pti science of quality

VeriPac 455 is the system designed for container closure integrity testing of high-risk Pharmaceuticals

Life Science
CCI Supporting Services

Holistic CCI & Packaging Quality Expertise

Delivering deterministic assurance across the full product and packaging lifecycle

- Testing, Training & Consulting Services
- Test Method Development Support
- Validation Support and Deployment

VeriPac systems provide reliable, repeatable, and deterministic leak detection in accordance with ASTM F2338. They support global method harmonization, accelerate validation, reduce the risk of batch investigations, and drive continuous improvements in sterility assurance—without destroying samples.

Why Quality Programs Standardize on the VeriPac 455

- Industry-leading leak detection sensitivity across both liquid and dry formats
- Consistently reliable, high-performance results
- Stable and repeatable measurements ideal for routine QC and production testing
- Proven deterministic performance in alignment with USP <1207> and ASTM F2338

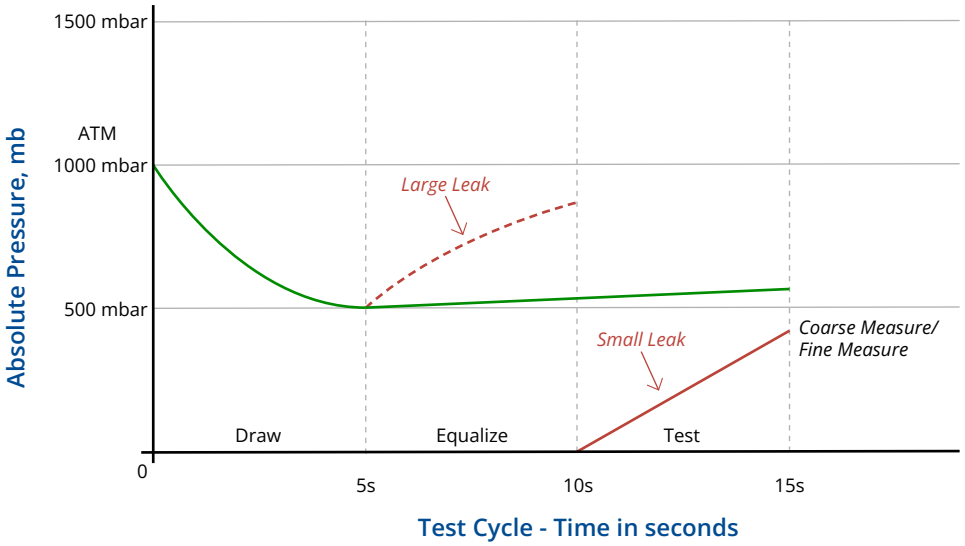
The VeriPac 455 is a deterministic vacuum decay system widely trusted in high-risk sterile manufacturing, where reliability, repeatability, and sensitivity are critical. Its patented dual-transducer PERMA-Vac technology uses two sensors simultaneously to detect even the smallest pressure changes caused by leaks. By continuously utilizing the readings from both transducers, the system minimizes baseline noise and enhances measurement stability, enabling highly sensitive, reproducible leak detection, even for container types and applications that are traditionally difficult to test.

Global Method Transfer

VeriPac systems enable validated leak detection methods across multiple facilities and contract manufacturing partners, ensuring consistent data, streamlined method transfer, and reduced validation effort.

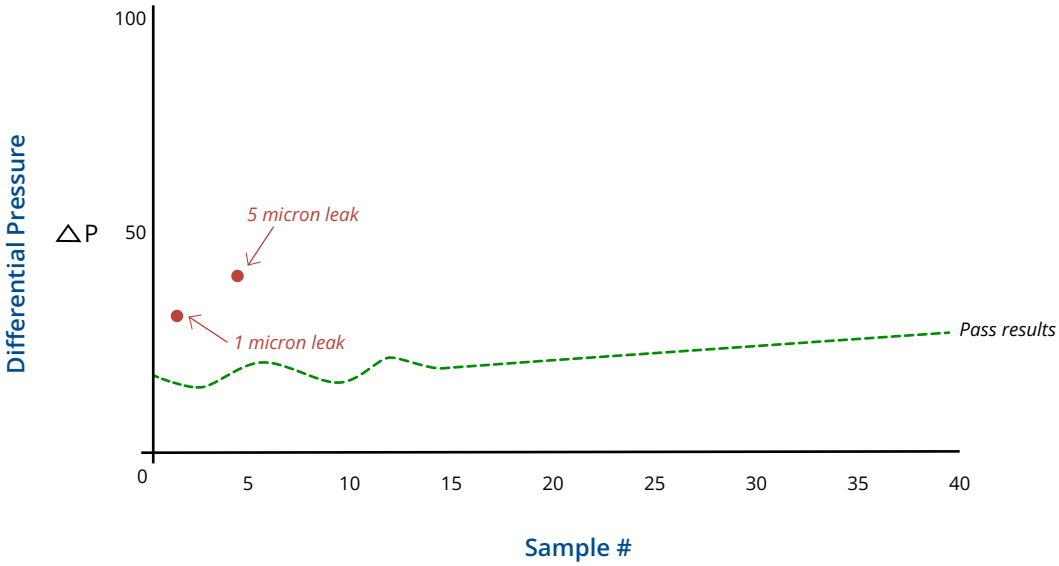
By providing reproducible results across labs and production sites, they support unified sterility assurance programs in both laboratory and production environments.

VACUUM DECAY



4× Signal-to-Noise Ratio (SNR)

TEST RESULTS



The VeriPac 455 detects minute pressure changes resulting from vapor transmission and micro-bubble formation along potential leak paths. Its dual-transducer system amplifies these subtle deviations, providing clear, quantitative, and highly reproducible evidence of container integrity.

Specifications

APPLICATION	Micro Leak Detection
PACKAGE TYPE	Empty & pre-filled syringes, Liquid filled & lyophilized vials (glass or plastic), Filled & sealed bottles, FFS bottles, Non-porous pouches, BPC (Bulk Pharmaceutical Chemical) containers
TEST CONFIGURATION	Offline laboratory and Production line applications
TEST SYSTEM*	Dual Transducer PERMA-Vac Technology*
TECHNOLOGY*	Differential Vacuum Decay
OPERATOR INTERFACE	10" Color Touch Screen
RECOGNIZED TEST METHOD	ASTM F2338-24 based on VeriPac leak testers, referenced in USP <1207>
TEST SENSITIVITY**	Down to 0.01 cc/min (Approximate hole size 1 micron)
TEST RESULTS/RESOLUTION	Pass/Fail Result in mBar and Pascal units
CFR SECURITY CAPABILITY	21 CFR, Part 11 PTI ETHOS Software
DATA COLLECTION	Collects test data for view on HMI touch screen and electronic data collection
DIMENSIONS/WEIGHT	14.5" W x 22" D x 12" H | 40 lbs.
POWER	100-240 VAC | 50/60 cycles
AIR	90 psi required only for automatic test chamber
OPTIONS	Validation Qualification Package (IQ/OQ/PQ) / Microcalibrator Flowmeter
ARTICLES/PUBLICATIONS	◦ PDA Journal of Pharmaceutical Science and Technology: Vacuum Decay Container/ Closure Integrity Testing Technology. Part 1. ASTM F2338-09 Precision and Bias Studies http://journal.pda.org/cgi/content/abstract/63/5/472 ◦ PDA Journal of Pharmaceutical Science and Technology: Vacuum Decay Container/ Closure Integrity Testing Technology. Part 2. Comparison to Dye Ingress Tests http://journal.pda.org/cgi/content/abstract/63/5/489
CERTIFICATIONS	CE

* U.S. Patents 5,513,516 6,513,366 8,544,315

**Test results may vary according to application and package specifications.