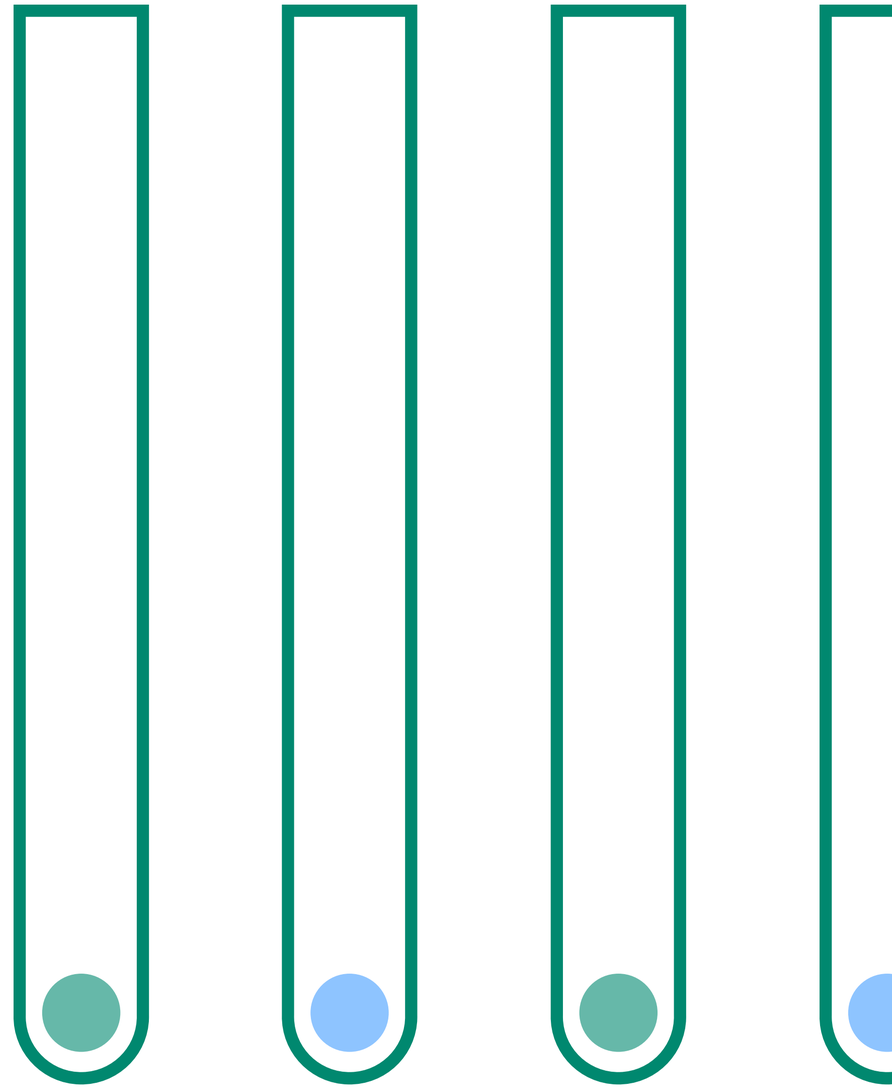
Nitrocellulose membranes with quality-assured manufacturing and defined lot-to-lot consistency

Vivid™ lateral-flow nitrocellulose membranes



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With quality-assured manufacturing and defined lot-to-lot consistency, our Vivid™ lateral-flow nitrocellulose (LFNC) membranes offer reliable media for development, manufacturing, and implementation of lateral-flow diagnostic point-of-care tests.

Membrane consistency for assay reproducibility and sensitivity

- **Increased sensitivity**

  Vivid LFNC membranes provide high sensitivity with dilute concentrations of target analytes.

- **Strong consistency and high duplication rate**

  When measuring intra- and inter-lot performance for wicking time and thickness Vivid LFNC membranes provide consistent results, resulting in low defined coefficients of variation.

- **Consistent reproducibility**

  Provides protein binding levels that are highly consistent to facilitate reliable assay performance.

- **Clear results**

  Demonstrates low background levels that enable crisp capture lines and easy-to-read results.

- **Dependable performance**

  Constructed using pure nitrocellulose that does not contain interfering substances or post-treatments that affect assay performance.

- **Clear surface appearance**

  Controlled surface quality of the membrane ensures freedom from visual defects, discolouration, and dust.

- **Result timing**

  Quality-assured wicking speed gives predictable result time.

Nitrocellulose membranes are the heart of lateral-flow assays and require highly consistent wicking rate and thickness. Variations in either can have detrimental effects on assay sensitivity, reproducibility, and reagent consumption. Vivid LFNC membranes are manufactured to ensure that these key parameters are tightly controlled with coefficients of variation (CV) between 5% and 10%.

Nitrocellulose is the globally preferred membrane substrate in diagnostic tests where antigenantibody binding occurs, e.g., pregnancy tests, urine-albumin tests, and C-reactive protein (CRP) detection. Vivid LFNC membranes fulfill all the criteria to enable the development and manufacture of a diverse range of tests with reliability and reproducibility, available with the following benefits:

- **Quality: designed and tested specifically for diagnostic applications to ensure the materials meet stringent requirements for diagnostic assay development and manufacturing**
- **Reliable, large-scale manufacturing capacity with lot-to-lot traceability**
- **Reproducibility: defined coefficients of variation for key performance parameters result in consistent performance**
- **Choice of defined capillary speeds to select sensitivity of diagnostic test**
- **Straight and uniform migration front**

Specifications

Membrane	Thickness	Wicking rate (s / 4 cm)
Vivid 90 LFNC	190–230 µm includes 95–105 µm polyester support	70–110
Vivid 120 LFNC	190–230 µm includes 95–105 µm polyester support	95–135

Thickness

The thickness of the reaction membrane has a direct impact on its signal generation. Consequently, any variations both intra- or inter-lot will have an impact on point-of-care test (POCT) device manufacturing and the final assay performance.

In the data drawn from these lots, measuring the thickness of the membrane every 2.5 cm down a sample piece of material, the coefficient of variation was measured as ≤4.6% for Vivid 120 LFNC membrane with average thickness for all sample points being 196.7 ± 8.1 µm (Fig 1) and for Vivid 90 LFNC membrane the coefficient of variation was ≤2.6% with average thickness for all sample points being 217.1 ±

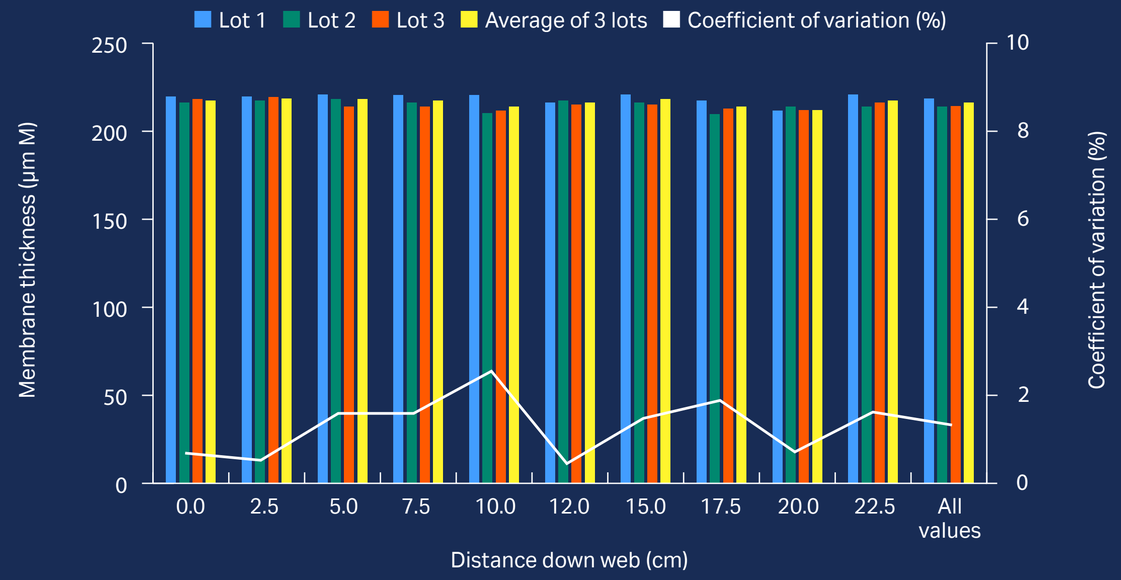


Fig 1. Thickness of Vivid 90 lateral-flow nitrocellulose membranes measured at intervals across a membrane from these different lots.

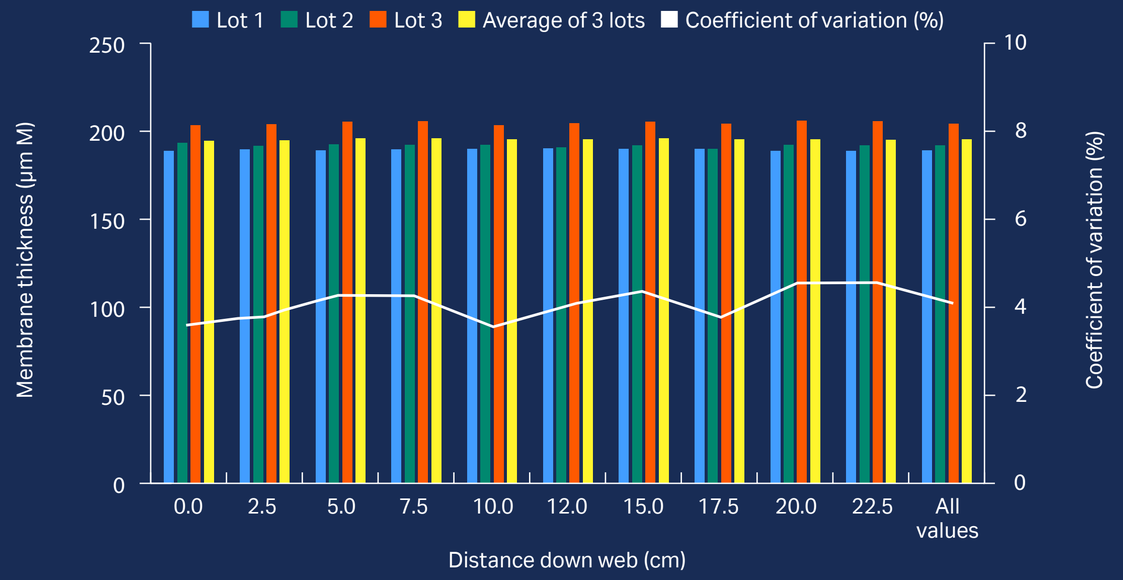


Fig 2. Thickness of Vivid 120 lateral-flow nitrocellulose membranes measured at intervals across a membrane from these different lots.

Capillary speed and wicking

Assay sensitivity is maintained with consistency of the wicking rate of the nitrocellulose membrane. By maintaining a uniform sample front that travels along the membrane at a consistent speed, the target analyte is maintained in a homogeneous concentration. This consistent speed ensures that the target analyte present in the sample has adequate time to bind to the capture antibody resulting in reproducible results from lot to lot. The wicking rate of the Vivid 90 and Vivid 120 LFNC membranes both exhibit CV's for intra- and inter-lot consistency of ≤ 10% (Table 2 and 3).

Membrane	Inter-lot wicking rate (s / 4 cm)			Average (s / 4 cm)	Standard deviation	Coefficient of variation
	Lot 1	Lot 2	Lot 3			
Vivid 90 LFNC	83.7	79.3	87.3	83.4	6.1	7.3%
Vivid 120 LFNC	130.7	117.3	117.7	121.9	7.8	6.4%

Table 2: Summary data of intrer-lot reproducibility (from three sample points) of capillary speed and inter-lot reproducibility across three lots.

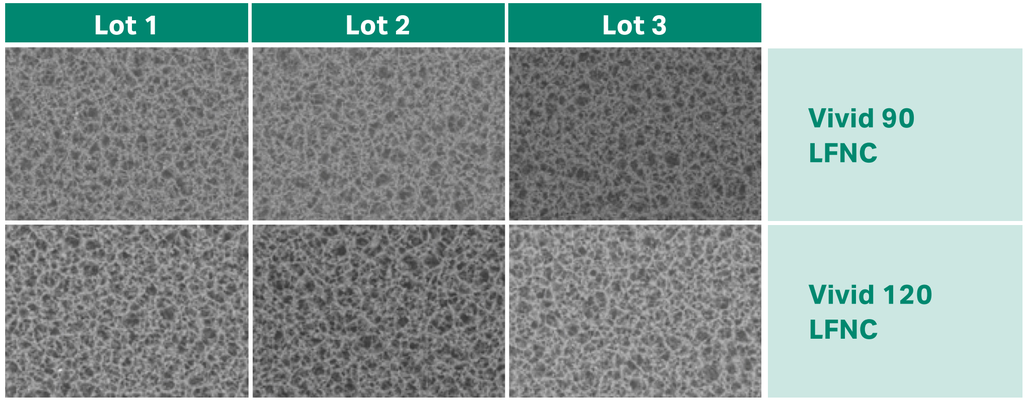
Membrane	Intra-lot wicking rate (s / 4 cm) Position on sample sheet			Average (s / 4 cm)	Standard deviation	Coefficient of variation
	Left	Center	Right			
Vivid 90 LFNC	80.7	84.3	85.3	83.4	2.5	2.9%
Vivid 120 LFNC	117.7	123.0	125.0	121.9	3.8	3.1%

Table 3: Summary data of intra-lot reproducibility (from three sample points) of capillary speed and inter-lot reproducibility across three lots.

The wicking rate of the Vivid 90 and Vivid 120 LFNC membranes both exhibit CV's for intra- and inter-lot consistency of

≤ 10%

Scanning electron microscopy



Scanning electron microscopic images for Vivid 90 and Vivid 120 lateral-flow nitrocellulose membranes at 1000× magnification to illustrate consistency of appearance for each product over these lots.

Related products

Leukosorb™ media.
Removal of white blood cells to prevent interference with PCR or molecular diagnostics.

Vivid plasma separation.
Removal of cellular components (red cells, white cell, platelets) in less than two minutes resulting in a supernatant with similar qualities to centrifuged material.

Ordering information

Product	Wicking rate (s / 4 cm)	Width	Length	Format	Product code
Vivid 120 LFNC sample	95–135	25 mm	300 mm	1 strip	VIV120SAMP
Vivid 120 LFNC	95–135	25 mm	3 m	1 roll	VIV1202503R
Vivid 120 LFNC	95–135	25 mm	50 m	1 roll	VIV1202550R
Vivid 90 LFNC sample	70–110	25 mm	300 mm	1 strip	VIV90SAMP
Vivid 90 LFNC	70–110	25 mm	3 m	1 roll	VIV902503R
Vivid 90 LFNC	70–110	25 mm	50 m	1 roll	VIV902550R

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