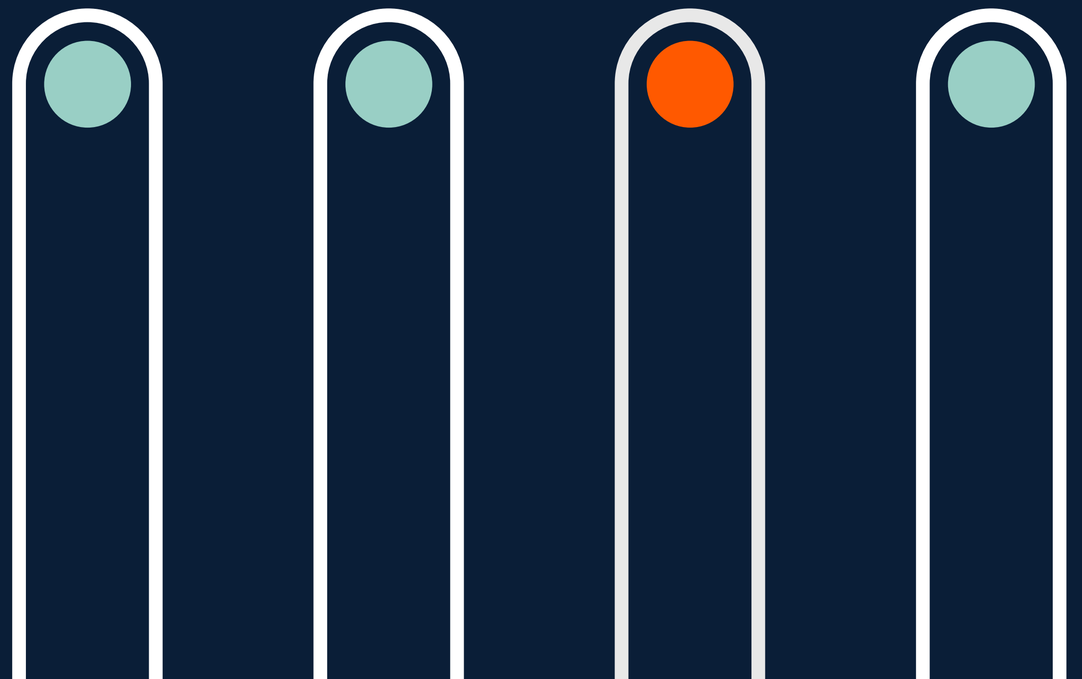
Helping you build a smarter diagnostic assay

- Membranes glass and cellulose fibers
- Customizable components
- Biosample collection
- Molecular diagnostics



cytiva

DOMINIQUE DUTSCHER SAS

Helping you build a smarter diagnostic assay

When you partner with Cytiva you get access to a wide selection of high performance, customizable components and solutions for immunoassay and molecular diagnostic applications. Our innovative stabilization technologies enable you to manufacture diagnostic kits that don't require refrigeration during shipping and storage, helping you to reach more patients at point of care. You also benefit from Cytiva's extensive experience and expertise, not only when unexpected issues emerge, but from design stage through launch. Our experts will help you optimize components, identify the best-suited technologies, and offer invaluable assistance to help expand your customer base and get you in-market earlier. That's what smart, reliable, and cost-efficient diagnostic solutions are made of.

DOMINIQUE DUSCHER SAS





Custom and contract manufacturing

A collaboration with Cytiva offers real benefits

Many of Cytiva's Amersham™ and Whatman™ products are used as tools and/or components in a range of applications in life sciences, diagnostics, pharmaceuticals, and environmental sciences. In addition, Cytiva can provide the extensive capabilities offered by our ISO-certified manufacturing centers and process rigor, including Design For Six Sigma (DFSS) and Lean manufacturing. Taken together, the portfolio and capabilities of Cytiva offer a world-class custom and contract manufacturing operation that provides all aspects of the manufacturing process to an assured quality.

Certification for our quality management systems

- ISO 9001
- ISO 13485

Table 1. Example of the scope of custom and contract manufacturing services

Contract manufacturing	Custom manufacturing

• Assay validation
• Formulation
• Kitting capability
  – Assembly and packaging
• Analytical services
• Final product testing
• Lean Six Sigma manufacturing
• Product design capability
	• Customer-specific products
	• Bulk supply
	• Room temperature assay stabilization
	  – Individual reagents
	  – Complete multiplex assays
	• Product design capability



bsi.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485: 2003

This is to certify that:

Cytiva
The Maynard Centre
Forest Farm est. Whitchurch
Cardiff
South Glamorgan
CF14 9FR
United Kingdom

Holds Certificate Number: MD 588911

and operates a Quality Management System which complies with the requirements of ISO 13485: 2003 for the following scope:

Design, control of manufacture and distribution of specimen collection devices for downstream analysis applications.

For and on behalf of BSI:

Gary Fenton, Global Assurance Director

Originally registered: 19/10/2012 Latest Issue: 19/10/2012 Expiry Date: 18/10/2015

Page: 1 of 1

...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate of Registration

Intertek

This is to certify that the quality management system of

Whatman GmbH

Main site: Hahnestrasse 3, 37586 Dassel, Germany

has been assessed and registered by Intertek as conforming to the requirements of

EN ISO 13485:2012

The quality management system is applicable to

Design and development, production and distribution of medical devices and related services for separation and analytical applications

Certificate Number: 52592
Initial Certification Date: 16 November 2009
Certificate Issue Date: 14 September 2015
Certificate Expiry Date: 26 June 2018

Thomas Andersson, CEO
Intertek Certification AB
P.O. Box 1103, SE-164 22 Kista, Sweden

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

The certificate remains the property of Intertek, to whom it must be returned upon request.

SWEDAC ACCREDITERING
1639
ISO/IEC 17021

Intertek Intertek Intertek Intertek

Fig 1. ISO certificates.

Contact us to learn more about our custom and contract manufacturing capabilities

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Helping you build a smarter diagnostic assay

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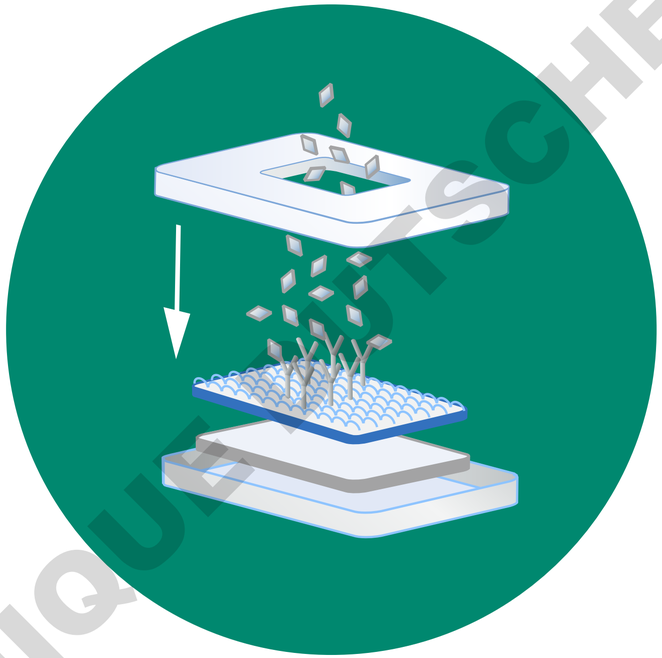
Point-of-care immunoassay

Rapid point-of-care tests are among the most widely used analytical technologies in diagnostics. Due to their high performance, ease of use and cost effectiveness, diagnostic rapid tests can deliver semiquantitative or quantitative results.



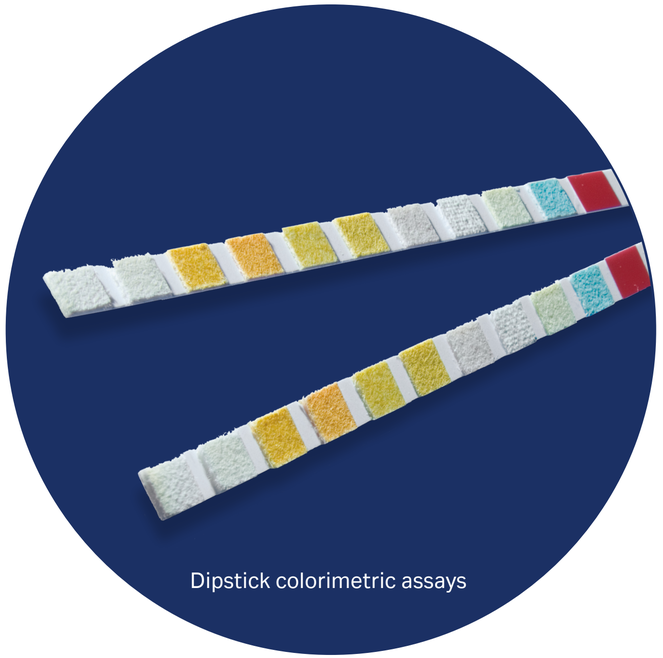
Lateral-flow immunoassays

- Sample pads **p. 12**
- Blood separators **p. 14**
- Conjugate release **p. 16**
- Membranes **p. 18**
- Absorption pads **p. 26**



Flow-through immunoassays

- Nitrocellulose membranes **p. 21**
- Absorbents **p. 28**



Dipstick colorimetric assays

Dipstick colorimetric assays

- Cellulose pads **p. 31**

DOMINIQUE DUTSCHER SAS

Molecular diagnostics

Reduce cost, gain greater geographical access, and simplify your workflow from sample collection to result by using our stabilization products and services.



Product Design

p. 33



FTA Elute card

Biosample collection with ambient temperature transport and storage

p. 46

- FTA card
- FTA Elute card



Sample purification or isolation

p. 37

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Molecular diagnostics

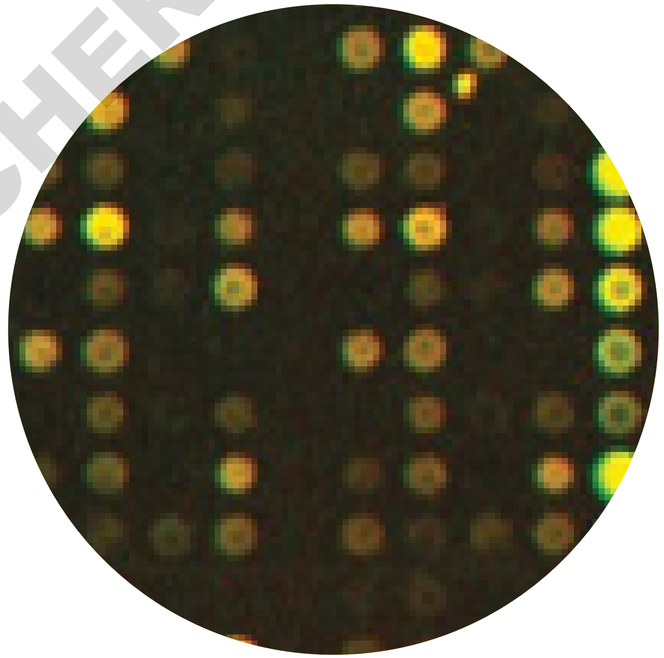


Assay components

p. 38

- Nucleotides
- PCR buffer components
- Fluorescent labeling reagents
- Enzymes and antibodies

Ready-To-Go™ assay stabilization technology
for room temperature storage.



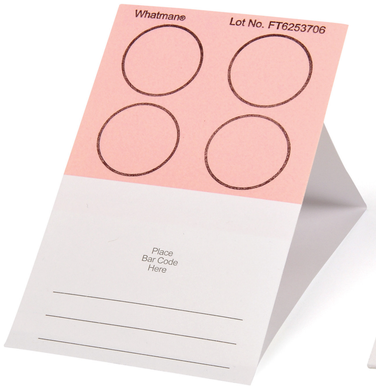
Sample clean-up and detection

p. 44

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Biosample collection with ambient-temperature transport and storage

Cytiva offers a broad portfolio of products and services for the ambient temperature collection, transport and storage of a range of biosamples including human blood, buccal (cheek) cells, and saliva.



FTA Classic indicating card



FTA Elute indicating card



Example of a custom buccal kit

Choose Cytiva matrices for ambient temperature biosample collection

DNA

- Whatman FTA cards **p. 46**
- Whatman FTA Elute cards **p. 46**

Customized sample collection kits and cards **p. 49**

Cytiva will contract manufacture customized kits (including cards and accessories) for sample collection prior to diagnostic assays.

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Track-etched membranes for diagnostic applications

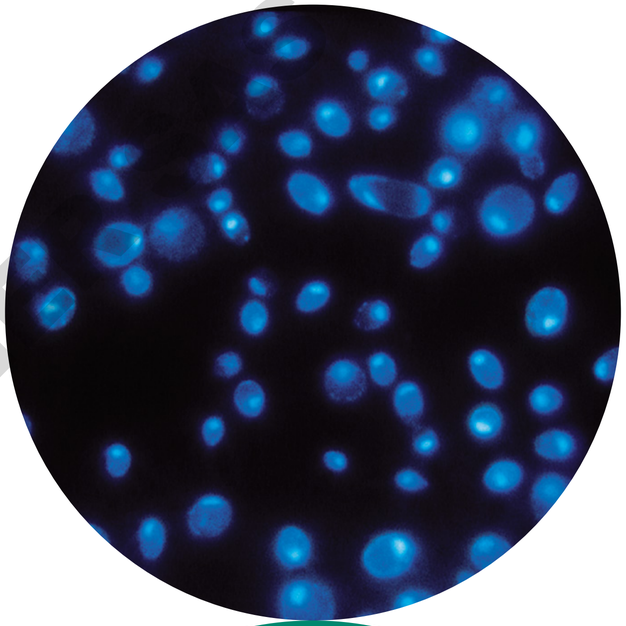
Cytiva provides a range of Whatman track-etched membranes (TEMs) whose advanced technical specifications make them an outstanding choice for a wide range of diagnostic applications.

Choose Cyclopore™ or Nuclepore™ track-etched membranes for use in many applications such as:

- Cell capture
- Particle-capture assays
- Biosensors

Two membrane materials: Polycarbonate or polyester membranes

More information on p. 52



DOMINIQUE DUTSCH

Point-of-care immunoassay

Cytiva is an established technology component provider for point-of-care immunodiagnostic assays, specifically:

- Lateral-flow immunoassays
- Flow-through immunoassays
- Dipstick colorimetric assays

We produce a vast array of cellulose and glass fiber substrates and nitrocellulose membranes to an assured quality, ensuring accurate and reproducible results.



DOMINIQUE DUTSCHER

Lateral-flow immunoassay

With a diverse array of products, Cytiva is one of the leading suppliers in lateral-flow technology. Our offering includes our wide range of blood separation products, conjugate release pads, nitrocellulose membranes, and absorbents.

Developments in lateral-flow immunoassay systems allow for single step assays that require only the addition of a sample. The sample flows through the device and comes in contact with dried reagents, usually a tagged secondary antibody. The antibody and analyte migrate to a capture zone of membrane-immobilized antibody. Any unreacted tagged antibody flows past the capture zone.

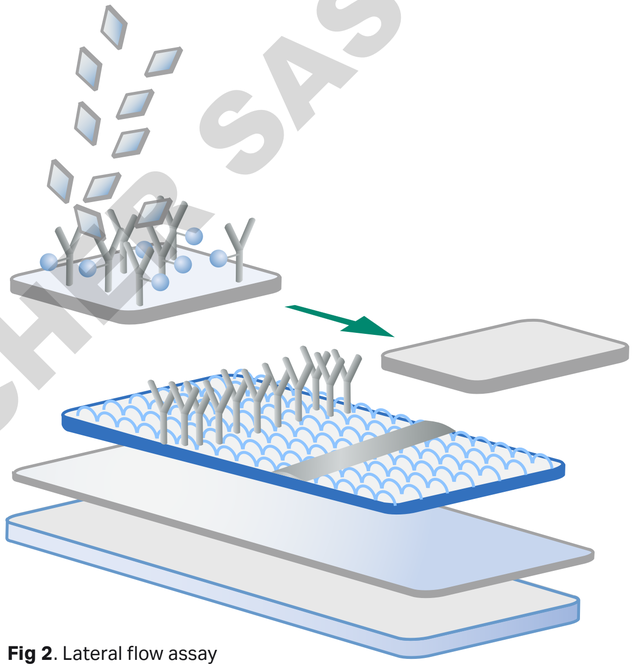


Fig 2. Lateral flow assay

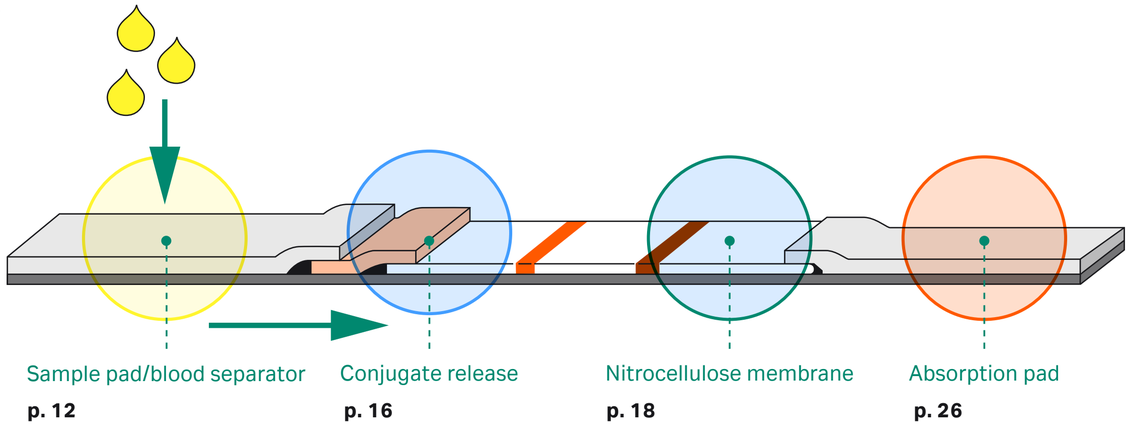


Fig 3. Drawing of a lateral flow immunoassay, showing its different components.

DOMINIQUE DUTSCHER SAS

Sample pads for lateral-flow immunoassay

Sample pads begin the assay by transporting samples from the point of application to the test components.

To ensure that your assay begins without complications, Cytiva offers a complete range of high-quality sample pad materials.

Features and benefits:

- **Consistent absorbency and wicking rates:** Ensures test-to-test reproducibility
- **Product manufactured in controlled environments from highest-quality material:.** No false results due to sample contamination
- **Low protein binding:** Minimal loss of analyte, so test sensitivity is maintained
- **Naturally hydrophilic:** Rapid rewetting after prolonged storage
- **Wide range of thickness, absorbency and wicking rate**
- **Compatible with most styles of housings**
- **Minimal leakage along the strip:** No contamination of test results

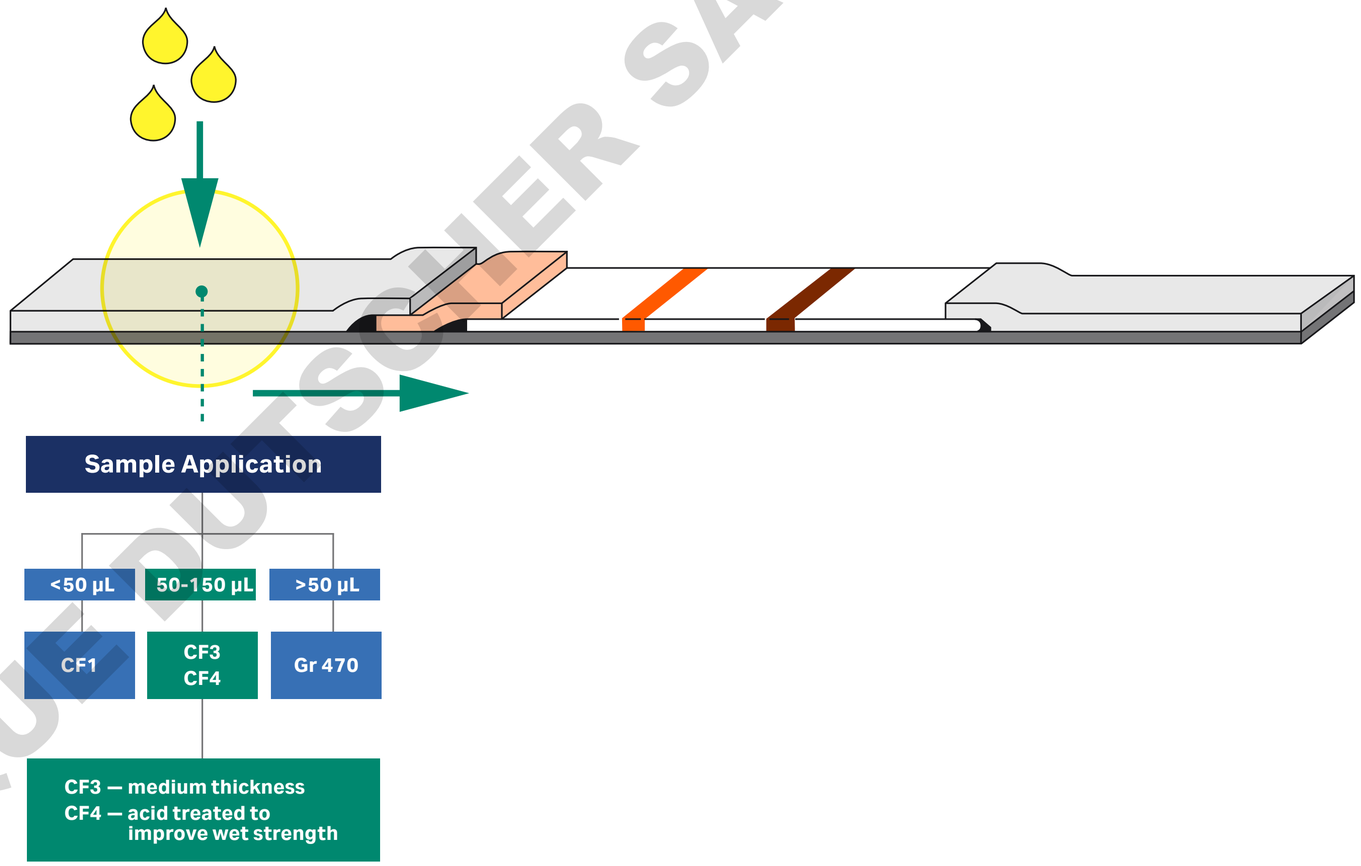


Fig 4. Sample pads selection tree.

DOMINIQUE DUTSCHER SAS

Technical properties

Product	Material	Properties	Thickness (µm @ 53 kPA)	Wicking Rate (s/4 cm)	Water absorption (mg/cm²)
CF1	100% cotton linter	Light, thin grade suitable for small volume	176	207.3	18.7
CF3		Medium weight	322	174.3	34.6
CF4			482	67.3	49.9
470			840	77	78
Standard 14	Bound glass fiber	Faster flow than cotton, with lower sample retention	355	23.1	50.9
Standard 17			370	34.5	44.9
GF/DVA		Works well with saliva samples and can act as a blood separator as well	785	28.2	93
LF1		Works well with whole blood or serum samples and can act as a blood separator as well	247	35.6	25.3
MF1			367	29.7	39.4
VF2			785	23.8	86.2

Ordering information

Catalog number	Description
8111-2250	CF1 22 mm × 50 m
8113-2250	CF3 22 mm × 50 m
8114-2250	CF4 22 mm × 50 m
8133-2250	STD 14 22 mm × 50 m
8134-2250	STD 17 22 mm × 50 m
8121-1750	LF1 17 mm × 50 m
8122-2250	MF1 22 mm × 50 m
8124-1750	VF2 17 mm × 50 m
10539995	GRADE 470 22 mm × 50 m

DOMINIQUE DUTSCHER SAS

Blood separators for lateral-flow immunoassays

Because of the increasing demand for whole-blood assays, Cytiva offers a family of blood separators to meet the strict requirements of the rapid diagnostic market. Our blood separators for lateral-flow immunoassays enable whole blood analysis, with no red cell hemolysis.

Features and benefits:

- **Separation in 30-120 s:** Rapid assays save time
- **No appreciable red cell hemolysis:** Improved reproducibility
- **Consistency of materials:** Reliability
- **Materials suitable for use in a range of tests:** Flexibility in test optimization
- **Choice of separation times:** Allows for test optimization
- **Separators appropriate for a range of blood volumes:** Enhances the separation rate according to the volume of blood available

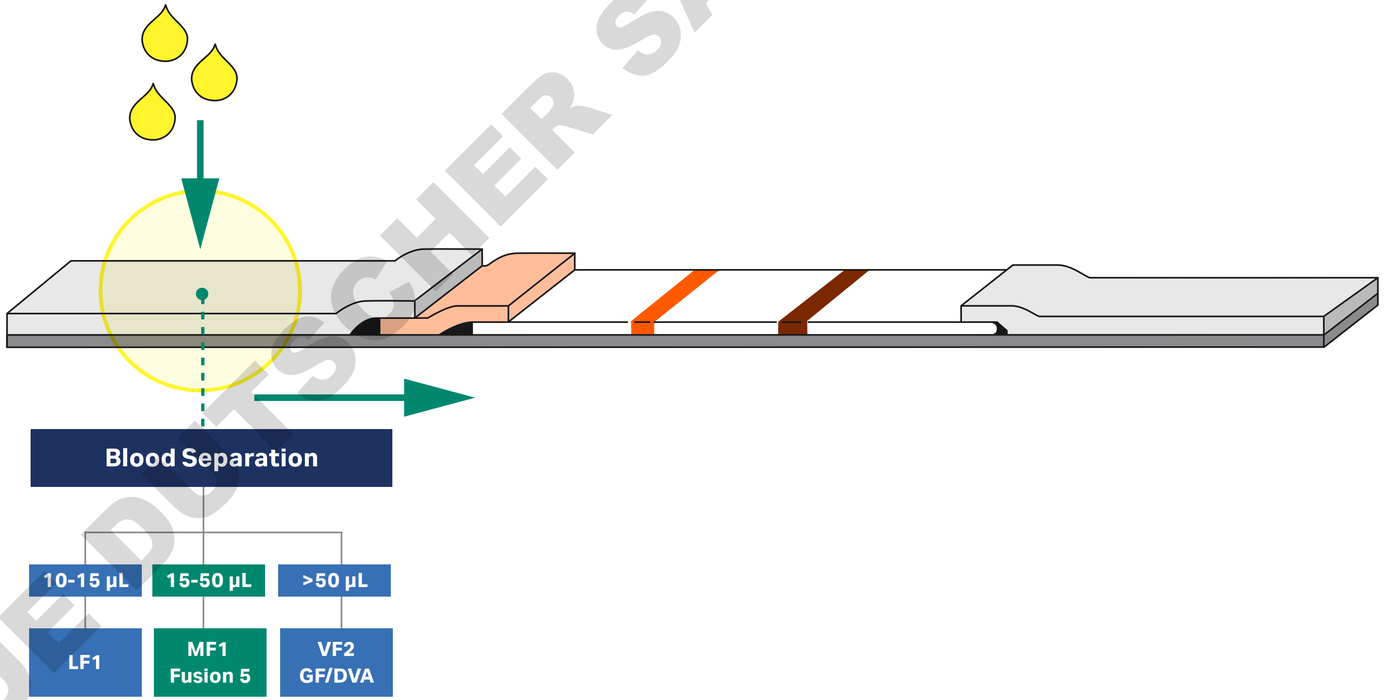


Fig 5. Blood separator selection tree.

DOMINIQUE DUTSCHER SAS

Technical properties

Product	Properties	Thickness (µm @ 53 kPA)	Wicking rate (s/4 cm)	Water absorption (mg/cm²)
GF/DVA	Bound glass fiber	785	28.2	93
LF1	May be used for lateral flow assays. Works well with one drop of whole blood	247	35.6	25.3
MF1	Used for lateral- or vertical-flow assays. Typically used for whole-blood volumes around 100 µL	367	29.7	39.4
VF2	Vertical separator used as single or multiple layers for separation of a wide range of blood volumes	785	23.8	86.2
Fusion 5	Can be used as a lateral flow blood separator with two drops of whole blood	370	43.9	42.3

Ordering information

Catalog number	Description
8121-1750	LF1 17 mm × 50 m
8122-2250	MF1 22 mm × 50 m
8124-1750	VF2 17 mm × 50 m
8151-9915	Fusion 5 22 mm × 50 m
8145-2250	GF/DVA 22 mm × 50 m

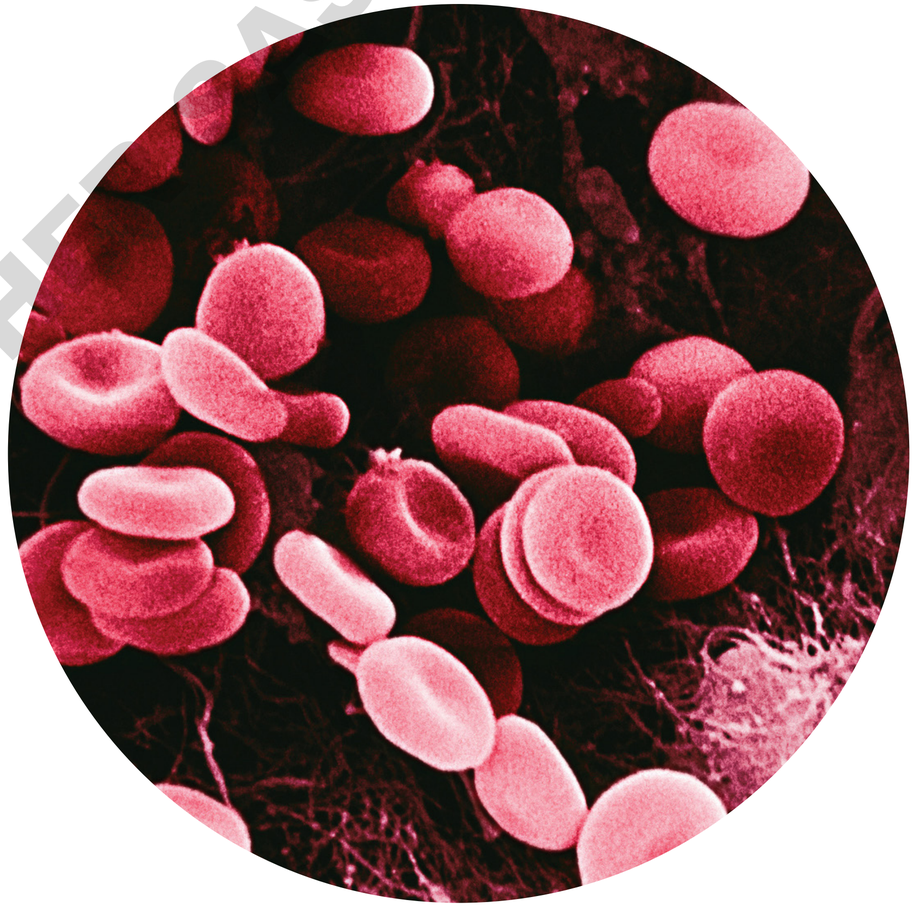


Fig 6. Enlarged view of blood separation.

DOMINIQUE DUTSCHER SAS

Conjugate release for lateral-flow immunoassay

Conjugate release pads are critical to lateral-flow immunoassays. To ensure consistent performance, the conjugate must dry without damage or aggregation and release rapidly when the sample comes into contact with it.

Whatman conjugate release pads do not require treatment prior to conjugate application, as they are inherently hydrophilic. The open structure of the material allows rapid penetration by both conjugate and sample.

Features and benefits:

- **Higher level of conjugate release:** Less waste means reduced reagent costs
- **Higher capture line intensity, as more conjugate gets to the capture line:** Improved sensitivity
- **Pad rewets naturally and rapidly every time:** Improved consistency

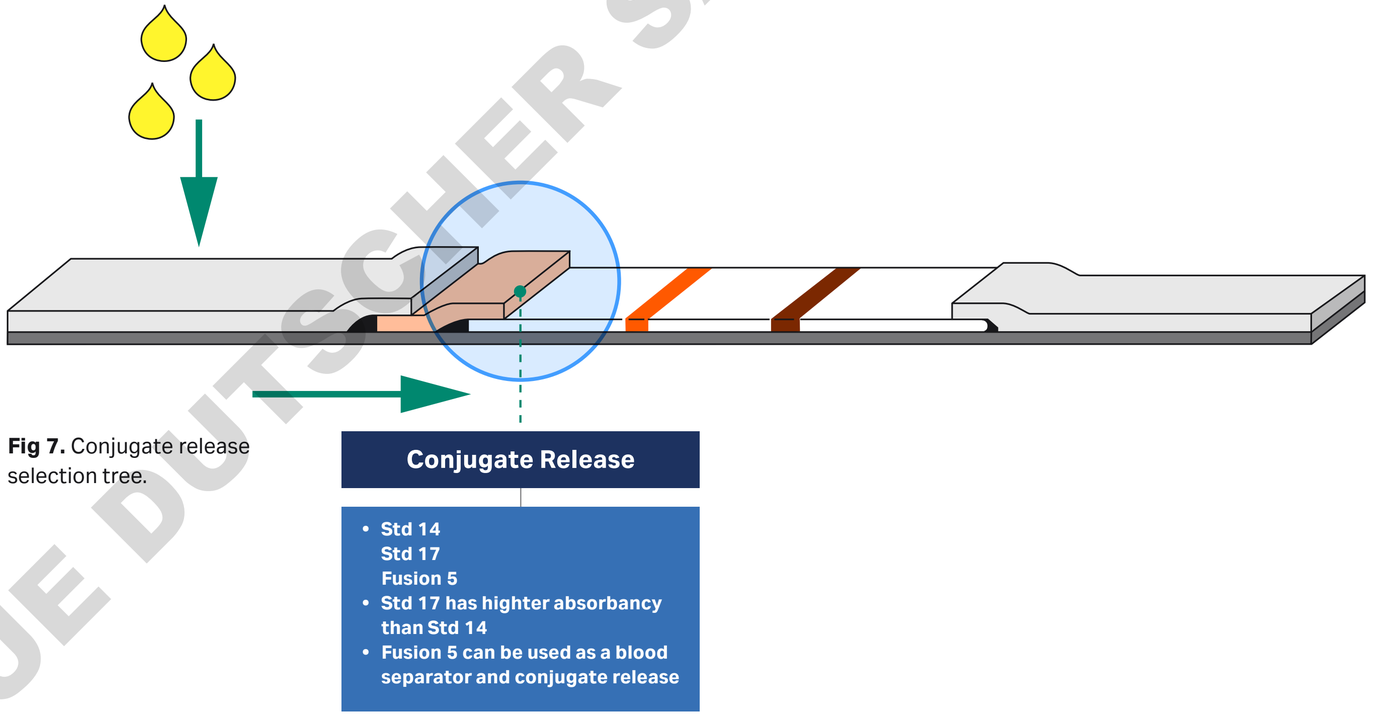


Fig 7. Conjugate release selection tree.

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Technical properties

Grade	Thickness (µm @ 53 kPA)	Wicking rate (s/4 cm)	Water absorption (mg/cm²)	Percent release of gold conjugate (after 90 s)
Standard 14	355	23.1	50.9	75
Standard 17	370	34.5	44.9	75
Fusion 5	370	43.9	42.3	>94

Ordering information

Catalog number	Description
8133-2250	STD 14 22 mm × 50 m
8134-2250	STD 17 22 mm × 50 m
8151-9915	Fusion 5 22 mm × 50 m

Other slit widths are available; please contact your Cytiva representative for more information.



Fig 8. Conjugate release.

DOMINIQUE DUTSCHER SAS

Membranes for lateral-flow immunoassay

Nitrocellulose membranes are a key functional part of lateral-flow immunoassays.

The membrane must provide sufficient protein binding to produce a sharp and intense capture line, but at the same time the level of nonspecific background must be low enough for easy interpretation of the results.

Nitrocellulose membranes are available in a range of wicking rates and formulations. The wicking rate of a membrane has a significant impact on test sensitivity.

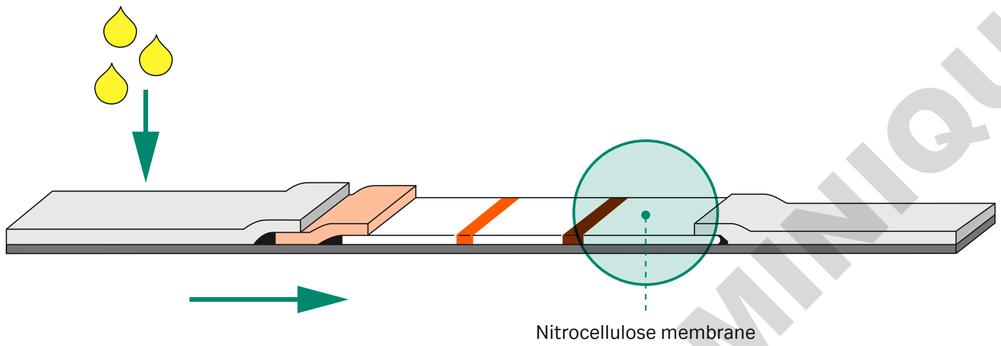




Fig 9. FF120HP membrane.

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Membrane selector according to sample type

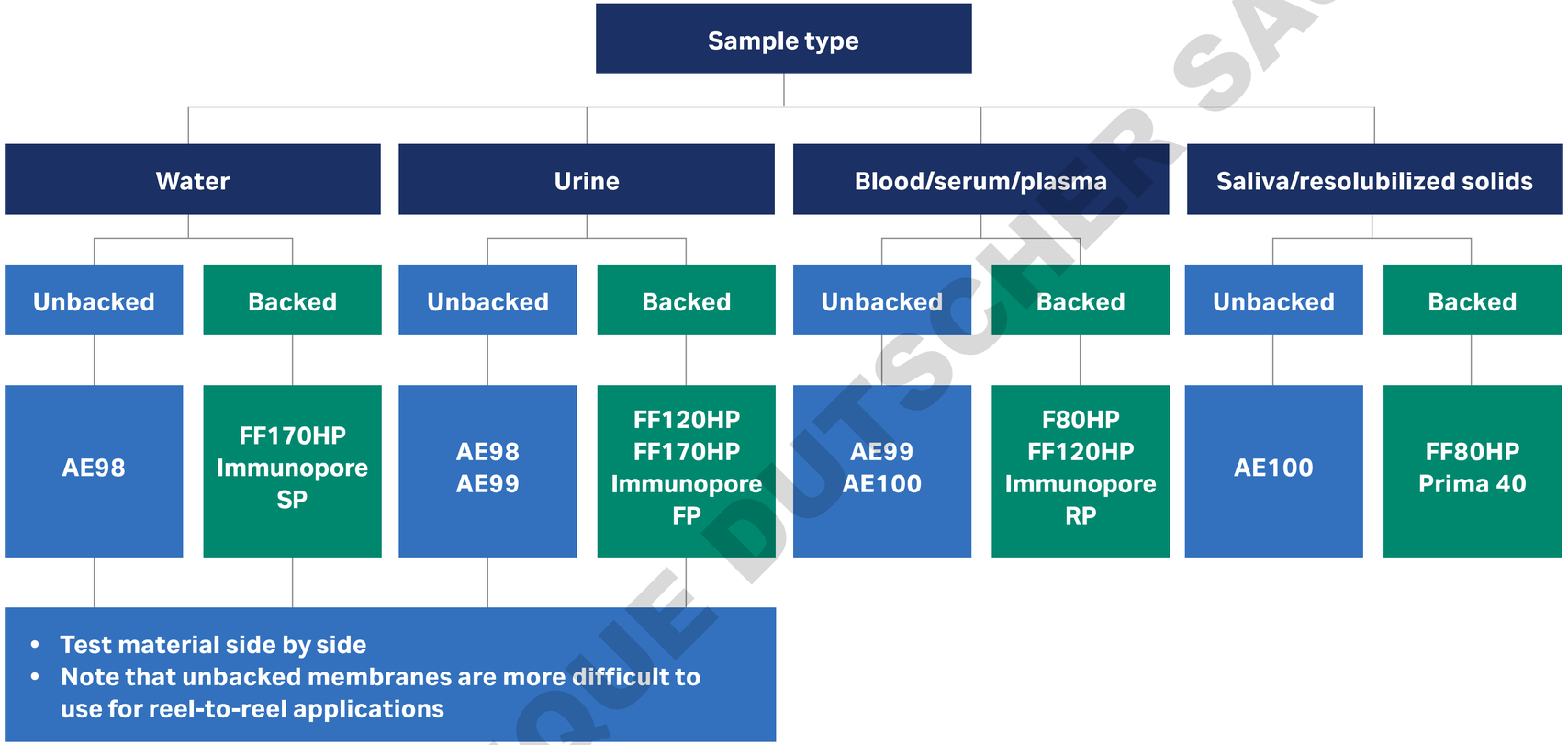


Table 2: Comparison between backed and unbacked membrane features

Backed membrane	Unbacked membrane
• Increased mechanical strength of the membranes, simplifying use in reel-to-reel machines • Direct contact is prevented between the nitrocellulose material and the adhesive from the lamination card where the test elements are mounted	• Enables assay suitability tests of both air and belt side of the membrane

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Unbacked membranes

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AE nitrocellulose membranes

Constructed of 100% nitrocellulose, the AE membrane family offers a higher level of purity and performance than that seen in post-treated materials. AE membranes have been used extensively since the development of the original lateral flow tests and have become a standard for manufacturers worldwide. There is a long history of success and experience for assay optimization using these products.

AE membranes are unbacked, which means either belt or air side of the membrane can be used.

Technical properties

Grade	Capillary rise (s/4 cm)	Total caliper (µm)	Properties
AE98	160–210	120	An unsupported membrane that gives good line intensity for use with low-viscosity samples
AE99	120–160	120	A general-purpose membrane for use with most sample types giving a good combination of sensitivity with fast wicking
AE100	90–120	120	A very fast wicking membrane for use with highly viscous samples, e.g., undiluted serum

Ordering information

Catalog number	Description
10548081	AE99 25 mm × 50 m 1/pk

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Backed membranes

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Immunopore — backed nitrocellulose membranes

Immunopore™ is a plastic-backed nitrocellulose membrane. A proprietary polymer is included in the membrane matrix to ensure rapid rewetting and low background signal, eliminating protein-binding interference commonly experienced with surfactants.

Technical properties

Grade	Capillary rise (s/4 cm)	Total caliper (µm)	Uses
Immunopore RP	90–150	200	Fast-flowing membrane, yielding shorter test times while still retaining excellent capture line intensity and reproducibility
Immunopore FP	140–200	200	Excellent general membrane that offers high capture line intensity coupled with fast flow/wicking rate
Immunopore SP	190–280	200	Highly suitable for use with low-viscosity samples when maximum capture line intensity is required

Ordering information

Catalog number	Description
78356403	Immunopore RP 25 mm × 50 m 1/pk
78336403	Immunopore FP 25 mm × 50 m 1/pk

DOMINIQUE DUTSCHER SAS

FF High Performance — backed nitrocellulose membranes

FF High Performance (HP) membranes are part of the AE family (see page 21) that are directly cast onto a plastic film.

The FF HP membranes are a result of improved membrane casting procedures, which result in enhanced intra- and inter-lot consistency and sharper lines.

The surface is uniform without any unincorporated nitrocellulose powder and the fine structure fiber distribution provides large internal surfaces for binding proteins.

Features and benefits:

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

A carefully designed and rigorous manufacturing process results in membranes with high reproducibility and very low intra- and inter-lot variability.

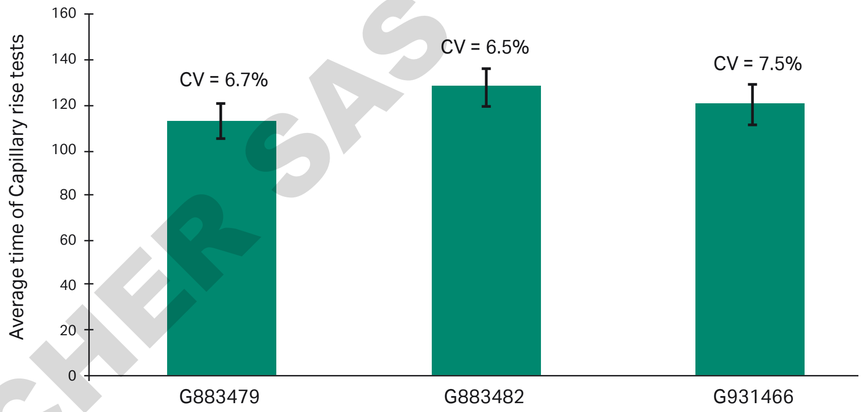


Fig 10. CV and average time of capillary rise tests of three batches. The average time of capillary rise for Lot G883479 was 112.6 ± 7.6 s while that of Lot G883482 was 127.7 ± 8.2 s. In addition, Lot G931466 had an average of 119.7 ± 8.9 s. The CVs for all three batches were 6.7%, 6.5%, and 7.5%, respectively.

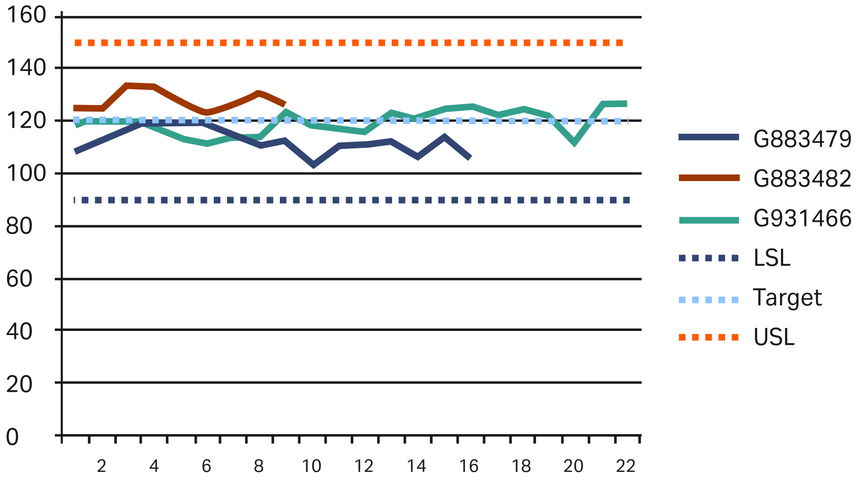


Fig 11. Representation of the capillary rise results shown in figure 10.

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Technical properties

Description	Capillary rise (s/4 cm)	Total caliper (µm)	Properties
FF80HP	60–100	200	A very fast wicking membrane for use with highly viscous samples, e.g., undiluted serum
FF120HP	90–150	200	A general-purpose membrane for use with most sample types
FF170HP	140–200	200	A membrane for use with low viscosity samples

Ordering information

Catalog number	Description
10547003	FF80HP 25 mm × 50 m 1/pk
10547002	FF80HP 20 mm × 50 m 1/pk
10547001	FF120HP 25 mm × 50 m 1/pk
10547006	FF120HP 20 mm × 50 m 1/pk
10547005	FF170HP 25 mm × 50 m 1/pk
10547004	FF170HP 20 mm × 50 m 1/pk

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Absorption pads

Absorption pads at the downstream end of tests control sample flow along the strip. Cytiva has also developed pads with excellent wicking characteristics that give rise to greater consistencies. Choosing an absorbent with sufficient capacity is an important consideration when designing an immunoassay.

Features and benefits:

- **Consistent absorbency:** Ensures test-to-test reproducibility
- **Product manufactured in controlled environments from highest-quality materials:** No false results due to contamination
- **Naturally hydrophilic:** Minimal loss of analyte, so test sensitivity is maintained
- **Wide range of thickness, absorbency and wicking rate:** Rapid rewetting after prolonged storage
- **Minimal Leakage along the strip:** No contamination of test results

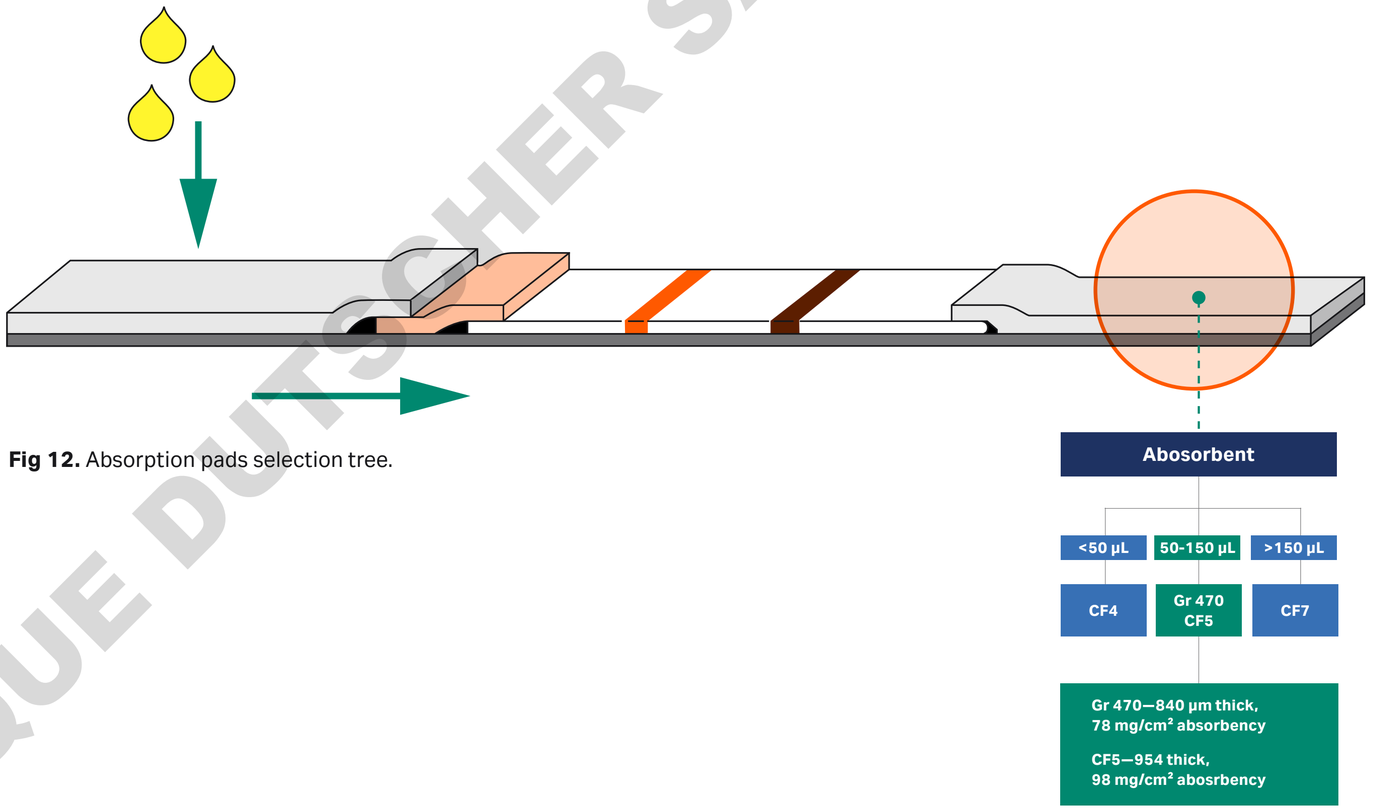


Fig 12. Absorption pads selection tree.

DOMINIQUE DUTSCHER SAS

Technical properties

Product	Material	Properties	Thickness (µm @ 53 kPA)	Wicking Rate (s/4 cm)	Water absorption (mg/cm²)
CF3	100% cotton linter	Medium weight	322	174.3	34.6
CF4			482	67.3	49.9
CF5			954	63.3	99.2
CF7		Thick materials suitable for high sample volume	1873	35	252.3

Ordering information

Catalog number	Description
8113-2250	CF3 22 mm × 50 m
8114-2250	CF4 22 mm × 50 m
8115-2250	CF5 22 mm × 50 m
8117-2250	CF7 22 mm × 50 m

DOMINIQUE DUTSCHER SAS

Flow-through immunoassays

In a flow-through immunoassay the sample is applied directly to the membrane surface and is allowed to wick through the membrane into an absorbent paper below.

Nitrocellulose membranes

Small-pore unsupported membranes such as BA83 and BA85 can be used; they are highly sensitive small-pore membranes with large surface area and high protein-binding capacity. However, they have to be carefully encapsulated, ensuring good contact between the membrane and the absorbent, to give good flow.

Features and benefits:

- **Manufactured for vertical-flow assays:** Eliminates problems caused by capillary rise
- **Small pore structure:** Accurate results; low nonspecific binding; greater sensitivity
- **One hundred percent pure nitrocellulose:** Provides high binding capacity

Absorbents

The absorbents used for flow-through assays must wick fast and be highly water absorbent. The volumes of liquids used in flow-through assays can be much higher than those in lateral flow. Thicker cellulose materials with fast wicking are therefore the material of choice.

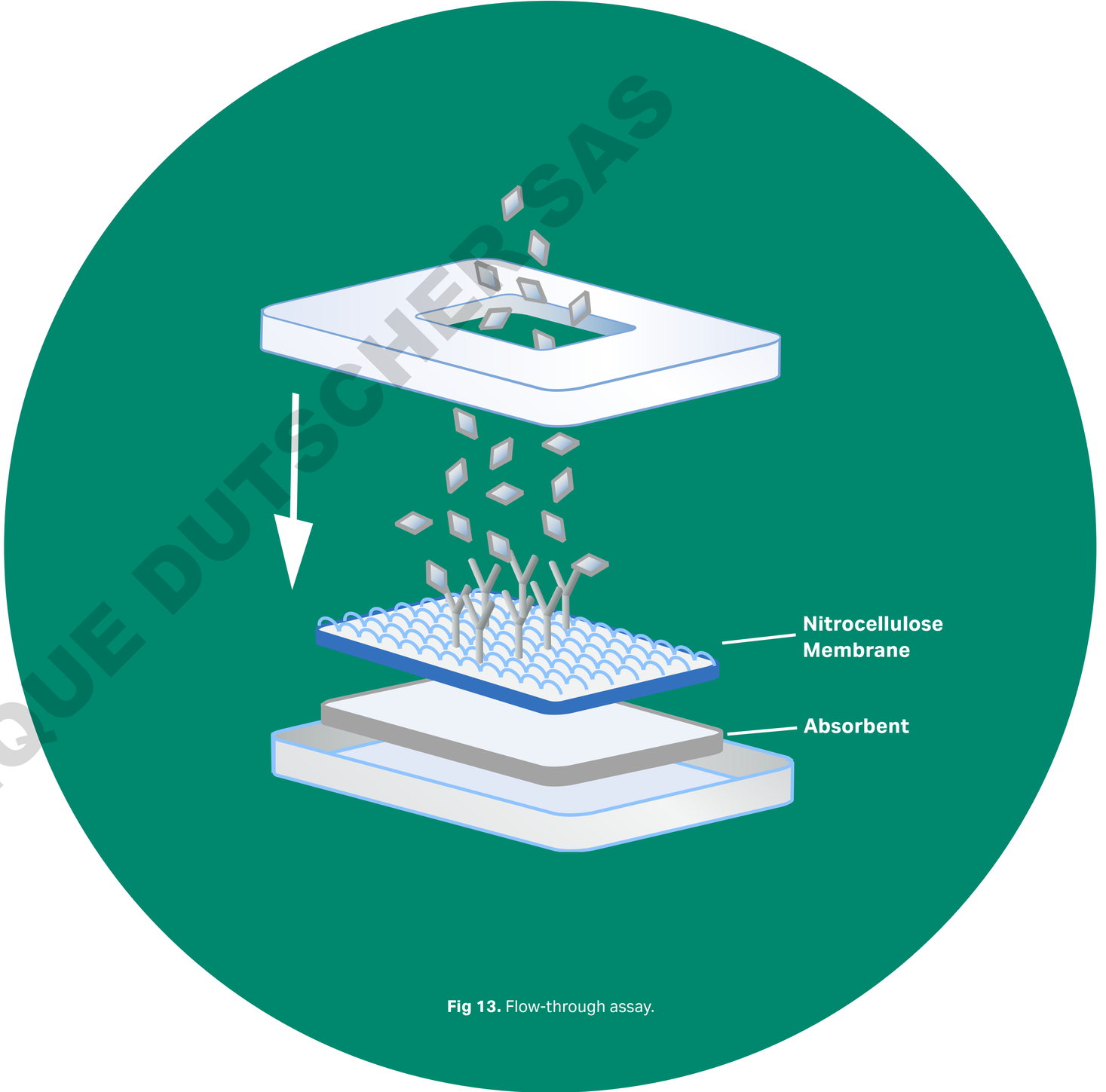
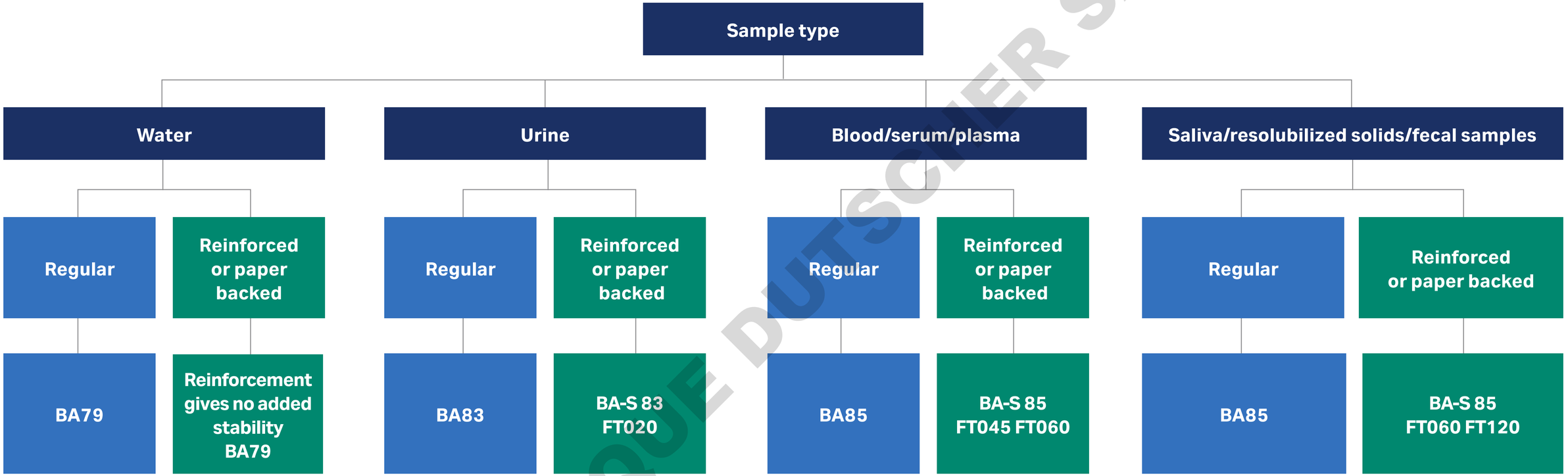


Fig 13. Flow-through assay.

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Membrane selector according to sample type



DOMINIQUE DUTSCHER SAS

Technical properties

Membranes

Grade	Pore size (µm)	Thickness (µm @ 53 kPA)
BA 79	0.10	120
BA 83	0.20	120
BA 85	0.45	120

Absorbents

Product	Thickness (µm @ 53 kPA)	Wicking Rate (s/4 cm)	Water absorption (mg/cm²)
CF4	482	67.3	49.9
CF5	954	63.3	99.2
CF6	1450	65	136.3
CF7	1873	35	252.3

Ordering information

BA Nitrocellusose membranes

Catalog Number	Description
please enquire	BA79
10401380	BA83, 300 mm × 600 mm
10401180	BA85, 300 mm × 600 mm

Absorbents

Catalog Number	Description
8114-2250	CF4 22 mm × 50 m
8115-2250	CF5 22 mm × 50 m
8116-2250	CF6 22 mm × 50 m
8117-2250	CF7 22 mm × 50 m

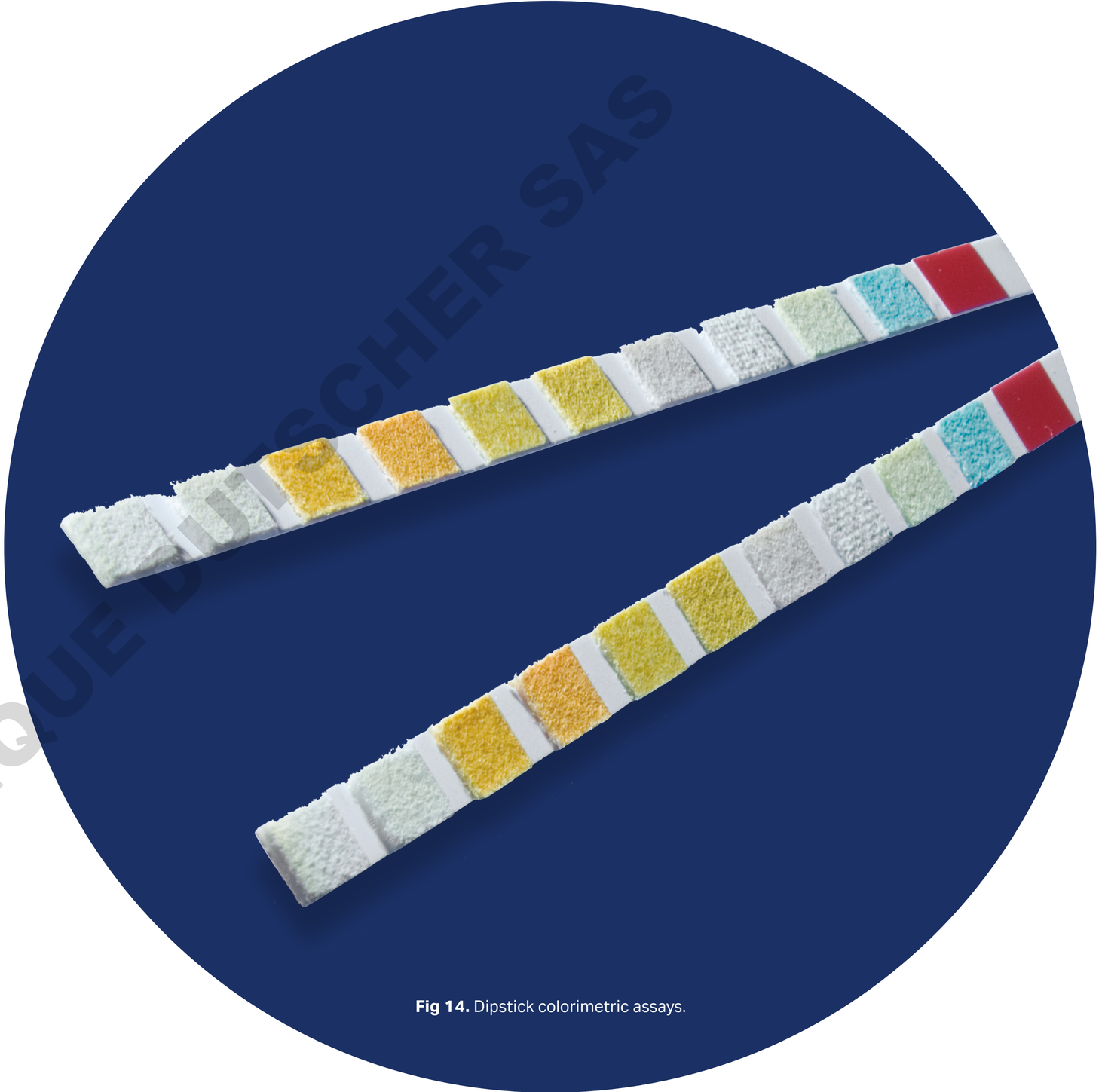
Other slit widths are available, please contact your Cytiva representative for more information.

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Dipstick colorimetric assays

Dipstick colorimetric assays, in which a cellulose pad is impregnated with a color reagent, are widely used in everything from urine testing to environmental assays. The base cellulose is a key part of the system, and the correct choice of absorbency, wicking rate, and wet strength are critical to producing a working assay. The Cytiva range of cellulose materials for dipstick colorimetric assays offers highly consistent and inert substrates for absorption of the active chemicals required for development of dipstick tests.

The purity of the cellulose base material coupled with Cytiva quality manufacturing practices make these papers an exceptional choice for large-scale manufacturing. The Cytiva range of Whatman papers also includes a wet strengthened grade.



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Fig 14. Dipstick colorimetric assays.

Technical properties

Grade	Thickness (µm @ 53 kPA)	Water absorption (mg/cm²)
CF1	176	18.7
CF2	172	16.1
CF3	322	34.6
CF4	782	49.9
CF7	1873	252.3

Ordering information

Catalog number	Description
8111-2250	CF1 22 mm × 50 m
8112-2250	CF2 22 mm × 50 m
8113-2250	CF3 22 mm × 50 m
8114-2250	CF4 22 mm × 50 m
8117-2250	CF7 22 mm × 50 m

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Molecular diagnostics

Molecular diagnostic tests using nucleic acid-based assays have become an essential component in the evaluation and early detection of many diseases. Applications in the areas of infectious diseases, oncology, inherited disorders, and prediction of genetic disease risk are rapidly becoming commonplace and are increasingly applied in the field of personalized medicine.

Cytiva's portfolio supports molecular diagnostic assay developers and manufacturers with their specific needs and includes:

- Sample collection formats
- Reagent and assay stabilization technologies
- Fluorescence technology, including labeling reagents and pre-labeled products
- Molecular biology products aligned with our tailor-made customization and manufacturing services

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Molecular diagnostic workflow

Reduce cost, gain greater geographical access, and simplify your workflow from sample collection to result by using our stabilization products and services.



Product Design

p. 35



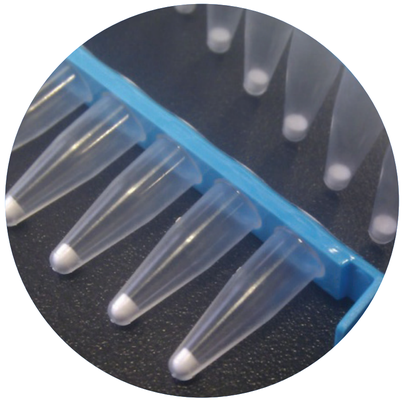
Biosample collection with ambient-temperature transport and storage

p. 36, p. 45



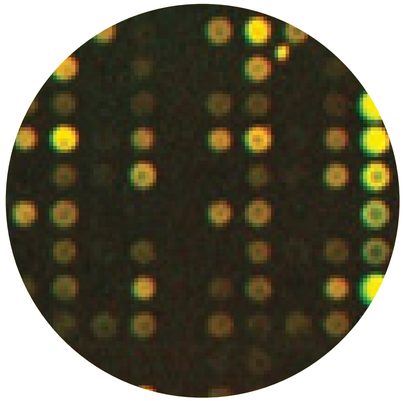
Sample purification or isolation

p. 37



Assay components and room-temperature stabilization

p. 38



Sample clean-up and detection

p. 44

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Product design

Cytiva has extensive capabilities for design optimization and development of custom components. If you start working with our custom design team while you're still in the conceptual stage, we can help you design towards optimal manufacturing.

We can help design and prototype your vials, tubes, and other cartridge and holder devices for stabilized reagents.

Table 3. Examples of Cytiva capabilities in design optimization and development of custom components

Conception	Certification	Specific manufacturing	Rigor
3D CAD	**ISO Certifications:** • ISO 9001 • ISO 13485	**Ultrasonic and UV welding** **Thermal bonding** **Custom labeling** **Hot stamping and pad printing** **Scale-up capabilities** **Kit manufacturing**	**Supply chain rationalization** • Source and validate raw materials • Shelf-life management **Logistics efficiency** • Streamlined transportation and storage • Security of supply

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Biosample collection with ambient-temperature transport and storage

Cytiva offers several standard and custom options for biosample collection, stabilization, and ambient-temperature transport for a number of sample types including blood, saliva, and urine.

Customized, ready-to-use sample collection kits

We configure and manufacture customized ready-to-use collection kits to your specification, for sample collection prior to diagnostic assays.

- Refer to page 49 for detailed information on Cytiva capabilities

Cytiva matrices for sample collection

FTA and FTA Elute matrices enable you to collect, archive, transport, and purify DNA, all at ambient temperature, simplifying your workflow.

- Refer to page 48 for detailed information on FTA and FTA Elute cards

Features and benefits:

- Collect
- Store
- Transport
- Purify
- All at ambient temperature

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Fig 15. Example of Indicating FTA Elute card.

Sample purification or isolation

Cytiva offers customized services and products for sample purification and isolation, simplifying your workflow.

Our solutions include:

- FTA technologies for sample collection and DNA purification (see page 47)
- Ion exchange chromatography
- Size exclusion chromatography
- Affinity chromatography matrices
- Magnetic bead-based products
- Standard kits for extraction and purification

Contact your Cytiva representative to get more information on what we offer.



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Assay components and room-temperature stabilization

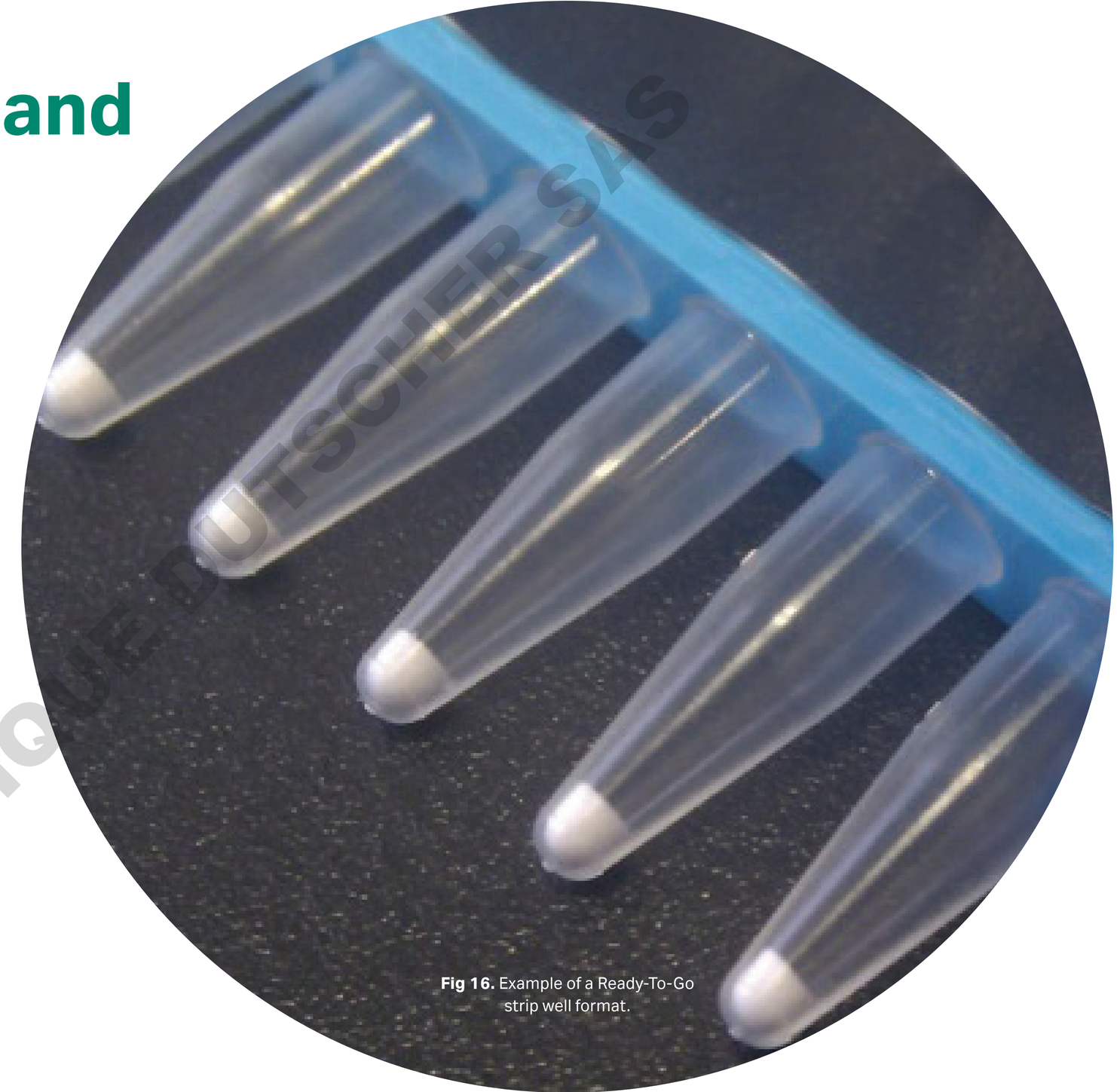
Ready-To-Go technology for custom reagent and assay stabilization

Cytiva's patented Ready-To-Go™ stabilization technology allows ambient-temperature shipping and storage of your individual reagents or complete multiplex assays in a convenient cake format.

Custom Ready-To-Go formulations can be prepared based on your existing assay composition.

Our in-house optimization expertise will assist the transfer to a stabilized format. Building on our existing portfolio of catalog Ready-To-Go products for research, we offer a full custom stabilization service.

With a dedicated custom team, including technical support, project management, and supply chain management, and ten years of development and manufacturing experience, we are well positioned to serve your molecular diagnostics application needs.



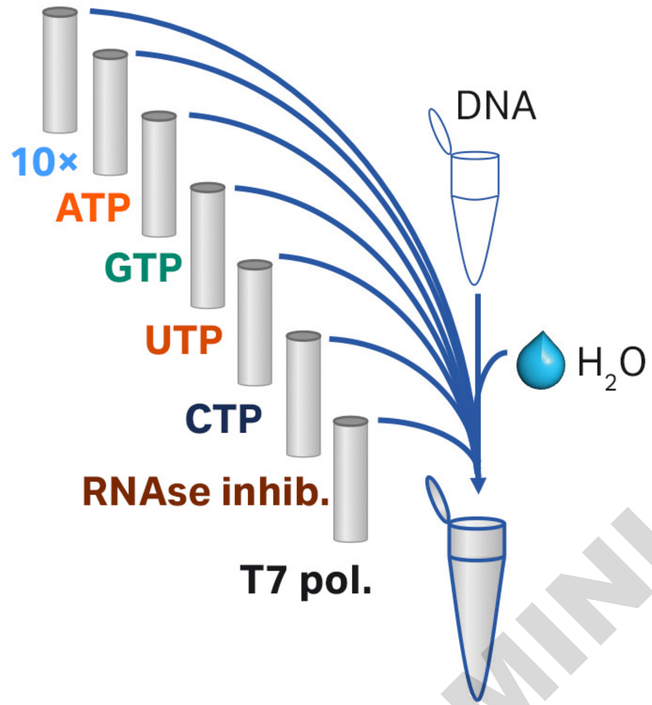
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Fig 16. Example of a Ready-To-Go strip well format.

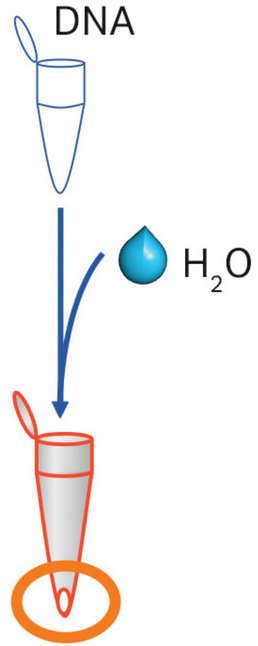
Comparison between Ready-To-Go and conventional approaches

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Conventional approach



Ready-To-Go approach



Ready-To-Go stabilized assay

Fig 17. Moving from a multiple step conventional approach to a simplified two-step custom Ready-To-Go solution.

Benefits of Ready-To-Go technology

	Benefits for diagnostic kit manufacturers	Benefits for diagnostic kit users
Stabilization of assay mixtures	• Two-year stability at ambient temperature • Suitable for complex mixtures including sensitive enzymes and master mix components • Customizable formulation	• Two-year stability at ambient temperature
Simplification — Pre-dispensed, single-dose reagents	• Supports reduced training requirements • Compatible with downstream applications and automation	• Supports reduced training requirements • Compatible with downstream applications and automation • Fewer pipetting steps reduces cross-contamination risk and improves data reliability and overall quality of the assay
Shipping — Does not require dry or wet ice	• Simplifies shipping across countries and protects from unforeseen delays • Enables access to remote regions • Provides significant cost savings • Eco friendly	
Storage — No need for refrigerator or freezer storage	• Simplified inventory management • Reduces storage space and costs • Reduced energy consumption • Opens up new markets and target groups for your assays	• Simplified inventory management • Reduces storage space and costs • Reduced energy consumption • Supports applications for in-field or near-patient use



Fig 18. Example of a Ready-To-Go 96-well format.

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Build your own Ready-To-Go diagnostic assay with your components or choose from a range of Cytiva components

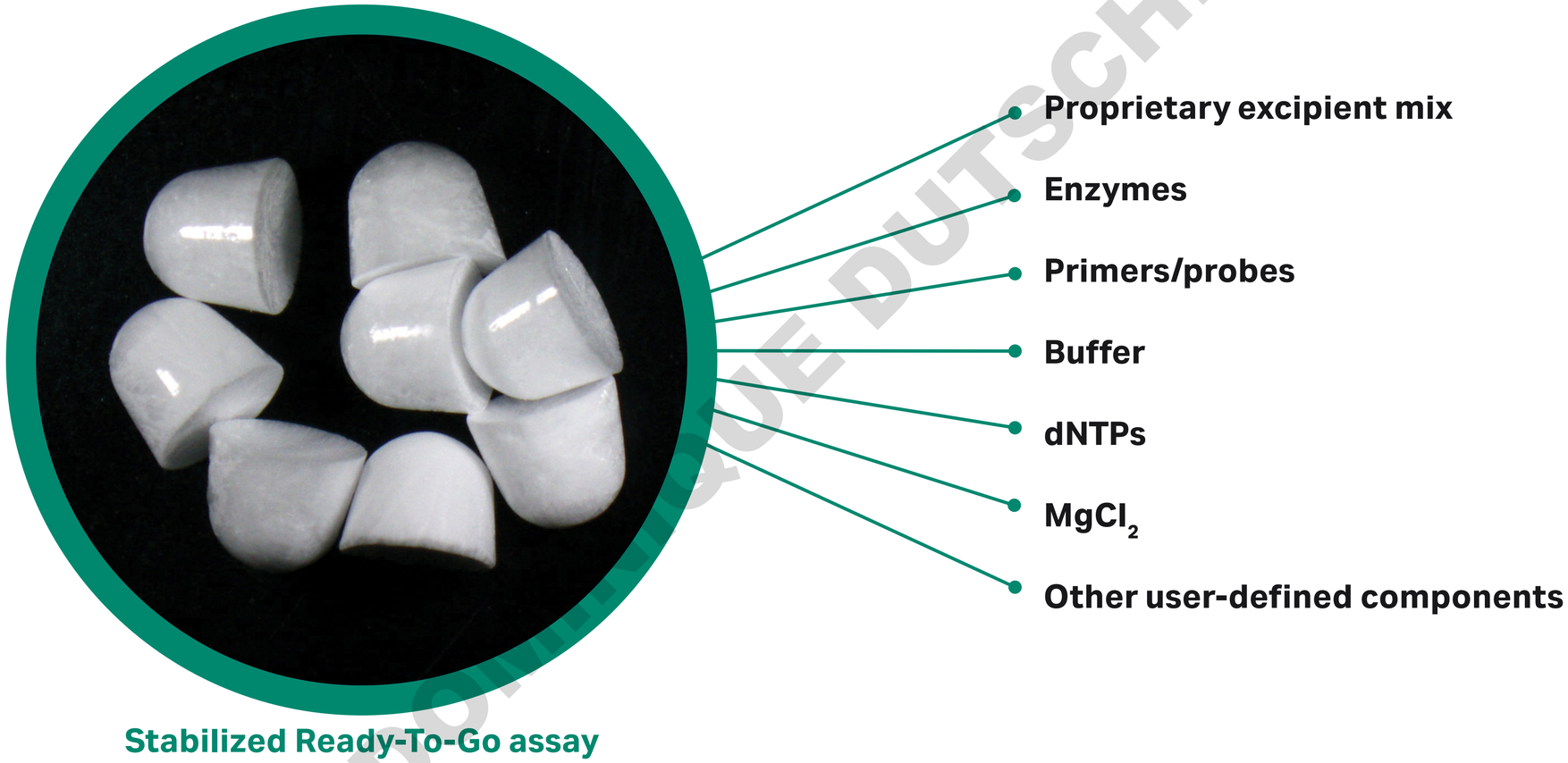


Fig 19. Example of basic components of a customized stabilized assay.

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Proven capabilities of custom Ready-To-Go technology

A variety of customized assays have been stabilized with Ready-To-Go technology, in areas such as:

- diagnostics
- food testing
- environment
- biothreat assays

Examples of Cytiva assay components

Amersham PCR Grade Nucleotides

Available for enzymatically sensitive applications including nucleic acid amplification, sequencing, and expression profiling.

- Free from DNase and RNase
- Greater than 99% triphosphate purity
- Buffer-free and ready-to-use solutions in multiple formats
- Functionally tested for long PCR (20 KB)

PuReTaq DNA polymerase

A proprietary formulation of recombinant Taq DNA polymerase, with exceptionally high purity.

Thermo Sequenase™

A thermostable DNA polymerase that uses dideoxynucleotide triphosphates (ddNTPs) as readily as deoxynucleotide (dNTP) substrates.

- Exonuclease-free
- Generates bands of uniform intensity
- Combines thermostability and accuracy

Shrimp alkaline phosphatase

Removes excess dNTPs remaining from a PCR mixture that would interfere with the labeling step of the sequencing process.

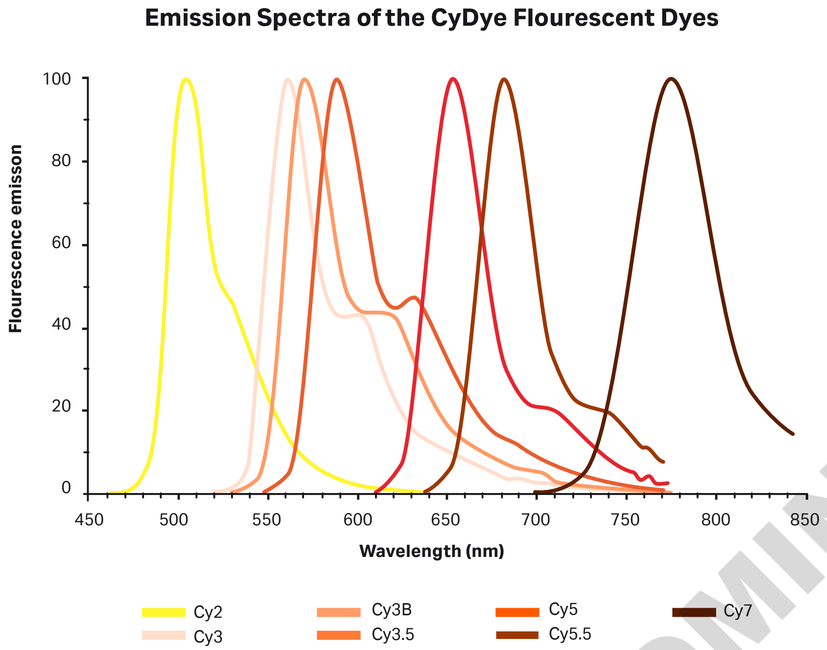
For a closer look at our range of custom enzymes and PCR buffer reagents, please contact your Cytiva representative.

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Cytiva components for isothermal amplification

Cytiva's isothermal amplification technology is based on the recombinant DNA polymerase from the phage Phi29, in combination with modified random hexamer primers.

- High processivity and excellent strand displacement activity
- Strong proofreading activity of Phi29 DNA polymerase leading to extremely accurate DNA replication
- Excellent fidelity
- GenomiPhi™ for isothermal whole genome amplification and TempliPhi™ for isothermal rolling circle DNA amplification



CyDyes for fluorescence labeling and detection

A comprehensive portfolio of bright and stable dyes offering a choice of labeling for most RNA/DNA/Proteins:

- Reactive Cy™3 and Cy5 NHS esters for post-labeling applications including microarrays and protein/antibody labeling
- Cy-labeled nucleotides for enzymatic incorporation in arrays such as array CGH
- Cy Amidites for incorporation of Cy3, Cy3.5, Cy5, or Cy5.5 fluorescent dyes during oligonucleotide synthesis



Fig 20. CyDye™ reagents.

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Sample clean-up and detection

Customizable Cytiva components for sample clean-up

ExoProStar

Containing Alkaline Phosphatase and Exonuclease I, ExoProStar™ is designed to purify PCR and sequencing set up reactions. ExoProStar removes unincorporated primers and nucleotides from amplification reactions in preparation for sequencing, cloning, genotyping, or further DNA modification reactions.

- Fast 30 minute protocol
- No loss of PCR product

AutoScreen

AutoScreen-96 well plate consists of a 96-well filter plate containing DNA Grade Sephadex™ G-50 for purification of sequencing reactions and other size exclusion applications.

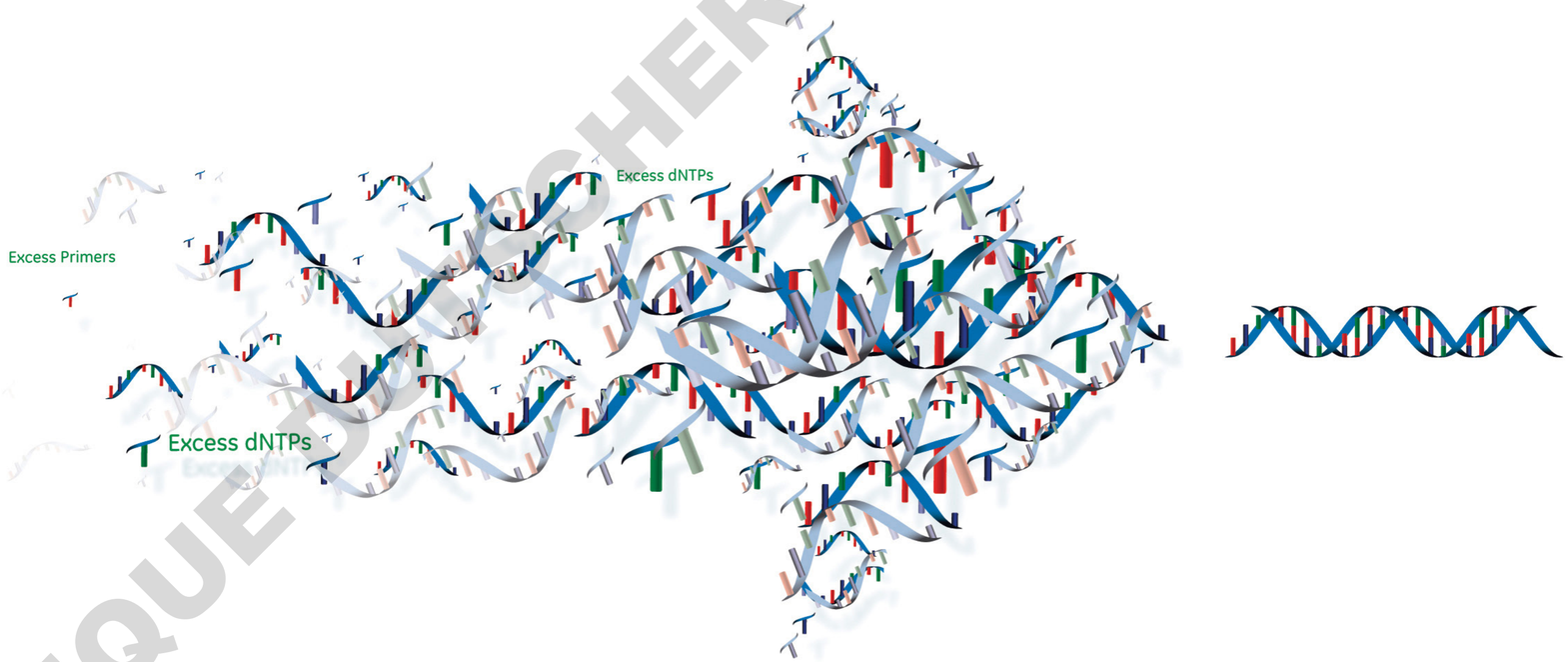


Fig 21. ExoProStar is formulated to remove unincorporatedprimers and nucleotides from amplification reactions.

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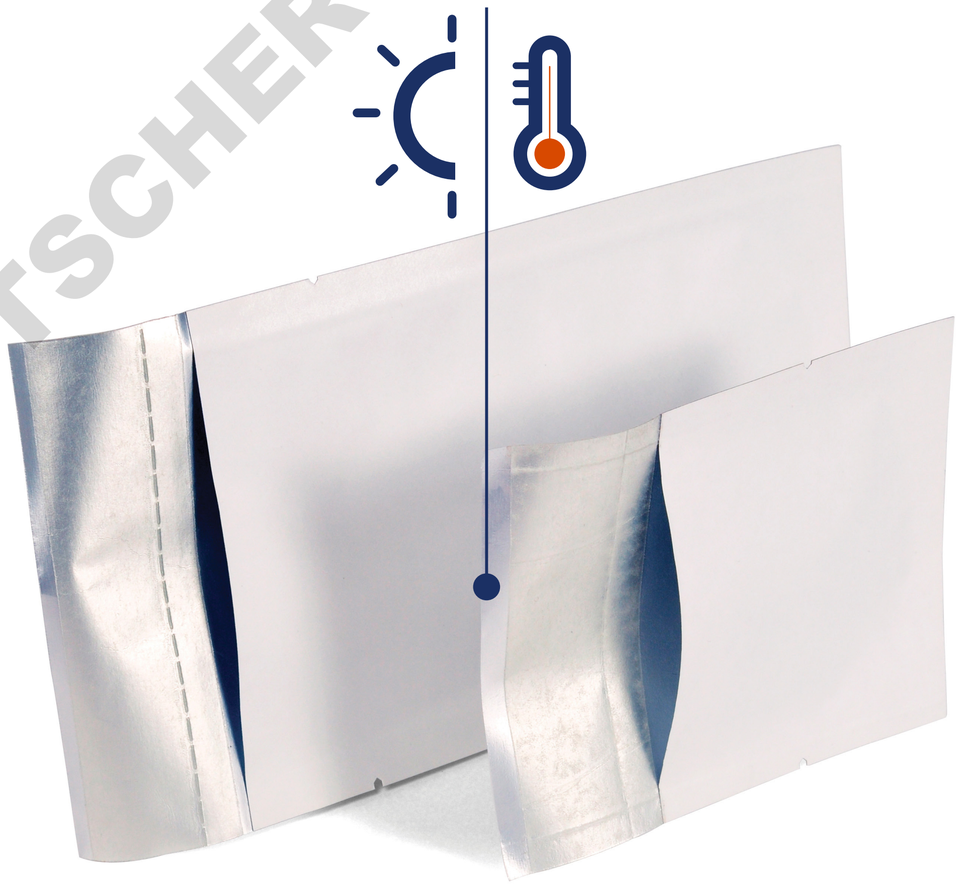
Biosample collection with ambient-temperature transport and storage

As diagnostic applications continue to drive personalized medicine, standardized biosample collection techniques are becoming increasingly important for the ambient-temperature collection, transport, and storage of a range of biomolecules.

Cytiva addresses this need with our Whatman FTA technology as highlighted in the table on the following page.

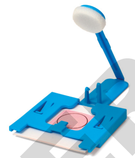
Further, our award-winning design and manufacturing facilities provide the capability to customize biosample collection cards and kits to your specific diagnostic requirements. Contact your Cytiva representative to design your **customized biosample collection kit**.

More information on page 49.



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Table 4. Selection guide for biosample collection, stabilization, transport, and storage matrices:

	FTA	FTA Elute	EasiCollect*	OmniSwab*
Product image				
Biomolecules	DNA	DNA	DNA	DNA
Stabilizes DNA from degradation	Yes	Yes	Yes	No
Long-term DNA storage at ambient temperature	Yes	Yes	Yes	No
DNA purification?	Yes	Yes	Yes	No
Once purified, DNA is	Bound to the matrix	Eluted into the solution	Bound to the matrix	NA
Applications or techniques	• PCR • WGA • Sequencing • STR analysis • Plasmid amplification • RFLP analysis	• PCR • Q PCR • Sequencing • STR analysis	• PCR • WGA • Sequencing • STR analysis • Plasmid amplification • RFLP analysis	• PCR-based assays
Sample type	• Blood • Buccal • Stool • Plant • Bacterial • Culture cells • Urine • Saliva	• Blood • Buccal • Stool • Plant • Bacterial • Culture cells • Urine • Saliva	• Buccal cells	• Buccal cells

* Please contact your Cytiva representative for more information on OmniSwab and EasiCollect.

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Whatman FTA card technology

Collect, transport, purify and store DNA — all at ambient temperature.

Whatman FTA cards are chemically coated matrices that have been shown to preserve DNA more efficiently than untreated matrices, protecting DNA for long term ambient-temperature storage.

As captured DNA is preserved at ambient temperature, FTA cards facilitate sample collection and simplify sample transport from non-clinical or remote locations. Consequently, biosamples can be collected in the field without the need for immediate refrigeration and shipped back to the laboratory without expensive special handling or dry ice and processed at your convenience.

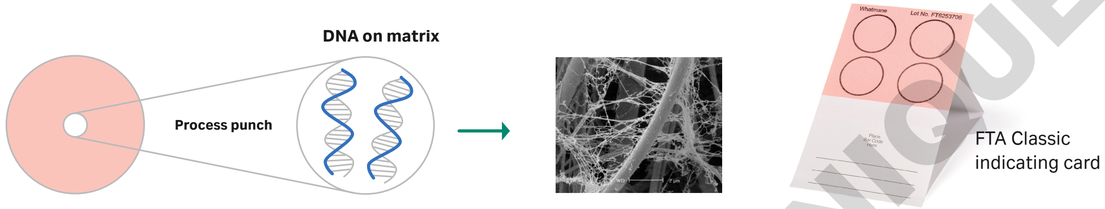
Whatman FTA technology consists of two distinct chemistries, FTA and FTA Elute, both simplifying your biosample collection and downstream workflow.

- Lyse cells on sample application
- Denature proteins
- Protect DNA for long term ambient storage

DNA has been successfully analyzed from 22 year-old blood and 12 year-old buccal samples with FTA.

FTA

With FTA, the DNA remains tightly bound while proteins and inhibitors are washed from the matrix.



Both FTA and FTA Elute cards are available as indicating cards for use with clear samples, such as buccal cells or saliva. They include a pink (FTA) or purple (FTA Elute) indicating dye that turns to white when a clear sample is applied.

FTA Elute

With FTA Elute, proteins remain tightly bound while DNA is eluted from the matrix.

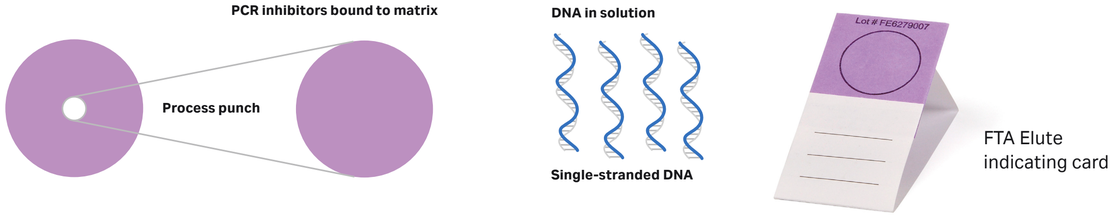


Fig 22. FTA and FTA Elute card technologies.

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FTA

Use for applications in which the DNA needs to be associated with the punch.

With FTA, the DNA remains tightly bound to the matrix while cell membranes and organelles are lysed and proteins and inhibitors are washed away (see figure 22).

The immobilized DNA is preserved for ambient temperature transport, immediate processing, and long-term storage.

Features and benefits:

- Collect sample and capture DNA in one easy step
- Purify DNA in less than 30 minutes for downstream applications such as PCR, SNP analysis, and RT-PCR
- Ambient temperature collection, transport, and storage eliminates high costs associated with shipping biosamples on ice and laboratory freezer storage requirements
- Suitable for a wide range of sample types, including blood, cultured cells, buccal cells, solid tissue, bacterial samples, and virus

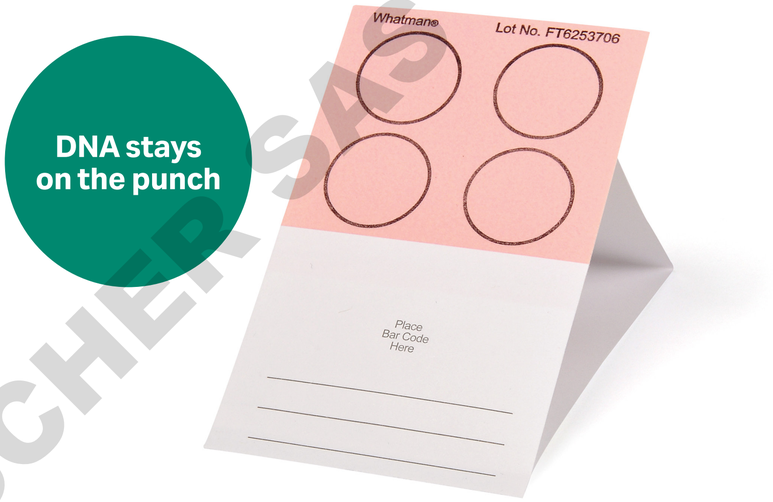


Fig 23. Example of Indicating FTA card.

FTA Elute

Use for applications in which the DNA is required in solution

With FTA Elute, cells are lysed upon contact and proteins remain tightly bound while DNA is eluted from the matrix in one step, providing you with pure DNA in a solution free of inhibitors (see Figure 22).

Features and benefits:

- Ambient temperature collection, transport, and storage eliminates high costs associated with shipping biosamples on ice and laboratory freezer storage requirements
- A simple protocol eliminates the need for a DNA purification kit and reduces the time to purify DNA to 15–30 minutes (compared to 4–16 hrs)
- Purified DNA is compatible with downstream sequencing applications including Q-PCR
- Small sample volume requirements (12–125 µL) eliminate the need for venous blood samples



Fig 24. Example of Indicating FTA Elute card.

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Cytiva customizable sample collection kits

We configure and manufacture customized ready-to-use collection kits for sample collection prior to diagnostic assays.

Cytiva offers customized collection cards for use in large sampling studies. Regardless of where a sample is collected, information about the sample must be recorded and cataloged for each sample.

Custom collection cards

- Barcode and sequential numbering for tracking
- Comprehensive portfolio of kit components
- FTA sample collection devices packed in clean-room to minimize contamination

Custom design and printing of collection cards

- Color coding
- Sample covers
- OCR compatibility

Sequential numbering

- For tracking, identification, and storage

Barcode sample tracking

- Cards with barcoding
- Removable adhesive barcodes
- Barcode strips

Transfer/mailing envelopes

- For mailing of samples to a central laboratory
- Breathable or moisture resistant (dried)

Translation services

- IFU in appropriate language

For a wide range of accessories such as punchers, transport pouches, purification reagents, or dry racks, please contact your Cytiva representative.



Fig 27. Custom FTA cards.



Fig 28. Example of a custom buccal kit (with EasiCollect device).

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Ordering information

These items are for research use only

FTA Cards

Catalog number	Product name	Number of sample areas per card	Maximum volume/sample area	Maximum total volume per card	Pack size
WB120462	EasiCollect	1	N/A	N/A	50/pk
WB120310	FTA Micro Card	1	125 µL	125 µL	25/pk
WB120355	FTA Mini Card	2	125 µL	250 µL	25/pk
WB120305	FTA Classic Card	4	125 µL	500 µL	25/pk

Indicating FTA Cards

Catalog number	Product name	Number of sample areas per card	Maximum volume/sample area	Maximum total volume per card	Pack size
WB120311	Indicating FTA Micro Card	1	125 µL	125 µL	25/pk
WB120356	Indicating FTA Mini Card	2	125 µL	250 µL	25/pk
WB120306	Indicating FTA Classic Card	4	125 µL	500 µL	25/pk

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Ordering information

FTA Elute Cards

Catalog number	Product name	Number of sample areas per card	Maximum volume/sample area	Maximum total volume per card	Pack size
WB120401	FTA Elute Micro Card	4	12–40 µL	160 µL	25/pk
WB120412	Indicating FTA Elute Micro Card	1	125 µL	125 µL	25/pk

Accessories

Catalog number	Description	Pack size
10537173	Dry rak (without Velcro™)	10/pk
10539521	Dry rak (with Velcro)	10/pk
10495010	Hand punch 3.1 mm	1/pk
10534150	Biohazard labels 7/8" × 7/8"	1000/pk
10534321	Foil-barrier ziploc bags (for cards 95 × 130 mm max)	100/pk
10548232	Plastic ziploc storage bags, 4" × 6"	100/pk
10548234	Desiccant pack	100/pk
10548236	Glassine envelopes, 3 1/4" × 4 7/8"	100/pk

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Track-etched membranes for diagnostic applications

Cytiva provides a range of Whatman track-etched membranes (TEMs) whose advanced technical specifications make them an outstanding choice for a wide range of diagnostic applications.

TEMs have very tightly controlled pore size distribution. This allows for quantification of cells or micro-organisms, which are captured on the membrane surface. TEMs are usually transparent at larger pore sizes, which allows complete transmission of light, ensuring excellent signal-to-noise ratio.

Features	Benefits
Biologically inert	Whole cell assays can be performed
Low protein binding and low extractables	There is no interference with assay results because of membrane
Choice of surface properties (hydrophilic and hydrophobic version available)	Assays can be designed with the appropriate flow or retention characteristics
Does not bind stains or labels	Gives lower background signal than traditional materials
True surface capture on a flat, smooth surface	Cells or particles are highly visible or available for sample recovery by backflushing
Low hold-up volume	Practically all the applied sample is available for analysis
Controllable optical properties (transparent, translucent, and/or dyed)	The optical properties can be chosen to ensure excellent signal-to-noise ratio. Clear materials allow complete transmission of light, whereas dyed varieties block signal from behind the membrane
PC or PET material	Allows easy attachment to a range of housings for design of components

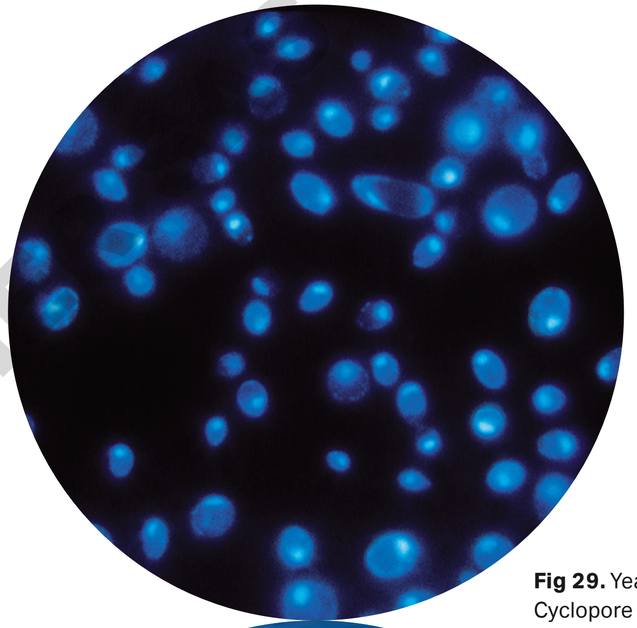


Fig 29. Yeast cells on Black Cyclopore with DAPI Stain.

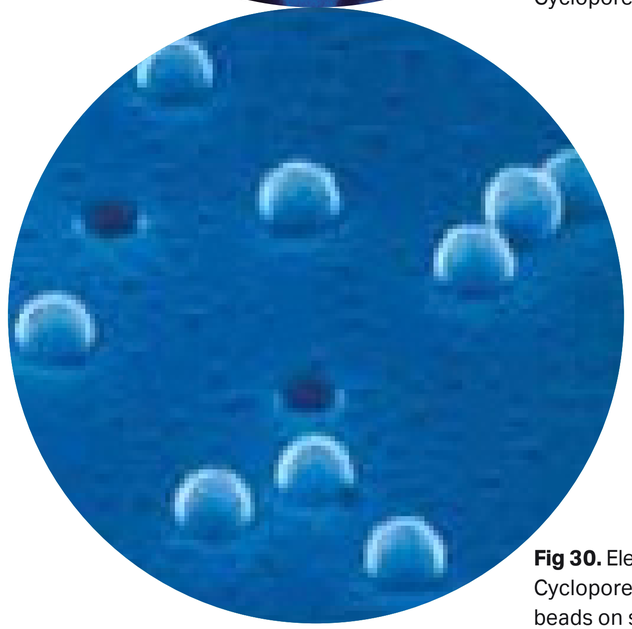


Fig 30. Electron micrograph of Cyclopore membrane with latex beads on surface.

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Application examples

Cell capture

Since TEMs have tightly controlled filtration characteristics, they can be used in cell capture applications. This application allows for easier identification of marked cells in a number of formats. The retention of cells upon the membrane surface allows cells to be stained and observed in a very clear environment. The improved resolution and accuracy have applications in any area of clinical chemistry in which cells are observed. The reduced likelihood of a false diagnosis also has a significant impact, especially in large-scale screening procedures.

Particle-capture assays

Using membranes for particle-capture tests is a relatively well-known technique. The usefulness of these assays can be enhanced by using dyed or fluorescent latex particles as a label. Such labels can produce a more sensitive or stable assay. Using a TEM for particle capture allows for a more specific capture reaction, and capturing the particles on the membrane surface rather than in the depth of the membrane matrix enhances sensitivity.

Biosensors

TEMs provide accurate flow control of diffusion properties in biosensor applications in which the membrane acts as a barrier to biological cells and controls their flow to the sensor. The membrane also serves as a barrier to many potential contaminants, improving the assay's specificity. In applications involving the presence of biochemical reagents to measure the reaction, the pores can be filled with the desired materials (e.g., antigen or enzymes). The complete biosensor can therefore be dried onto the membrane.

Cytiva offers a complete range of track-etched membranes manufactured using proprietary technology to produce a precision membrane filter with a closely controlled pore size distribution.

Please contact your Cytiva representative for more information on track-etched membranes.

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