

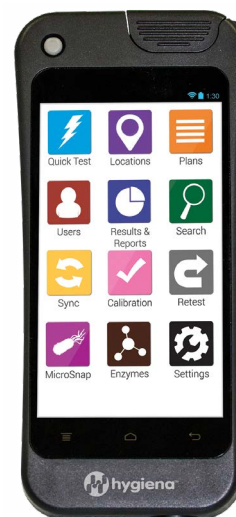
Comparing the Performance of ATP Hygiene Monitoring Systems

Hygiena™ vs 3M™



ATP Hygiene Monitoring

ATP hygiene monitoring is a simple, rapid and quantitative testing method to verify cleaning effectiveness. For a surface to be verifiably clean, all food debris and other organic matter must be removed. Food debris, organic matter, and microorganisms contain ATP. Microorganisms are very tiny and individually contain only small amount of ATP. Thus, large numbers of microbes (~10,000) are required to be detectable by ATP test systems, which measure ATP residue in Relative Light Units (RLU). Systems are highly sensitive and can detect extremely low levels of ATP molecules, which means they can detect extremely small amounts of organic matter or food debris on surfaces. Effective cleaning removes both microbes and food residues. This means the lower the ATP reading is, the higher the cleaning standards are, resulting in a lower risk of microbial contamination.



What Has Changed?

Over the past 10 years, some systems have been re-designed, and some have received 3rd party certification by AOAC-RI under the *Performance Tested MethodsSM* Program.

Hygiena Changes

- Hygiena released the **EnSURE Touch™** to complement its **SystemSURE™ Plus** and **EnSURE™** luminometers.
- UltraSnap™** Surface ATP Test remains the same and is fully compatible with all three luminometers.
- UltraSnap** is an AOAC-validated method when used with **EnSURE** and **EnSURE Touch**.

3M Changes

- 3M discontinued the CleanTrace NG and replaced it with **CleanTrace LM1** luminometer.
- CleanTrace** swab device remains the same.

Key Performance Characteristics of ATP Hygiene Systems

The critical performance characteristics of ATP hygiene monitoring systems are:

- Sensitivity** - the smallest amount of ATP and food residues detectable
- Consistency** - the variation of result from repeated tests of the same sample
- Accuracy** - the measured ATP value compared to the true value
- Precision** - the repeatability of the test to produce the same result

These parameters are determined using samples containing several different concentrations of ATP, including a sample without ATP. Ten replicates at each concentration level are tested. The data generated is used to calculate the limit of sensitivity, consistency, accuracy and precision.

Sensitivity

The table below shows the smallest amount of ATP detectable by each ATP hygiene monitoring system. Hygiena systems have maintained high sensitivity over the past 10 years, whereas the performance of 3M CleanTrace systems has decreased and become less sensitive. The consistent sensitivity of Hygiena systems mean the instruments and swabs are capable of measuring lower amounts of ATP and monitoring the efficacy of higher cleaning standards. If greater sensitivity is required for high risk operations, then Hygiena's SuperSnap™ High-Sensitivity Surface ATP Test provides an additional 5-fold increase in sensitivity (not shown in table).

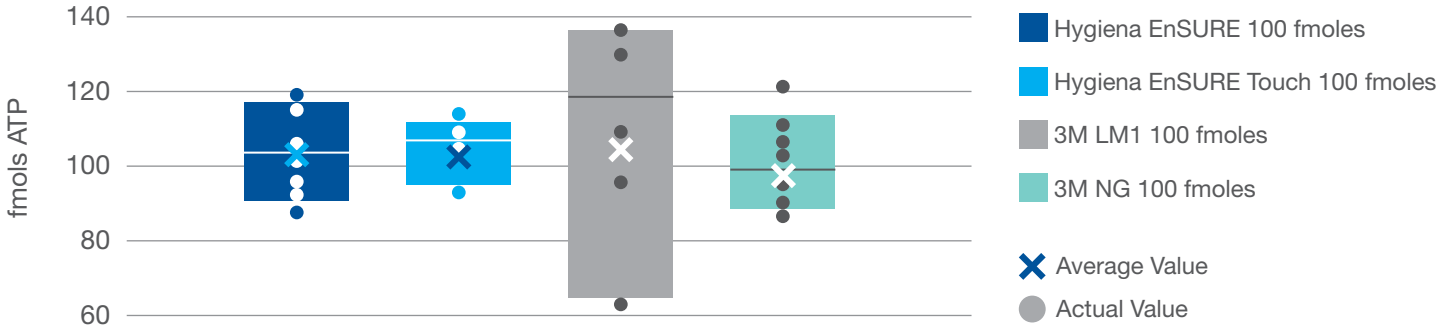
Lowest amount of ATP (fmols) detected = greater sensitivity	Hygiena UltraSnap			3M CleanTrace	
	EnSURE Touch	EnSURE	SystemSURE Plus	LM1	NG
	<1.0	1.0	1.0	3.0	1.0

Data provided by Hygiena AOAC certificate #101803 and 3M AOAC certificate #041901.

Sensitivity (continued)

Typical Pass / Fail threshold limits of ATP are set at 10 / 100 fmols. The graph below shows that the 3M CleanTrace LM1 system is the most variable. This means RLU results have a wider range in readings (taller bar). Also, 3M results were further from the actual value, represented by the **grey line**. The combination of these two facts means that results from the 3M ATP system are less reliable. The NG3 was better than the LM1, but it still had problems with precision (height of **green bar**) and accuracy (**grey line**).

EnSURE Touch (**light blue bar**) produces the most consistent result closest to the actual value. Both Hygiena's EnSURE TOUCH and EnSURE systems have greater precision and accuracy than the 3M products.



High Precision / High Accuracy

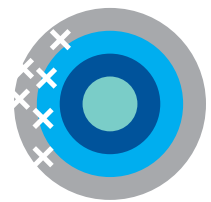
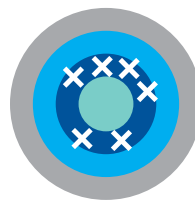
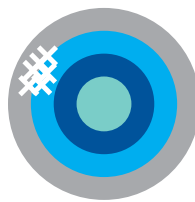
High Precision / Low Accuracy

Low Precision / High Accuracy

Low Precision / Low Accuracy



Hygiena
BEST



3M
WORST

Detection of food residues and microbes

AOAC data* shows Hygiena detected slightly smaller or similar amounts of food residues on surfaces compared to 3M. In the earlier Siliker study, different foodstuffs and experimental design was used. Both systems showed similar sensitivities to food residues.

The AOAC study* showed that both systems were able to detect bacteria and yeast. The smallest number of microbes detected by the Hygiena system was ~50,000 bacteria and 1000 yeasts. This is consistent with the 2010 Siliker study in which 3M CleanTrace NG showed a similar level of detection. However, a different experimental design was applied in the AOAC study* for 3M CleanTrace LM1 from which it is only possible to get an approximation of its sensitivity (~100 bacteria or yeast). This is not consistent with ATP measurement in the same study or in the earlier Siliker study.

The ATP surface cleaning verification test is not intended to be a surrogate bacteria test because it does not have the required sensitivity (typically 250/100cm² swab area).

	ATP System	ATP System
Food residues on surfaces (AOAC study)	Hygiena EnSURE	3M CleanTrace LM1
Cooked meat	< 1 in 100,000	<1 in 25,000
Raw meat	1 in 100,000	1 in 25,000
Orange juice	<1 in 100,000	1 in 1 million
Yogurt	1 in 1,000	<1 in 10,000

Summary

- Both Hygiena's EnSURE and EnSURE Touch ATP systems are more sensitive, accurate and consistent than both the 3M LM1 and NG ATP systems.
- Hygiena's EnSURE Touch is the most sensitive, accurate and consistent ATP system.
- 3M CleanTrace LM1 is a less sensitive and more variable ATP system than the previous 3M CleanTrace NG model.

*Data provided by Hygiena AOAC certificate #101803 and 3M AOAC certificate #041901.