User Guide

Integrity Test Kit

For Small Volume Devices

SLTEST000

Introduction

This document describes how to use the Integrity Test Kit with membrane surface areas of less than 15 cm^2 (2.3 in^2). Larger devices can be integrity tested using an Integritest® automated system.

NOTE: The pressure gauge has an accuracy of 2% at mid-range. We certify that the SLTEST000 gauge was calibrated at the time of manufacture, in a system that complies with the most recent revision of ISO®-10012. Although the gauge has been calibrated, we recommend that the gauge be placed into a calibration maintenance program upon receipt. The gauge should be calibrated at least once a year. Depending on the criticality and frequency of use, it may be necessary to calibrate twice a year.

Precautions

- Use the Integrity Test Kit with membrane filter units only. Do not use it to integrity test non-membrane prefilter units.
- Do not use syringes smaller than 50–60 milliliter (mL), because smaller syringes can generate pressures in excess of the filter unit's maximum pressure rating. Consult filter unit user guide to ensure that these pressure limits are not exceeded during the test.
- Do not exceed the integrity tester maximum pressure when using compressed gas to test a vented filter unit.

Materials Required

The following materials are needed to run an integrity test on a filter unit:

- Integrity Test Kit assembly
- 60 mL syringe (preferably Luer-Lok™ fitting)
- Wetting fluid:
  - Laboratory-grade water for hydrophilic filter
  - Methanol for hydrophobic filter
- Sampling tube (M00000001) or a 10 cm (4 in.) long piece of 3.2 mm (⅛ in.) inner diameter (ID) transparent, flexible tubing
- 50 mL beaker or container

Additional materials required for testing vented filter units

- Compressed gas source (air or nitrogen) with two-stage regulator
- Luer-Lok™ connection for gas source. See Product Ordering.

Integrity Test for Non-vented Filters

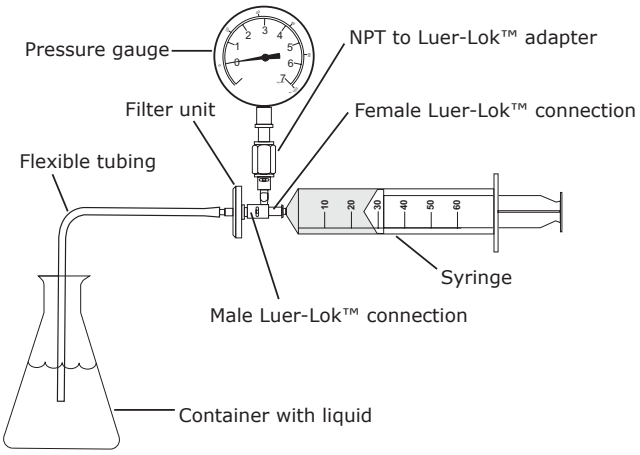
1. Aspirate appropriate wetting fluid into the syringe (refer to previous table).

If testing:	Then use...
Millex® filter	5–10 mL of wetting fluid
Sterivex™ filter	20–30 mL of wetting fluid
Other	2–3 mL/cm² effective membrane area

NOTE: You may use product or sample to wet the filter unit. However, due to differences between the surface tension and contact angle of product compared with the recommended wetting fluid, the bubble point may be different from the manufacturer's minimum specification.

2. Attach the inlet of the filter unit to the male Luer-Lok™ connection on the Integrity Test Kit assembly as shown below.

Figure 1.



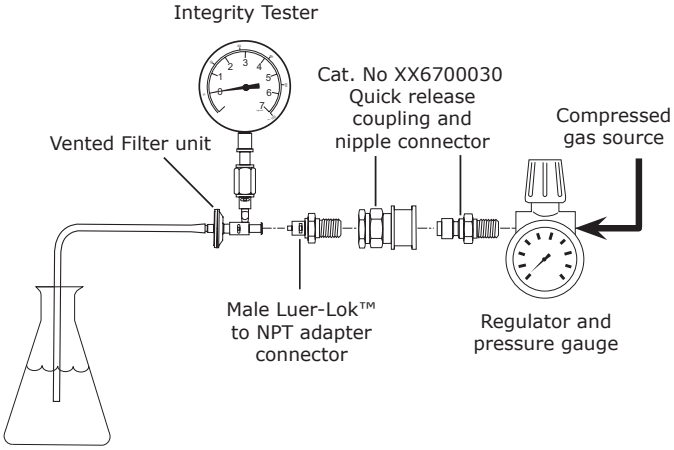
3. Attach the flexible, plastic end of the sampling tube to the outlet of the filter unit.
4. Connect the syringe to the female Luer-Lok™ connection of the Integrity Test Kit assembly. If the syringe has a Luer-slip connection, **hold the syringe onto the assembly at all times during this procedure**.
5. Push the syringe barrel to wet the filter unit and deliver the wetting fluid into a container.
6. Disconnect the syringe from the Integrity Test Kit assembly. If there is any liquid left in the syringe, push the syringe plunger to empty.
7. Withdraw the syringe plunger to the 60 mL line to fill the syringe with air.
8. Connect the syringe to the female Luer-Lok™ connection of the Integrity Test Kit assembly. Submerge the open end of the tubing in liquid. Gradually push the syringe plunger to increase the pressure on the filter unit and pressure gauge.
9. Continue to increase the pressure until a stream of bubbles starts to come out of the tubing. This is the bubble point. Record the gauge pressure and compare it to the manufacturer's minimum bubble point specification. For the typical minimum bubble point value for your filter unit, contact Technical Service.

Integrity Test for Vented Filters

Wetting out a vented filter is done with a syringe in the same manner as for the non-vented filter. However, because the vent "bleeds" pressure, it is not possible to generate enough pressure with a syringe to overcome the vent "bleed". A compressed gas source must be used to generate the pressure required to overcome the vent bleed and reach the filter bubble point. Refer to Figure 2 (below) for an example of how to connect the filter to a compressed gas source. This assembly assumes that the gas regulator has a ¼ in. female national pipe thread outlet.

1. To wet out the vented filter unit, follow steps 1–6 of for testing non-vented filters.
2. Disconnect the syringe from the Integrity Test Kit assembly and connect the assembly to the compressed gas source as shown below. Wrap male threads with polytetrafluoroethylene (PTFE) tape before assembling. Submerge the open end of the tubing in liquid.

Figure 2.



3. Increase the gas pressure gradually until you see a stream of bubbles coming out of the outlet tube. This is the bubble point. Record the integrity tester gauge pressure and compare it to the manufacturer's minimum bubble point specifications. For the typical minimum bubble point value for your filter unit, refer to the Certificate of Quality, or call Technical Service.
4. Turn off the compressed gas source and wait until the pressure gauge on the Integrity Test Kit assembly reads "0". Disconnect the assembly from the gas source.

Cleaning and Storage

After use, attach flexible tubing to male Luer-Lok™ connection of the integrity tester. Fill syringe with laboratory-grade water, attach to the female Luer-Lok™connection, and flush integrity tester with at least 100 mL of water. Separate components at the Luer-Lok™ connections and allow to air dry. Store at room temperature in a clean, dry environment where the gauge is protected from physical damage and shock.

Specifications

Maximum pressure	5.6 kg/cm^2 (80 psi)
Temperature limit	45 °C (113 °F)
Maximum filter surface area	15 cm^2
Dimensions	Approximately 14.9 cm (5.9 in.) tall by 7.4 cm (2.9 in.) wide
Connections	Inlet: female Luer-Lok™ (for attaching to syringe) Outlet: male Luer-Lok™ (for attaching to filter unit)
Weight	Approximately 148.4 g (5.2 oz)
Materials of construction	Luer-Lok™ connectors: nickel-plated brass Gauge: 316 stainless steel internal components
Gauge	Range: 0–7 kg/cm^2 (1–100 psi) Accuracy: 2% at mid-scale

Statement Regarding Compliance with the Pressure Equipment Directive, 2014/68/EU

We certify that this product complies with the European Pressure Equipment Directive, 2014/68/EU of 15 May 2014. This product is classified under Article 4 § 3 of the Pressure Equipment Directive. It has been designed and manufactured in accordance with sound engineering practices to ensure safe use. The product is accompanied by user instructions and bears markings to permit identification us as the manufacturer or authorized representative of this product within the European Community. In compliance with Article 4 § 3 of the Pressure Equipment Directive, this product does not bear the CE mark.

Product Ordering

This section lists the catalogue numbers for Integrity Test Kit and accessories. See Technical Assistance for contact information. You can purchase these products on-line at SigmaAldrich.com.

Description	Qty	Catalogue Number
Integrity Test Kit	1	SLTEST000
Accessories		
316 Stainless Steel Male Luer Lock to ¼" NPT Male Threads	1	-
Quick-release nipple and coupling (¼ in. male NPT nipple and ¼ in. female NPT coupling)	1	XX6700030
Sterile sampling tube 3.5 mm (0.14 in.) ID × 12.7 cm (5 in.) long, polyvinyl chloride	100	M00000001

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