pti science of quality

VeriPac Delta – the Standard for Practical, Repeatable and Globally Harmonized CCI

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 Delta is a deterministic container closure integrity platform designed for organizations requiring reliable, repeatable leak detection that can be standardized across multiple facilities and packaging formats. By integrating both Vacuum Decay (ASTM F2338) and Pressure Decay (ASTM F2095) in a single system, Delta ensures the test method aligns with the actual failure mode—minimizing method mismatches, reducing investigation cycles, and enhancing validation confidence.

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 Organizations Standardize on Delta:

- Repeatable PASS/FAIL clarity independent of operator or site
- Works for both liquid & dry products without re-platforming
- Faster method transfer and validation across global operations

Technologies

Dual measurement modes allow Delta to match the physics of the failure mode.

- Vacuum decay → micro-channel / stopper / seal interface defects
- Pressure decay → gross leakage / structural or mechanical breach
- Sensitivity: "Detects down to 0.2 ccm (approx. 5 microns)."

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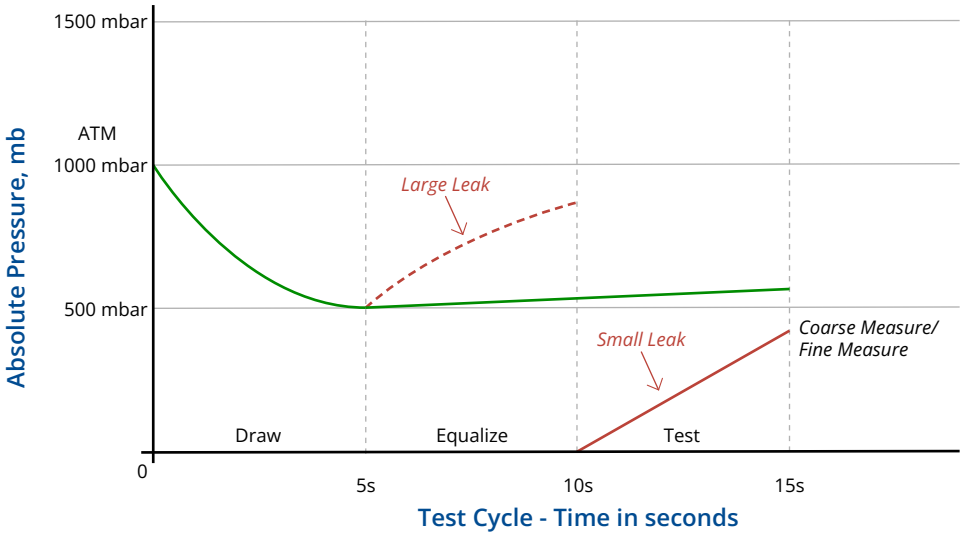
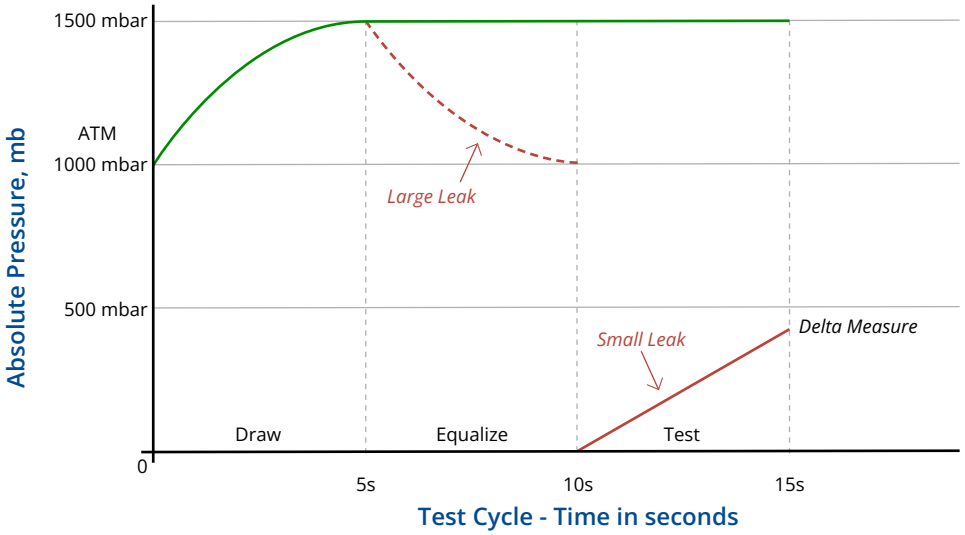
VACUUM DECAY



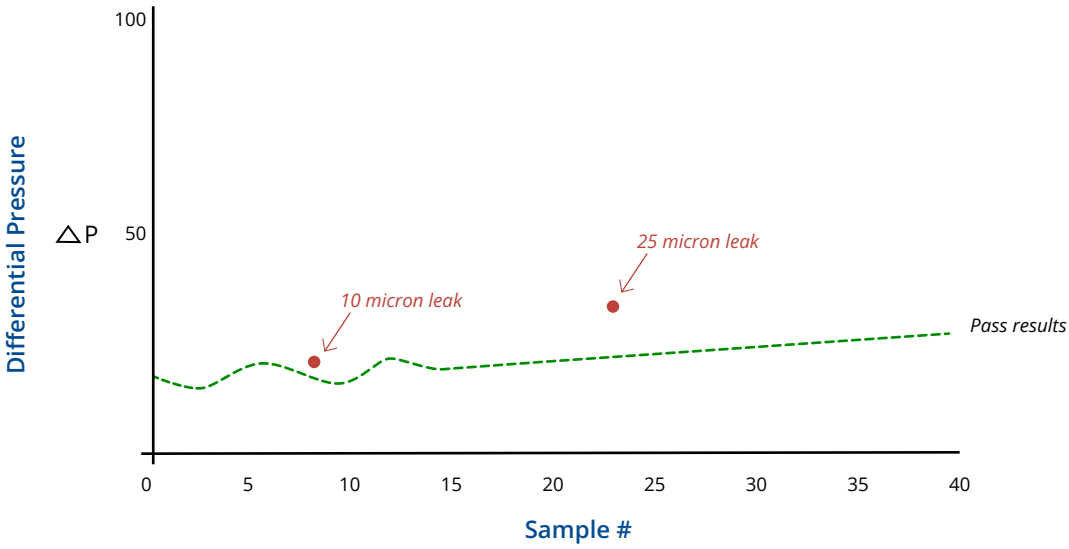
4× Signal-to-Noise Ratio (SNR)

PRESSURE DECAY



4× Signal-to-Noise Ratio (SNR)

TEST RESULTS



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Specifications

APPLICATION	◦ Package Integrity Testing ◦ Container Closure Integrity Testing
PACKAGE TYPE	◦ Empty & prefilled syringes ◦ Liquid filled & lyophilized vials ◦ Filled & sealed bottles & cups ◦ Ampoules ◦ Non-porous pouches ◦ BPC (Bulk Pharmaceutical Chemical) containers ◦ API (Active Pharmaceutical Ingredient containers ◦ BFS containers ◦ Ophthalmic dropper bottles
TEST CONFIGURATION	Offline laboratory
TEST SYSTEM*	High resolution absolute transducer
TECHNOLOGY*	Vacuum Decay and Pressure Decay
RECOGNIZED TEST METHOD	Vacuum Decay ASTM F2338-24, referenced in USP <1207> and Pressure Decay ASTM F2095
OPERATOR INTERFACE	Touch screen
TEST SENSITIVITY	Down to 0.2 ccm (approximate hole size 5 micron)
TEST RESULTS/RESOLUTION	PASS/FAIL result in mBar
DATA COLLECTION	Collects test data for view on HMI touch screen and MES data integration
TESTER DIMENSIONS	12” W – 18.5” D – 10” H
WEIGHT	33 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

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

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