Comparison Study of the Vi-CELL® XR Cell Viability Analyzer and Z2™ Coulter Counter

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Kathryn Kilbride, Mary Meza, Robert Anglea *Bangs Laboratories, Inc., 9025 Technology Drive, Fishers, IN 46038*

ABSTRACT

Introduction:
Analytical instruments must be appropriately qualified before being commissioned to ensure that they are suited to their intended use, and that results have acceptable accuracy and precision. When adding a second Vi-CELL®XR cell viability analyzer to our laboratory, it was important to demonstrate equivalent performance to our first Vi-CELL XR to ensure that the instruments could be used interchangeably for our purposes. In addition, as Bangs Laboratories is a manufacturer of instrument standards (e.g. ViaCheck™), we wished to demonstrate comparability of the Vi-CELL's image-based technology with another independent and well-accepted technology, i.e. the Coulter Principle (Coulter Z2™).

Methods:
ViaCheck microsphere standards in a range of cell viabilities (0% - 100%) and concentrations ($1e^{+6}$ - $8e^{+6}$) were run by two operators on both Vi-CELL XR analyzers, VC1 (existing) and VC2 (new acquisition). The same Lots of ViaCheck products were also run on a qualified Coulter Z2 to assess total concentrations and counts of constituent "live" and "dead" bead populations.

Results:
Vi-CELL results were found to be in high agreement with one another and with results from the Coulter Z2. The results met established in-house acceptance criteria.

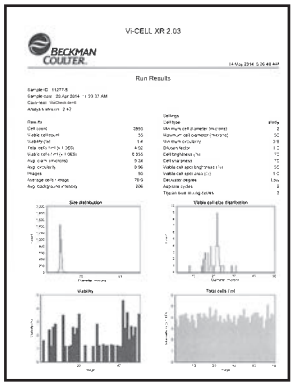
Conclusions:
The present comparison study demonstrated that the second Vi-CELL XR (VC2) was in agreement with existing instrumentation (Vi-CELL XR, VC1) and an independent technology (Coulter Principle, Coulter Z2). The instrument passed this portion of the qualification, readying it for a final gage study and user-specfic training. The present comparison study also served as a foundation for routine instrument QC and technician proficiency programs.

INTRODUCTION

Instrumental methods for cell count and viability provide significant advantages over manual determinations, offering high accuracy, precision and throughput, in addition to superior analytics. However, as with all analytical instruments, cell viability analyzers must be appropriately qualified to ensure reliable performance across the intended range of use. Qualification activities may also involve correlation studies to ensure comparable performance between instruments for programs where interchangeable use is required, as was the case with our acquisition of a second Vi-CELL instrument.

The Vi-CELL is an image-based cell viability analyzer that is based on the Trypan Blue dye exclusion method. Cell samples are exposed to the membrane-impermeable dye Trypan Blue; those with compromised cell membranes (dead / dying) will take up the blue dye, while those with intact membranes (live) will exclude the dye and remain uncolored. The Vi-CELL analyzes images of stained cell samples and provides basic data regarding average cell size (diameter) and morphology (circularity) in addition to %viability and concentration (cells / mL).

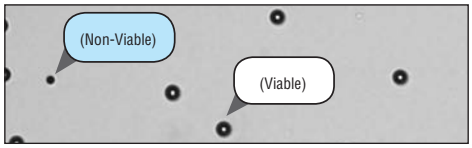
ViaCheck Cell Viability and Concentration Controls were utilized to compare performance between the existing and new Vi-CELL XR instruments, and with an alternate and well-accepted particle counting technology (Coulter Principle).



Sample printout from Vi-CELL XR analyzer

MATERIALS AND METHODS

ViaCheck standards are comprised of individual or mixed populations of microspheres that simulate samples of live / dead (or dying) cells stained with Trypan Blue. They are suitable for use with image-based instruments that rely on the Trypan Blue dye exclusion method.



Several ViaCheck standards were utilized to assess instrument capability with respect to viability and concentration through the expected working ranges.

Specifically:

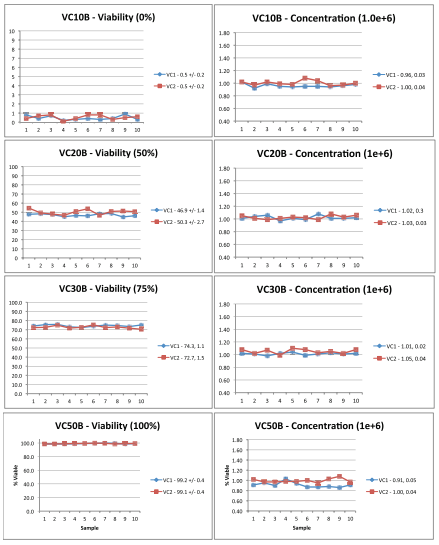
Ten samples of each of four ViaCheck Viability Controls (0%, 50%, 75%, 100%; all at a concentration of 1e+6) were analyzed on each of the two Vi-CELL analyzers, VC1 (existing) and VC2 (new). Nine samples of each of three ViaCheck Concentration Controls (1e+6, 4e+6 and 8e+6) were analyzed on the new Vi-CELL (VC2) and the Coulter Z2.

Synthetic microspheres and biologic cells have different settling profiles, and special care was taken to ensure that the ViaCheck suspensions were well-dispersed before sampling and analysis. Suspensions were gently mixed prior to sampling (rotation and/or manual inversion), proper sampling technique was observed, and no more than three samples were loaded into the carousel at a time to avoid settling.

RESULTS

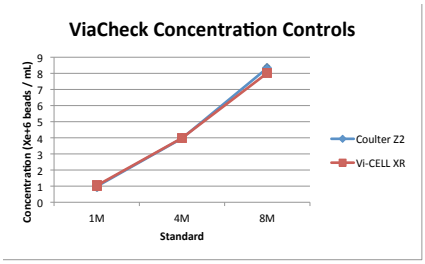
ViaCheck Viability Control Comparison for Vi-CELL XR-1 (VC1) AND Vi-CELL XR-2 (VC2)

Results for %Viability (0%, 50%, 75%, 100% viability) and Concentration (1e+6 beads / mL) were found to be highly comparable between the two instruments.



ViaCheck Concentration Control Comparison for Vi-CELL XR-2 (VC2) and CoulterZ2

Results for Concentration were found to be highly comparable between the two instruments / technologies across concentrations (1e+6 – 8e+6 beads / mL). Each point represents the average of nine runs.



Using ViaCheck standards, the new Vi-CELL analyzer (VC2) demonstrated equivalent performance to an existing analyzer (VC1) for Cell Concentration and Cell Viability, and to a Coulter Z2 (Coulter Principle, electrical sensing zone technology) for Cell Concentration.

CONCLUSION

Analytical instruments such as cell viability analyzers must be appropriately qualified before being placed into routine use. Qualification is a comprehensive process that is undertaken to ensure that each instrument meets expected capabilities, and is suited to its intended use. Comparative studies featuring appropriate external standards, such as those described here, can be an important part of the instrument qualification process, and serve as a foundation for ongoing QC and proficiency programs.