAT 1 SYSTEM TECHNICAL BULLETIN

K₂EDTA and K₃EDTA Customization for Hematocrit on the i-STAT System

PURPOSE

This Technical Bulletin contains the information needed to select the K₂EDTA or K₃EDTA customization option for reporting hematocrit results on the i-STAT System.

HEMATOCRIT CALIBRATION

The reference method for hematocrit is the microhematocrit (MH) method. All instruments measuring hematocrit are expected to be traceable, or calibrated, to this reference method.¹⁻³

The microhematocrit reference method described in CLSI H7-A3³ permits both K₂EDTA and K₃EDTA anticoagulant sample collection tubes. K₃EDTA anticoagulant shrinks red blood cells relative to K₂EDTA anticoagulant, causing microhematocrit results from K₃EDTA samples (MH-K₃EDTA) to be lower by approximately 2 – 4% than results from K₂EDTA samples (MH-K₂EDTA).^{3,4}

Consequently, instruments calibrated to MH-K₃EDTA report lower hematocrit results than analyzers calibrated to MH-K₂EDTA.

SELECTION OF THE K₂EDTA OR K₃EDTA CUSTOMIZATION SETTINGS ON THE i-STAT SYSTEM

i-STAT provides two customization settings for reporting hematocrit results: The “K₃EDTA” customization reports hematocrit results traceable to MH-K₃EDTA. The “K₂EDTA” customization reports hematocrit results traceable to MH-K₂EDTA.

For best agreement of i-STAT and hematology analyzer hematocrit results, the i-STAT customization setting is selected according to the calibration of the comparative hematology analyzer (MH-K₂EDTA or MH-K₃EDTA). (Note: The default setting on the i-STAT System is K₃EDTA.)

If the calibration of a comparative method is uncertain, determine the customization setting by minimizing the average bias between methods as follows:

- Check that the results from hematocrit controls for both i-STAT and comparative methods are acceptable.
- If i-STAT hematocrit results obtained using the “K₃EDTA” setting are consistently lower than those on the comparative method, the “K₂EDTA” setting may be a better choice. If agreement is better after multiplying the “K₃EDTA”-customized i-STAT results by 1.0425, the customization setting should be switched to “K₂EDTA”.
- Conversely, if i-STAT hematocrit results obtained using the “K₂EDTA” setting are consistently higher than those on the comparative analyzer, the “K₃EDTA” setting may be a better choice. If agreement is better after dividing the “K₂EDTA”-customized i-STAT results by 1.0425, the customization setting should be switched to “K₃EDTA”.
- If an unacceptable system bias still exists, contact i-STAT Technical Support at 1-800-366-8020, option 1.

HEMATOLOGY ANALYZERS AND K₂EDTA AND K₃EDTA SAMPLE COLLECTION TUBES

Hematocrit results on hematology analyzers from samples collected in K₃EDTA and K₂EDTA tubes will be equivalent. This is because the osmotically-balanced diluent reverses the red blood cell shrinkage caused by the anticoagulant.⁵ It should be clear that results from K₂EDTA and K₃EDTA tubes will be equivalent, but lower, on an analyzer calibrated to MH-K₃EDTA than on an analyzer calibrated to MH-K₂EDTA.

i-STAT has become aware that some customers have selected their i-STAT hematocrit customization according to the type of EDTA anticoagulant in the collection tube used for samples for the hematology analyzer. As explained above, the selection of the “K₂EDTA” or the “K₃EDTA” customization for i-STAT analyzers is based upon the microhematocrit method (MH-K₂EDTA or MH-K₃EDTA) to which the hematology analyzer is calibrated, rather than on the collection tube used for the hematology analyzer.

EXPECTED LEVEL OF METHOD AGREEMENT

Average i-STAT hematocrit results over a group of samples should normally agree with those from the comparative method within ± 2 %PCV at 29 %PCV and below, ± 3 %PCV from 30 to 50 %PCV, and within 10% above 50 %PCV when the following conditions are met:

- i-STAT analyzers are customized correctly.
- Comparative analyzer is calibrated correctly.
- Sample handling is optimal for both i-STAT and comparative methods.
- Samples are unaffected by factors listed in the i-STAT Cartridge and Test Information sheet for Hematocrit or in the user documentation for the comparative method.

REFERENCES

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5. Parikh, M. Evaluation of BD Vacutainer™ Plus Plastic 4.0mL K₂EDTA, 2.0mL K₂EDTA and Glass 5.0mL K₃EDTA Tubes for CBC, WBC Differential Count and Reticulocyte Count. (Technical Literature). Becton, Dickenson and Company, 2003.

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