PALL Life Sciences

Materials for Diagnostic Assays

Consistent membranes and materials for use in diagnostic assays

- **Unique** – Innovative and patented materials for plasma separation and white blood cell (WBC) isolation from whole blood samples.
- **Reproducible** – Tight coefficients of variation (CV) for key performance parameters result in consistent performance lot after lot.
- **Efficient** – High performing materials help to reduce assay costs by minimizing assay variation, material scrap, and reagents usage.
- **Comprehensive** – Portfolio of materials includes all components needed for lateral flow diagnostic assays.
- **High quality** – Designed and tested specifically for diagnostic applications to ensure the materials meet stringent requirements for diagnostic assay development and manufacturing.

Applications

- Lateral flow assays
- Plasma separation from whole blood
- WBC isolation
- Nucleic acid isolation
- Microfluidic-based diagnostic assays

*Filtration. Separation. Solution.*SM

Vivid™ Plasma Separation Membrane

One step plasma separation from whole blood

- Specifically engineered for plasma-based diagnostics.
- Generate high quality plasma in under two minutes with yields typically greater than 80%.
- Greater efficiency than glass fiber-based separation which reduces the starting volume of whole blood required.
- Robust separation results in low hemolysis and low non-specific binding of target analytes.
- Ideal for lateral flow and microfluidic-based platforms as plasma can be delivered to the assay eliminating the need of centrifugation upstream in the process.

Material Feature	Performance Benefit
High efficiency	Robust separation mechanism achieves ≥ 80% plasma yields and lowers the volume of whole blood required per assay.
Low hemolysis	The asymmetric structure of the membrane gently captures the cellular components of whole blood without lysis. Contamination as a result of red blood cell (RBC) shearing and lysis is not observed.
Low non-specific binding	Performance of the membrane has shown that it does not bind key diagnostic biomarkers, such as Troponin I (Figure 1).

Applications

- Plasma separation from whole blood
- Lateral flow diagnostic assays
- Microfluidic diagnostic assays

Specifications

Membrane
Asymmetric polysulfone

Typical Thickness
12.99 +/- 0.79 mils (330 +/- 20 µm)

***Typical Plasma Separation Time**
≤ 2 minutes

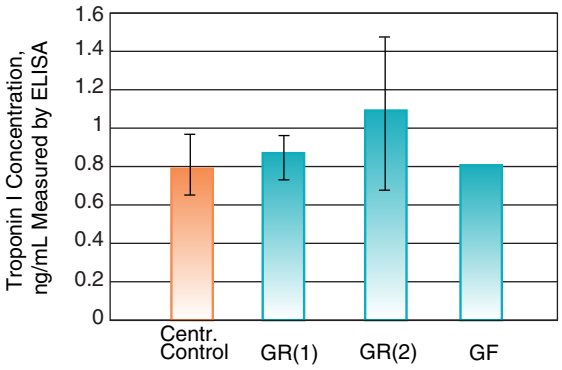
***Typical Minimum Plasma Recovery (%)**
GF: ≥ 60%
GX: ≥ 60%
GR: ≥ 80%

Recommended Blood Volume Capacity (µL/cm²)
GF: 20
GX: 20-30
GR: 40-50

*The separation time and plasma recovery data was determined using EDTA collected whole blood with a typical hematocrit content of 45.6%.

Performance

Figure 1
Vivid Plasma Separation Membrane Exhibits Low Binding of Relevant Protein Biomarkers



Troponin I concentration was measured in plasma samples filtered through Vivid Plasma Separation membrane (blue columns) versus control centrifuged plasma (orange column). All plasma samples were generated from the same sample of fresh EDTA blood spiked with Troponin I at 1 ng/mL. Protein concentration in each sample was measured in triplicate.

Table 1
Vivid Plasma Separation Membrane Quality

Sample	WBC (K/µL)	RBC (M/µL)	PLT (K/µL)	Hemoglobin (Hb) (g/dL)
Whole Blood	7.3	5.2	338	14.8
Centrifuged Control Plasma	0.1	0.0	7-12	0.1
Vivid Plasma Separation GF Filtered Plasma	0.0	0.0	0.0	0.1
Vivid Plasma Separation GR Filtered Plasma	0.0	0.0	0.0	0.1

WBC, RBC, and platelet (PLT) cell concentrations, as well as RBC hemoglobin (Hb), was measured in whole blood and centrifuged plasma samples and then compared to plasma separated with two grades of the Vivid Plasma Separation membrane. The Vivid Plasma Separation membrane effectively removes the cellular components of whole blood with low levels of hemolysis.

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Vivid 170 Nitrocellulose Membrane

Highly consistent material for lateral flow diagnostics

- Manufactured to ensure that key consistency measures are tightly controlled resulting in reproducible results lot after lot.
- Low CVs for critical parameters, such as thickness and wicking rates, help ensure assay reproducibility.
- Minimize material scrap, reduce reagent costs, and maintain assay sensitivity due to low material variation.
- Uniform surface structure results in even distribution of the sample front.
- Stringent quality control release criteria assures functional performance.

Material Feature	Performance Benefit
Uniform thickness	When the thickness of the membrane is consistent, signal generation is maintained and bright, crisp capture lines result (Figure 3). In addition, sample volumes are maintained to achieve the desired test sensitivity.
Consistent wicking rates	The sample front travels evenly along the test strip. Concentration of the target analyte is maintained and reaction kinetics of the assay are not altered.
High surface quality	The visual nature of lateral flow assays result in the need for the membrane to be free from defects, scratches, and powder. The surface of the Vivid 170 Nitrocellulose membrane is bright white resulting in easy to read results.

Applications

- Lateral flow diagnostic assays

Specifications

Membrane
Nitrocellulose

Backing
Polyester

Typical Thickness
7.28 +/- 0.79 mils (185 +/- 20 µm)

Typical Wicking Rate
150-225 sec/4 cm
(Capillary wicking rate performed with water.)

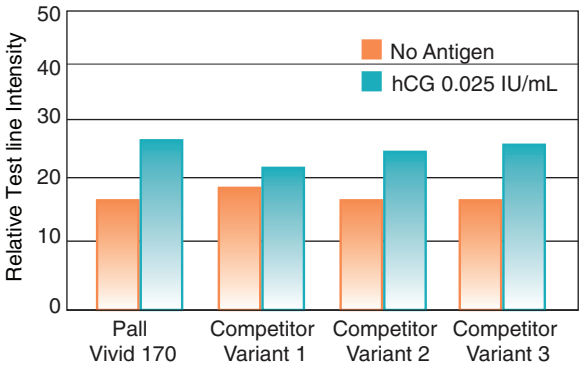
Typical Protein Binding
≥ 45 µg/cm² of BSA

Typical Tensile Strength
≥ 12N, measured on a 15 x 1000 mm strip using DIN 53 112, part 1

Performance

Figure 1

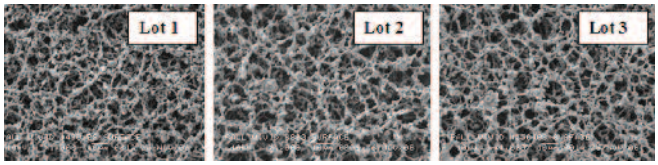
Higher Test Line Intensity at Low Antigen Concentration



hCG immunoassay performance of Pall's Vivid 170 Nitrocellulose membrane versus three variants of a competitive nitrocellulose. hCG test line intensity at low antigen concentration is compared to no antigen controls. The Vivid 170 Nitrocellulose membrane exhibits higher test line intensity at low antigen concentrations as compared to competitive membranes.

Figure 2

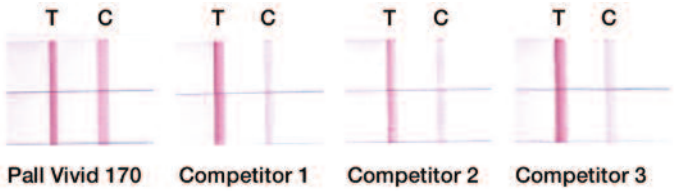
Uniform Membrane Structure Facilitates Assay Reproducibility



SEM images of three different Vivid 170 Nitrocellulose membrane production lots at 1000X magnification. Even distribution of surface microporous structures demonstrates high inter-lot consistency.

Figure 3

Crisp Capture Lines with Vivid 170 Nitrocellulose Membrane



The above images represent hCG immunoassay test strips at 1 IU/mL antigen concentration. The Vivid 170 Nitrocellulose membrane exhibits crisp capture lines with a decreased amount of capture antibody as compared to competitive membranes. Note that the test lines on the competitive membranes display a "leading edge" effect whereas the effect was not noticeable on the Vivid 170 Nitrocellulose membrane.

Leukosorb® White Blood Cell Isolation Medium

Efficient isolation or removal of leukocytes from whole blood

- Unique material is a robust sample preparation tool for WBC harvest and nucleic acid purification from whole blood samples.
- Highly wettable, fibrous media efficiently collects WBCs while allowing RBCs and most platelets to pass.
- Can be used for the concentration and/or recovery of WBCs or the reduction of RBCs.
- Harvest and purify nucleic acids via *in situ* lysis of WBCs.
- The quality and yield of isolated nucleic acids can be analyzed using UV spectrophotometry, agarose gel electrophoresis, PCR, and RT-PCR analysis.

Material Feature	Performance Benefit
Efficient capture	High WBC capture efficiency results minimize the concern over WBC contamination in the sample effluent. For molecular diagnostic applications, consistent capture of WBC allows for reproducible nucleic acid harvest.
High capacity	Can process standard vacutainer volumes of whole blood (7-12 mL) through the Leukosorb medium without any significant breakthrough of WBC into the effluent.

Applications

- WBC isolation
- WBC removal
- Nucleic acid isolation
- RBC reduction
- Molecular diagnostics

Specifications

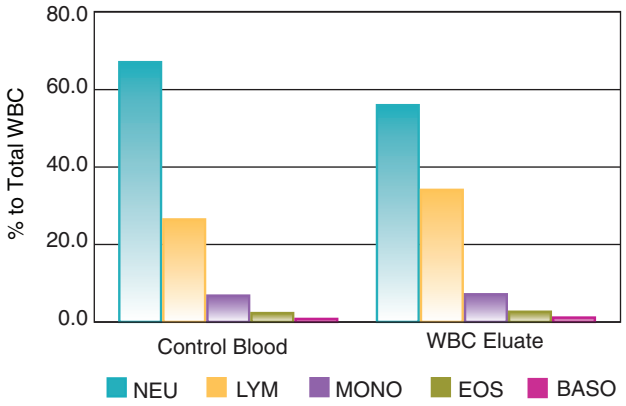
Pore Size
8.0 µm

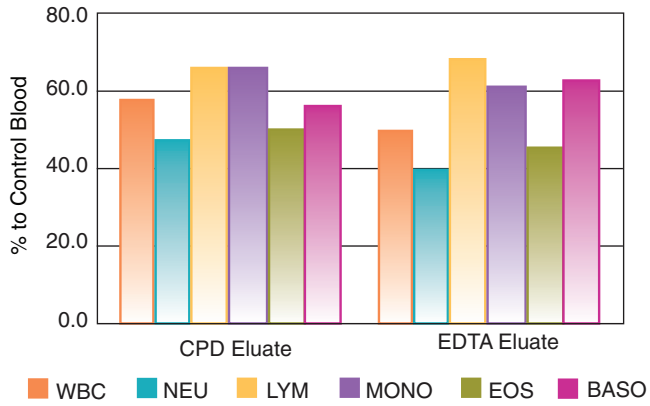
Typical Thickness
14.0-22.0 mils (355.6-558.8 µm)

Performance

Figure 1

Processing Through Leukosorb Medium Does Not Alter Cell Populations





Compositions of WBC population of control blood and cell's eluate recovered from the Leukosorb filter after blood processing. Freshly collected 9 mL samples of EDTA or citrated human whole blood were passed via gravity through the 25 mm Acrodisc® PSF with LK-4 media. WBCs trapped on the filter media were recovered into an elution buffer by filter back flush after washing away of the residual RBC. The concentrations of Neutrophils (NEU), Lymphocytes (LYM), Monocytes (MONO), Eosinophils (EOS), and Basophils (BASO) in the cell's eluate and whole blood were measured using a Cell DYN 3700 Counter. Comparative studies showed no significant changes of WBC population profile during cell separation and recovery procedures (top graph). The WBC composition is largely unchanged before and after processing of EDTA and citrated whole blood (bottom graph).

Conjugate Pads

For the immobilization and release of detector reagents

- Available in multiple base materials, thicknesses, and water absorption capacities to meet the varying needs of in-vitro diagnostic test development.
- Materials demonstrate efficient capture and release of the conjugate from the pad, which contributes to the development of consistent crisp capture lines on the reaction membrane.
- Hydrophilic nature of the pads facilitates uniform resuspension of the conjugate and even distribution of the sample/conjugate complex to the reaction membrane.
- Low non-specific binding ensures robust signal intensity and assay sensitivity.
- Low extractable levels minimize concern over assay interference downstream.

Material Feature	Performance Benefit
Uniform wetting	Hydrophilic materials rapidly and efficiently take up water which ensures that the conjugate will be homogeneously applied to the material. This results in uniform release of the conjugate as the sample enters the pad, as well as consistent development of the capture lines downstream.
Uniform absorption	Pad materials with consistent bed volumes result in even distribution of conjugate to the pad. Minimizing variation in the amount of conjugate applied to the membrane helps to reduce reagent cost and material scrap. Consistent dispersal of the sample/conjugate complex also facilitates reproducibility at the capture lines.
Low non-specific binding	Materials that exhibit low non-specific binding properties do not sequester the target analyte or detector reagent in the pad. This results in robust signal generation and increased assay sensitivity as concentrations of the analyte and detector reagent are maintained.

Applications

- Conjugate release
- Membrane supports
- Sample pads

Specifications

Grade	Base Material	Typical Thickness mils	Typical Thickness µm	Typical Basis Weight (g/m²)	Tensile Strength (lbs in MD)
6613	Spun bonded polyester (binder free)	15.5-17.5	393.7-444.5	97.0-103.1	31.4
6615	Spun bonded polyester (binder free)	17.9-22.1	454.7-561.3	131.6-139.7	105.0
8301	Cellulose and synthetic blend with PVA binder	14.0-17.5	355.6-444.5	45.0-55.0	10.3
8964	Borosilicate glass fiber with PVA binder	14.0-20.0	355.6-508.0	72.0-78.0	0.9
8975	Borosilicate glass fiber with PVA binder	9.0-13.0	228.6-330.2	47.5-52.5	24.5

Performance

Figure 1

Achieve Efficient Conjugate Release

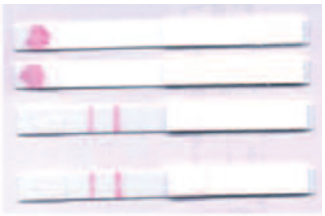


Image of test strips composed of Conjugate Pad Type 8301 before and after hCG immunoassay performed with 1 IU/mL antigen concentration. The conjugate can be seen prior to release in the two upper strips and then following release in the two lower strips. Note the full release of conjugate (no pink color left on conjugate pads of two bottom strips) and high signal intensity on all strips after the assay.

Absorbent Pads

For uniform wicking and absorbency in diagnostic assays

- The naturally hydrophilic nature ensures rapid wetting, consistent wicking rates, and uniform delivery of the sample.
- Assay reproducibility is achieved due to uniform sample absorption.
- The pure nature of the materials does not leach interfering substances.
- Low non-specific binding minimizes the loss of target analyte and maintains assay sensitivity.

Material Feature	Performance Benefit
Purity	Constructed of 100% pure cellulose fibers, the material will not introduce interfering substances that can negatively affect assay sensitivity and performance.
Consistency	The hydrophilic nature of the pads facilitate rapid wetting, consistent wicking rates, and uniform delivery of the sample to the conjugate pad.
Low analyte binding	Assay sensitivity is maintained due to minimal loss of the target analyte due to non-specific binding to the pad.

Applications

- Sample pad
- Absorbent sink
- Wicks
- Membrane support

Specifications

Grade	Base Material	Typical Thickness		Typical Basis Weight (g/m^2)	Typical Wicking Rate (sec/3 cm)	Typical Water Absorption Capacity ($\mu L/cm^2$)
		mils	µm			
111	100% pure cellulose fibers	12.0-18.0	304.8-457.2	63.3-77.3	9.3-10.7	38.2-41.8
113	100% pure cellulose fibers	12.0-14.5	304.8-368.3	175.8-193.3	163.1-174.9	29.1-30.9
133	100% pure cellulose fibers	30.0-35.0	762.0-889.0	277.7-302.3	36.2-41.8	30.7-47.3
165	100% pure cellulose fibers	66.0-77.0	1676.4-1955.8	414.8-464.0	7.3-8.5	153.5-168.5
197	100% pure cellulose fibers	92.0-102.0	2336.8-2590.8	681.9-724.1	11.6-14.4	199.2-204.8

Ordering Information

Vivid Plasma Separation Membrane

Part Number	Description	Pkg
T9EXPPA0200S00A	Vivid Plasma Separation GF membrane, 8” x 11” sheet	1/pkg
T9EXPPA0200S00X	Vivid Plasma Separation GX membrane, 8” x 11” sheet	1/pkg
T9EXPPA0200S00R	Vivid Plasma Separation GR membrane, 8” x 11” sheet	1/pkg

Vivid 170 Nitrocellulose Membrane

Part Number	Description	Pkg
VIV170SAMP	Vivid 170 Nitrocellulose membrane, 25 mm x 300 mm strip	1/pkg
VIV1702503R	Vivid 170 Nitrocellulose membrane, 25 mm x 3 m roll	1/pkg
VIV1702550R	Vivid 170 Nitrocellulose membrane, 25 mm x 50 m roll	1/pkg

Leukosorb White Blood Cell Isolation Medium

Part Number	Description	Pkg
BSP0669	Leukosorb B medium, 8” x 10” sheet	5/pkg

Conjugate Pads

Part Number	Description	Pkg
SMCON13PK1	Conjugate Pad Type 6613, 8” x 10” sheet	1/pkg
SMCON15PK1	Conjugate Pad Type 6615, 8” x 10” sheet	1/pkg
SMCON01	Conjugate Pad Type 8301, 8” x 10” sheet	1/pkg
SMCON64	Conjugate Pad Type 8964, 8” x 10” sheet	1/pkg
SMCON75	Conjugate Pad Type 8975, 8” x 10” sheet	1/pkg

Absorbent Pads

Part Number	Description	Pkg
S70006	Cellulose Absorbent Pad 111, 8” x 10” sheet	1/pkg
S70007	Cellulose Absorbent Pad 113, 8” x 10” sheet	1/pkg
S70008	Cellulose Absorbent Pad 133, 8” x 10” sheet	1/pkg
S70009	Cellulose Absorbent Pad 165, 8” x 10” sheet	1/pkg
S70010	Cellulose Absorbent Pad 197, 8” x 10” sheet	1/pkg

Additional Information

Related Literature

- Product Datasheet, Vivid Plasma Separation Membrane, PN 33549
- Product Datasheet, Vivid 170 Nitrocellulose Membrane, PN 33550

Related Products

- **AcroPrep™ Filter Plates** offer superior performance for high throughput sample preparation procedures.
- **Syringe Filters** are available in a variety of pore sizes, membrane types, and processing volumes for single sample processing.
- **Centrifugal Devices** concentrate and purify samples of < 50 µL to 60 mL with efficient recovery and low non-specific binding.

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