FF High Performance (HP) is a high-quality membrane with a low coefficient of variation

There is an increasing demand within the diagnostic industry for the development of test kits that produce rapid and reliable results, especially in the detection of target molecules in liquids such as water, urine, blood, saliva, etc. The target molecules may include legal and illegal drugs and their metabolites (very small molecules), human chorionic gonadotrophin (hCG, a molecule of medium size), and antibodies directed against bacteria or viruses such as HIV (i.e., relatively large molecules).

The general solution is to provide a family of membranes that have the same raw material composition, but differ with respect to capillary rise times. The best variability among commercially available test kits is currently a coefficient of variation of > 10% (best) to > 20% (worst).

The new FF High Performance nitrocellulose membranes from Cytiva are optimized for reproducibility. We developed the new FF HP membranes using improved casting procedures that yield a uniform, powder-free surface that delivers razor-sharp lines and highly reproducible results.

The FF HP membranes possess superior intra- and inter-lot consistency as demonstrated by a coefficient of variation (CV) for capillary rise of < 10%.

This excellent reproducibility means that FF HP membranes give you:

- Improved assay consistency
- More consistent limit of detection
- Reduced assay optimization costs

We performed capillary rise studies in order to evaluate the reliability (wicking rate) of each membrane. This is because a reliable membrane could reduce the amount of resources you may need for development, validation, and manufacturing. The analysis was based on data from three separate manufacturing runs. Samples (940) were taken from 47 master rolls. Twenty samples were taken from each roll. The samples were a representation of each region of the membrane.

Table 1. Physical characteristics of membranes used to make FF High Performance

Description	Capillary rise[1] (s/4 cm)	Caliper[2] (µm)
FF80HP	60–100	200
FF120HP	90–150	200
FF170HP	140–200	200

[1] Cross web measured with water (rise time with serum or other liquids will differ)
[2] Including standard polyester backing which is 100 µm thick

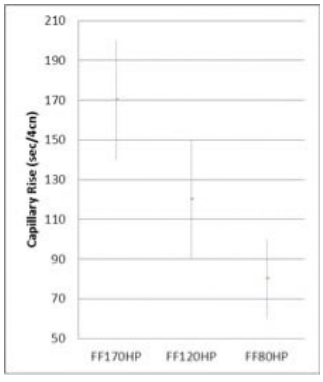


Fig 1. Flow rate ranges.

A carefully designed and rigorous manufacturing process results in membranes with high reproducibility (Fig 2) and minimal variation in intra- and inter-lot variability (Fig 3).

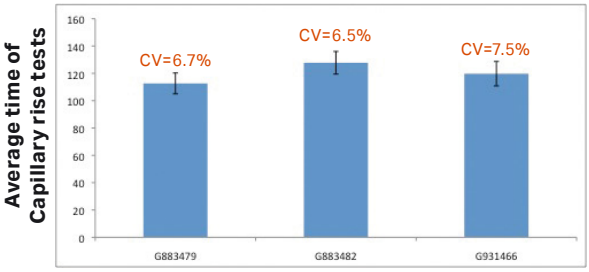


Fig 2. The graph demonstrates the CVs and the average time of capillary rise tests of three batches. The average of capillary rise for Lot G883479 was 112.6 ± 7.6 s while that of Lot G883482 was 127.7 ± 8.2 s. In addition, Lot G931466 had an average of 119.7 ± 8.9 s. The CVs for all three batches were 6.7%, 6.5%, and 7.5%, respectively.

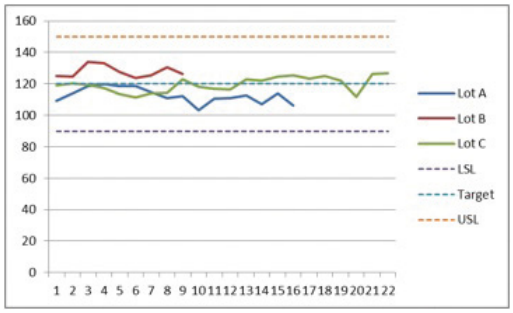
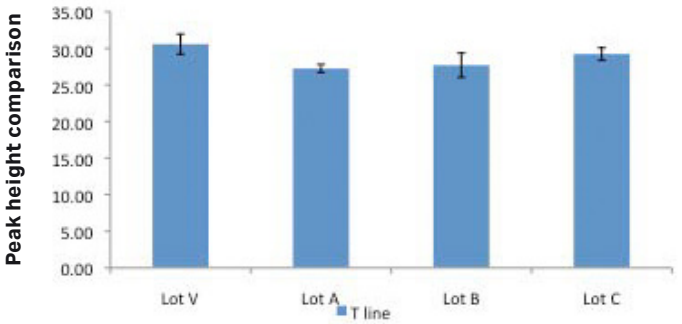


Fig 3. Graph represents the capillary rise results.

In order to investigate how wicking rate (physical measurement) relates to functional performance, we prepared a model system using hCG as the analyte to evaluate the performance of the membrane under simulated test conditions. Briefly, an analyte specific reagent was immobilized onto the membrane and a second analyte was labeled with colloidal gold. In the presence of the analyte (hCG), two lines will be formed (i.e., the "test" line and the "control" line).

The signal intensities for the test lines were inspected using a vision system and the results were tabulated. The results (Fig. 4A and 4B) indicate a low coefficient of variation (< 10%) for both intra-lot and inter-lot analysis. This correlates with the intra- and inter-lot variation seen during the physical evaluation of the membrane. Physically consistent membrane leads to functionally consistent test performance.

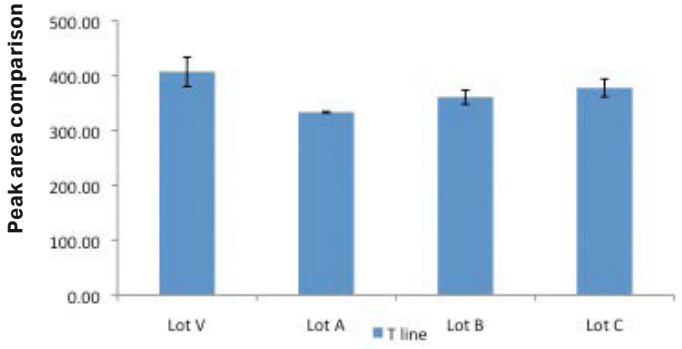
(A)



T-line inter-lot variation = 5.29%

Description	Lot V	Lot A	Lot B	Lot C
Test line mean	30.58	27.25	27.7	29.23
Test line STD	2.23	1.65	2.08	2.28
Test line CV	7.31%	6.00%	7.49%	7.79%

(B)



T-line inter-lot variation = 8.34%

Description	Lot V	Lot A	Lot B	Lot C
Test line mean	407	333.32	360.78	377.65
Test line STD	35.65	23.18	28.74	37.38
Test line CV	8.76%	6.95%	7.97%	9.90%

Fig 4. We noticed consistent inter- and intra-lot test line intensities in peak heights and areas.

FF High Performance membrane are optimized for lateral flow assays. The low CV of < 10% for capillary rise observed results in an improved assay consistency. In addition, we observed the same results in a model test system.

Ordering information

Cat No.	Description
10547002	FF80HP 20 mm × 50 m 1/pk
10547003	FF80HP 25 mm × 50 m 1/pk
10547006	FF120HP 20 mm × 50 m 1/pk
10547001	FF120HP 25 mm × 50 m 1/pk
10547004	FF170HP 20 mm × 50 m 1/pk
10547005	FF170HP 25 mm × 50 m 1/pk

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