Repeatability of Coulter Z2 and Vi-CELL Counts Using ViaCheck™ 0.5e+6 Concentration Controls

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INTRODUCTION

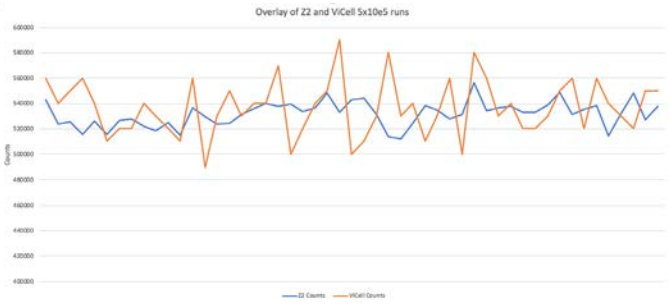
ViaCheck™ Viability and Concentration Controls (Bangs Laboratories) are available in a range of viabilty and concentration levels, the latter of which include 1e+6 beads/mL, 4e+6 beads/mL and 8e+6 beads/mL standards. Before introducing a new, lower-count standard (0.5e+6 beads / mL) to the ViaCheck product line, we endeavored to both confirm the repeatability of lower-end counting capabilities of the instruments featured in our in-house Quality Assurance program, and ensure that instrument performance supported intended product specifications.

METHOD AND RESULTS

All samples were prepared and run by operators trained in proper sample preparation (including mixing and pipetting), instrument set-up and instrument operation[3,4]. Particle / cell counting instruments, including the Z2 (Coulter) and Vi-CELL® XR (Coulter) were properly calibrated and configured using standardized instrument settings[1,6].

REPEATABILITY: INTRA-INSTRUMENT PRECISION

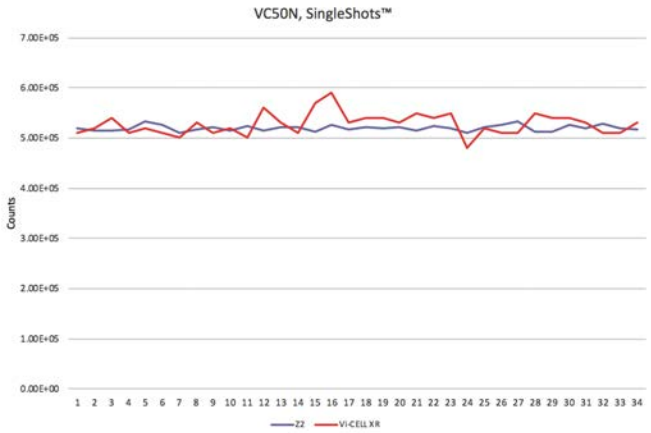
To determine the range of within-instrument variation for the new lower-count ViaCheck standard (0.5e+6 beads/mL (VC50N), a total of 102 samples were run (51 on the Vi-CELL XR and 51 on the Z2). Precision was found to be acceptable for both the Z2 (<2%)[2] and Vi-CELL XR (<6%)[5].



RESULTS	Z2	Vi-CELL® XR
Avg conc. (n = 51 [each])	5.32e+05 (beads/mL)	5.36e+05 (beads/mL)
Std. Dev.	9.90e+03 (beads/mL)	2.21e+04 (beads/mL)
%CV	1.86%	4.11%

CONFIRMATION OF MANUFACTURING PRODUCT SPECIFICATIONS

Runs were performed against a product (count) specification range of 0.41e+6 – 0.59e+6 beads/mL (Coulter Z2). Per in-house policy, QC runs for each product Lot include both formal counts on the Z2, and confirmatory checks on the Vi-CELL XR. Each Lot is dispensed under a Squeglia Zero-Based Acceptance Sampling Plan; dispensing runs for 20mL and <1mL SingleShot™ volumes of the new 0.5e+6 beads/mL ViaCheck Concentration Control were evaluated. Product (count) specifications were found to be acceptable for both product formats, 20mL bottles and SingleShot vials.



Manufacturing Specification	0.41e+6 – 0.59e+6 beads / mL	
RESULTS	Z2	Vi-CELL XR
Avg conc. (n = 34 [each])	5.20e+05 (beads/mL)	5.28e+05 (beads/mL)
Std. Dev.	5.79e+03 (beads/mL)	2.20e+04 (beads/mL)
%CV	1.11%	4.17%

Manufacturing Specification	0.41e+6 – 0.59e+6 beads / mL	
RESULTS	Z2	Vi-CELL XR
Avg conc. (n = 13 [each])	5.10e+05 (beads/mL)	5.34e+05 (beads/mL)
Std. Dev.	5.97e+03 (beads/mL)	2.47e+04 (beads/mL)
%CV	1.17% (beads/mL)	4.62% (beads/mL)

CONCLUSIONS

Both the Z2 and Vi-CELL XR demonstrated acceptable precision for counts of 0.5e+6 beads/mL, with the Z2 exhibiting slightly less variation. This performance difference is as documented in the literature, and is likely due to the underlying instrument methodology (Z2 – impedance; Vi-CELL XR – imaging). The additional reason for the difference in variation is likely and the number of counts typically performed in a run (Z2 – rate measured in kilocounts/sec, <100,000 counts; Vi-CELL – 50 fields/images, <2000 counts). All results fell within the specified count range for manufacturing (0.41e+6 – 0.59e+6 beads/mL), confirming the acceptability of the specification.

REFERENCES & FURTHER READING

1. Beckman Coulter, Inc. (2011) *Vi-CELL XR Cell Viability Analyzer Reference Manual* (Publication No. 383674BA). Brea, CA
2. Beckman Coulter, Inc. (2007) *PROService™ Advisor: Z-Series* (Publication No. 05-2007-045). Brea, CA.
3. Bangs Laboratories, Inc. (2017) *ViaCheck for Cell Viability Analyzers: Best Practices.* (Tech Support Doc 0711) Fishers, IN.
4. Bangs Laboratories, Inc. (2017) *Handling & Pipetting Concentration Standards.* (Tech Support Doc 0706) Fishers, IN.
5. Lew C, Gomez JA, Rhyner MN. (2012) *Instrument-to-instrument variability in the Vi-CELL automated viability analyzer.* (Publication No. IB-17279A) Brea, CA. Beckman Coulter, Inc.
6. Kilbride K, Anglea B, Bavender A. (2017) *Optimization of Vi-CELL® XR settings for calibration checks using ViaCheck™ Controls.* (Application Note 0708.) Fishers, IN. Bangs Laboratories, Inc.