PALL Life Sciences

Instructions For Use

USD 2848

Pegasus™ SV4 Virus Removal Membrane Filter Discs

Filterability Testing and Virus Challenge – Constant Pressure Test Method

*Filtration. Separation. Solution.*SM

Contents

1. Recommended Equipment Set-Up

See Figure 1 and Table 1 for recommended equipment details*

The equipment and parts listed for these procedures are as used normally by the Pall Corporation Scientific and Laboratory Services Department. Comparable equipment can be used, but should be qualified as fit for purpose prior to substitution in the test set up. The exception is the FTK200 disc holder, which is highly recommended in all Pegasus SV4 47 mm disc testing to ensure accurate flow measurements and an integral viral seal.

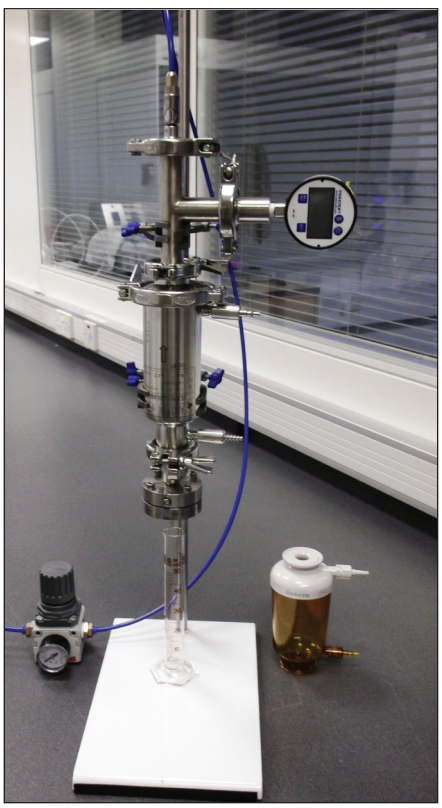
1. Install the 1 inch sanitary adapter to the intlet side of the FTK200 disc holder and install the Stäubli♦ connector or an appropriate hose barb fitting onto the outlet side of the FTK200 disc holder. Use fluoropolymer thread seal tape.
2. Connect the FTK disc holder to a reservoir, e.g. a Sealkleen™ or Novasip™ filter housing, which should be installed in the opposite flow direction to minimize the stagnant volume. Use the 1 inch sanitary fitting.
3. Mount the reservoir disc holder assembly securely and vertically and ensure that there is sufficient space below for the collection vessels.
4. Connect the upstream of the reservoir to a regulated pressure source (capable of delivering at least 5.9 bar (85 psi) using the Stäubli adapter or other appropriate fitting. Connect a calibrated pressure gauge as close as possible to the reservoir.

   Caution: All the upstream tubing and connectors used should be rated to at least 6.6 bar (95 psi).

5. Remove the pressure source from the top of the reservoir and the FTK disc holder from the base of the reservoir ready for membrane installation and water addition.

Figure 1

Laboratory Equipment to use



Recommended Lab assembly (See Table 1)

Required FTK200 disc holder

Table 1
Recommended Equipment Details

Part	Pall Part No.	Supplier
Sealkleen Pressure vessel	ZLK702G23LHKH4	Pall
Novasip pressure vessel (optional)	C3EP1	Pall
FTK-200 Membrane disc holder	FTK-200	Pall
Adapter 1 in. TC/Male Stäubli-compatible connector plug (3 mm) [Pressure vessel inlet fitting]	GFX0290	Pall
Adapter 1 in. TC connector plug R ¼ in. NPT [FTK-200 inlet fitting]	GFX0390	Pall
TC/Male Stäubli-compatible connector plug (3mm) R ¼ in. NPT [FTK-200 outlet fitting]	GFX0235	Pall
TC clamp + TC seal H4 [2 each]	SLK1TC23H4	Pall
Calibrated pressure gauge and connectors	–	Lab Supplier
Tubing	–	Lab Supplier
Fluoropolymer thread seal tape	–	Lab Supplier
Graduated cylinder	–	Lab Supplier
Serological pipette (optional, recommended 5 – 25mL)	–	Lab Supplier
Petri-dish (optional)	–	Lab Supplier
Pegasus SV4 filter membrane – 47 mm discs	FTKSV404705 FTKSV4047025	Pall

2. Membrane Wetting

Note: The membrane should always be handled by the edges only, preferably using blunt-ended forceps and always wearing gloves. The correct orientation must be maintained at all times with the upstream side adjacent to the Pall-logo glassine always facing up and the non-woven support always on the bottom.

1. Carefully remove a disc from the box with the Pall glassine and unmarked glassine spacer discs upstream and downstream of the dual-layer Pegasus SV4 disc and non-woven support disc (see Figure 2).
2. Remove and retain the glassine layers, keeping the side adjacent to the Pall logo glassine facing upwards.
3. Float the membrane on 0.2 µm filtered (or finer) deionized (DI) water using a flat dish (e.g. a petri dish).
4. After approximately 1 minute, pipette DI water onto any dry (opaque) patches until the membrane is fully translucent. Leave to soak for a further 5 minutes.
5. Air bubbles trapped between the layers are typical and should be removed by placing the disc on a flat surface between the glassine layers and rolling it with a serological pipette or another clean, smooth, cylindrical object (see Figure 3). Alternatively trapped air bubbles can be removed by careful use of gloved fingers (see Figure 4).

Figure 2
Components of the 47 mm disc product

1. Upstream Pall glassine spacer
2. Pegasus SV4 two-layer membrane
3. Non-woven membrane support
4. Downstream glassine spacer

Figure 3
Air bubble removal using a serological pipette

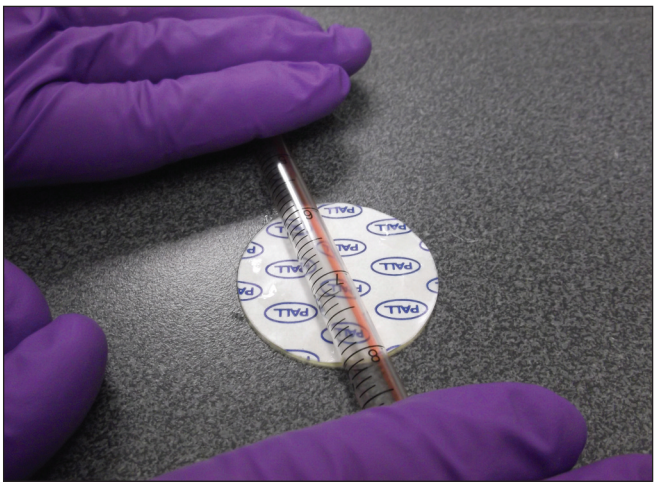
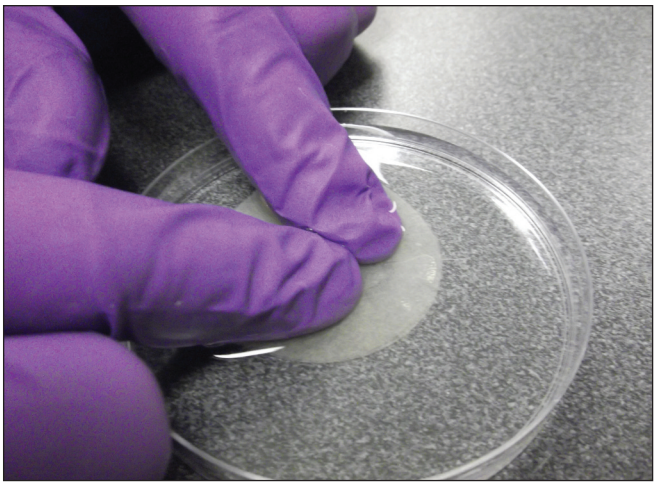


Figure 4
Air bubble removal using gloved fingers



3. FTK200 Disc Holder and Membrane Installation

1. Remove the four hex screws of the disc holder. Inspect the support screen and silicone o-ring for damage and cleanliness. The support screen must be the original stainless steel screen with concentric circles (see Figure 1).
2. Carefully place the non-woven support layer and dual layer disc onto the support screen. Ensure there are no creases, that all layers are aligned and that no portion of the membrane is located outside of the recess.

   Note: Ensure the correct orientation of the membrane has been kept during wetting so that the side that was adjacent to the Pall-logo glassine paper is upstream as the disc is installed into the filter housing and the non-woven support layer on the downstream is in contact with the stainless steel support screen.
3. Replace the four hex screws, and tighten evenly. Tighten opposite pairs together, taking care to slowly tighten all screws at the same level and keep the inlet and outlet sections of the housing parallel. Hand tighten first, then repeat using a 3/16 inch hex key and for best results finish off with a torque wrench set to 4.5 N.m (40 lb.in).
4. Attach the disc holder to the reservoir using the 1 inch sanitary clamp.

4. Pre Challenge Water Flow Test

To confirm the proper installation and operation of the disc, the water flow measured in Section 4.7 must be within the water flow test range in Table 2.

1. Add approximately 30 – 40 mL of 0.2 µm filtered (or finer) DI water into the reservoir.
   Ensure that the disc holder bleed port is closed using a 3/16 inch hex key.
2. Clamp the upstream cover assembly to the test system and connect to the regulated pressure line.
3. Remove any air through the bleed port by raising the pressure to approximately 0.2 bar (3 psi) and loosening the bleed port.
4. Tighten the bleed port.
5. Flush the disc for at least 5 minutes, to ensure complete wetting. Use an operating pressure of 2.1 bar (30 psi).
6. Measure the flow rate over a minimum of 10 minutes and a differential pressure of 2.1 bar (30 psi). Measure the average water temperature during the flow rate test.
7. Slowly vent the system pressure.
8. The variation of water viscosity at different temperatures must be accounted for. Measure the temperature of the water and correct the water flow rate to an equivalent value at + 20 °C by multiplying the flow rate by the appropriate correction factor (see Table 3).
9. If the corrected water flow is outside of specification then repeat installation with a new disc. Retain the out-of-specification disc and contact your local Pall representative.

Table 2
Water Flow Test Range

			Test Range* **	
Filter Part No.	**Filter Type**	**Effective Filter Area* [cm²]**	**Minimum [mL/min]**	**Maximum [mL/min]**
FTKSV4	47 mm	11.1	0.56	0.81

** Using a Pall virus filter disc holder of type FTK200 only*
*** Temperature: + 20 °C, differential pressure: 2.1 bar (30 psi)*

Table 3

Temperature Correction Factors for Water Flow Rate to Calculate Equivalent Values at 20 °C

Temperature (°C)	Temperature Correction Factor	Temperature (°C)	Temperature Correction Factor
15	1.14	23	0.93
16	1.11	24	0.91
17	1.08	25	0.89
18	1.05	26	0.87
19	1.03	27	0.85
20	1.00	28	0.83
21	0.98	29	0.81
22	0.95	30	0.80

5. Pre Challenge Buffer Conditioning (Recommended)

To reduce the risk of product stability issues with pure water, an optional buffer conditioning step is recommended. Use the same carrier buffer as the product solution.

1. Disconnect the upstream cover assembly, open the bleed port and drain the system of water.
2. Close the bleed port.
3. Pour the about 20 – 30 mL of 0.2 µm filtered (or finer) buffer into the reservoir and reconnect the upstream cover assembly using the clamp.
4. Remove any air through the bleed port by raising the pressure to approximately 0.2 bar (3 psi) and loosening the bleed port.
5. Tighten the bleed port.
6. Carefully increase the air pressure and begin filtration at the desired pressure until at least 3 mL of buffer has been collected. A pressure of 2.1 bar (30 psi) or the filterability/challenge pressure should be used.
7. Measure the flow rate (optional).
8. Slowly vent the system pressure.

6. Filterability/Viral Challenge Test Procedure

1. Disconnect the upstream cover assembly, open the bleed port and drain the system of water or buffer.
2. Close the bleed port.
3. Pour the required product in the reservoir and reconnect the upstream cover assembly using the clamp. For virus challenges it is recommended to spike the test virus to target a 6 log input concentration or another suitable level. Please refer to Pall publication USD2846: Filterability Testing and Virus Challenge of Pegasus SV4 Virus Removal Membrane Filter Discs.
4. Place a clean graduated cylinder or other appropriate collection vessel below the FTK200 outlet.
5. Remove any air through the bleed port by raising the pressure to approximately 0.2 bar (3 psi) and loosening the bleed port.
6. Tighten the bleed port.
7. Carefully increase the air pressure and begin filtration at the desired operating pressure until the required volume of effluent has been collected or the flow ceases. A differential pressure of 3.1 bard (30 – 45 psid) is recommended and the operating pressure should not exceed 5.0 barg (73 psig).
8. Measure the flow rate.
9. Slowly vent the system pressure.
10. If required, a post-use buffer flush to increase product recovery can be implemented by repeating Section 5.

7. Post Challenge Pressure Hold Test (Optional)

The pressure hold test is not a correlated integrity test and is not mandatory, given that virus retention results supersede any integrity test result. This gross integrity check is optional to confirm successful installation.

1. Disconnect the upstream cover assembly, open the bleed port and drain the system of product if there is any remaining.
2. Close the bleed port.
3. Fill approx. 10 mL of buffer or DI water in the reservoir.
4. Post-flush the disc until the reservoir is empty or post-flush the disc for at least 10 minutes. Use the same inlet pressure as used during challenge.
5. Open the bleed port and empty the housing through the bleed port of the disc holder by applying 0.2 bar (3 psi) of air pressure.
6. Close the bleed port.
7. Gradually increase the pressure to 5.8 bar (85 psi).
8. Stabilize the system for five minutes and allow downstream water to drain out.
9. Connect an empty piece of tubing to the downstream port of the disc holder and submerge the other end of the tubing in a beaker of water.
10. Hold the pressure for at least 60 seconds. No air bubbles should be observed coming from the outlet tubing during this time.

    Note: If any air bubbles are observed, discard the test disc and repeat the previous sections.

11. Carefully lower the air pressure to zero and disconnect the upstream cover from the test system.

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