Guide

Rapid diagnostic test development: focus on sample preparation and collection

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cytiva

Introduction

In former times, the need for diagnosis was intrinsically tied to diseases. People went to see the doctor when they were suffering from symptoms, and diagnostic assessments were performed to define diseases and decide on therapies. However, we've since switched from this old, symptom-based disease management to disease prediction and prevention. We've also seen diagnostic testing expanding from only human clinical tests to applications in areas such as veterinary medicine, agriculture, and even food and beverage production. This growth has been made possible by the increasing capabilities of diagnostics as well as the successful transfer of diagnostic technologies to point-of-care use. One of the most widely used analytical technologies in diagnostics is the immunoassay, which is now firmly established alongside more traditional, instrument-based techniques like ELISA, immunohistochemistry, and flow cytometry. Commonly used immunoassays take the form of lateral-flow, flow-through, dipstick, dry chemistry, or line-blot assays.

Cytiva manufactures high-quality products and has a presence in diagnostics component and service supply spanning decades. Our membranes and our cellulose and glass fiber materials have been used in immunochromatographic devices since the early beginnings of this technology. Now, our portfolio of products offers a broad range of membranes with properties such as high capillary flow rates and high protein binding capacities. As a single-source vendor, Cytiva offers a wide range of membrane, glass, and paper-based products.

This guidebook was created as an aide to help newcomers to sample preparation and collection and gives an overview of the relevant diagnostic test components in an application-focused way. This overview, combined with the troubleshooting section, makes this book also a valuable resource of information for the experienced diagnostics assay developer and producer.

Introduction to sample preparation

Today's modern analytical techniques offer the opportunity to achieve extremely high levels of sensitivity. However, to benefit from the increased sensitivity offered by these techniques, significant improvements in sample preparation are necessary. These improvements in sample preparation prior to the assay will result in reduction of both false-positive signals and the amount of the analyte or target cells used in the assay.

The use of filtration-based techniques offers major advantages. The use of a filter in a simple housing or plate format allows very rapid and cost-effective sample preparation.

The choice of membrane influences the ability to remove red blood cells to stop interference by heme and to stop problems caused by contaminants. In molecular diagnostics, the removal of host DNA by removal of white blood cells has proved to be a very effective way of improving the detection limit for some assays. For example, use of a filtration material that removed white blood cells produced a 50-fold increase in sensitivity on a PCR-based malaria assay.

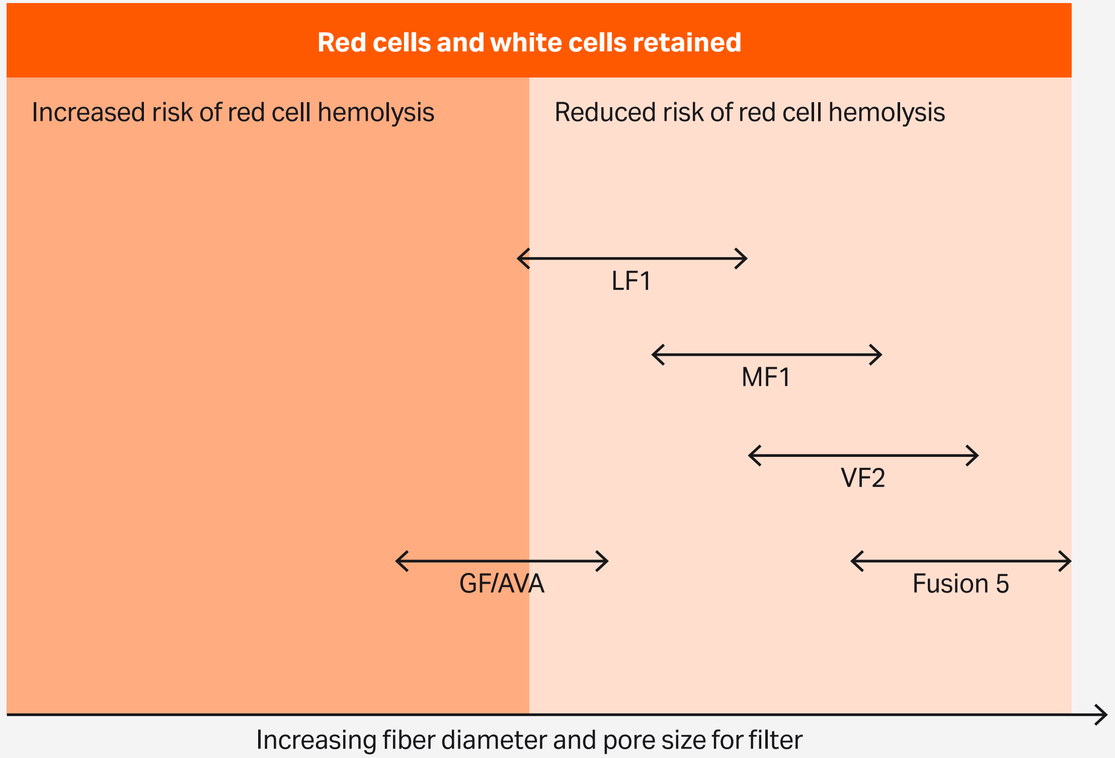


Fig 1. Whole blood separation.

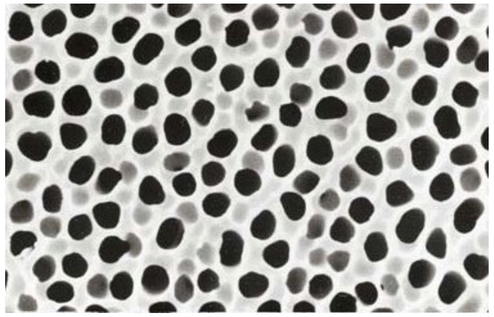
Glass fiber media for sample preparation of whole blood

Grade	Materials and uses	Particle retention* liquid (µm)	Binder	Volume (per cm^2)	Thickness (µm at 53 kPA)	Wicking rate (s/4 cm)	Water absorption (mg/cm^2)
VF2	Vertical separator used as single or multiple layers for separation.	3.0	None	> 50 µL	785	23.8	86.2
GF/DVA	Untreated bound glass fiber.	3.5	PVA†	> 50 µL	785	28.2	93
MF1	Untreated bound glass fiber suitable for whole blood or serum. Typically used for whole blood volumes between 30 µL and 100 µL.	2.0	None	10–50 µL	367	29.7	39.4
LF1	Untreated bound glass fiber suitable for whole blood or serum. Performs well with one or two drops of whole blood.			10–15 µL	247	35.6	25.3
Fusion 5	A proprietary, single-layer matrix membrane that can perform all of the functions of a lateral-flow strip. It can be used as sample pad as well as a blood separator with excellent separation efficiency.			10–50 µL	370	43.9	42.3

* 98% particle retention rating
† PVA = polyvinyl alcohol

Membranes for sample preparation

Cytiva offers an extensive line of filter membranes. In a number of areas, the combination of properties connected with Whatman™ filtration membranes makes them suitable for use in *in vitro* diagnostics (IVD). Particularly suitable are Anopore™, regenerated cellulose, and track-etched membranes.

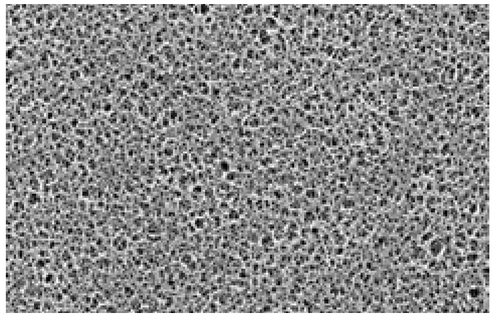


Anopore membrane pore structure

Anopore inorganic membranes

Anopore inorganic membrane is ideal for a wide range of laboratory filtration applications. This unique material has a precise, nondeformable, honeycomb pore structure with no lateral crossovers between individual pores.

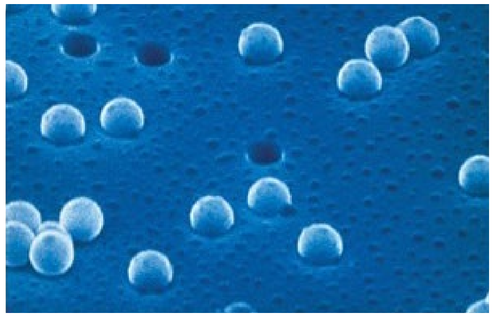
Anopore membranes are composed of a high-purity alumina matrix that is manufactured electrochemically. The membrane also exhibits low protein binding, has minimal autofluorescence, is nontoxic, and supports cellular growth.



Electron micrograph of regenerated cellulose

Regenerated cellulose membranes

Regenerated cellulose membranes consist of pure cellulose and do not contain any wetting agent. These membranes wet spontaneously and have a very good wet strength. They are extremely chemically resistant and suitable for aqueous as well as organic media.



Electron micrograph of Cyclopore™ membrane

Track-etched membranes (TEMs)

TEMs are very thin and have tightly controlled pore sizes. They were traditionally used for high-specification filtration in many laboratory applications. These thin films have discrete pores that are formed through a combination of charged particle bombardment (or irradiation) and chemical etching.

Membranes for sample preparation

Product name	Properties	Quantity	Size	Thickness	Product code
Cyclopore™ polycarbonate membrane	Negligible absorption and adsorption of filtrate, non-hygroscopic. No particle shedding provides ultra clean filtrate.	100 per pack	25 mm	0.2 µm	10417606
		100 per pack	47 mm	0.2 µm	10417612
		100 per pack	210 × 297 mm	0.2 µm	10417650
		100 per pack	25 mm	0.4 µm	10417706
		100 per pack	13 mm	0.4 µm	10417701
		100 per pack	47 mm	0.4 µm	10417712
		25 per pack	210 × 297 mm	0.4 µm	10417750
		100 per pack	25 mm	2 µm	7060-2511
		100 per pack	47 mm	8 µm	7060-4714
		25 per pack	10 × 50 mm	8 µm	112915
		100 per pack	47 mm	10 µm	10418450
		100 per pack	25 mm	12 µm	10418552
		100 per pack	47 mm	12 µm	10418550

Product name	Properties	Quantity	Size	Thickness	Product code
Nuclepore™ polycarbonate hydrophilic membrane	Negligible absorption and adsorption of filtrate, non-hygroscopic. No particle shedding provides ultra clean filtrate.	100 per pack	25 mm	0.03 µm	110602
		100 per pack	19 mm	0.05 µm	800308
		100 per pack	13 mm	0.2 µm	10417001
		100 per pack	19 mm	0.2 µm	10417004
		100 per pack	25 mm	0.2 µm	10417006
		100 per pack	47 mm	0.2 µm	10417012
		100 per pack	50 mm	0.2 µm	10417014
		100 per pack	90 mm	0.2 µm	10417018
		25 per pack	142 mm	0.2 µm	10417031
		25 per pack	293 mm	0.2 µm	10417051
		100 per pack	293 mm	0.2 µm	10417039
		25 per pack	8 × 10 inches	0.2 µm	10417050
		100 per pack	19 mm	0.3 µm	800307
		100 per pack	13 mm	0.4 µm	10417101
		100 per pack	19 mm	0.4 µm	10417104
		100 per pack	25 mm	0.4 µm	10417106
		100 per pack	47 mm	0.4 µm	10417112
		100 per pack	50 mm	0.4 µm	10417114
		25 per pack	90 mm	0.4 µm	10417118
		25 per pack	293 mm	0.4 µm	10417139
		100 per pack	25 mm	0.6 µm	10417206
		100 per pack	47 mm	0.6 µm	10417212
		100 per pack	140 × 140 mm	0.6 µm	10417251
		100 per pack	19 mm	0.8 µm	10417304
		100 per pack	25 mm	0.8 µm	10417306
		100 per pack	37 mm	0.8 µm	10417309
		100 per pack	47 mm	0.8 µm	10417312
		25 per pack	210 × 293 mm	0.8 µm	10417551

Product name	Properties	Quantity	Size	Thickness	Product code
Nuclepore polycarbonate hydrophilic membrane	Negligible absorption and adsorption of filtrate, non-hygroscopic. No particle shedding provides ultra clean filtrate.	100 per pack	13 mm	1 µm	10418701
		100 per pack	19 mm	1 µm	10418704
		100 per pack	25 mm	1 µm	10418706
		100 per pack	47 mm	1 µm	10418712
		25 per pack	90 mm	1 µm	10418718
		25 per pack	142 mm	1 µm	10418731
		25 per pack	293 mm	1 µm	10418739
		100 per pack	25 mm	2 µm	10418806
		100 per pack	47 mm	2 µm	10418812
		25 per pack	90 mm	2 µm	10418818
		100 per pack	13 mm	3 µm	10418301
		100 per pack	25 mm	3 µm	10418306
		100 per pack	47 mm	3 µm	10418312
		25 per pack	90 mm	3 µm	10418318
		100 per pack	13 mm	5 µm	10417401
		100 per pack	25 mm	5 µm	10417406
		100 per pack	47 mm	5 µm	10417412
		100 per pack	50 mm	5 µm	10417414
		100 per pack	25 × 80 mm	5 µm	10417450
		100 per pack	13 mm	8 µm	10417501
		100 per pack	47 mm	8 µm	10417512
		100 per pack	13 mm	10 µm	10418401
		100 per pack	25 mm	10 µm	10418406
		100 per pack	47 mm	10 µm	10418412
		100 per pack	13 mm	12 µm	10418501
		100 per pack	25 mm	12 µm	10418506
		100 per pack	47 mm	12 µm	10418512
		100 per pack	50 mm	12 µm	10418514
		100 per pack	90 mm	12 µm	10418551
		100 per pack	25 mm	15 µm	800203

Product name	Properties	Quantity	Size	Thickness	Product code
Anopore membrane	Inorganic membranes, supplied as Anodisc™ membrane filters, are an aluminum oxide membrane with a honeycomb pore structure that facilitates highly precise filtration. Their transparency and surface retention enable efficient light or electron microscopy.	100	13 mm	0.02 µm	6809-7003
		100	47 mm	0.02 µm	6809-5502
		100	13 mm	0.1 µm	6809-7013
		100	13 mm	0.2 µm	6809-7023
		100	47 mm	0.2 µm	6809-5522

Product name	Properties	Quantity	Size	Thickness	Product code
Regenerated cellulose membrane RC 55	Cellulose membrane filters are microporous cellulose acetate filters made without wetting agents. RC60 offers low extractables and wide compatibility in both organic and aqueous media.	100	50 mm	0.2 µm	10410314
		100	25 mm	0.45 µm	10410206
		100	50 mm	0.45 µm	10410214
		100	57 mm	0.45 µm	10410212
		25	100 mm	0.45 µm	10410219
		25	110 mm	0.45 µm	10410224
		25	142 mm	0.45 µm	10410229
Regenerated cellulose membrane RC 58		100	47 mm	0.2 µm	10410312
		25	100 mm	0.2 µm	10410319
		5	300 × 600 mm	0.2 µm	10410380
Regenerated cellulose membrane RC 60		100	50 mm	1 µm	10410014

Encapsulation options

Cytiva can encapsulate filter media into various formats, such as microplate, syringe filter, and centrifuge tube filter. The wide range of devices can meet the sample volume and throughput you require.

Filtration microplates

Microplates allow faster, high-throughput sample preparations for assays such as ELISA. The multiwell format also allows you to significantly lower the cost of your assay per sample.

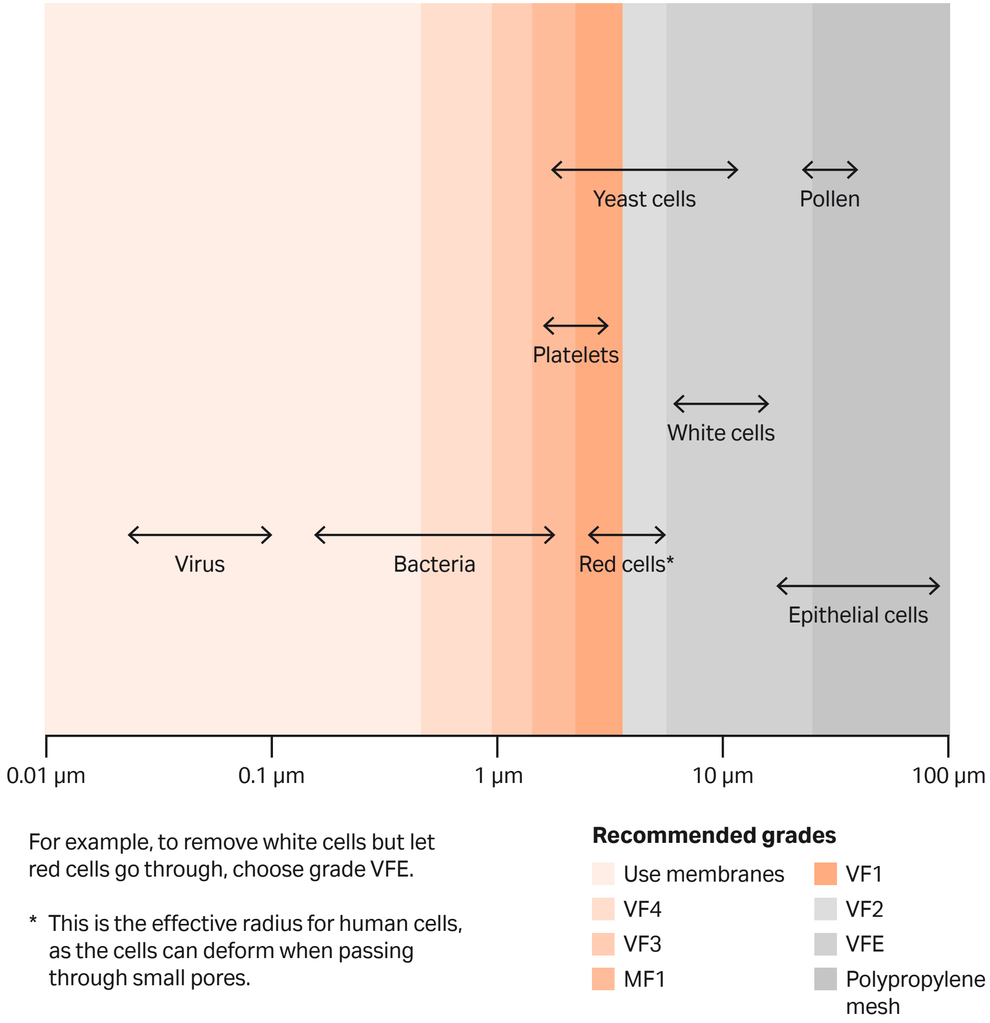


Fig 2. Cell separation.

Introduction to sample collection

For accurate and reliable collection of samples that can be collected and dried before being processed, Cytiva offers an extensive range of cellulose paper-based media. These media have a wide range of absorbencies to accommodate varying sample types. To ensure minimal sample interference, Cytiva uses only high-purity raw materials in its manufacture of papers. The wide range of papers available can be used to collect and transport bodily fluid samples including blood, saliva, urine, sweat, plasma, tears, and feces.

Untreated cellulose media for sample collection

Grade	Properties	Thickness (µm at 53 kPA)	Wicking rate (s/4 cm)	Water absorption (mg/cm^2)
CF2	A thin, smooth-surfaced paper containing an FDA approved resin that binds the cellulose fibers together. Suitable for small volumes.	172		16.1
CF3	A medium thick cotton linter paper, originally used for separation of inorganic compounds. For larger sample volume than CF1.	322	174.3	34.6
CF5	100% cotton linter can handle medium to high volumes	954	63.3	99.2
CF7	100% cotton linter can handle medium to high volumes	1873	35	252.3
CF10	A medium thick cotton linter paper with similar absorbency to CF4, for medium volumes.	490		42

Useful content:
point-of-care testing

Infographic:
Considerations for membrane selection

Blog:
Membranes 101: A guide to membranes for POC diagnostics

Checklist:
10 top tips for LFA development

Infographic:
Top 5 tips for testing stability in lateral-flow assays

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