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MEMO: EMTEK Air Sampler Comparison Data Summary

DATE: September 06, 2016

ISSUED/APPROVED BY: Erik Swenson / VP Operations / EMTEK LLC

TEST PROTOCOL - SUMMARY

The following chart and data table summarize internal data from comparison testing performed on August 9th, 2013, between the EMTEK V100 with R2S Sampler, V100 with RAS Sampler, and P100 Portable Microbial Air Sampler. Sampling was performed at 28.3 LPM (1 CFM) for all devices and testing performed, with test volumes of 1000L (2), 500L (2), and 250L (7) being taken. A total of 11 test runs were performed. Testing was performed in a clean, but uncontrolled lab area. Samplers were within 1 foot (30cm) of each other, and were shifted between the three locations on the testing rack every run. Test media used for the comparison testing was 90mm Trypticase Soybean Agar (TSA) plates, from Hardy Diagnostics (PN G60). Test plates were read after approximately 94-hours (4-days) of incubation at 29-31°C.

RESULTS - SUMMARY & DISCUSSION

In regard to comparisons of microbial air sampling devices, it is expected that when a replacement technology for microbial (or viable) air sampling is being assessed, it should have equivalent or better recovery than the device it is replacing, and it should meet the guidance referenced in ISO 14698-1. In regard to EMTEK's microbial air sampling devices, the R2S Air sampler had previously been tested by a third party, Labor Dr. Rabe HygieneConsult, of Essen, Germany (Jan 2006). The R2S did extremely well in this testing, which included 15 different devices, compared to a standard (liquid impinger). Liquid impingers are considered to be 100% recovery devices as the sample volume is bubbled through the liquid, offering no "escape" or pass through of viable particulates. Of all 15 microbial air sampling devices in the study, the R2S had the most consistent capture across the three challenge organisms used (chosen to meet requirements in ISO 14698-1), which had differing particle sizes and capture sensitivities (Staphylococcus epidermidis, Penicillium citrinum, and Bacillus subtillis). The R2S showed consistent excellent recovery, averaging 173% of the standard across the organisms tested. The link to the Labor Dr. Rabe HygieneConsult study follows:

http://emtekair.com/wp-content/themes/agency/webmanuals/r2s-biological-0026-physical-efficiency-by-hygiene-consult.pdf

With this, the R2S has been employed as the standard to which to compare other EMTEK devices during development and final testing. The results from this internal test are shown below.

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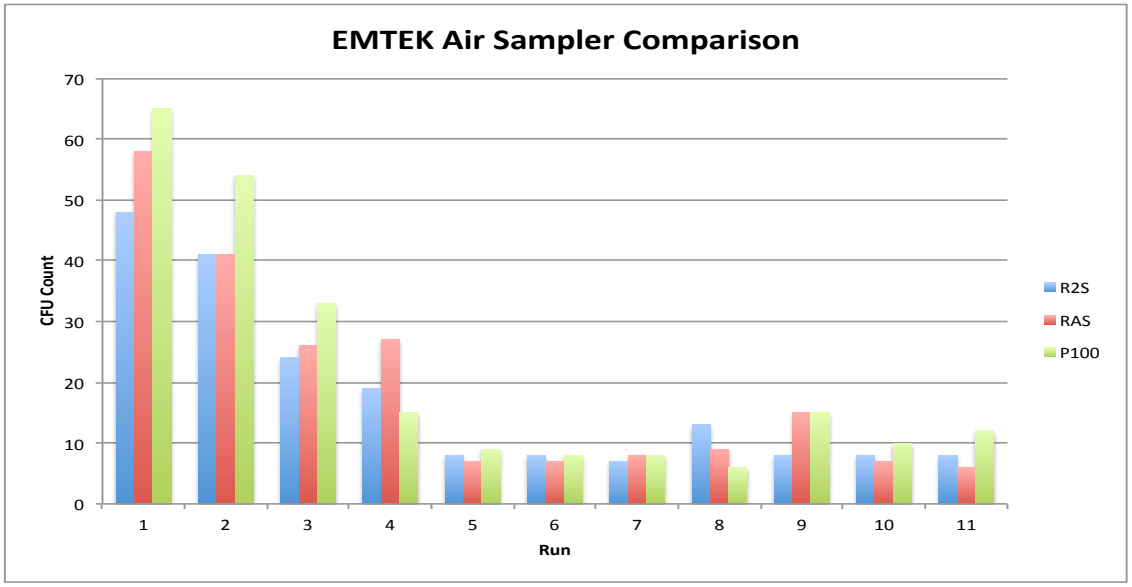
EXAMPLE SAMPLER PLACEMENT DURING TESTING
(Samplers were rotated between locations during various test runs)



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TEST DATE:		AUG 0-9 2013	Final Read - AUG 13 2013 (13:15)			%Recovery of Standard (R2S)	
START TIME	VOLUME (Liters)	RUN	CFU/Run R2S	RAS	P100	RAS	P100
10:25	1000	1	48	58	65	121%	135%
11:08	1000	2	41	41	54	100%	132%
11:50	500	3	24	26	33	108%	138%
12:11	500	4	19	27	15	142%	79%
12:37	250	5	8	7	9	88%	113%
13:23	250	6	8	7	8	88%	100%
13:35	250	7	7	8	8	114%	114%
13:49	250	8	13	9	6	69%	46%
14:05	250	9	8	15	15	188%	188%
14:17	250	10	8	7	10	88%	125%
14:29	250	11	8	6	12	75%	150%
		CFU/TOTAL	**192**	**211**	**235**	**110%**	**122%**

BLUE = R2S/Standard - Baseline Data GREEN = Recovery ≥ Standard ORANGE = Recovery < Standard

NOTE: Flow rate of 28.3 LPM used with all devices.

CONCLUSION

In the recent past in microbiology, a result value in the range of ± 30% was considered to be comparable result. Within USP <1223>, a Relative Standard Deviation (RSD) in the range of 15-35% (dependent on CFU recovered) could be employed to determine Precision of the plate count results obtained, with which one could use to compare an alternative method/device. As seen in the results graph and table, both the RAS and P100 have comparable, or better recovery than that of the R2S, supporting their use as additional alternatives for microbial air sampling of critical clean room environments.