GE Healthcare
Life Sciences

Cassette integrity test

The cassette airflow integrity test is an air diffusion test commonly used for determining a cassette's integrity. The cassette integrity test involves pre-wetting a cassette with water, pressurizing the cassette with compressed air, and then measuring the air diffusion rate through the membrane (Figure 3). High airflow rates (non-diffusive flow) observed during the cassette integrity test indicates a damaged cassette (broken seal, pin holes, etc.). The test is used solely to verify the integrity of a cassette, and does not correlate to the membrane pore size of a cassette.

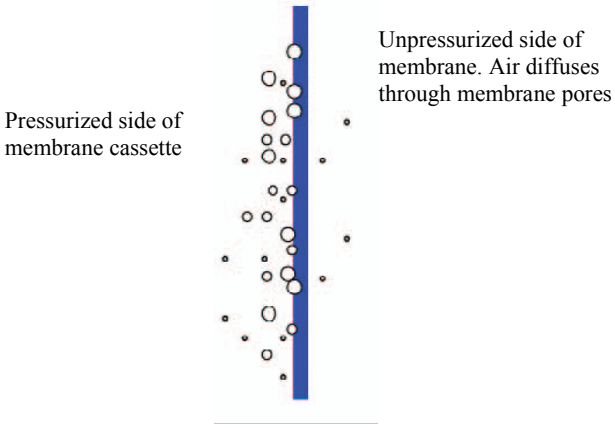

Figure 1. Airflow during cassette integrity testing

Cassette integrity testing is typically required for most applications as a method of verifying proper cassette performance. Although an airflow integrity test is conducted on each cassette prior to quality assurance release, GE Healthcare recommends that users complete a pre-use integrity test on cassettes. The test verifies that the cassette has not been damaged during transportation and is properly installed. Users should test used cassettes before use to ensure no damage occurred during cleaning and storage.

GE Healthcare cassette integrity test involves fully wetting the cassette with water, then applying pressurized air at 1 barg (15psig) to the feed side. After a stabilization period, airflow is measured on the permeate side.

Airflow integrity test results are reported in ml/min at 1 barg (Table 1. Results of cassette integrity tests). Cassettes at the high end of the integrity specification were further challenged with a marker to ensure the proper performance of the cassette (Table 2).

Table 1. Results of cassette integrity tests

Cassette average airflow integrity test results ml/min at 1 barg (15 psig)			
Membrane type	**Batch 1**	**Batch 2**	**Batch 3**
Kvick Lab™ 100 cm² (0.11 ft²)			
10 KD select	1.0	1.0	—
10 KD	0.7	0.8	0.6
30 KD	1.3	1.0	—
50 KD	1.1	—	—
100 KD	1.3	0.8	—
Kvick Lab 0.11 m² (1.2 ft²)			
10 KD select	12.0	9.6	3.6
10 KD	2.4	6.0	4.8
30 KD	6.0	21.6	9.6
50 KD	9.6	22.8	9.6
100 KD	32.4	24.0	3.6
Kvick Flow™ 0.46 m² (5 ft²)			
10 KD select	55	65	60
10 KD	20	20	45
30 KD	20	40	25
50 KD	70	80	70
100 KD	125	125	65
Kvick Flow 2.33 m² (25 ft²)			
10 KD select			
10 KD			
30 KD	Call GE Healthcare for updated information		
50 KD			
100 KD			

Table 2. Results of solute rejection on cassettes with acceptable— but high—integrity test results

Membrane type	Integrity test results (ml/min @ 15 psig) (ml/min @ 1 barg)	Marker type	Passage (%)*
10 KD Select	10.3	PVP C15	36.4
10 KD	12.1	BSA	0.1
30 KD	22.5	BSA	0.1
50 KD	34.0	BSA	1.5
100 KD	36.5	H IgG	2.6

* Percent passage after processing at 1.7 barg (25 psig) of TMP

Cassette water flux

Cassette water flux testing is used to evaluate the permeability of a cassette. Although not a quality control test, the cassette water flux study was conducted on multiple membrane and manufacturing lots to determine the typical water flux values for the cassettes for each membrane molecular weight cut-off. Kvick Lab cassettes were used in the study (Table 3). Cassette water flux results are normalized to surface area and reported as LMH (liter/m²/hour) per psig.

Table 3. Water flux test results for Kvick Lab cassettes

Membrane type	Integrity test results LMH at .0068 barg (1 psig) of TMP
10 KD select	12
10 KD	17
30 KD	23
50 KD	27
100 KD	42

Cassette cross flow

Cross flow provides the sweeping force across the membrane surface to remove or reduce the potential build up of solutes. Insufficient cross flow may lead to gel layer formation, decreased flux, and increased solute rejection, etc. Cross flow requirements also influence the pump and piping selection.

The cross flow rate of a cassette is a function of differential pressure (delta P) from the feed to the retentate port. Cross flow is impacted by factors such as screen type, channel height, flow path length, and the process solutions, etc. Consistency of cross flow rate among cassettes is critical, as it will influence the process operation and system design.

The cassette cross flow test—conducted on each cassette prior to quality control lot release—measures the cross flow rate through the retentate side of a cassette at a given delta P. The solution used is the cassette storage solution consisting of 0.1 to 0.2N NaOH and 20 to 22% glycerin by weight.

Results of the cassette cross flow test on three cassette validation batches are reported in ml/min at 2 barg (30 psig) of ΔP (Table 4).

Table 4. Results of cassette cross flow measurements using a solution of 0.1 to 0.2N NaOH and 20 to 22% glycerin by weight

Cassette Avg. cross flow-ΔP test results* ml/min @ ΔP of 2 barg (30 psig)			
Membrane type	**Batch 1**	**Batch 2**	**Batch 3**
Kvick Lab 100 cm² (0.11 ft²)			
10 KD select	104	115	—
10 KD	108	117	98
30 KD	104	115	—
50 KD	115	—	—
100 KD	115	120	—
Kvick Lab 0.11 m² (1.2 ft²)			
10 KD select	1370	1373	1364
10 KD	1358	1345	1426
30 KD	1195	1394	1338
50 KD	1351	1322	1269
100 KD	1405	1216	1381
Kvick Flow 0.46 m² (5 ft²)			
10 KD select	5520	4750	5850
10 KD	5000	4750	5300
30 KD	5535	5045	5910
50 KD	5875	5090	5460
100 KD	5335	4850	5870
Kvick Flow 2.33 m² (25 ft²)			
10 KD select			
10 KD			
30 KD		Call GE Healthcare for updated information	
50 KD			
100 KD			

* Storage solution results are typically 80% of results obtained with water.

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