

M Dialysis Calibration Verification Test Kit

Instructions for Use

Calibration Verification Kit

Each package contains:

5 Levels of Calibration Verification Material (Bottles I thru V)
Product Insert
Specification Sheet
Instruction for Use

Calibration Verification Testing Procedure: (System must have reagents installed and system calibrated prior to running samples)

1. Remove and save the large stopper at the wide end of a microvial.
2. Using a micropipette or a disposable syringe, fill the micro vial with 50 μ L of the Calibration Verification sample. Recap the microvial. (Ensure sample is at “thin end” of vial with no air bubbles.)
3. Place microvial in microvial rack.
4. Repeat steps 1 – 3 for each level of Calibration Verification Solution (I thru V).
5. **Let samples come to room temperature before analyzing.**
6. Register a patient. Always use abbreviations that include the “Facility”, “Test” and “Date” (i.e. XXXCalVerMM-YYYY). You cannot add spaces. Use “CalVer” for first and last name.
7. Add a catheter named CalVer
8. On “Settings and Controls” screen, select “Settings”, then select “Analyses”.
9. Click on “Use vial ID”
10. Click on “Multiple Samples Injections” and change sample repetitions to 5.
11. On “Settings and Controls” screen, select “Batch Analysis”. Batch Analysis is described on page 24 in the ISCUS^{flex} User’s Manual (US).
12. Make sure the vial in the first position is selected, then follow the instructions for Batch Analysis Setup.
13. “Patient ID”: CalVer, “Catheter”: CalVer, “Vial ID”: 1 for the first position. Enter a date and time at least 5 hours before the current time. Activate all analytes. Click on vial position 5 to complete the Batch Analysis Setup.
14. Click “Check” to verify that the setup is correct.
15. Click “Vials Out”. Remove samples from microvial rack and place in vial holder in the appropriate corresponding sample positions.
16. Select “OK” to start analysis of the samples.

When Completed:

1. Deregister the patient. Patient (CalVer Results) will be deregistered and stored in the M Dialysis Database
2. Change “Multiple Sample Injections” back to 1.
3. To save the data:
 - a. Go to “Settings and Controls” screen. Select “Patient Database”.
 - b. Insert a USB (on side of analyzer).
 - c. Select CalVer Patient
 - d. Select “Store”

Interpreting Results:

1. Refer to Product Insert
2. Email results to usa@mdialysis.com.
3. Results will be analyzed in EP Evaluator and a report will be returned to the client within 7 days via email.