



**Training and
Research Institute**

Helium Leak Testing: Pharmaceutical CCI Methods and applications

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Why Helium?

Helium Possesses Key Qualities which make its use ideal for High Sensitivity Seal Integrity Testing

1. Extremely Small:

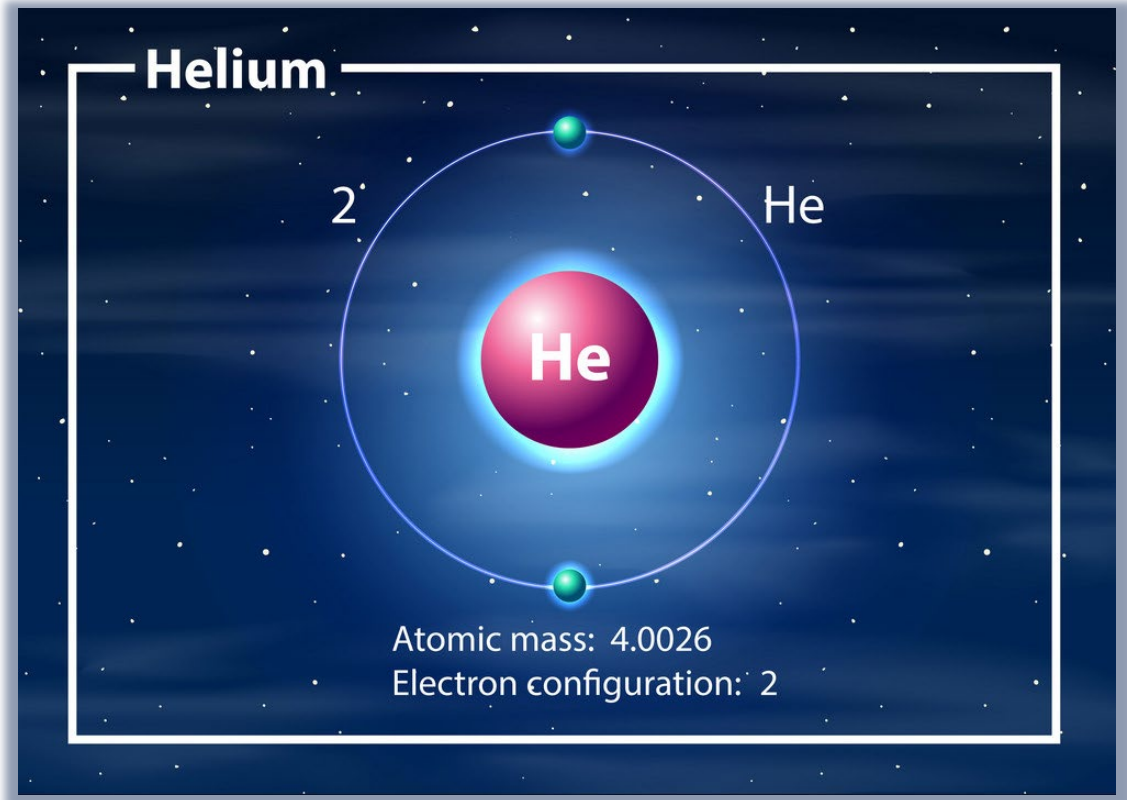
- Helium is the second smallest atom
- Atom size allows flow through extremely small leak pathways

2. Noble Gas:

- Chemically Inert & non-flammable
- Non-toxic & odorless

3. Atmospherically Rare:

- Approx. 5ppm
- Excellent signal to noise ratio



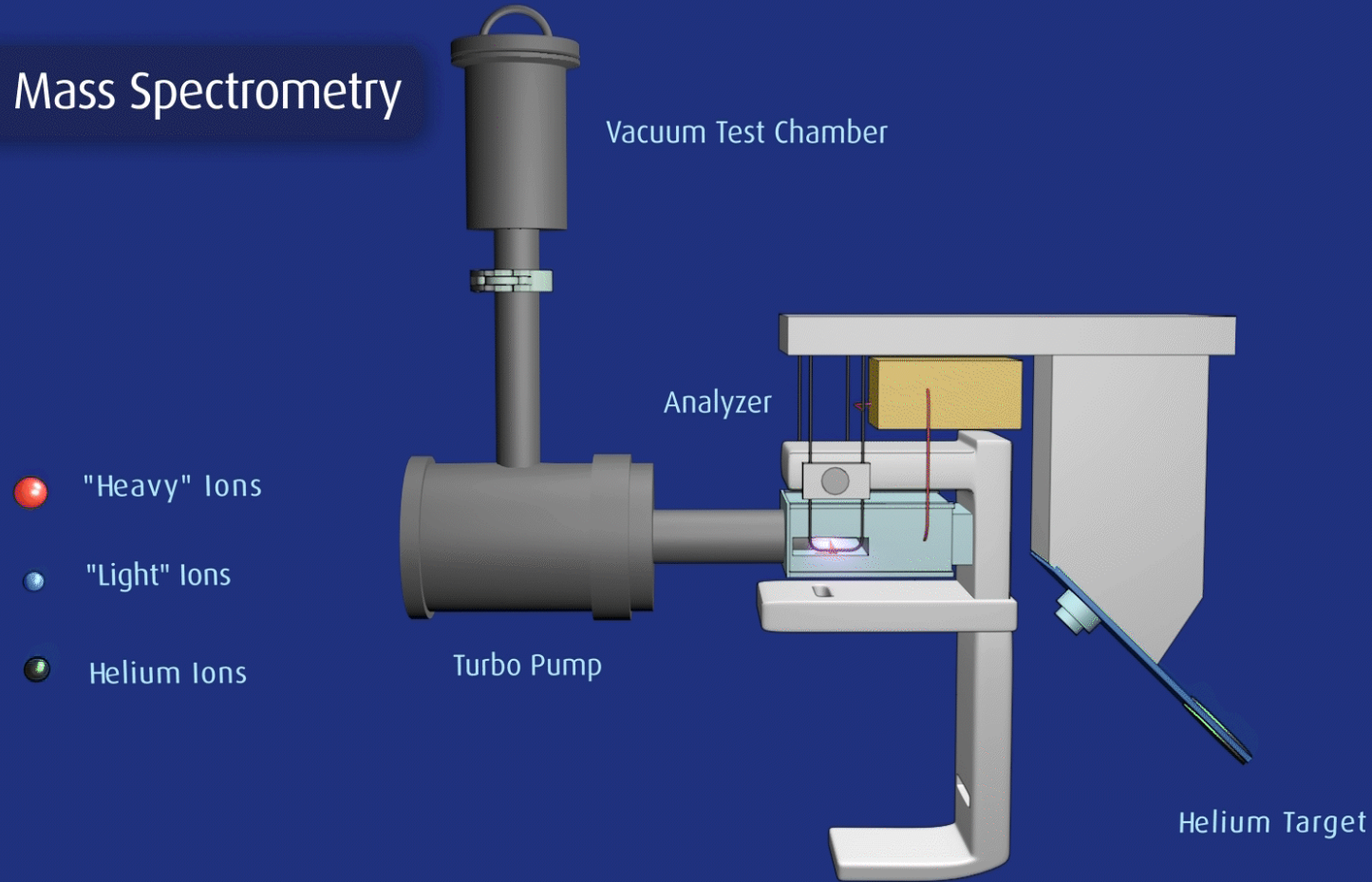
Benefits of Using Helium Leak Testing Methods:

- Enables discovery of extremely small leaks that other leak testing methods cannot detect.
- High leak detection sensitivity makes for the ideal test method for moisture/oxygen sensitive products and for confirming microbial/sterility barrier.
- Using a high vacuum technique, the leak test thresholds can be set down to as low as 1×10^{-11} mbar-L /sec, a sensitivity level allowing unique comparisons between various packaging components and packaging materials.
- Ideally suited for high-barrier packages –CFF blistercards, glass vials & cartridges, foil pouches, syringes.
- Applications for Plastic Packaging formats possible with proper test fixtures (i.e. “tooling”).
- Relatively short test cycle times. Most less than 1 minute.
- Quantitative analysis.
- Autocalibration and machine validation with known helium leak standards.

- Gas molecules flow into an ionization chamber/analyzer cell.
- Filament electron beam ionizes molecules.
- Ions travel according to an acceleration voltage, and a magnetic field causes deflection relative to mass/charge.
- The analyzer cell is specifically tuned for the mass/charge of helium.
- Stream of helium ions hitting the target is reported as leak rate.
- Mass Spectroscopy is a four-step process: ionize, accelerate, deflection, & detect.
- Leak rate is expressed as a flow rate, i.e., mbar-L/sec

Helium Leak Testing – Gas Flow Animation

Helium Mass Spectrometry



- Helium present inside a closed system (sample package/container) leaks in a vacuum environment.
- Ionized gases pass through spectrometer analyzer cell and helium ions are separated and quantified to a leak rate (flow rate).

Approx. Hole Diameter Correlation to Leak Rate Charts

Approximate Hole Diameter	Leak rate (<u>mbar-L</u>)/S
1.0 cm	10^4
1.0 mm	10^2
0.1 mm	10^0
0.01 mm	10^{-2}
1.0 micron	10^{-4}
0.1 micron	10^{-6}
0.01 micron	10^{-8}
1.0 nanometer	10^{-10}
1.0 Angstrom	10^{-12}

Size of leak in std cc/sec	1 std cc of helium leaking every
1.0×10^0	1 second
1.0×10^{-1}	10 seconds
1.0×10^{-2}	100 seconds
1.0×10^{-3}	17 minutes
1.0×10^{-4}	2.7 hours
1.0×10^{-5}	1.15 days
1.0×10^{-6}	11.5 days
1.0×10^{-7}	115 days
1.0×10^{-8}	3.2 years
1.0×10^{-9}	32 years
1.0×10^{-10}	320 years
1.0×10^{-11}	3,200 years

Source: Leybold – Fundamentals of Leak Detection



Hard Vacuum Method – Helium Pre-Fill

- Sample filled/flushed with helium, placed in vacuum chamber, chamber evacuated, and global helium leak rate obtained.
- Examples: Vials, Blistercards, pouches
- Need Helium concentration to normalize Helium Leak rate obtained from the vacuum chamber test.

100% Helium Flow

- Area of leak interest is placed under vacuum using custom designed fixtures.
- 100% helium gas flow is maintained on atmosphere pressure side of test fixture. Any increase over background leak rate is a breach or leak pathway
- Ex: Any Plastic container: vials, bottles, syringes, cartridges. Glass containers with pre-drilled hole for helium gas flow.
- No need for leak rate correction since 100% helium concentration is used during test.
- Fast, simple method. Most cycles < 30 seconds

Sniffer Mode Method

- Site specific probe used to scan for helium leakage in packages/objects containing helium gas.
- Ex: IV bag seals & port fittings, large vessels & tubing
- Not quantitative – pass/fail only – helium in atmosphere limits detection

He Leak Testing: Hard Vacuum Method/Helium Pre-Fill Apparatus



Rectangular Chambers –
Blistercards/Pouches



Cylindrical Chambers -Vials

Sample Prep

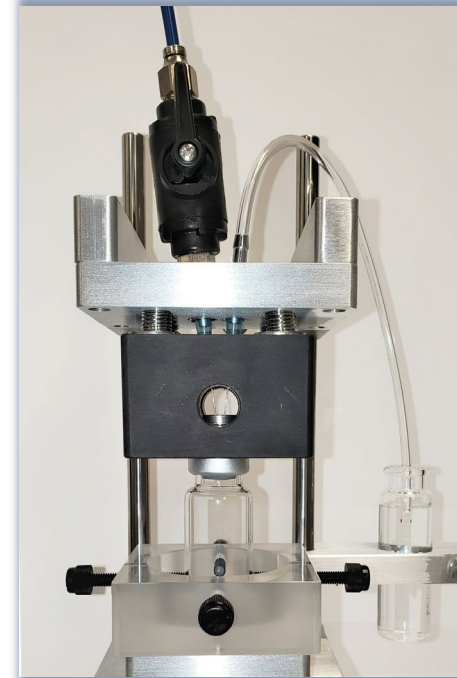
- Helium Fill: post-sealing

Test Sequence:

- Filled sample placed in chamber
- Vacuum pulled; leak rate obtained
- Helium concentration measured - leak rate normalized to 100% helium



Vial Filler



Vial shown being
flushed with Helium
gas

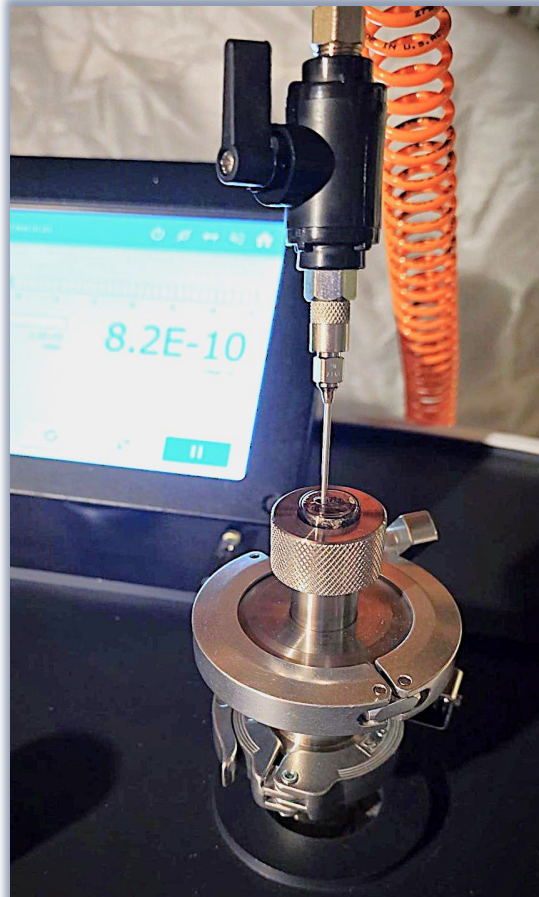


SIMS 1915+



Vial
Chamber





Glass Vial Test Fixture with
Helium Flow Nozzle

Hard Vacuum Method

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100% Helium Flow – Continuous Helium Flow

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- Ex: IV bag seals & port fittings, large vessels & tubing
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Sample Prep:

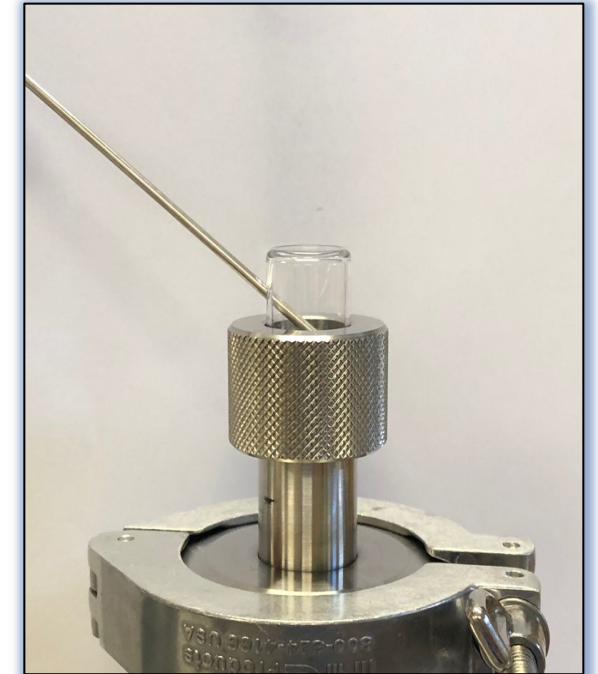
Create access port for continuous Helium flow

Test Sequence:

- Sample fixtured in place
- Vacuum cycle started
- Baseline observed; 100% helium introduced
- Helium leak rate recorded – helium concentration correction not required – measured leak rate is the actual leak rate



Sample Fixture set-up. Note drilled hole in vial sidewall



100% Helium Flush during test cycle

He Leak Testing: 100% He Flow Apparatus



Plastic Vial Test Fixture



Plastic Vial Fixture
(test ready)



Foil Tube - Closure
Leak Test Fixture

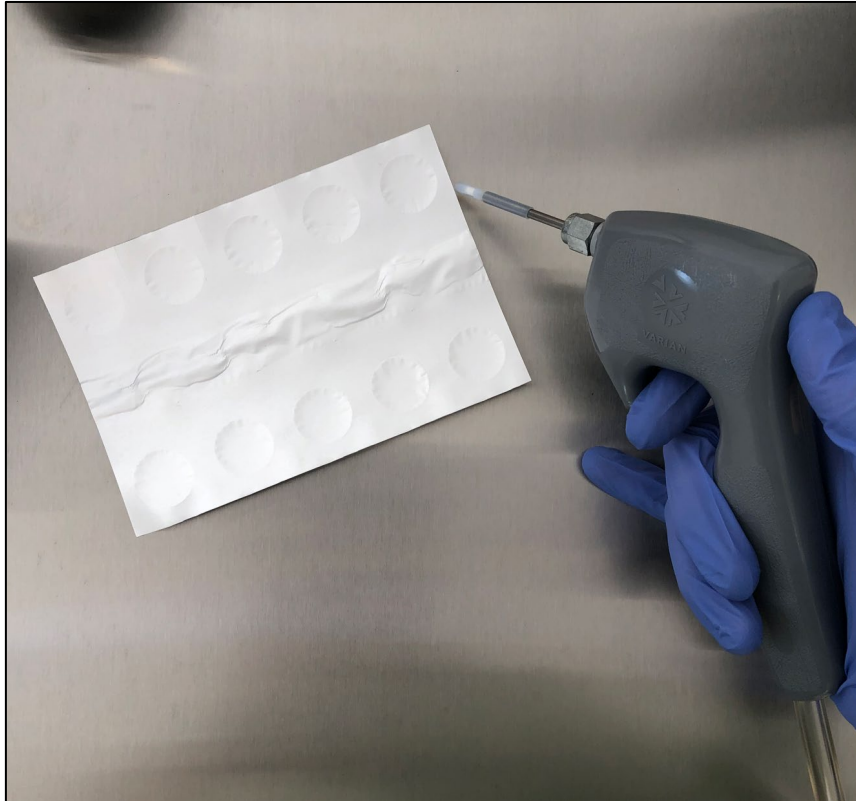
He Leak Testing: 100% He Flow Apparatus



Induction Seal
Vacuum Fixture



Syringe Barrel
Needle Fuse Leak Test Fixture



Hard Vacuum Method – Helium Pre-Fill

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Sniffer Mode Method

- Site specific probe used to scan for helium leakage in packages/objects containing helium gas.
- Ex: IV bag seals & port fittings, large vessels & tubing, blister cards (for leak location)
- Not quantitative – pass/fail only – helium in atmosphere limits detection

He Leak Testing: Sniffer Mode



Helium Sniffer Probe



Foil Bag Sniff Leak Test

Cold Temp Helium Leak Testing



- Enables low temperature vial & syringe leak testing at temperatures from 0°C to ~ -150 °C
- Provides real-time sample temperature monitoring via TC connection; vacuum chamber attaches to inlet port of Helium Detector

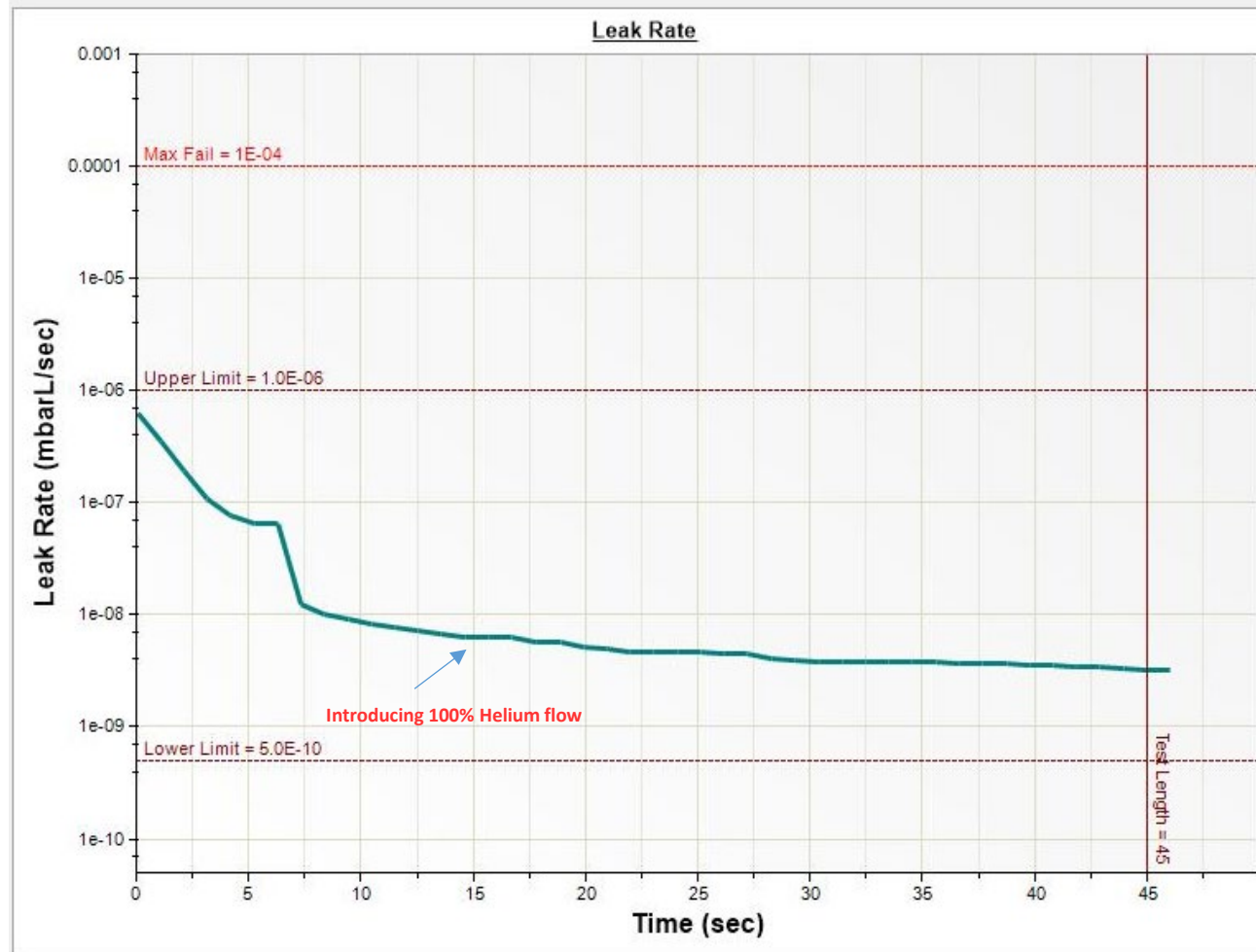
He Leak Testing: Validation Hardware



External Helium Leak Standards

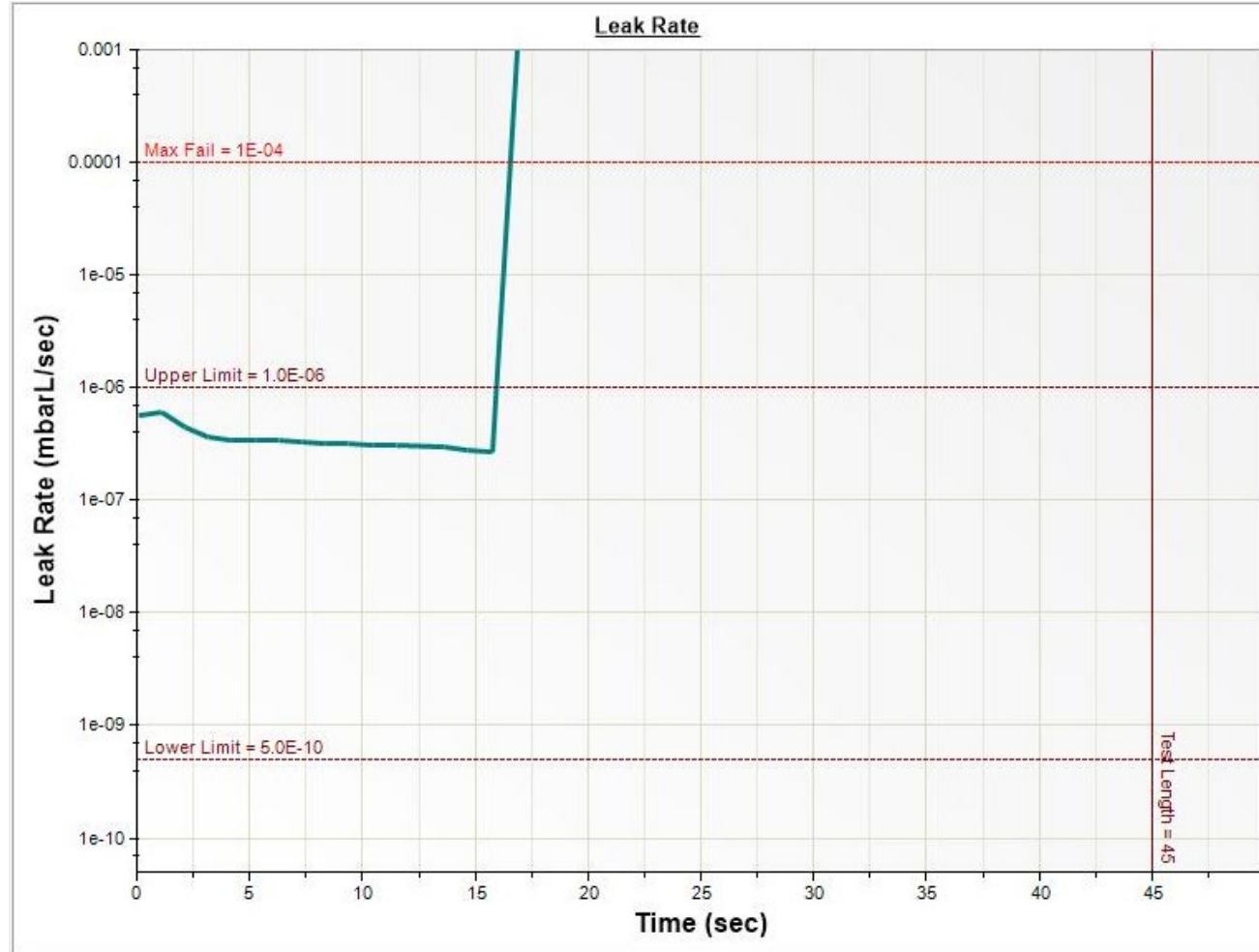
- NIST traceable Helium Leak standards are available in a wide range of helium leak rates
- Validates the detector response of the SIMS Helium Leak Testing systems up to the test port – point of sample testing.
- Direct connection to Helium Leak Detector inlet port.

Helium Leak Testing Graphical Response: Leak Rate vs. Time



Typical Response Curve – Well Sealed Container – No Helium Leakage detected

Helium Leak Testing Graphical Response: Leak Rate vs. Time



Typical Response Curve – Poorly Sealed Container – Gross Helium Leakage detected

Scan the QR code to join the Quiz

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For additional information, please contact me:

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Or visit our site:

<https://www.pti-ccit.com/technologies/helium-leak-detection>

