Comparing the Performance of ATP Hygiene Monitoring Systems
Hygiena™ vs Merck MVP ICON®

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/ml) 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, 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 Methods*SM *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.

MVP ICON Changes

- Released MVP ICON in 2013 to replace MVP LIGHTNING (BioControl).
- MVP LIGHTNING uses photomultiplier detector; MVP ICON has photodiode detector.
- Launched MVP ICON II in 2018 (Merck acquired BioControl)
- System doesn't have AOAC-certification.
- Surface sampling 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 show a continual improvement over the past 10 years, whereas the MVP system performance has declined. This is largely due to the instrument and detector, because the chemistry and swab have remained the same. In fact, Hygiena's ATP system is 4.7x more sensitive than the MVP ICON luminometer. 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).

Hygiena UltraSnap			MVP Surface Swab	
EnSURE Touch	EnSURE	SystemSURE Plus	MVP LIGHTNING	MVP ICON
<1.0	1.0	1.0	1.0	4.7

Lowest amount of ATP (fmols) detected = greater sensitivity

Key Factors Affecting Sensitivity, Precision and Linearity

Each detection system will generate a response when there is no ATP in the sample. This is called background noise and is caused by impurities in the chemistry. If not removed, these impurities significantly affect the performance of the system. For freeze-dried reagents like that found in Merck's MVP Surface Swab, these impurities are locked in at the point of manufacture. Unlike Merck, Hygiena's liquid stable chemistry remains active and impurities are removed.

To compensate for background noise, MVP ICON instruments have a built-in bias that does not display results at low RLU (<5). While this may hide background noise, it limits the system's ability to detect low levels of ATP and reduces precision and accuracy (see table below).

Hygiena's liquid stable chemistry reduces background noise and eliminates the need for built-in biases. This means Hygiena's systems are able to detect ATP at lower levels. Hygiena's systems provide more reliable, linear and sensitive measurements, particularly at low level detection required for cleaning verification (see figure below).

At typical Pass / Fail threshold limits (e.g. 10 / 100 fmols of ATP), Merck MVP ICON does not provide linear results – this is the critical zone for precise linear measurements. In contrast, Hygiena systems deliver the most consistent result closest to the expected value. Accordingly, Hygiena systems have greater precision and accuracy.

ATP (fmols)	Hygiena ENSURE Touch			Merck MVP ICON		
	Precision (%)	Accuracy (%)	CV (%)	Precision (%)	Accuracy (%)	CV (%)
100	98.5	98.4	1.5	85.2	100	14.8
10	91.4	95.1	8.6	79.8	39.3	20.2
1.0	64.6	110	35.4	ND	ND	ND

Comparison of linearity of Hygiena's EnSURE Touch versus Merck's **MVP ICON** at critical levels.

Linearity at low ATP levels (0, 1, 10 and 100 femotomoles)
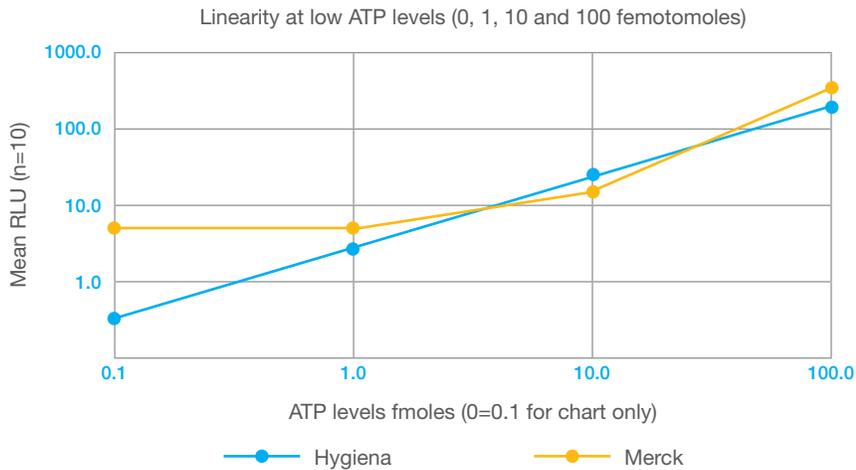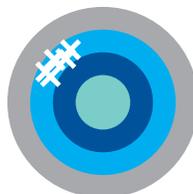

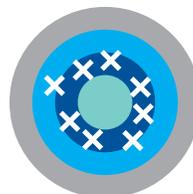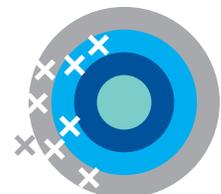High Precision / High Accuracy   High Precision / Low Accuracy   Low Precision / High Accuracy   Low Precision / Low Accuracy

Hygiena *BEST*

MVP ICON *WORST*

Detection of Food Residues and Microbes

Internal data shows Hygiena detected similar or smaller amounts of food residues directly added to swabs compared to MVP ICON. In the earlier Siliker study with MVP LIGHTNING, different foodstuffs and experimental design was used, but both systems showed similar sensitivities to food residues.

The AOAC study* for EnSURE and EnSURE Touch showed that both systems were able to detect bacteria and yeast. The smallest number of microbes detected by Hygiena systems was ~5,000 bacteria and 100 yeasts per swab, which is 2-3 times more sensitive than MVP ICON. This was similar to the results from the Siliker study of 2010.

The ATP surface cleaning verification test is not intended to be a surrogate bacteria test because it does not have the required sensitivity (typically 250/100cm^2 swab area).

Note: There is no data available for Merck MVP ICON because an AOAC study does not exist.

Food residues added directly to swabs (internal comparison data 2020)	ATP System	ATP System
	Hygiena EnSURE Touch	Merck MVP ICON
Ground beef	1 in 1,000	1 in 100
Yogurt	1 in 1,000	1 in 1,000
Orange juice	1 in 10,000	1 in 10,000

Summary

- Hygiena systems are the most sensitive, accurate and consistent. They are certified independently and have maintained best-in-class performance over the past 10 years.
- EnSURE and EnSURE Touch are certified by the AOAC-RI *Performance Tested Methods*[SM] Program.
- Merck MVP ICON is less sensitive and more variable than all Hygiena systems.
- Merck MVP ICON has poorer sensitivity than MVP LIGHTNING but results are less variable.
- Merck MVP systems are not certified by the AOAC-RI *Performance Tested Methods*[SM] Program.