Cell Viability Incorporated

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Verify Instrument Performance

Official Certification and Verification of the Vi-Cell should be only performed by a Beckman Coulter trained representative that had official training on the service operation of the instrument. This document is NOT intended to serve as a replacement to the recommended Certification and Verification procedure recommended by Beckman Coulter. This document is intended to be a guidance document to inform the end-user of recommended things to check the operation of the Vi-Cell that is inline with what a Service Engineer would do for Certification and Verification.

Recommended Materials

- Vi-Cell Reagent Quad Pack (our part number 2400102, 2400101 or Beckman part number 383722, 383260, or 383198)
- Vi-Cell Concentration control, Beckman part number 175478, Fisher part number NC9552505
- Vi-Cell replacement Syringe (our part number 2400105)

1. SAVE THE STORED SETTINGS FOR YOUR INSTRUMENT BEFORE PROCEEDING.

A. Save the Calibration Values for your Vi-Cell system:
   1. On the system software, click on the File menu.
   2. Click the **CONFIGURATION** option.
   3. Click on the **CALIBRATION** tab.
   4. Save all the values shown by writing them down or taking a screen capture. Save this as reference information.

   NOTE: FOR Vi-CELL systems (not XR). Save the reading on the focus wheel. This is the position of the focal point that is important to have recorded

2. CLEANING AND INSPECTION.

A. Check all outside surfaces. Clean all areas and ensure dust and residue is removed. Be sure to war proper protective equipment (gloves, glasses, etc.).
B. Check all exposed tubing for any cracks or damage both outside and inside where the sample reagents are loaded.
C. Ensure all cables for power and video are properly installed, secure and are not damaged.
D. Replace the system syringe. This is typically done once per year and as part of an annual certification / verification that your Beckman Coulter representative performs.
E. Once replaced, ensure that the top connection of the new syringe is finger tight. Do not over tighten. Also ensure the syringe lock is fully rotated and locked in place.
F. Tighten the screw on the bottom of the plunger to the syringe arm.
G. Lastly, ensure all the tubing connections on the top distribution valve are finger tight. Be sure NOT to over tighten these fittings. Just ensure they are finger tight.

3. PERFORMACE CHECK

A. For Vi-CELL XR systems, dispense more than 0.5 milliliters but no more than 2.5 milliliters of water into a sample cup that comes with your reagent pack. Place this vial in the autosampler carousel in any location and begin a new run.
B. For older Vi-CELL systems, dispense more than 1.0 milliliters but no more than 2.5 milliliters of water into a sample cup that comes with your reagent pack. Place this vial in the autosampler carousel in any position and begin a new run.
C. During the analysis, view the image on the software screen and verify that the optics are clean and free from dust or any static marks. The goal is to ensure the field of view shown on the screen is uniform and clean. If it is not, please run the de-contamination procedure outlined in your system manual.
D. Ensure that the light intensity (value shown on the instrument software screen) is 205 ±15. Record this value. If the value is below 190, it is possible that your sample cell has residue and requires cleaning as per the de-contamination procedure outlined in your system manual. Be sure to record the light intensity value for future reference.
E. Check the alignment of the sample carousel by ensuring the sample cup stops as close as possible to the center of the cup sipper tube aspiration area.
F. Ensure that the aspiration tube depth is low enough to aspirate all the sample in the sample cup. Also ensure the sipper tube is aligned toward the center of the sample cup.
G. Ensure all the LED lights on the front of the instrument are all operating properly.
    a. The bottom LED is green and will illuminate showing the power is on.
    b. The middle LED is also green and will illuminate when the cup is in the sample analysis position.

4. PERFORMANCE VERIFICATION

Note: Run Concentration Control to verify calibration when performing a certification. Run Concentration Control if applicable during service verification.

A. For Vi-CELL XR systems, dispense more than 0.5 milliliters but no more than 2.5 milliliters of Concentration Control into a sample cup that comes with your reagent pack. Place this vial in the autosampler carousel in any location and begin a new run.
B. For older Vi-CELL systems, dispense more than 1.0 milliliters but no more than 2.5 milliliters of Concentration Control into a sample cup that comes with your reagent pack. Place this vial in the autosampler carousel in any position and begin a new run.
C. Verify that the total concentration reported is within 10% of the assay value. Record these results as reference information.

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