

Repeatability Study of ATP Hygiene Monitoring Systems in 77 Food and Beverage Manufacturing Sites in the United States.

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Introduction:

ATP hygiene monitoring systems are used to verify that cleaning of manufacturing equipment and the manufacturing environment has been carried out effectively. A key aspect of these (or any) testing systems is the repeatability of the test - how likely is the test to give the same answer when measuring the same level of ATP. Repeatability has very practical implications in the food testing environment as it has a direct effect on the prevalence of false positive and false negative results.

It is well understood that all measuring systems have a certain level of error. This error can be determined by measuring a standardized sample multiple times and looking at the variability in the resulting measurements.

The purpose of the experiments reported here was to compare the repeatability of the ATP testing system currently in use by a food manufacturer. By dosing swabs with a defined amount of ATP, the precision of the testing systems could be directly compared in the food manufacturing plant.

Materials For Each Study:

One 3mg/Vial of ATP Positive Control, One vial of Sterile Water, Transfer pipette (10 of each are available in the 3M™ Clean-Trace™ Water Positive Control Kit (Product Code LWATP10) were used to create a vial of ATP solution of approximately 0.3 ng ATP/mL. The Li'l Pet fixed volume micro pipettor capable of 25µl volumes was used to dose the ATP solution onto the surface swabs. Ten 3M™ Clean-Trace™ Surface ATP swabs were supplied by 3M and 10 test swabs from the ATP system used by the food manufacturing facility were supplied by the food manufacturing facility for the test.



Method:

- At each manufacturing site, a 3M salesperson and/or a member of the manufacturing site's quality team performed an evaluation as follows:
 - 1) Allow swabs to come to room temperature.
 - 2) Dilute one vial of 3M Clean-Trace ATP Positive Control standard with 1ml of sterile water to make a 3.0 ng/ml (~5,000 fmoles/ml).
 - 3) Once the pellet is fully dissolved, transfer the diluted ATP back to the vial of sterile water to make a 0.3 ng/ml (~500 fmoles/ml) dilution of ATP.
 - 4) For each vendor's swab, pipette a swab with 25µl of the ~500 fmoles/ml solution (~12.5 fmoles ATP/swab) — spot onto the side of the swab (or end of sponge for sponge samplers).
 - 5) Activate the swab according to the manufacturer's directions.
 - 6) Read in the vendor's instrument.
 - 7) Record the results in the Excel spread sheet.
 - 8) Repeat step 4-7 nine additional times so that you have 10 results for each ATP testing system being compared.
 - 9) Calculate the Mean and Standard Deviation for the 10 data points for each ATP testing system*.
 - 10) Calculate the CV by dividing the Standard Deviation by the Mean and then expressing the result as a percentage.

Each of the spreadsheets for the individual site ATP Challenge Studies were filled out and collected. The CV for each of the individual sites were collated into the Tables to the right and an overall CV for the various swab manufacturers' systems were calculated.

Results:

Table 1A & 1B: Results of ATP Challenge Study conducted in 77 food and beverage manufacturing sites in the United States. Each line represents a different location with the CV calculated based on the results of 10 swabs dosed with 25 microliter aliquots of a 0.3 ng/mL solution of ATP.

Table 1A						Table 1B						
City	State	System	CV	Competitive System	CV	City	State	System	CV	Competitive System	CV	
Lakeville	MN	3M Clean-Trace	17.92%	BioControl® Instrument Not Specified	34.05%	Jerome	ID	3M Clean-Trace	7.58%	Hygiene UltraSnap™	11.81%	
Boscobel	WI	3M Clean-Trace	15.88%	BioControl Instrument Not Specified	49.95%	Aurora	OR	3M Clean-Trace	6.49%	Hygiene UltraSnap	25.23%	
Columbus	OH	3M Clean-Trace	6.51%	BioControl Lightning®	52.63%	Richlin	WA	3M Clean-Trace	10.18%	Hygiene UltraSnap	11.76%	
St. Louis	MO	3M Clean-Trace	22.27%	BioControl Lightning	35.91%	Eugene	OR	3M Clean-Trace	13.93%	Hygiene UltraSnap	24.56%	
Tacumseh	NE	3M Clean-Trace	13.30%	BioControl Lightning	29.14%	Wheeling	IL	3M Clean-Trace	10.17%	Hygiene UltraSnap	37.00%	
Riverside	CA	3M Clean-Trace	12.94%	BioControl Lightning MVP™	50.75%	Baxter Spgs	KS	3M Clean-Trace	8.54%	Hygiene UltraSnap	13.62%	
Gardena	CA	3M Clean-Trace	21.35%	BioControl Lightning MVP	72.33%	Bakersfield	CA	3M Clean-Trace	9.48%	Hygiene UltraSnap	34.45%	
Bloomington	CA	3M Clean-Trace	19.12%	BioControl Lightning MVP	52.49%	Acvin	CA	3M Clean-Trace	7.48%	Hygiene UltraSnap	54.13%	
		Ave	16.12%		Ave	47.16%	Duluth	GA	3M Clean-Trace	4.16%	Hygiene UltraSnap	60.23%
New Century	KS	3M Clean-Trace	11.47%	Charm Firefly 2®	13.88%	Gwynon	OK	3M Clean-Trace	12.23%	Hygiene UltraSnap	47.72%	
Allamogosa	MO	3M Clean-Trace	12.17%	Charm FireFly (not tested)		Chambersburg	PA	3M Clean-Trace	8.14%	Hygiene UltraSnap	28.83%	
Tulane	CA	3M Clean-Trace	4.99%	Charm Lumiflow	32.53%	Green Bay	WI	3M Clean-Trace	16.77%	Hygiene UltraSnap	22.51%	
Burlington	NC	3M Clean-Trace	11.58%	Charm Lumiflow	26.09%	Keans	UT	3M Clean-Trace	17.65%	Hygiene UltraSnap	24.33%	
Yemassee	GA	3M Clean-Trace	15.02%	Charm LUMIMaster™	32.24%	Baltimore	OH	3M Clean-Trace	4.40%	Hygiene UltraSnap	20.99%	
Bakersfield	CA	3M Clean-Trace	9.48%	Charm novel LUM	17.86%	Irvine	CA	3M Clean-Trace	18.67%	Hygiene UltraSnap	108.65%	
Onasha	NE	3M Clean-Trace	18.35%	Charm novel LUM	48.37%	Corona	CA	3M Clean-Trace	21.27%	Hygiene UltraSnap	48.78%	
Bremers	GA	3M Clean-Trace	13.41%	Charm novel LUM	43.99%	Santa Maria	CA	3M Clean-Trace	6.88%	Hygiene UltraSnap	21.21%	
Lakeland	FL	3M Clean-Trace	12.46%	Charm novel LUM	28.48%	Lansing	IL	3M Clean-Trace	17.37%	Hygiene Ultra-Snap	47.63%	
Savannah	GA	3M Clean-Trace	8.97%	Charm novel LUM	28.75%			Ave	14.19%		Ave	38.74%
Fort Worth	TX	3M Clean-Trace	6.78%	Charm novel LUM	32.21%	Gwynon	OK	3M Clean-Trace	12.23%	Neogen AccuPoint®	38.23%	
Elk City	OK	3M Clean-Trace	9.97%	Charm novel LUM	12.58%	Lubbock	TX	3M Clean-Trace	17.87%	Neogen AccuPoint	71.73%	
Gartner	NC	3M Clean-Trace	8.17%	Charm novel LUM	22.17%	Battleboro	NC	3M Clean-Trace	9.43%	Neogen AccuPoint	85.84%	
Claysburg	PA	3M Clean-Trace	5.16%	Charm novel LUM	42.84%	Battleboro	NC	3M Clean-Trace	9.43%	Neogen AccuPoint	285.72%	
Brownfield	CO	3M Clean-Trace	14.73%	Charm novel LUM	21.49%	Chicago	IL	3M Clean-Trace	21.06%	Neogen AccuPoint	53.55%	
Hyrum	UT	3M Clean-Trace	9.65%	Charm novel LUM	43.92%	Franklin Park	IL	3M Clean-Trace	19.97%	Neogen AccuPoint	63.96%	
Salt Lake City	UT	3M Clean-Trace	5.38%	Charm novel LUM	33.27%	Salinas	CA	3M Clean-Trace	14.03%	Neogen AccuPoint	156.96%	
West Jordan	UT	3M Clean-Trace	5.78%	Charm novel LUM	70.55%	Atwater	CA	3M Clean-Trace	16.67%	Neogen AccuPoint	30.49%	
Minster	OH	3M Clean-Trace	9.75%	Charm novel LUM	31.46%	Denver	CO	3M Clean-Trace	14.43%	Neogen AccuPoint	156.05%	
Allendale	MI	3M Clean-Trace	5.38%	Charm novel LUM	28.74%	Salt Lake City	UT	3M Clean-Trace	19.14%	Neogen AccuPoint	26.00%	
Remus	MI	3M Clean-Trace	6.08%	Charm novel LUM	46.25%	Mason	OH	3M Clean-Trace	6.85%	Neogen AccuPoint	148.50%	
Canton	OH	3M Clean-Trace	4.37%	Charm novel LUM	24.99%	Santa Ana	CA	3M Clean-Trace	3.89%	Neogen AccuPoint	64.77%	
Phoenix	AZ	3M Clean-Trace	14.22%	Charm novel LUM	19.85%	Guadalupe	CA	3M Clean-Trace	20.75%	Neogen AccuPoint	68.07%	
Dubuque	IA	3M Clean-Trace	17.30%	Charm novel LUM	37.97%	Irwindale	CA	3M Clean-Trace	16.03%	Neogen AccuPoint	72.62%	
Moscatoine	IA	3M Clean-Trace	9.67%	Charm novel LUM	30.56%	St. Joseph	MO	3M Clean-Trace	7.55%	Neogen AccuPoint	36.44%	
Nebraska City	NE	3M Clean-Trace	16.36%	Charm novel LUM	27.79%	Waycross	GA	3M Clean-Trace	10.05%	Neogen AccuPoint	23.20%	
Bridgeview	IL	3M Clean-Trace	20.99%	Charm Lumimeter not recorded	50.67%	Headland	AL	3M Clean-Trace	7.18%	Neogen AccuPoint	44.19%	
Wheeling	IL	3M Clean-Trace	25.83%	Charm Lumimeter not recorded	53.65%	Albany	GA	3M Clean-Trace	13.23%	Neogen AccuPoint	19.90%	
Mason	OH	3M Clean-Trace	6.85%	Charm Lumimeter not recorded	25.58%	Henderson	NV	3M Clean-Trace	7.47%	Neogen AccuPoint	195.30%	
Green Bay	WI	3M Clean-Trace	16.77%	Charm Lumimeter not recorded	44.94%	Lamont	CA	3M Clean-Trace	33.31%	Neogen AccuPoint	43.45%	
Albert Lea	MN	3M Clean-Trace	12.25%	Charm Lumimeter not recorded	30.09%			Ave	14.03%		Ave	84.25%
		Ave	11.23%		Ave	32.76%						

Table 2: Summary of ATP Challenge Study results. Total number of swabs tested (n) and the resulting average Coefficient of Variation by Swab Type.

ATP System	n	CV%
3M Clean-Trace	770	12.46%
BioControl Lightning	80	47.16%
Charm PocketSwab® Plus	310	32.70%
Hygiene UltraSnap	180	35.74%
Neogen AccuPoint	200	84.25%

Interestingly, the range of CV's encountered varied a great deal. For the 3M swabs, the operator had a large effect on the CVs encountered. A sales representative with a degree in Biochemistry routinely obtained CV results below 10%, while other sales representatives had somewhat higher CV results.

Summary:

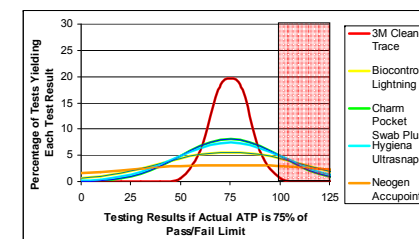
At each of the 77 plants visited from March –December 2008, the 3M Clean-Trace Surface ATP System demonstrated superior repeatability compared to the system in use by the plants at the time of the study.

Discussion:

Repeatability of a test system has important implications in the day-to-day operation of a food manufacturing plant. When decisions regarding the release of a manufacturing line for production – or to re-clean the manufacturing line – are based on the results of an ATP system, it is essential to have confidence in the result that is being given by the test system.

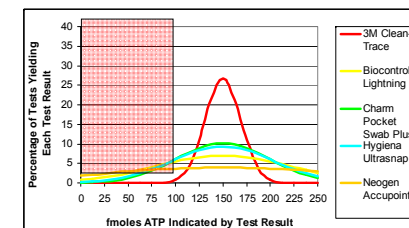
To demonstrate the practical importance of a repeatable test, a histogram of results based on the Coefficient of Variation can be produced for a couple of scenarios in the food plant. The histograms assume a normal distribution of test results and are created here using the NORMDIST function in Microsoft® Excel.

In the first example, if a surface that is cleaned to 75% of the passing limit were to be tested by systems with the CV's determined in this study, the resulting histogram of results would be produced:



The low CV test from 3M would give a very tight distribution of results around the actual value. The ATP systems with a higher CV would give a broader distribution of results. In this example, any test results below the pass/fail limit (100) represents a false-positive result which would lead to lost production capacity, wasted labor, wasted chemicals for sanitation, and increased discharge of chemicals and rinse water.

In a second example, if a surface is 50% dirtier than the pass/limit were to be tested the following would be the theoretical result:



In this example, any test results below the pass/fail limit (100) represents a false-negative result which would lead to increased risk to the product because the manufacturing line would be released for production despite being 50% dirtier than the acceptable limit.

