Comparison of the Innovate System to Traditional Methods for the Detection of Microorganisms in Finished Product

Introduction

Traditional methods for microbiological testing can take 7 - 15 days for results and require manual processes which are prone to technician error. In addition, results are not quantitative and require visual inspection for interpretation. In the case of pH, results are unreliable as many organisms generate little change in product acidity initially, if at all, and certain food products can mask the detection of contamination by pH due to their buffering capacity.

The objective of this study was to evaluate the Innovate System for detection of microorganisms in a variety of foods from a large number of companies using the RapiScreen™ Dairy kit. This report will highlight the potential for the Innovate System to detect contamination when spiked into finished products as a high probability of detection over a range of incubation times/days. Results from the Innovate System, as RLU values for ATP detection, will be compared to traditional plating results to support equivalence between methods.

(Typically, a product is incubated in its own packaging to enrich the ATP from any contaminating microbial cells. Pre-established baselines obtained from uncontaminated product are used to determine positive results.)

Report Structure

Traditional Methods

The data from all past Innovate applications was compiled and de-identified from a large variety of foods and companies. The data was collected when the following parameters were met:

1. Products tested were free from measurable contaminants.
2. Microorganisms were added at low levels <1 CFU/mL product.
3. Microorganisms added were either type cultures or of known provenance.
4. Assays were run for Innovate, plating and pH on sequential days.
5. RLUs recorded were mean RLUs from 3 replicates of 3 packs in most cases.

The report is structured to examine each microbe separately, where possible the microbes in question were examined axenically but some microorganisms were grouped together based on phenotype to produce a better statistical analysis.

Group	Species
Common Organisms	*Bacillus cereus*
	Geobacillus stearothermophilus
	Staphylococcus aureus
	Pseudomonas aeruginosa
	Salmonellae
Bacillus spp.	*B. subtilis, B. spizizenii, B. coagulans*
Clostridium spp.	*C. perfringens, c. sporogenes*
Coliforms	*E. coli, Citrobacter freundii, Enterobacter spp.*
Pseudomonas spp.	*P. putida, P. fluorescens*
Yeast	*Saccharomyces, Zygosaccharomyces, Candida, Toluraspora*

Bacillus cereus

Data & Results

For this data, 117 products were tested from 21 companies with a total of 2,106 data points. Breakdown and results are shown below. As shown in Figure 1, the mean RLU level remains above 10,000 RLUs through Day 10 (240 h). This can be explained as *B. cereus* continues to grow over this time period, producing detectable ATP. Table 2 shows the range of values over time and the number of samples analyzed at each time point.

Table 1: Breakdown of food matrices tested

A = Sauces, soups	5
B = Dairy based	25
C = Protein based	43
D = Non-dairy plant based	44

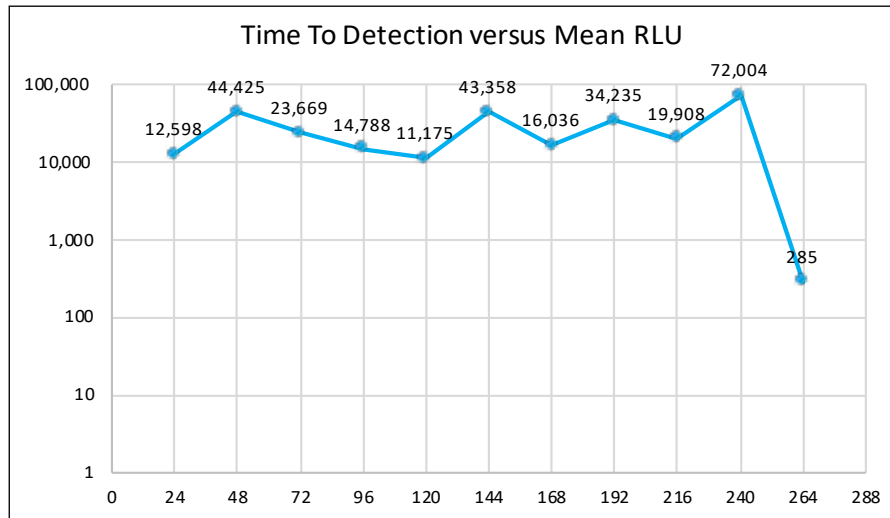**Figure 1: Mean RLU from Innovate at each tested incubation period (24 hours)**

Table 2: Statistical analysis of data from each incubation period (24 hours)

	CFU Spike	24 hours	48 hours	72 hours	96 hours	120 hours	144 hours	168 hours	192 hours	216 hours	240 hours	268 hours
Min	1	10	2	1	2	3	2	48	2	479	2	12
Max	3,700	25,186	563,385	395,776	147,132	112,884	191,188	52,749	142,358	93,281	221,082	671
Mean	143	12,598	44,425	23,669	14,788	11,175	43,358	16,036	34,235	19,908	72,004	285
Mode	54											
Median	47	12,598	8,728	7,564	4,529	1,709	46,109	6,145	13,299	2,584	44,243	198
Counts	117	2	96	110	115	103	18	5	19	6	10	6
% Counts		1.7%	82.1%	94.0%	98.3%	88.0%	15.4%	4.3%	16.2%	5.1%	8.5%	5.1%

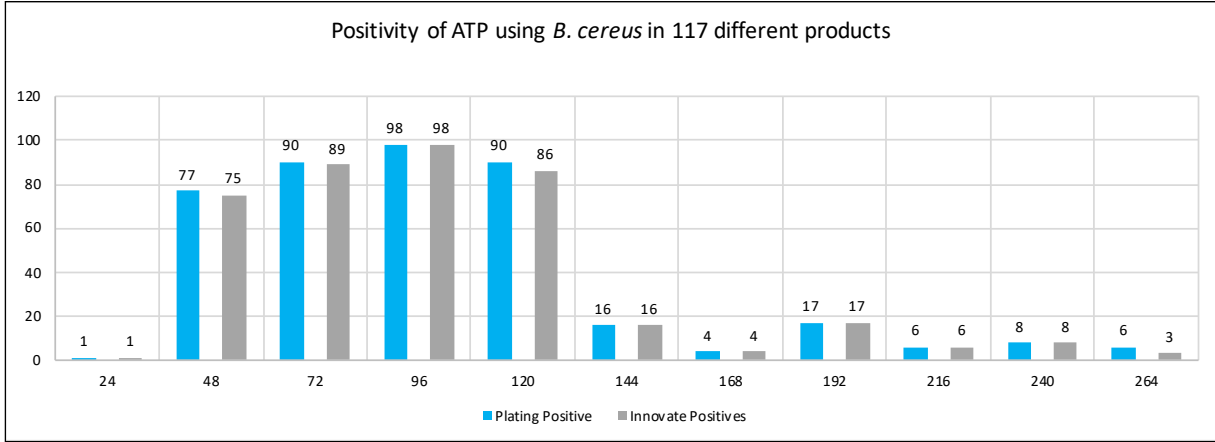**Figure 2: PoD% Analysis from each incubation period (24 hours) comparing plating with Innovate**

Positivity of ATP using *B. cereus* in 117 different products

Table 3: Tabulated PoD% expressed as % for each incubation period (24 hours)

	24 hours	48 hours	72 hours	96 hours	120 hours	144 hours	168 hours	192 hours	216 hours	240 hours
PoD%	100%	97%	99%	100%	96%	100%	100%	100%	100%	100%

Table 4: Standard analysis of all individual RLUs and plates

Sensitivity	98.54%
Specificity	97.30%
Precision PPV%	99.51%
NPV%	92.31%

As is shown above in Figure 2 and Table 3, the probability of detection (PoD%) from both the Innovate System and traditional plating was similar for all days measured. This demonstrates that the growth of the *Bacillus* species aligns whether analyzed by the production of ATP or plate viability.

Geobacillus stearothermophilus

Data & Results

For this data, 23 products were tested from 5 companies with a total of 414 data points. Breakdown and results are shown below. As shown in Figure 3, *Geobacillus* produces an appreciable decline in output RLUs; this can been seen clearly in the descending RLU levels from 24 hours onwards. This decline is due to the organism sporulating as it completes its lifecycle. This organism only grows at 55 °C and complete the growth in dairy products exceptionally quickly and undergoes this senescent behavior. Table 6 shows the range of values over time and the number of samples analyzed at each time point.

Table 5: Breakdown of food matrices tested

A = Sauces, soups	0
B = Dairy based	10
C = Protein based	0
D = Non-dairy plant based	13

Figure 3: Mean RLU from Innovate at each tested incubation period (24 hours)
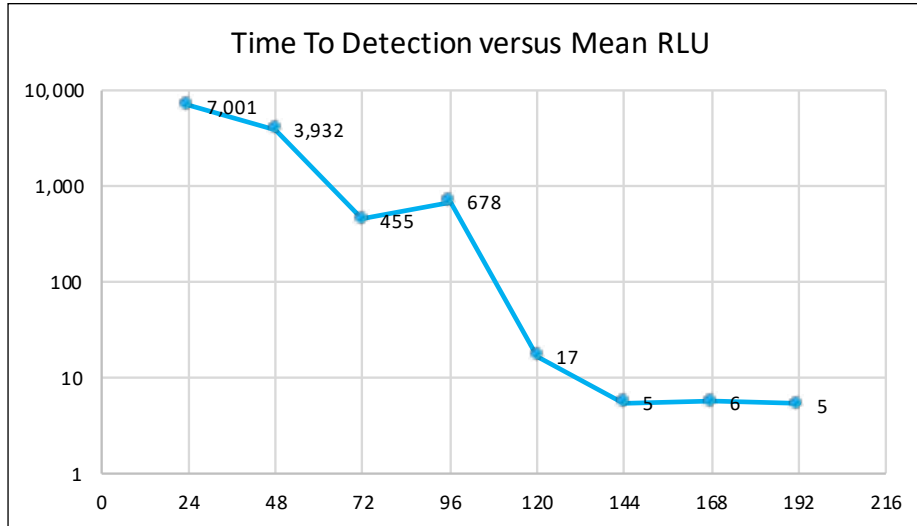

Time To Detection versus Mean RLU

Table 6: Statistical analysis of data from each incubation period (24 hours)

	CFU Spike	24 hours	48 hours	72 hours	96 hours	120 hours	144 hours	168 hours	192 hours	216 hours	240 hours
Min	3	2,584	2	2	1	2	2	2	1	0	0
Max	30,000	11,221	36,966	2,219	7,745	96	11	15	11	0	0
Mean	4,502	7,001	3,932	455	678	17	5	6	5	No Data	No Data
Mode	3										
Median	54		8	4	13	3	4	4	4	No Data	No Data
Counts	23	4	22	18	20	6	14	8	18	0	0
% Counts		**17.4%**	**95.7%**	**78.3%**	**87.0%**	**26.1%**	**60.9%**	**34.8%**	**78.3%**	**0.0%**	**0.0%**

The Innovate System will continue to detect this organism until the thresholds are undermined by the reduction in ATP. From the data it is recommended that detection of this organism be measured as early as possible: 24, 48, or 72 hours are optimal with 96 hours showing some fractionality. Figure 4 and Table 7 below show the drop in PoD% at 96 and 120 hours.

Figure 5 clearly demonstrates the rapid growth of *G. stearothermophilus* at all dilutions in UHT milk. The immediate outgrowth of the spores added result in a huge and rapid RLU increase to a plateau at 8 - 12 hours, making detection rapid (less than 24 hours).

Figure 4: PoD% analysis from each incubation period (24 hours) comparing plating with Innovate
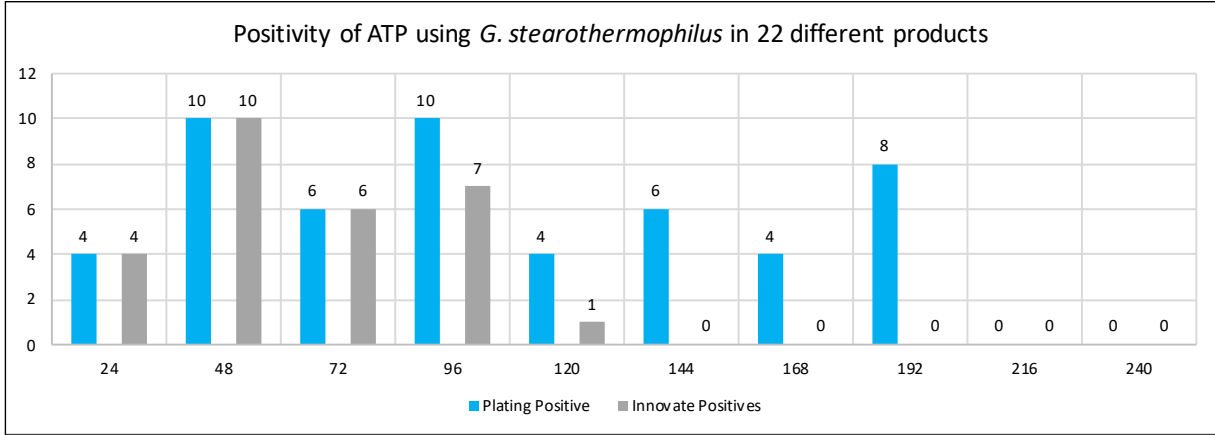

Positivity of ATP using *G. stearothermophilus* in 22 different products

- ■ Plating Positive ■ Innovate Positives

Table 7: Tabulated PoD% expressed as % for each incubation period (24 hours)

	24 hours	48 hours	72 hours	96 hours	120 hours	144 hours	168 hours	192 hours	216 hours	240 hours
PoD%	100%	100%	100%	70%	25%	0%	0%	0%	ND	ND

Figure 5: Time course growth of *G. stearothermophilus* at 55 °C measured for ATP content using Innovate at early incubation periods: 4 hours, 8 hours, 24 hours, and 48 hours
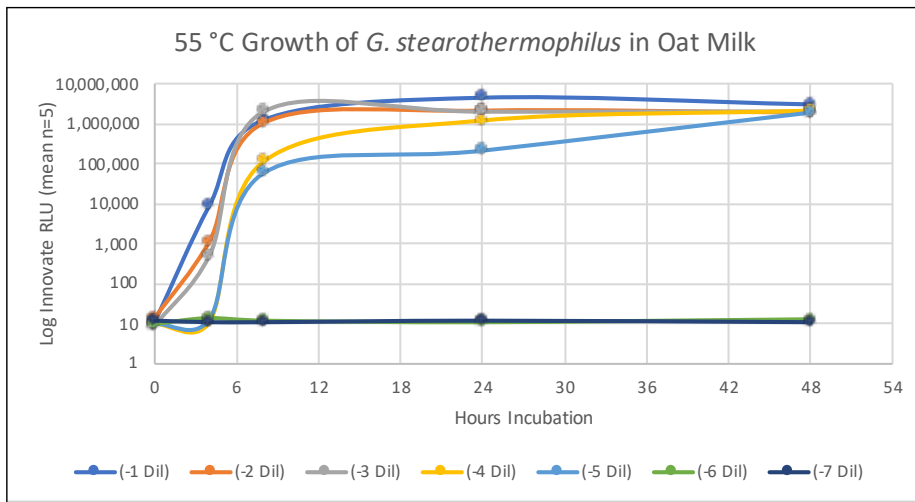

55 °C Growth of *G. stearothermophilus* in Oat Milk

Log Innovate RLU (mean n=5) vs Hours Incubation

- ●— (-1 Dil) ●— (-2 Dil) ●— (-3 Dil) ●— (-4 Dil) ●— (-5 Dil) ●— (-6 Dil) ●— (-7 Dil)

Table 8: Standard analysis of all individual RLUs and plates for all incubation periods to 8 days

Sensitivity	56.00%
Specificity	100.00%
Precision PPV%	100.00%
NPV%	75.56%

Table 8: Standard analysis of all individual RLUs and plates for all incubation periods to 4 days

Sensitivity	90.32%
Specificity	100.00%
Precision PPV%	100.00%
NPV%	95.77%

The two tables above show the effect of cutting the maximum incubation period to 4 days from 8 days. The inclusion of the Innovate System false negatives significantly reduces the probability of detection at 8 days. The data indicates that a maximum of 4 days incubation at 55 °C be the outermost used in risk assessments for this organism. The data also suggests testing as soon as possible, 24 - 48 hours would be advisable for this organism, saving significant time to results.

Staphylococcus aureus

Data & Results

For this data, 114 products were tested from 20 companies with a total of 2,114 data points. Breakdown and results are shown below. As shown in Figure 6, *S. aureus* maintains consistent output of a mean RLU above 5,000 through day 10. This indicates that *S. aureus* does not display senescent behavior over time which would lead to a reduction in ATP levels. Table 11 shows the range of values over time and the number of samples analyzed at each time point.

Table 10: Breakdown of food matrices tested

A = Sauces, soups	3
B = Dairy based	24
C = Protein based	43
D = Non-dairy plant based	44

Figure 6: Mean RLU from Innovate at each tested incubation period (24 hours)
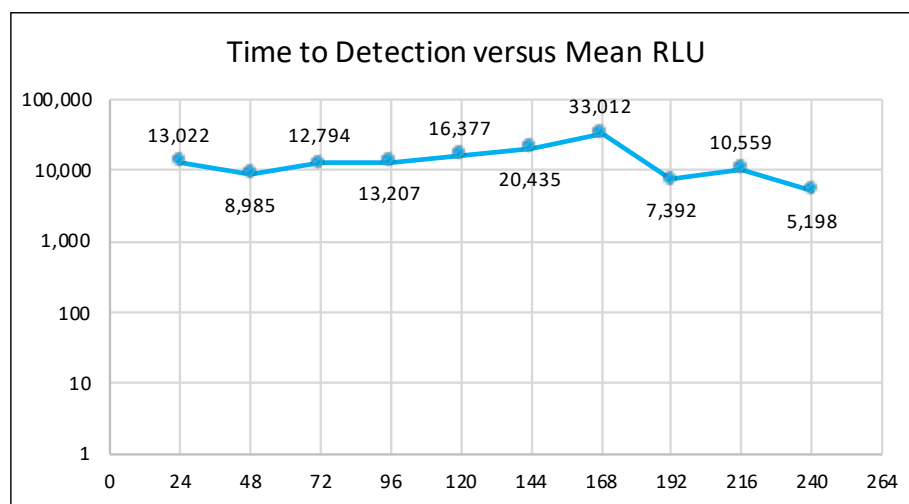
Table 11: Statistical analysis of data from each incubation period (24 hours)

	CFU Spike	24 hours	48 hours	72 hours	96 hours	120 hours	144 hours	168 hours	192 hours	216 hours	240 hours
Min	8	3	2	1	4	8	451	151	233	59	3,889
Max	85,000	87,987	88,200	91,165	92,339	187,171	68,070	91,239	14,624	38,565	6,469
Mean	3,116	13,022	8,985	12,794	13,207	16,377	20,435	33,012	7,392	10,559	5,198
Mode	61										
Median	48	180	224	3,807	6,675	6,388	16,954	36,403	7,309	1,807	5,237
Counts	114	21	102	112	102	98	6	19	6	4	3
% Counts		**18.4%**	**89.5%**	**98.2%**	**89.5%**	**86.0%**	**5.3%**	**16.7%**	**5.3%**	**3.5%**	**2.6%**

Figure 7: PoD% Analysis from each incubation period (24 hours) comparing plating with Innovate

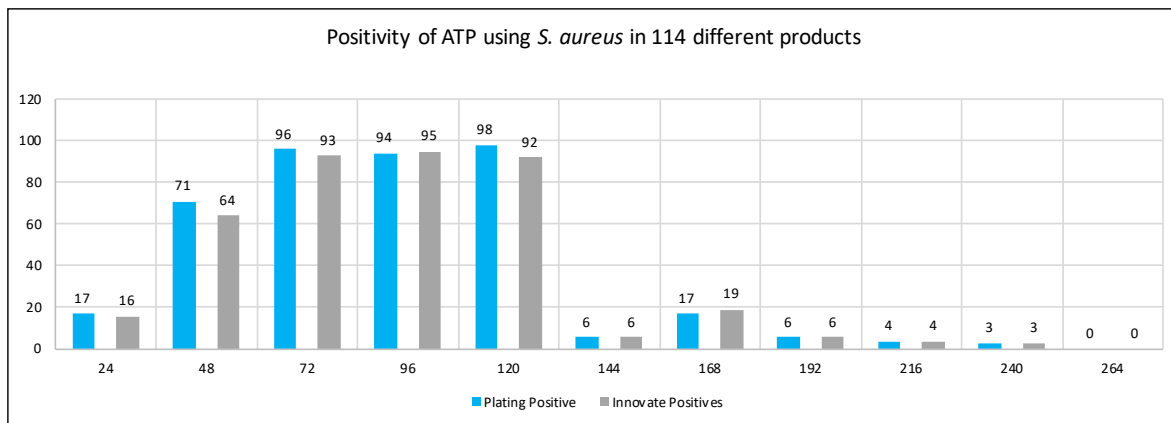Positivity of ATP using *S. aureus* in 114 different products

Table 12: Tabulated PoD% expressed as % for each incubation period (24 hours)

	24 hours	48 hours	72 hours	96 hours	120 hours	144 hours	168 hours	192 hours	216 hours	240 hours
PoD%	94%	90%	97%	101%	94%	100%	112%	100%	100%	100%

Table 13: Standard analysis of all individual RLUs and plates for all incubation periods

Sensitivity	97.08%
Specificity	98.41%
Precision PPV%	99.75%
NPV%	83.78%

Figure 7 and Table 12

The PoD% analysis for *S. aureus* shows maximal detection using the Innovate System at 72 hours (Figure 7). The PoD% at 24 and 48 hours is at 94% and 90%, respectively (Table 12); this is mainly due to *S. aureus* being a small Gram-positive coccus with a lower ATP content per cell. The effect of the products on the growth of this organism means it may not reach thresholds until 72 hours for all products supporting its growth.

As shown in Table 13, the sensitivity and selectivity are high for this organism. The lower NPV% will be increased significantly if the analysis is performed at 72 hours of incubation.

Bacillus subtilis, B. spizizenii and B. coagulans

Data & Results

For this data, 10 products were tested from 3 companies with a total of 180 data points. Breakdown and results are shown below. As shown in Figure 8, these *Bacillus* species maintains consistent output of a mean RLU above 5,000 from day 2 through day 5. This decline is due to the organism sporulating as it completes its lifecycle. There is an increase from day 1 to day 2 and a drop from day 5 to day 7. However, the levels of ATP do not drop below threshold levels. Table 15 shows the range of values over time and the number of samples analyzed at each time point.

Table 14: Breakdown of food matrices tested

A = Sauces, soups	0
B = Dairy based	10
C = Protein based	0
D = Non-dairy plant based	0

Figure 8: Mean RLU from Innovate at each tested incubation period (24 hours)
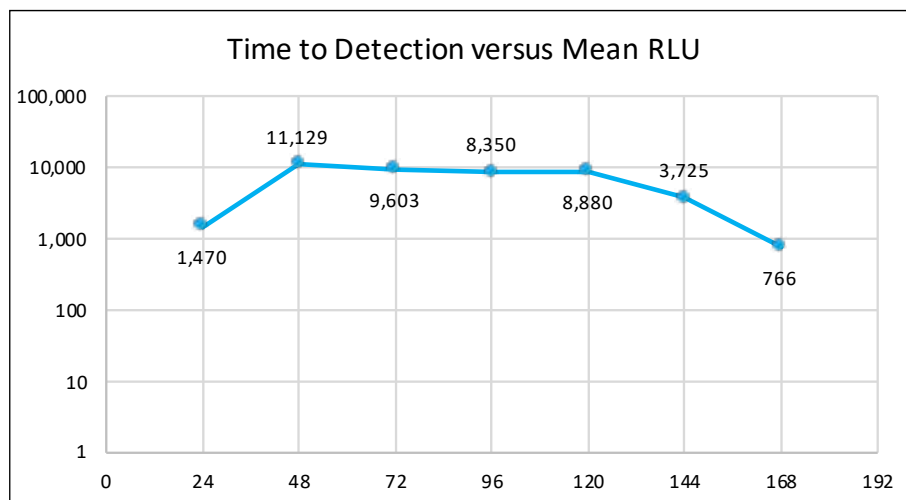
Table 15: Statistical analysis of data from each incubation period (24 hours)

	CFU Spike	24 hours	48 hours	72 hours	96 hours	120 hours	144 hours	168 hours	192 hours	216 hours	240 hours
Min	4	5	1,709	1,378	2,829	2,416	2,014	468	0	0	0
Max	78	5,098	24,865	25,106	11,129	15,709	6,012	1,064	0	0	0
Mean	34	1,470	11,129	9,603	8,350	8,880	3,725	766	No Data	No Data	No Data
Mode	78										
Median	15	250	11,771	8,484	11,093	8,404	3,148	766	No Data	No Data	No Data
Counts	10	5	10	8	3	6	3	2	0	0	0
% Counts		**50.0%**	**100.0%**	**80.0%**	**30.0%**	**60.0%**	**30.0%**	**20.0%**	**0.0%**	**0.0%**	**0.0%**

Figure 9: PoD% Analysis from each incubation period (24 hours) comparing plating with Innovate

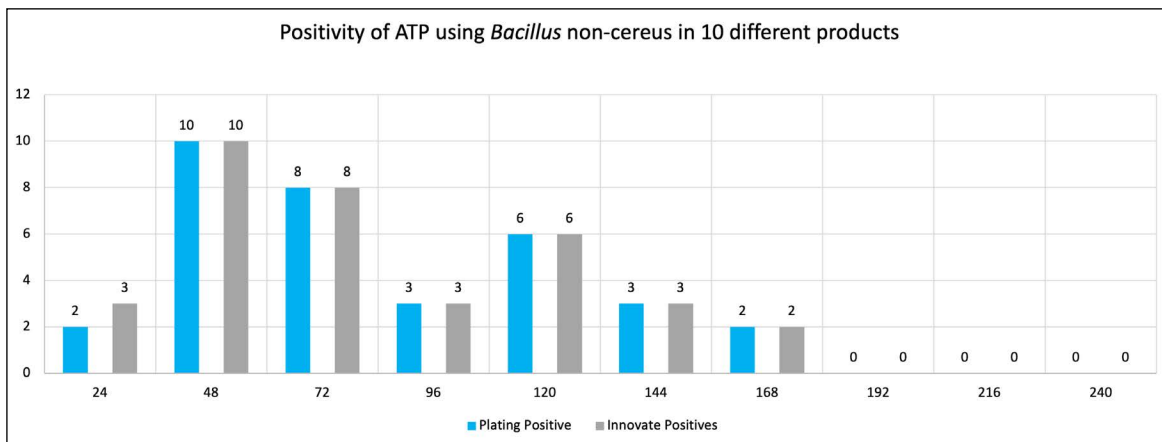Positivity of ATP using *Bacillus* non-cereus in 10 different products

Table 16: Tabulated PoD% expressed as % for each incubation period (24 hours)

	24 hours	48 hours	72 hours	96 hours	120 hours	144 hours	168 hours	192 hours	216 hours	240 hours
PoD%	150%	100%	100%	100%	100%	100%	100%	No data	No data	No data

Table 17: Standard analysis of all individual RLUs and plates for all incubation periods

Sensitivity	100.00%
Specificity	94.44%
Precision PPV%	97.37%
NPV%	100.00%

As seen in Figure 9, the PoD% for these *Bacillus* species remained at 100% during the entire incubation period tested. The sensitivity and sensitivity are very high for this organism group (Table 17).

Clostridium perfringens, C. sporogenes

Data & Results

For this data, 111 products were tested from 18 companies with a total of 1,960 data points. Breakdown and results are shown below. As shown in Figure 10, the mean RLU level remains above 5,000 RLUs through Day 10 (240 h). This can be explained as these organisms continue to grow over this time period, producing detectable ATP. Table 19 shows the range of values over time and the number of samples analyzed at each time point.

Table 18: Breakdown of food matrices tested

A = Sauces, soups	2
B = Dairy based	25
C = Protein based	41
D = Non-dairy plant based	43

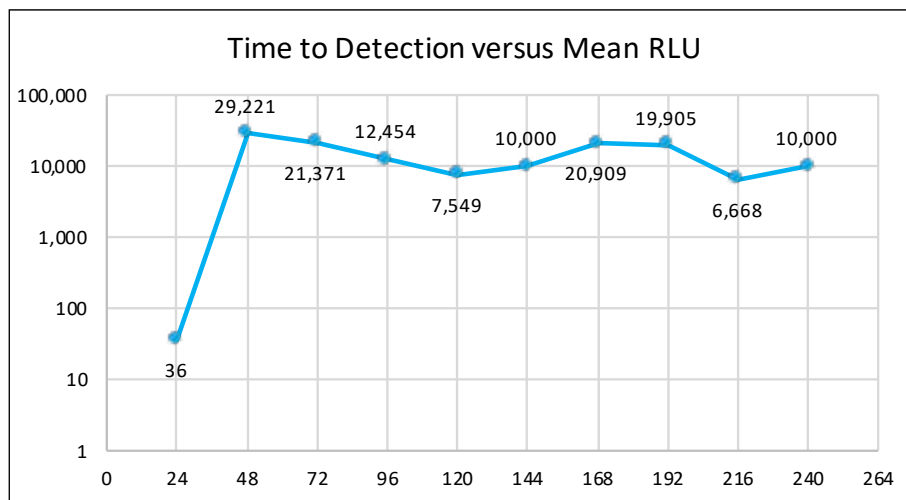**Figure 10: Mean RLU from Innovate at each tested incubation period (24 hours)**

Table 19: Statistical analysis of data from each incubation period (24 hours)

	CFU Spike	24 hours	48 hours	72 hours	96 hours	120 hours	144 hours	168 hours	192 hours	216 hours	240 hours
Min	1	1	2	1	1	1	10,000	3	41	2	10,000
Max	10,800	104	303,544	242,935	123,048	49,427	10,000	118,876	59,579	10,000	10,000
Mean	253	36	29,221	21,371	12,454	7,549	10,000	20,909	19,905	6,668	10,000
Mode	1										
Median	16	28	6,828	8,454	8,315	10,000	10,000	10,000	10,000	10,000	10,000
Counts	108	19	96	108	93	100	4	16	4	6	0
% Counts		**16.7%**	**842%**	**94.7%**	**81.6%**	**87.7%**	**3.5%**	**14.0%**	**3.5%**	**5.3%**	**0.0%**

Figure 11: PoD% Analysis from each incubation period (24 hours) comparing plating with Innovate
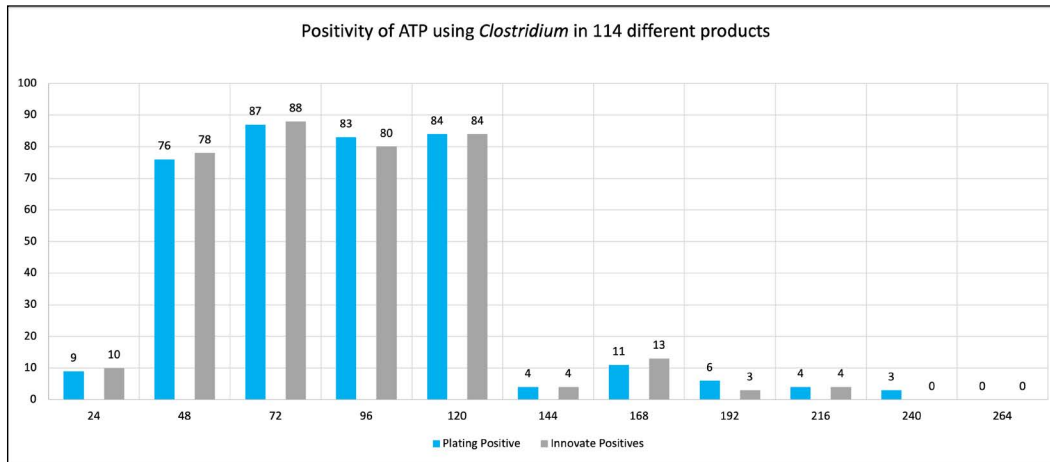

Table 20: Tabulated PoD% expressed as % for each incubation period (24 hours)

	24 hours	48 hours	72 hours	96 hours	120 hours	144 hours	168 hours	192 hours	216 hours	240 hours
PoD%	111%	103%	101%	96%	100%	100%	118%	50%	100%	0%

Table 21: Standard analysis of all individual RLUs and plates for all incubation periods

Sensitivity	97.60%
Specificity	100.00%
Precision PPV%	100.00%
NPV%	90.91%

As seen in Table 20, the PoD% for these *Clostridium* species remains at 100% for almost all of the incubation period. The PoD% table does take into account non-growing organisms; if the organism being investigated does not grow on the Innovate System and is not detected on plates, it will not appear in this table. A non-growing organism would be considered as a low risk for products.

In addition, the sensitivity and selectivity are high for this organism group (Table 21).

Pseudomonas aeruginosa

Data & Results

For this data, 111 products were tested from 21 companies with a total of 2,124 data points. Breakdown and results are shown below. As shown in Figure 12, the mean RLU level remains steady and above the threshold through 196 hours. This can be explained as these non-fermenting bacilli continue to grow over this time period, producing detectable ATP. Table 23 shows the range of values over time and the number of samples analyzed at each time point.

Table 22: Breakdown of food matrices tested

A = Sauces, soups	2
B = Dairy based	25
C = Protein based	41
D = Non-dairy plant based	43

Figure 12: Mean RLU from Innovate at each tested incubation period (24 hours)
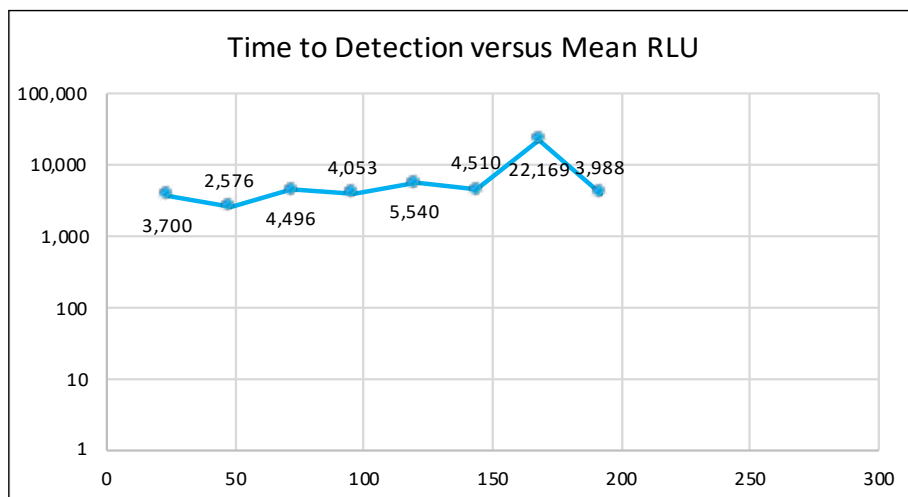

Time to Detection versus Mean RLU

Table 23: Statistical analysis of data from each incubation period (24 hours)

	CFU Spike	24 hours	48 hours	72 hours	96 hours	120 hours	144 hours	168 hours	192 hours	216 hours	240 hours
Min	7	7	2	5	2	8	100	149	2,822	0	0
Max	70,000	17,035	24,481	39,246	81,116	74,854	16,135	95,566	5,153	0	0
Mean	2,526	3,700	2,576	4,496	4,053	5,540	4,510	22,169	3,988		
Mode	13	17,035	16	5	449	42		4,194			
Median	25	868.5	531	1,458	1,491	1,525	3,226	7,730.5	3,987.5		
Counts	107	18	95	105	95	95	6	20	2	0	0
% Counts		**16.8%**	**88.8%**	**98.1%**	**88.8%**	**88.8%**	**5.6%**	**18.7%**	**1.9%**	**0.0%**	**0.0%**

Figure 13: PoD% analysis from each incubation period (24 hours) comparing plating with Innovate

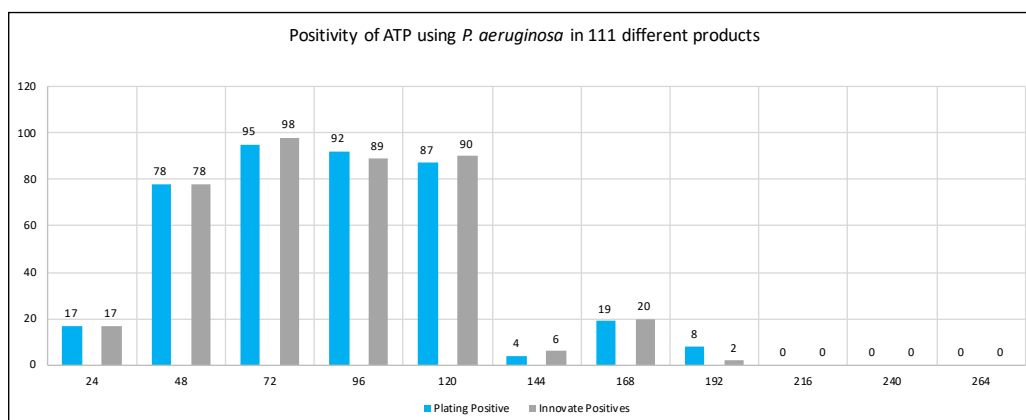Positivity of ATP using *P. aeruginosa* in 111 different products

Table 24: Tabulated PoD% expressed as % for each incubation period (24 hours)

	24 hours	48 hours	72 hours	96 hours	120 hours	144 hours	168 hours	192 hours	216 hours	240 hours
PoD%	100%	100%	103%	97%	103%	150%	105%	25%		

Table 25: Standard analysis of all individual RLUs and plates for all incubation periods

Sensitivity	99.49%
Specificity	91.11%
Precision PPV%	98.99%
NPV%	95.35%

As shown in Figure 13, the PoD% for *Pseudomonas aeruginosa* remains at 100% for the incubation period up to 168 hours; at 192 hours there is a significant downturn in RLU levels. The sensitivity and selectivity are high for this organism group (Table 25).

Salmonella spp.

Data & Results

For this data: 15 products were tested from 4 companies with a total of 117 data points. Breakdown and results are shown below. As shown in Figure 14, the mean RLU level remains significantly high, above 10,000 RLUs through Day 8, causing many of the cartons to burst (shown as 10,000 CFUs in Table 27). This can be explained as these organisms grow very rapidly, producing large amounts of H2S (the gas causing the packs to expand and burst).

Table 26: Breakdown of food matrices tested

A = Sauces, soups	0
B = Dairy based	1
C = Protein based	1
D = Non-dairy plant based	13

Figure 14: Mean RLU from Innovate at each tested incubation period (24 hours)
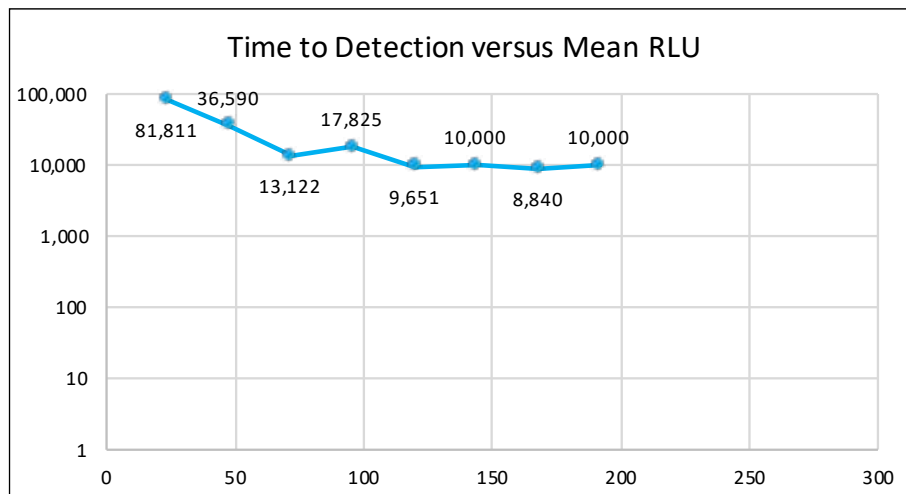
Table 27: Statistical analysis of data from each incubation period (24 hours)

	CFU Spike	24 hours	48 hours	72 hours	96 hours	120 hours	144 hours	168 hours	192 hours
Min	11	8	523	261	5,247	1,456	10,000	3,780	10,000
Max	9,900	152,439	78,682	51,442	54,112	22,159	10,000	10,000	10,000
Mean	1,880	81,811	36,590	13,122	17,825	9,651	10,000	8,840	10,000
Mode	79	127,496	63,259	10,000	10,000	10,000		10,000	
Median	79	109,965.5	42,982	10,000	10,000	10,000	10,000	10,000	10,000
Counts	15	12	15	15	10	8	2	11	2
% Counts		80.0%	100.0%	100.0%	66.7%	53.3%	13.3%	73.3%	13.3%

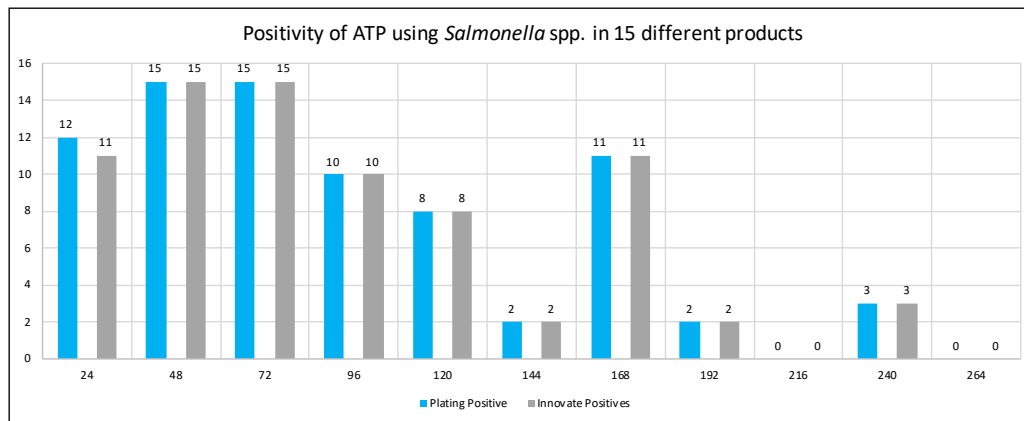**Figure 15: PoD% analysis from each incubation period (24 hours) comparing plating with Innovate**

Positivity of ATP using *Salmonella* spp. in 15 different products

Table 28: Tabulated PoD% expressed as % for each incubation period (24 hours)

	24 hours	48 hours	72 hours	96 hours	120 hours	144 hours	168 hours	192 hours	216 hours	240 hours
PoD%	92%	100%	100%	100%	100%	100%	100%	100%		100%

Table 29: Standard analysis of all individual RLUs and plates for all incubation periods

Sensitivity	98.72%
Specificity	100.00%
Precision PPV%	100.00%
NPV%	90.00%

As shown in Figure 15, the PoD% for *Salmonella* species remains at 100% for the entire incubation period. The sensitivity and specificity are also very high for this organism group (Table 29).

Pseudomonas species *(non-aeruginosa; P. putida)*

Data & Results

For this data, 108 products were tested from 5 companies with a total of 1,944 data points. Breakdown and results are shown below. As shown in Figure 16, the mean RLU level remains steady and above the threshold throughout all time points, even though the values were low. This can be explained as the main species in this group was *P. putida* which is known to not produce high levels ATP. Table 31 shows the range of values over time and the number of samples analyzed at each time point.

Table 30: Breakdown of food matrices tested

A = Sauces, soups	2
B = Dairy based	24
C = Protein based	38
D = Non-dairy plant based	28

Figure 16: Mean RLU from Innovate at each tested incubation period (24 hours)
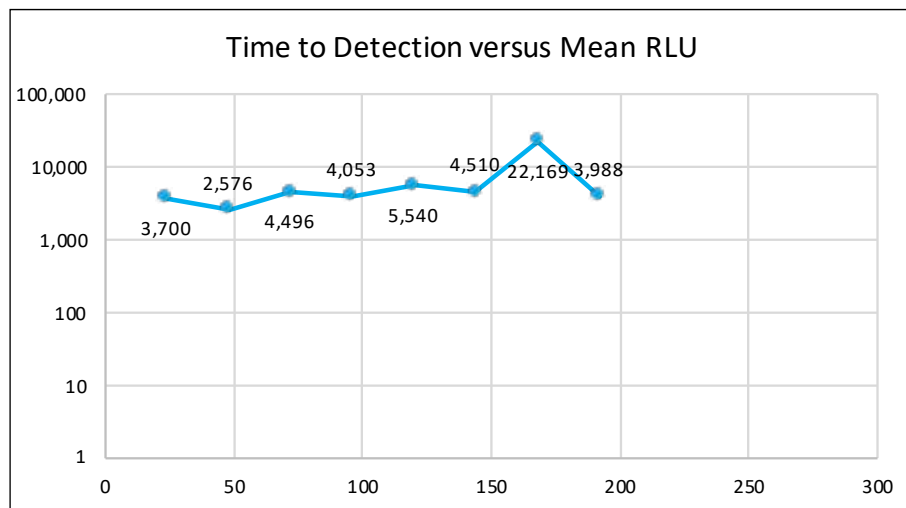

Table 31: Statistical analysis of data from each incubation period (24 hours)

	CFU Spike	24 hours	48 hours	72 hours	96 hours	120 hours	144 hours	168 hours
Min	1	349	2	1	1	2	0	57
Max	99	349	4,525	29,126	21,364	25,535	0	525
Mean	37	349	270	1,297	1,301	1,618	1,001	291
Mode	26		7	1	3	3		
Median	31	349	32	83	125	247.5		291
Counts	89	1	77	89	88	88	0	2
% Counts		**0.9%**	**72.0%**	**83.2%**	**82.2%**	**82.2%**	**0.0%**	**1.9%**

Figure 17: PoD% Analysis from each incubation period (24 hours) comparing plating with Innovate

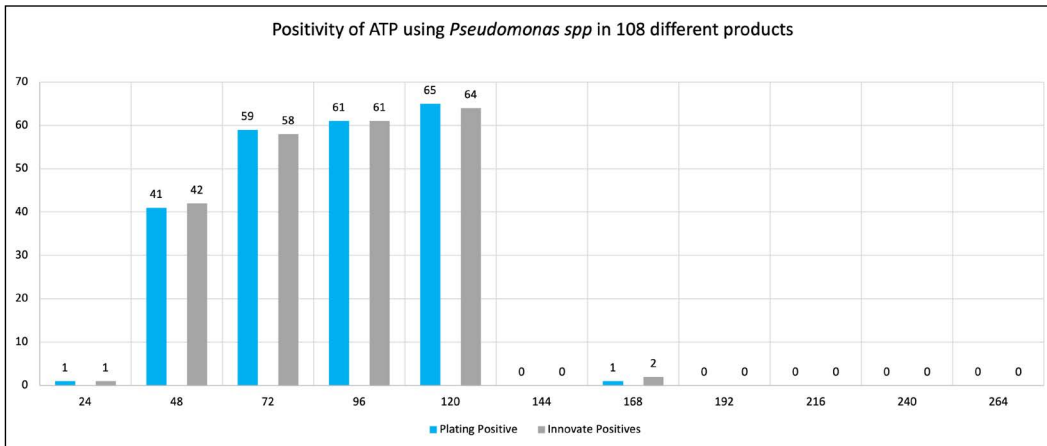Positivity of ATP using *Pseudomonas spp* in 108 different products

Table 32: Tabulated PoD% expressed as % for each incubation period (24 hours)

	24 hours	48 hours	72 hours	96 hours	120 hours	144 hours	168 hours
PoD%	100%	102%	98%	100%	98%		200%

Table 33: Standard analysis of all individual RLUs and plates for all incubation periods

Sensitivity	97.70%
Specificity	99.12%
Precision PPV%	99.53%
NPV%	95.73%

As shown in Figure 17, the PoD% for the *Pseudomonas* species remains at 100% for the entire incubation period. In addition, the sensitivity and selectivity are high for this organism group (Table 33).

Yeast *(Saccharomyces, Zygosaccharomyces, Candida, Toluraspora)*

Data & Results

For this data, 29 products were tested from 7 companies with a total of 330 data points. Breakdown and results are shown below. As shown in Figure 18, the mean RLU output remained relatively high, but begins to decline after 24, but remains above 3,000 RLU, even at Day 10. Table 35 shows the range of values over time and the number of samples analyzed at each time point.

Table 30: Breakdown of food matrices tested

A = Sauces, soups	0
B = Dairy based	9
C = Protein based	12
D = Non-dairy plant based	8

Figure 18: Mean RLU from Innovate at each tested incubation period (24 hours)

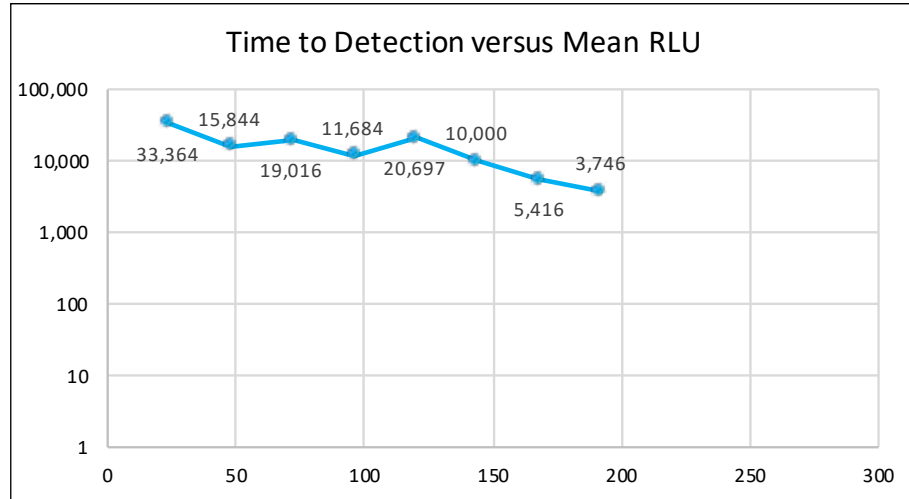Time to Detection versus Mean RLU

Table 35: Statistical analysis of data from each incubation period (24 hours)

	CFU Spike	24 hours	48 hours	72 hours	96 hours	120 hours	144 hours	168 hours	192 hours
Min	14	4	3	2	2	2	10,000	4	5
Max	1,600	116,688	106,516	223,957	167,012	205,210	10,000	10,000	10,000
Mean	159	33,364	15,844	19,016	11,684	20,697	10,000	5,416	3,746
Mode	33	77	10	10,000	10,000	10,000		10,000	
Median	32	77	277	1,322	2,500	3,016.5	10,000	5,940	1,101
Counts	29	7	30	30	27	14	1	12	6
% Counts		23.3%	100.0%	100.0%	90.0%	46.7%	3.3%	40.0%	20.0%

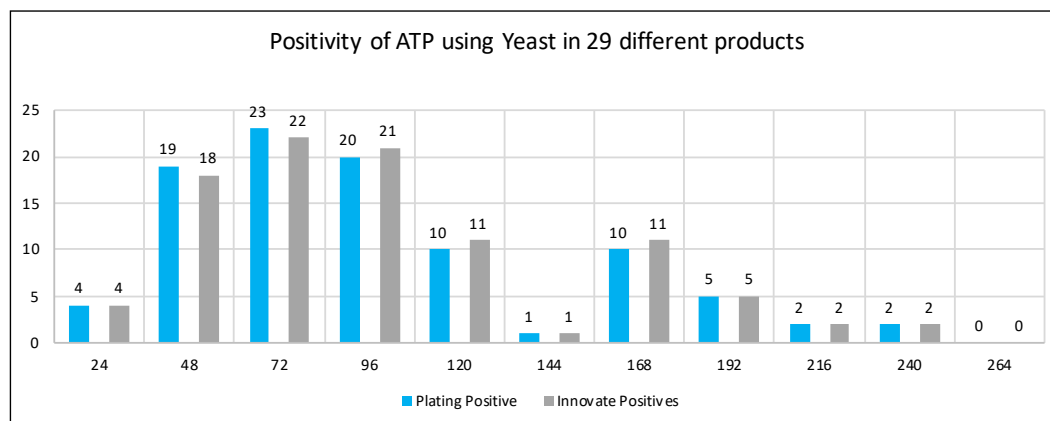**Figure 19: PoD% Analysis from each incubation period (24 hours) comparing plating with Innovate**

Positivity of ATP using Yeast in 29 different products

Table 36: Tabulated PoD% expressed as % for each incubation period (24 hours)

	24 hours	48 hours	72 hours	96 hours	120 hours	144 hours	168 hours	192 hours
PoD%	100%	95%	96%	105%	110%	100%	110%	100%

Table 37: Standard analysis of all individual RLUs and plates for all incubation periods

Sensitivity	97.85%
Specificity	100.00%
Precision PPV%	100.00%
NPV%	95.12%

As shown in Figure 19, the PoD% for mixed yeast remains above 95% for the entire incubation period. In addition, the sensitivity and selectivity are high for this organism group (Table 37).

Coliforms *(E.coli, Citrobacter, Enterobacter)*

Data & Results

For this data: 15 products were tested from 4 companies with a total of 125 data points. Breakdown and results are shown below. As shown in Figure 20, the mean RLU output remained relatively high, and doesn't decline throughout all incubation periods tested. Table 39 shows the range of values over time and the number of samples analyzed at each time point.

Table 30: Breakdown of food matrices tested

A = Sauces, soups	0
B = Dairy based	1
C = Protein based	1
D = Non-dairy plant based	13

Figure 20: Mean RLU from Innovate at each tested incubation period (24 hours)
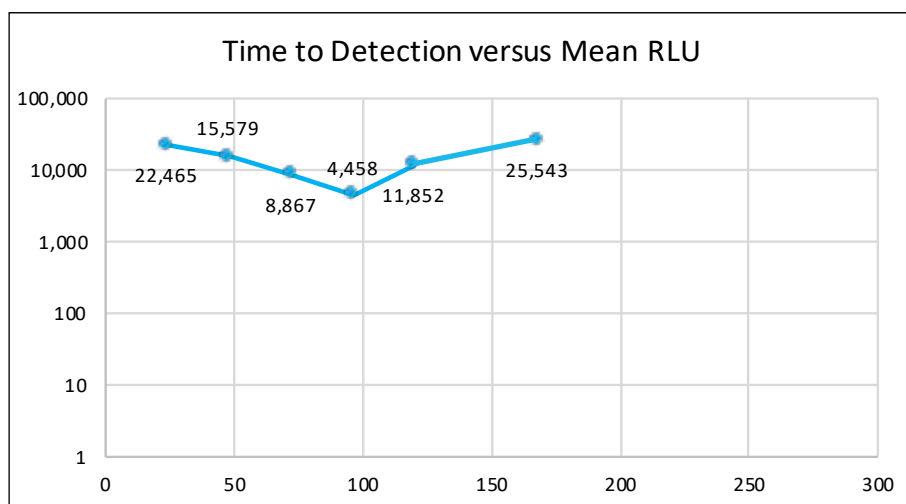
Table 39: Statistical analysis of data from each incubation period (24 hours)

	CFU Spike	24 hours	48 hours	72 hours	96 hours	120 hours	168 hours
Min	3	2	3	3	23	2	2
Max	1,500	120,769	50,285	27,146	15,487	104,422	106,969
Mean	255	22,465	15,579	8,867	4,458	11,852	25,543
Mode	87		3				
Median	77	8,206	5,553	6,260	1,161.5	944	4,757
Counts	15	12	11	13	4	10	8
% Counts		**80.0%**	**73.3%**	**86.7%**	**26.7%**	**66.7%**	**53.3%**

Figure 21: PoD% Analysis from each incubation period (24 hours) comparing plating with Innovate

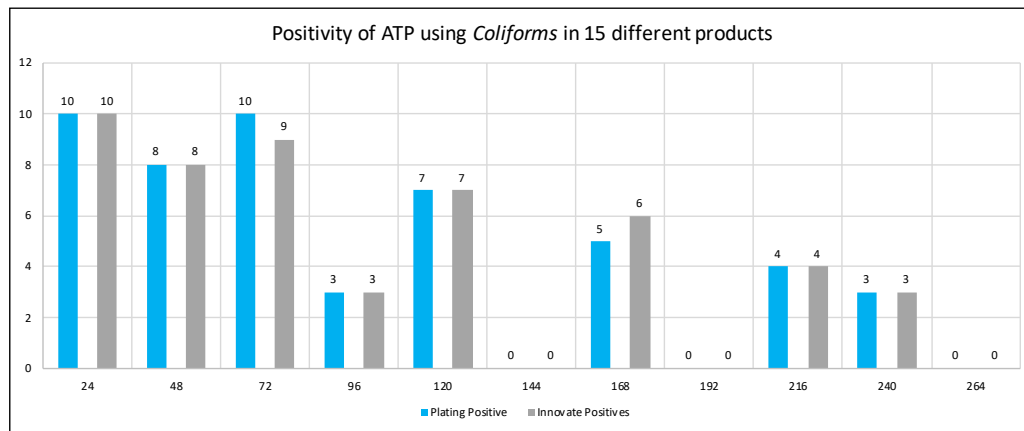Positivity of ATP using *Coliforms* in 15 different products

Table 40: Tabulated PoD% expressed as % for each incubation period (24 hours)

	24 hours	48 hours	72 hours	96 hours	120 hours	144 hours	168 hours	192 hours	216 hours	240 hours
PoD%	100%	100%	90%	100%	100%		120%			100%

Table 41: Standard analysis of all individual RLUs and plates for all incubation periods

Sensitivity	100.00%
Specificity	100.00%
Precision PPV%	100.00%
NPV%	90.00%

As shown in Figure 21, the PoD% for mixed coliforms remains above 90% for the entire incubation period. In addition, the sensitivity and selectivity are high for this organism group (Table 41).

Conclusion

This study was conducted to compare the performance of the Innovate System versus traditional microbial testing (plating) using organisms commonly seen as contaminants in dairy and plant-based dairy products. As seen with all organisms tested, results from the Innovate System were at least comparable to plating and in some cases, superior to plating. The probability of detection (PoD%) was used for analysis of growth of the microorganisms, showing measuring the production of ATP versus plate viability were aligned. In some cases, the Innovate System detected growth (ATP) days earlier than traditional plating with a similar PoD%. In addition, sensitivity and specificity were always above 90% and, in most cases, over 97%. These results demonstrate that the Innovate System can reduce time-to-results, saving you time and holding costs. In addition, the Innovate System allows you to run up to 96 individual samples at once and provides numerical results in less than 30 minutes, simplifying your testing processes and reducing the risk of error or missing a low level of contamination.

Summary

Traditional culture methods (plating) can take 7 - 15 days for results and require manual processes which are prone to technician error. In addition, results are not quantitative and require visual inspection for interpretation. In the case of pH, results are unreliable as many organisms generate little change in product acidity initially, if at all, and certain food products can mask the detection of contamination by pH due to their buffering capacity.

By choosing the Innovate System, an alternative method for measuring contamination using ATP detection, you can overcome the drawbacks of traditional culture and pH testing methods. The Innovate System provides measurable results, more rapidly, and with little risk of false-negatives or false-positives. This means you can feel confident in releasing final product, reducing inventory and holding costs, and streamlining processes.