



USP<787> Small Volume testing on the HIAC 9703+



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By their very nature, biological therapeutics are not only expensive to manufacture but are often produced in small volumes. USP<787> permits the testing of small volumes (0.2ml-5.0ml) and smaller aliquots than described in USP <788>. Generating accurate data with small sample volumes can be error prone especially due to run to run variances that can skew the data. Small volume testing requires an instrument that can precisely deliver selected volumes while at the same time minimize count errors. The HIAC 9703+ has demonstrated small volume (0.2ml) accuracy that is > 98% and count errors that are < 10%.

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Introduction

The introduction of USP <787> provides a test method to qualify biological samples at volumes down to 0.2ml. While there are practical advantages to testing small volume samples, this places a greater importance on the volume and counting accuracy of the instrument being used. Any variability in the sample volume delivered to the counter will be reflected in the resulting particle count data. For this reason it is critical to ensure that both volume and count accuracy are measured and a count standard used to ensure reliable data. This application note will quantify both the volume accuracy and the ability of the HIAC 9703+ to accurately count small volume samples.



Method / Results

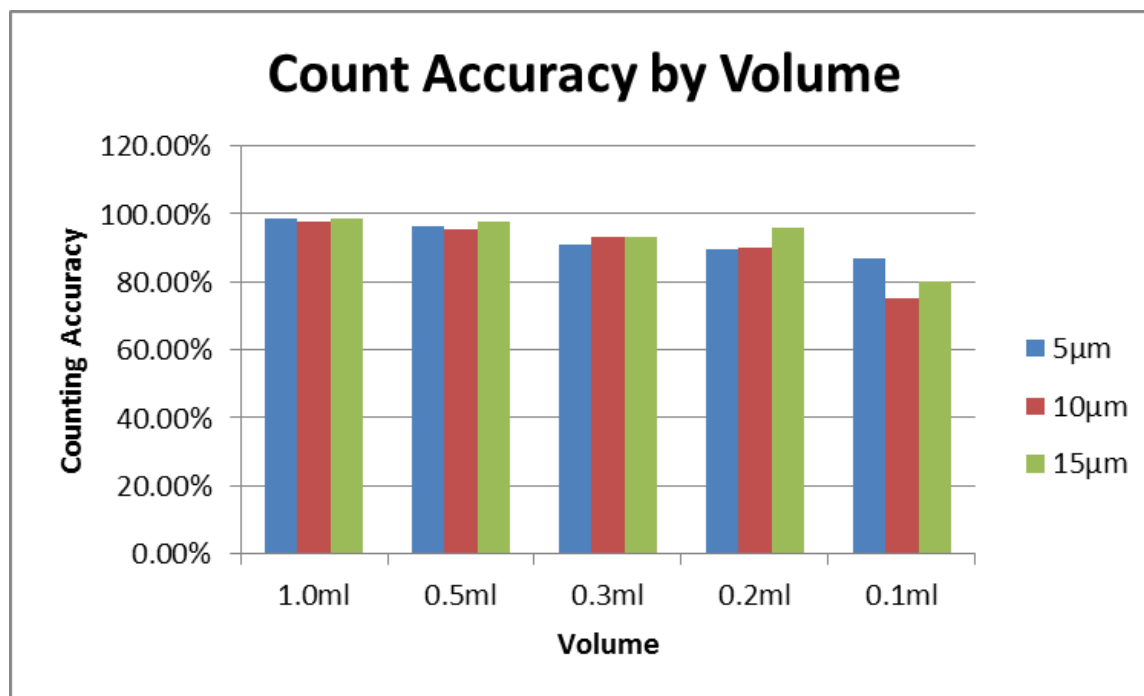
An initial assessment of the volume accuracy of the HIAC 9703+ was conducted to ensure that the sample delivery mechanism could precisely deliver the desired volumes. Table 1 shows the accuracy of the five volumes that are examined in this application note. With the exception of 0.1ml, the HIAC 9703+ demonstrated itself to be extremely accurate as witnessed by quantitation of volume accuracy ranging from Table 1.

Gravimetric Data - Volumetric Weight					
	1.0ml	0.5ml	0.3ml	0.2ml	0.1ml
Draw 1	0.99970	0.50000	0.30010	0.20500	0.11080
Draw 2	0.99740	0.49870	0.30000	0.20060	0.10180
Draw 3	0.99740	0.49890	0.29960	0.20120	0.10010
Draw 4	0.99860	0.49860	0.29950	0.20000	0.10010
Draw 5	0.99740	0.49900	0.30000	0.20440	0.10030
Average	0.99810	0.49904	0.29984	0.20224	0.10262
S.D.	0.00093	0.00050	0.00024	0.00205	0.00414
Total volume (ml)	4.99050	2.49520	1.49920	1.01120	0.51310
Volume Accuracy	0.09%	0.10%	0.08%	1.02%	4.03%

Table 1

To determine the counting accuracy of the HIAC 9703+, known suspensions of Ezy Cal from Thermo Scientific were used at the specific volumes noted in Table 1. In addition to being able to quantify the degree of accuracy of the instrument, using a known count standard helped identify the threshold volume where the instrument began to lose its precision. As seen in Graph 1 below, count accuracy data for the HIAC 9703+ was >90% for nearly all of the sample volumes.

Graph 1



Conclusion

Prior to the introduction of USP <787>, the smallest sample volume that could be tested per USP guidelines was 5.0ml. For biopharmaceutical companies producing small batches of biological therapeutics, the requirement to test 5.0ml samples can prove to be expensive both in terms of the quantity of product consumed during test and manufacturing expense. The introduction of USP<787> now provides the option of testing samples down to 0.2ml which requires an instrument that can accurately measure, dispense and count at these small volumes.

By using EzyCal to confirm count accuracy and gravimetric weight to confirm volume, the HIAC 9703+ has shown it can accurately count small volumes called out in USP<787>. Quantitative data shows that 9703+ users wishing to sample small volumes should be confident that the instrument can provide accurate data

down to sample volumes of 0.2ml. Small volume adaptor kits are offered as an accessory for the 9703+ and information on the kit as well as the HIAC 9703+ can be found at www.particle.com.

The HIAC 9703+ uniquely offers users volumetric and count accuracy combined with automated compendial updates and sampling routines. These features, among others, streamline workflow and increase sample throughput. A global service team is available to support the instrument and provides onsite service and calibration, helping to eliminate costly downtime.

About the Author

Dave Dunham is a Global Marketing Manager for Beckman Coulter Life Sciences. He manages the HIAC portfolio of liquid particle counters and has helped drive the development of both the HIAC 8011+ and the HIAC ROC. Dave is also a member of the ASTM Committee D02 on Petroleum Products, Liquid Fuels, and Lubricants. He has a B.S. in Microbiology from Oregon State University and an MBA from Marylhurst University.

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