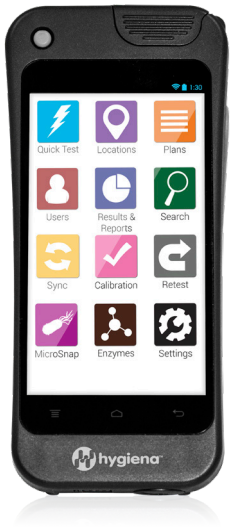
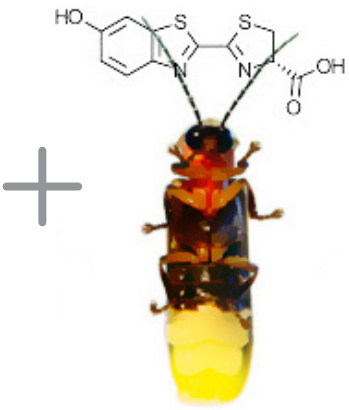
Sensitivity, accuracy, repeatability and overall performance of ATP testing systems is defined by 3 key components:

3 Critical Components:



ATP Luminometer



Bioluminescence Chemistry

Test Device

ATP Testing Component # 1: Instrument Sensor

The instrument (luminometer) quantifies the bioluminescent reaction from the ATP test. A luminometer should see low levels of light, be user friendly, and durable to work in all types of environments. Historically and even today, luminometers have used Photomultiplier Tube (PMT) sensors to detect low levels of light. However, with advancements in technology, new solid-state Photodiodes (PD) now have the ability to detect similarly low levels of light and offer lots of additional benefits over PMT. Hygiena® instruments use advanced PD sensors and electronics, giving them the ability to detect lower levels of light than PMT based instruments. The chart on page 2 lists the pros and cons for each sensor.

Photomultiplier Tube (PMT) sensors are considered slightly more sensitive. It is extremely important for the end users to understand how two other components (Bioluminescence Chemistry and Swab Design) offset Photomultiplier Tube (PMT) sensitivity and make Hygiena's system overall better-performing.

Comparison between Photomultiplier Tube (PMT) and Photodiodes (PD) Sensors

Table 1 - Comparison of Light Sensor Characteristics

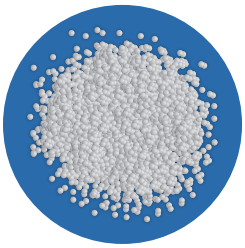
Electrical Characteristics	Photomultiplier Tubes	Photodiodes	Comment /Advantages and Disadvantages
Available Wavelengths (µm)	0.2-0.9	0.2-2.0	Both are suitable for measurement of ATP bioluminescence at 0.4 – 0.6 µm.
Performance-to-cost ratio	Fair	Good	Photodiodes provide best value and performance.
Sensitivity (also see discussion below)	Excellent	Very Good	Little difference in performance between PMT and photodiodes. PMT amplifiles the light signal but also amplifies the background electric noise. Photodiodes give a direct measurement of the light signal without amplication and associated complications.
Linearity	Good	Excellent	Photodiodes provide best performance.
Ambient Noise Performance	Fair	Very Good	Photodiodes provide best performance and are more robust. The low background noise of photodiodes means there is less interference, so precision and reliability of results can be guaranteed, especially at low RLU measures. This directly impacts the limit of detection (sensitivity) of the system (see below).
Dynamic Range	Very Good	Excellent	Photodiodes provide best performance.
Stability	Very Good	Very Good	Little difference in performance between PMT and photodiodes. Overexposure to high light sources can damage PMT but photodiodes are not affected in the same way. PMT are susceptible to external magnetic fields and are temperature sensitive
Construction	Glass vacuum tube	Solid semiconductor	Photodiodes are very robust and do not drift over time. PMT are fragile and contain glass that is considered a dangerous foreign body in many industrial manufacturing processes. PMT drift over time and need regular calibration which means high maintenance cost.

Table 1 - Comparison of Light Sensor Characteristics (Cont.)

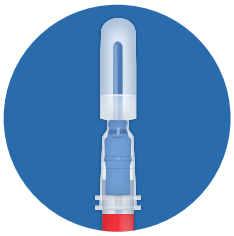
Electrical Characteristics	Photomultiplier Tubes	Photodiodes	Comment /Advantages and Disadvantages
Voltage requirement	Very high	Low	PMT need expensive lithium batteries and regular recharging or a main supply. Photodiodes use low-cost (1.5 v) batteries that are free, available, and have a long life.
Reproducibility	Fair	Excellent	Photodiodes provide best performance.
Cost	High	Low	Photodiodes provide best value.
Ruggedness	Poor	Excellent	Photodiodes provide best performance and robustness for industrial application.
Physical Size	Large	Small	Photodiodes can be used to make small instruments.
Ease of Customization	Poor	Easy	Photodiodes provide best value.
Cost of Customization	Very high	Low	Photodiodes provide best value.

ATP Testing Component # 2: Bioluminescence Chemistry

Chemistry in test devices is also a critical element of system performance, as it facilitates the bioluminescent reaction that is measured by the instrument. The more reliable the chemistry, the more reliable the results. Two types of chemistry on the market are lyophilized chemistry and liquid-stable chemistry.



Lyophilization has historically been the technology used to stabilize enzymes prior to use. Water is quickly evaporated out of the sample, leaving a pellet that can be reconstituted with a liquid. The pellet requires complex, expensive manufacturing, dry storage, and rehydration at point of use that causes larger variability from test to test. The pellets require time to dissolve. Due to manufacturing variance, environment temperature variance, swabs activation techniques variance and sample variance, pellets dissolve at different times which creates overall inconsistency and variance in the test results.



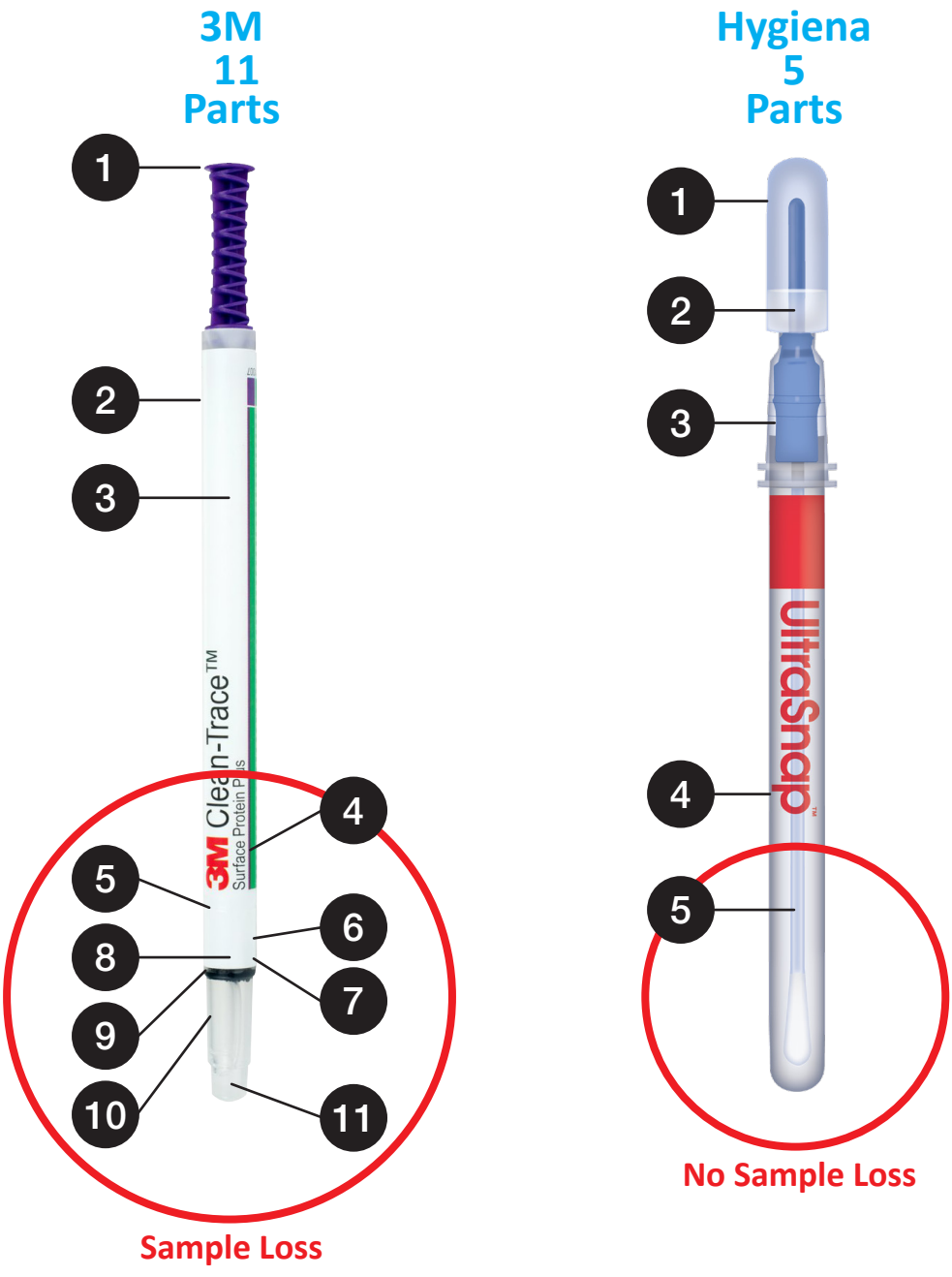
Hygiena's liquid-stable chemistry eliminates the need for lyophilization and stabilizes the enzymes in a liquid format. This eliminates costly manufacturing steps and reconstitution of the enzyme giving more reproducible results and better accuracy. Fewer manufacturing steps also reduces test costs.

ATP Testing Component # 3: Swabs Design

Hygiena's test devices are made of less components than any other device. Fewer elements in the device means less room for error from manufacturing variance and less raw material costs.

Our patented Snap-Valve technology eliminates the need for additional compartments that require foil seals. Other test devices require the swab bud to puncture through several foil seals in order to activate the device. This leaves sample behind on the foil and reduces accuracy of the reading, resulting in lower or variable ATP readings.

By keeping our test design simple, Hygiena can reduce costs, limit variability, and provide reliable accurate test results and overall best performance.



Additional ATP Testing Components and Factors:

Calibration Verification

Hygiena has developed LED Calibration Verification kit for quick validation of the ATP units that should be done on monthly basis. In-house calibration checks confirm the Hygiena luminometer is working properly and demonstrate due diligence that a monitoring system is in control. CalCheck verifies your instrument's calibration in-house as part of a quality control program and eliminates the need for manufacturer calibration checks, saving you hundreds of dollars each year.

AOAC Approval

Hygiena's ATP testing system is AOAC Performance Tested which further solidifies outstanding performance of Hygiena's ATP testing products.

Sodium Azide

The Hygiena devices are deemed nonhazardous because the Sodium Azide content is the devices is below the hazardous threshold per Directives 67/548/EEC and 199/45/EC. The devices may be disposed of as nonhazardous materials observing local regulations.

The lowest concentration of Sodium Azide to be taken into consideration for health or environmental effects is ≥0.1% w/w.

The concentration of Sodium Azide in Hygiena's devices is ≤0.05%.

Furthermore, each device contains only <0.5 mL of the solution containing Sodium Azide. This solution does not come in contact with either the swabbing surface or the person performing the test under normal use.