mdi
Membrane Technologies

DIAGNOSTIC
PRODUCT GUIDE

Company Profile

Advanced Microdevices (**mdi**) is a leader in innovative membrane technologies. Starting from a single person R&D operation in 1976, **mdi** has developed into a dedicated team of more than 1000 plus, manufacturing more than 800,000 products.

The company's core competence is its ability to develop new membrane technologies and innovate existing ones to deliver advantages to the customer for high end purification and separation as well as medical diagnostic applications in a wide range of industries such as pharmaceuticals, biopharmaceuticals, biotechnology, food and beverage, hospitals, and immunodiagnostics.

Strong R&D capabilities have propelled **mdi** to the position of technology leader in immunodiagnostic membranes and materials worldwide. **mdi** produces the most consistent Nitrocellulose Membranes for Rapid Immunodiagnostic Tests.

For filtration applications, as membranes end up being incorporated into user friendly devices, plastic design, moulding and sealing technologies become an integral part of the chain to deliver value to the customer. Realizing this, **mdi** has grown into a vertically integrated company that helps deliver prototypes rapidly to the customer.

Over the years **mdi** has created a position for itself by developing latest technologies at low cost and commercializing internationally accepted products at competitive prices. **mdi** products are exported to over 50 countries worldwide, including major exports to USA, Western Europe, China, and South Korea.

Unit 1 (10,000 sq M)

Unit 3 (10,000 sq M)

mdi's modern GMP facilities with large ISO 7 Clean Areas more than meets the required standards. The products are manufactured in ISO 9001:2015 certified facility with the help of trained manpower meeting or exceeding industry standards. Many **mdi** products are recognized as the best available in the world.

mdi has a strong pipeline of new products constantly being developed in its well equipped R&D labs. It is known for providing specialized solutions to all customers ranging from R&D Labs and beginners to small, medium and large scale production houses. Let us discuss what **mdi** can offer for different scales of production.

Contents Page

Introduction to Rapid Tests

Rapid Immunoassays or Rapid Tests represent a well established technology appropriate for use in a wide variety of point-of-care (POC) or field-use applications. Rapid tests are used for the specific qualitative or semi-quantitative detection of many analytes including antigens, antibodies, and even the products of nucleic acid amplification kits. One or several analytes can be tested simultaneously in the same device for clinical diagnosis and urine, saliva, serum, plasma, whole blood, feces and exudates (from wounds or lesions) can all be used as test samples. In environmental or other non-clinical applications the sample may be derived from soils, dust, vegetation, food, or environment swabs such as from food processing plants.

Rapid test is a technology intended to detect the presence (or absence) of a target analyte in sample. Often produced in a lateral flow format, it is a form of immunoassay in which the test sample flows along a solid substrate via capillary action. After the sample is applied to the test, it encounters a colored reagent which mixes with the sample and transits the substrate encountering lines or zones which have been penetrated with an antibody or antigen. Depending upon the analytes present in the sample the colored reagent can become bound at all the test line or zone. Rapid test can be operated as either competitive or sandwich assays.

Other rapid test formats based on principles of immunofiltration and immunodiffusion are also available.

Advantages of Rapid test

Membrane based rapid tests are available for a wide range of clinical applications. Although most are used by healthcare professionals in clinical settings, an increasing numbers of tests are approved for use by relatively untrained home-users.

Rapid tests offer many advantages such as ease of use, small sample volume, speed, reliability and low cost.

1) Ease of Use

Perhaps more than any other feature, ease of use has made the category of rapid tests a viable commercial format. Generally speaking, such tests make use of versatile and uncomplicated biochemical technology that require little or no experience to operate, no lab infrastructure, no equipment and no electricity. User-oriented features that improve ease of use include single-step operation and a clear, easy-to-read test result.

2) Small Sample Volume

Tests that require only a small sample are strongly favored by clinicians and home-users alike. These tests have the advantages of requiring less user-experience in collecting a sample, generally faster performance, less potential for harming or causing pain to the patient, and reduced waste.

3) Speed

Rapid tests can provide test results in as less as 3 minutes making these ideal for emergency situations such as myocardial infractions.

4) Reliability

Rapid tests provide high reliability with high sensitivity (<1% false negatives), high specificity (<1% false positives), and good long-term stability (12 months or more).

5) Low Cost

Rapid tests involve much lower costs per result in comparison to clinical laboratory tests involving instrumented analysis.

What mdi offers for Rapid Tests

For R&D Labs and Beginners

mdi offers Easypack Starter Kits for developing rapid tests (Page 15). These can be used to select the best materials for immunoassay development and are the starting point for those who are new to immunodiagnostics as well as for the skilled in the art who want to develop new immunoassays. Different types of Easypack Starter kits include the solid supports required for immunoassay development (both lateral flow and flow through tests), reagents for getting familiar with the development techniques, as well as packaging materials for the final test. Please refer to Easypack Starter kits section for details. Different types of plastic cassettes/devices are also available for startups as it is sometimes difficult to get your own plastic molds in the initial phase.

mdi also offers machines for development of lateral flow tests. Easyprinter is one such machine which is suitable for printing reagent lines on Nitrocellulose membrane without any wastage of reagents. It is ideal for development and for Quality Control labs. Economical Strip Cutting machine is also available to cut the test strips into desired widths for developmental phase. Please refer to page 16 for detailed specifications.

For Small to Medium Scale Production

Once the test has been developed and all the components have been finalized, **mdi** will provide the selected device components suitable to meet manufacturing process requirements.

For Lateral Flow Tests, **mdi** can provide Nitrocellulose membrane laminated on the plastic backing (Page 6) as per the dimensions/design required by the customer so the customer does not have to invest in a lamination machine in the beginning. Other pad materials such as Sample Pad, Conjugate Pad and Absorbent Pad can also be provided in strip form of desired width instead of sheets or rolls which eliminates the requirement of special cutters for cutting sheets/rolls into strips. Other components such as Cover Tapes, blood separation membranes, etc. can also be provided precut in required dimensions.

For Flow Through tests, **mdi** can provide Nitrocellulose membrane placed in a snap-fit plastic housing with absorbent pads to make complete immunofiltration device (Page 11). Flow Through Membranes are also available in required strips/sheets to be used in the test manufacturer's own device. **mdi** also offers RBC separating filter funnels for whole blood flow through tests. Special Flow Through Membranes are also available for quantitative detection of the analytes.

For Medium to Large Scale Production

mdi produces most consistent and most sensitive nitrocellulose membrane and are being used by the largest production houses of Rapid Tests worldwide.

For Lateral Flow Tests, **mdi** provide Nitrocellulose membrane in rolls of desired width which can be used with lamination machines. Conjugate Pads, Blood Separation Membranes, Cover Tapes and selected Absorbent Pads can also be provided in the roll form of desired width. Other components such as Sample Pads and selected Absorbent pads which are not available in rolls can be offered in sheets of required dimensions.

For Flow Through tests, **mdi** can provide Nitrocellulose Membrane and Absorbent Pad in sheet form. Special Flow Through Membranes for quantitative detection can be provided in rolls or sheets.

Production Machines

For Lateral Flow Tests manufacturing, **mdi** offers Reagent Dispenser as well as Strip Cutter for High Volume Production as well as for the development phase. Please refer to page 14 for detailed specifications.

Lateral Flow Test Components

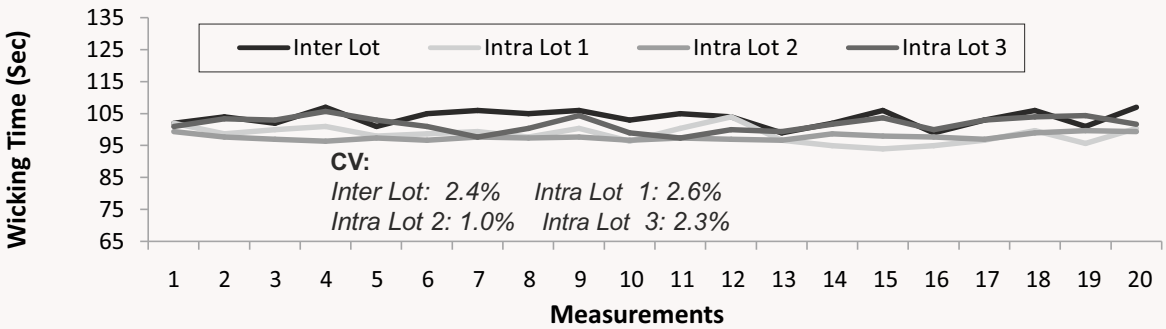
NITROCELLULOSE MEMBRANES

The development of rapid diagnostic tests involve selection and validation of various test components. Many permutation-combinations are tried before freezing a set of components for a test under development. This makes it very important that all the components exhibit high inter and intra-lot consistency.

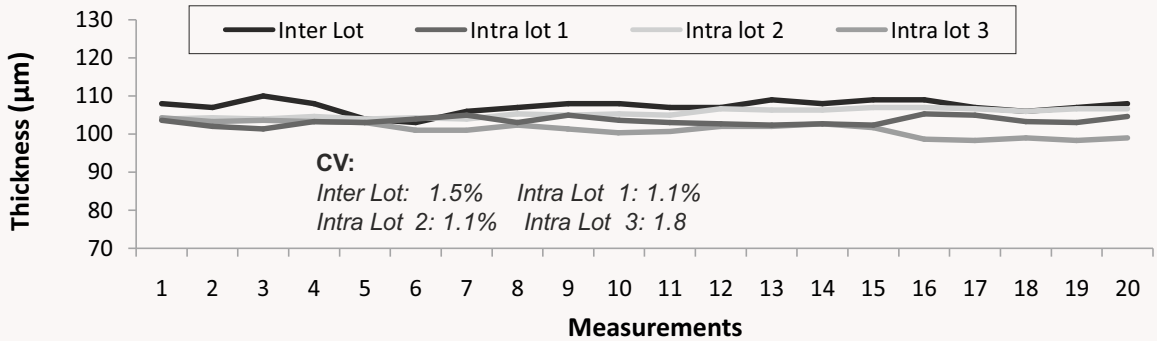
Keeping pace with advances in detection technologies, **mdi** thoroughly understands the assay design process and offers a wide variety of very high quality rapid test components.

Among the lateral flow test components, Nitrocellulose Membrane is pivotal as it is the platform on which the final reaction takes place. The membrane is required to provide sufficient protein binding for strong test lines and at the same time should give least non-specific background. By an optimized surface chemistry and unique processing techniques **mdi** has resolved these issues. **mdi** membranes are highly consistent and exhibit extremely low variation. Typical coefficient of variation for wicking rate is 2.4% whereas that for the thickness of membranes is 1.5%.

Inter and Intra Lot Variation in 4cm Wicking Time of 15µ NC Membrane



Inter and Intra Lot Variation in Thickness of 15µ NC Membrane



Note: **Intra Lot:** 20 measurements along the length of a 100 meter long reel of 3 different lots

Inter Lot: Mean data rate of 20 lots produced over a period of 4 months

Technical Information

The wicking rate is an important characteristic of NC membrane for lateral flow tests and primarily determines the reaction kinetics.

mdi membranes are designated by pore size/wicking rate and have reproducible and defined wicking rates. The wicking rates of blocked membranes will, however, depend on blocking protocol. Although wet blocking of membrane (dipping the membrane in solution and drying) is cumbersome and adds cost to the production process, it is sometimes necessary to achieve important assay requirements such as stabilizing the Ab, reducing nonspecific reaction, improving the wicking front, and migration of particles etc. Many excellent assays, however, can be made without wet blocking the membrane.

All **mdi** membranes exhibit extremely stable wicking rates with time without blocking and can be used successfully for making assays without blocking.

Types Available

A wide variety of membranes is available to meet the requirements of different tests. These membranes are directly cast on a transparent polyester backing to improve the handling strength. Standard polyester film is 100 µm thick, although other thickness can be available on order.

Type CNPF - Lower protein binding

Type CNPC - Higher protein binding

Type CNPH-N - Highest protein binding

Type	Sub-Type	Rating	Mylar Thickness (µm)	Membrane Thickness (µm)	4cm Wicking Time (sec)
CNPF	SN12	5µm	100	100	220
		8µm	100	100	170
		10µm	100	100	125
CNPC	SS12	10µm	100	105	140
		12µm	100	105	120
		15µm	100	105	100
CNPH-N	SS60	200	100	110	200
	SS40	150	100	110	150
		90	100	110	90
		70	100	110	70

Type CNPC and CNPF are rated by pore size (nominal)
Type CNPH is rated by Wicking Time

How to Select

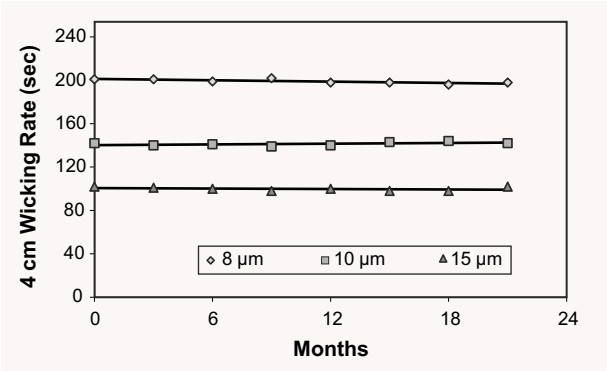
Selection of membrane depends on the assay. Highest sensitivity is obtained with smaller pore size (slower wicking rate). For high affinity Ag/Ab reaction, use of bigger pore size (faster wicking rates) can result in faster test with adequate sensitivity.

Membrane Pore Size	Wicking Time	Sensitivity	Migration Speed	Test Time	Line Intensity	Typical Application
5, 8 µm	165-245 sec	Highest	Slower	Longer	Sharp	- HbsAg Serum Test - Urine Ab Tests - Environmental and Agricultural Analytes - Milk Testing
10, 12 µm	110-150 sec	Medium	Medium	Medium	Sharp	- hCG - Heart disease markers - Cancer markers - Drugs of Abuse - Infectious disease tests - Whole blood tests - Environmental and Agriculture Analytes
15 µm	90-110 sec	Lower	Faster	Quick	Less Sharp	- hCG - Malaria - Whole blood tests

Storage

At **mdi**, membrane is stored in specially designed cold storage areas.

We recommend storage of membrane rolls in original foil packing at 1 °C to 35 °C for longer shelf life. The membrane rolls should be kept away from direct sunlight and heat radiators. The membrane is inflammable when subjected to direct heat.



Ordering Information

Information	Membrane Type	Width of roll (in mm)*	Length of roll (in meters)**	Quantity
Example 1	CNPC-SS12,15 µm	25 mm	50 M or 100 M	20,000 M
Example 2	CNPF-SN12, 10 µm	20 mm	50 M or 100 M	15,000 M
Example 3	90CNPH-N-SS40	28 mm	50 M or 100 M	18,000 M

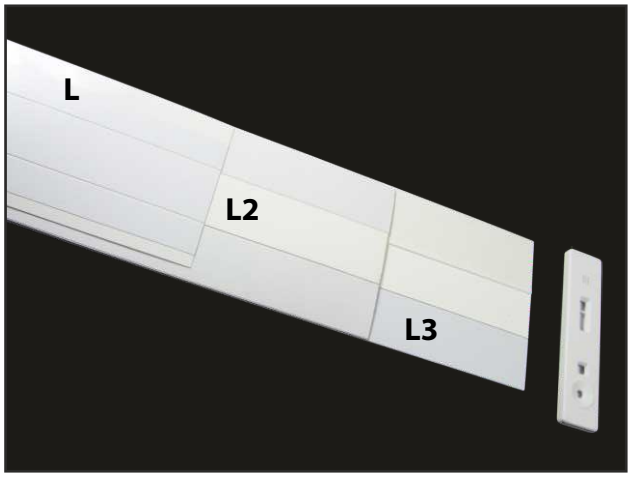
* The width is as per the customer requirement. 25 mm is most widely used membrane size.

** The membranes in reel form are supplied on standard 3 inches plastic core.

Lateral Flow Test Components

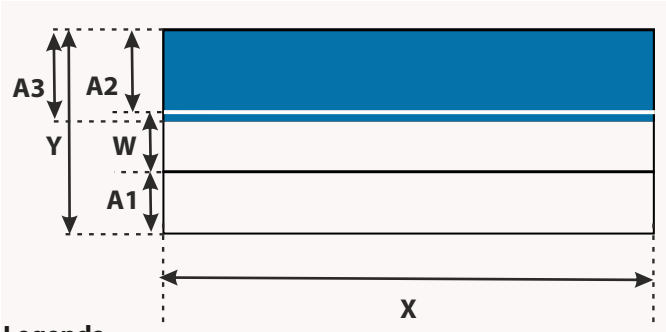
MEMBRANE LAMINATES

Production of a lateral flow test requires the NC membrane and other materials to be attached to a plastic backing. **mdi** laminates or cards are such ready-to-use sub-assemblies of membrane, adhesive, and plastic. These are convenient to handle for application of reagents, and later cutting into strips to make the complete test.



Advantages of mdi Laminates

- Allow immediate development and scale up for production
- Can be custom designed to fit existing cassette or dipstick design
- All components are proven and will not interfere with the immunoassays



Legends

A1 - Width of adhesive for Sample Pad
A2 - Width of adhesive for Absorbent Pad
A3 - Width of Absorbent Pad(Edge Overlaping the NC Membrane for L3 Laminates)
W - Width of NC Membrane
X - Total length of Laminate
Y - Total width of Laminate

Laminate Types

S. No.	Type	Components Placed on the Plastic Backing		
		Sample Pad	Nitro-Cellulose Membrane	Absorbent Pad
1	L-P25	No	No	No
2	L-H50	No	No	No
3	CNP*-L2-P25	No	Yes	No
4	CNP*-L2-H50	No	Yes	No
5	CNP*-L3-P25	No	Yes	Yes
6	CNP*-L3-H50	No	Yes	Yes

Note:

- P25- Plastic backing of 250 µm thickness
- H50- Plastic backing of 500 µm thickness
- CNP* indicates the type of nitrocellulose membrane e.g. CNPC-SS12
- When a component is not placed on plastic backing (indicated by No in the the above table), adhesive with liner is provided to allow the user to stick the component to the plastic backing

Storage

mdi recommends storage of membrane laminates at 1 °C to 35 °C for longer shelf life. The membrane is inflammable when subjected to direct heat. The laminates should be kept away from heat radiators and direct sunlight and should not be allowed to lie in the open for long periods.

Ordering Information

To order a membrane laminate, please specify the membrane, laminate type, membrane pore size, and the dimensions A1, A2, A3, W, X, and Y.

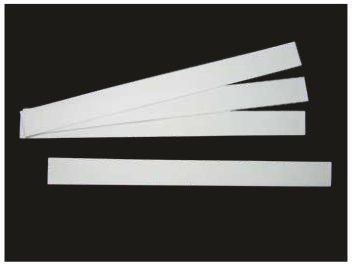
Lateral Flow Test Components

SAMPLE PAD

mdi Glassfiber sample pad type GFB exhibits high absorption capacity and does not bind proteins. It forms the platform where sample/analyte is placed at the time of testing. The non-reactive and non-binding properties of glassfiber material allows steady and uniform flow of analyte and prevents nonspecific binding of sample components to the pad.

GFB pads are available in standard thickness of 0.35 mm and 0.60 mm in sheet /strip form.

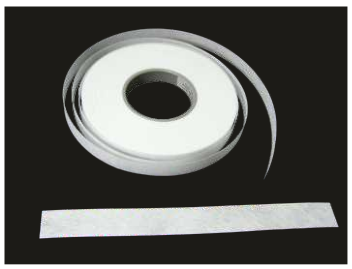
Specially impregnated pads can be offered to meet specific needs and for difficult to filter samples such as **stool, milk** etc.



Type	Application
GFB-R4	With minimal additives, allowing a user to include additives as per requirement
GFB-R7L	With buffers and detergents

CONJUGATE RELEASE MATRIX

mdi Conjugate Pad is a polyester matrix. It is the platform where the assay detection conjugate (such as gold conjugate) is placed in dried form. The synthetic material composition of conjugate pad ensures its quick and efficient release along with the flow of test sample by rehydrating it. The 'detection conjugate-analyte' complex moves into and up the nitrocellulose membrane.



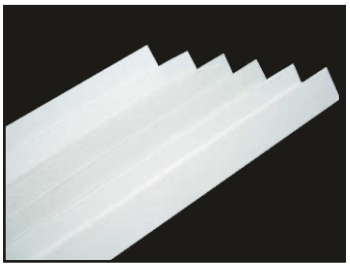
Type	Application
PT-R1	Includes blocking agents
PT-R5	Incorporates minimal additives. User may include additives as per requirement
PT-R6	Includes buffers and detergents to maintain sample pH
PT-R7	Includes buffers for uniform movement of gold

Conjugate pads are available in reel, sheet as well as strip formats.

ABSORBENT PADS (SINK PADS)

Absorbent pads, located at downstream end of the test, control the sample flow along the strip. These are hydrophilic in nature, have excellent absorption capacity and thus help drive the flow of test fluids across the nitrocellulose membrane.

mdi offers cellulose fiber based absorbent pads for dipstick as well as device formats.



Type	Thickness	Application
AP045	0.40 mm	Dipstick Tests
AP080	0.80 mm	Device Tests
AP110	1.10 mm	Device Tests
AP120	1.40 mm	Device Tests

AP045 and AP080 are available in reel, sheet as well as strip formats, however AP110 and AP120 is available in strip and sheet format only.

Ordering Information

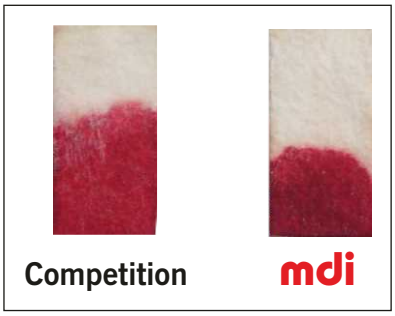
To order for Sample Pad, Conjugate Release Matrix and/or Absorbent Pad, please specify the desired length and width along with quantity.

Lateral Flow Test Components

BLOOD SEPARATION MEMBRANES

Introduction

Advancements in blood separation research at **mdi** has resulted in a unique set of Red Blood Cell (RBC) separation materials which satisfy the long standing demands of the lateral flow diagnostic test manufacturing industry.



mdi's Unique High Performance Blood Separator

Blood separators are useful as they offer following advantages to a point of care rapid test manufacturer.

- Eliminates the need for storage, centrifugation, or clotting of blood samples.
- No technical expertise and lab equipment is required.
- True one step method. No liquid buffer is required in the kit with type WFR1.
- On the spot results in critical situations.
- Results are reliable as intermixing of patient's sample is avoided.

mdi Solution to Commonly Faced Problems with Blood Separators

Problems	Solutions Offered by mdi Blood Separators
Leakage of RBC onto the membrane (specially at high hematocrit level).	Higher void volume and extremely high retention efficiency of **mdi** Blood Separators results in full stoppage of RBC.
The migration of plasma on the membrane is very slow resulting in delayed results.	The unique composite design of **mdi** Blood Separators facilitates faster migration of plasma through the separator.
High volume of blood is required due to poor plasma recovery.	The unique composite structure of **mdi** Blood Separators allows high plasma recovery making it possible to make one step whole blood assays with as little as 25µl whole blood.
The separator may work for fingerprick blood but does not work with stored blood (with anticoagulant).	**mdi** Blood Separators work well with fingerprick as well as stored blood.
The separator adsorbs the analyte resulting in reduced sensitivity.	The adsorption of the analyte in **mdi** Blood Separators is minimal resulting in higher sensitivity.

Blood Separation Membrane	Time for Plasma to Reach Window of Devices (sec)	Time for Plasma to Cross the Window (sec)	Hemolysis	Volume of Blood Sample Added
WFR1	50	180	No	3 drops
Competition C	250	360	Seen after 10 minutes in some samples	4 drops

Types Available

mdi RBC Separator Type FR Suitable for Tests Using Liquid Buffer	
Variants	**Features**
• FR1(0.35) • FR1(0.6) • FR2(0.7)	This acts as a sample pad and stores the Red Blood Cells (RBCs). A separate conjugate release pad is required which is in direct contact with the NC membrane. The blood separation matrix does not touch the NC membrane.

mdi RBC Separator Type WFR Suitable for Tests Without Using Liquid Buffer	
Variants	**Features**
• WFR1	This is a composite assembly comprising of a polyester matrix and a white matrix. The white matrix is attached at one end of polyester matrix with biochemically inert glue. This composite assembly acts as sample pad as well as conjugate pad, and is placed on the laminate in such a manner that the white matrix is in direct contact with NC membrane.

How to Use mdi RBC Separation Membrane

Mode 1:
Whole Blood Test Using Type FR with Liquid Buffer

mdi blood separation membrane type FR1 and FR2 are used in this format. A liquid buffer is provided with the test kit to drive the plasma through the sample pad and the membrane to complete the assay. Minimal quantity of whole blood can be used.

Blood separator acts as the sample pad and stops the RBC. Typically 5-50 µl whole blood is applied in the hole of the device and 2-3 drops of buffer are added to drive the plasma. A separate conjugate release pad is required.

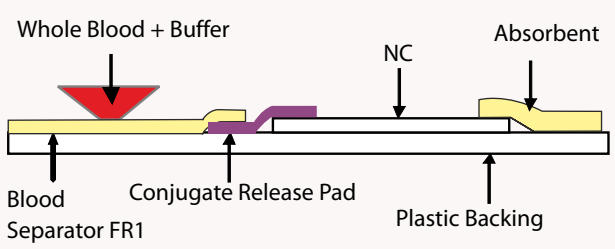


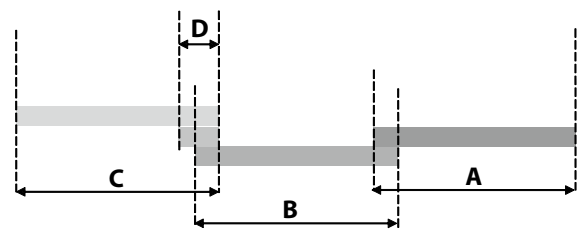
Figure 1: Typical Design of FR1/FR2 Test

Blood Volume Requirement (µl)		Type (Mode 1) FR1	FR2
With Buffer	Min.	5 µl	5 µl
	Max.	30 µl	50 µl

Mode 2:
Whole Blood Test Using Type WFR without Liquid Buffer

mdi blood separation membrane type WFR1 is used in this format. The test kit does not require any liquid buffer. Plasma separated from applied whole blood itself migrates up the membrane to complete the assay. The polyester matrix of WFR1 stops some RBC allowing free flow of plasma whereas the white matrix stops the remaining RBC completely allowing only plasma to flow through the NC membrane. Due to the design and construction of above material the RBC do not leak to the membrane assuring a valid assay even if excess blood is applied.

To conserve plasma and enhance the speed of flow, WFR1 also acts as conjugate release matrix. A schematic of placement of various components of rapid test using WFR1 is shown here.



A: *Absorbent Pad* placement on dipstick
B: *NC Membrane* placement on dipstick
C: *Polyester Matrix of WFR1* placement
D: *White Matrix of WFR1* placement between B and C

Figure 2: Placements of WFR1 on Dipstick

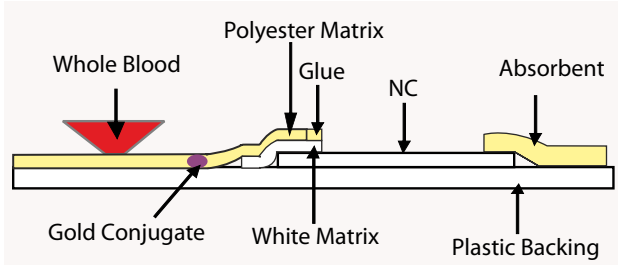


Figure 3: Typical Design of WFR1 Test

Ordering Information

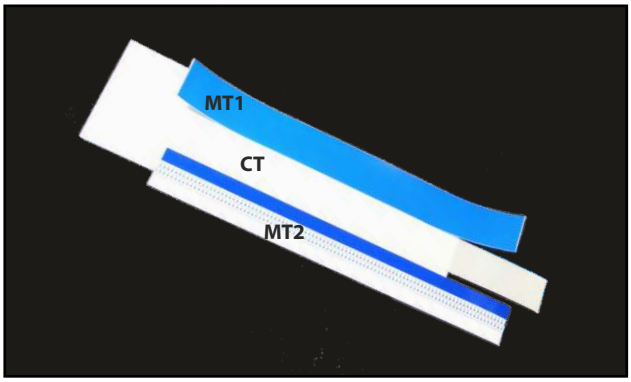
Type	Format	Quantity
FR1 (0.35)/(0.6)	Sheet, Strip/Roll	Numbers/Meters
FR2 (0.7)	Sheet, Strip/Roll	Numbers/Meters
WFR1	Strip	Numbers

Lateral Flow Test Components

COVER TAPES

Cover tapes are required for dipsticks to maintain good contact between the membrane, the sample pad, and the sink pad. These also prevent evaporation of samples when running besides offering mechanical strength to the delicate test components.

mdi cover tapes use special adhesives which are non-reactive and non-migrating, and therefore do not interfere with the nitrocellulose membrane characteristics to affect its flow properties.



Types Available

On the basis of application, the cover tapes have been named as given in the table below:

Type	Application
Masking Tape MT1 and MT2	These are used on the absorbent pad (MT1), and sample pad (MT2) sides of the test strip.
Clear Tape CT	Clear transparent tapes cover the NC membrane. These are required specially to reduce the effect of sample evaporation when serum tests are run in hot weather.

Ordering Information

The Masking Tapes are offered in desired sizes in strip formats and can be custom printed.

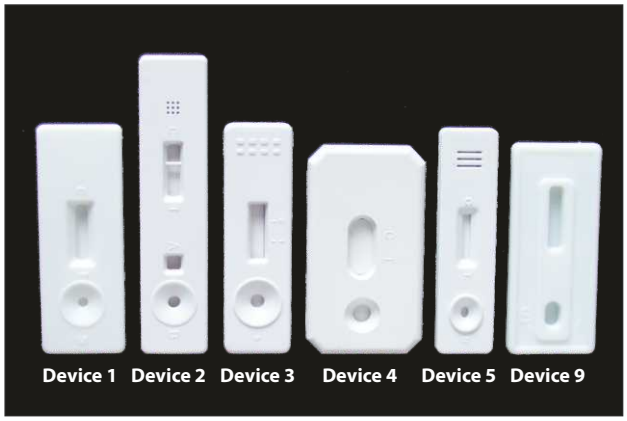
The Clear Tape is available, both, in strip as well as roll format.

Kindly specify the format, size, and quantity.

PLASTIC CASSETTES

High quality standard 2 piece snap-fit plastic housing for lateral flow tests are available for 4 mm, 5 mm, and 8 mm wide strips. The plastic cassettes prevent the test strip from damage and makes handling safer and easier. Slot is made for pouring the test sample and the result can be seen through the window.

Special 5 mm housing with 2 holes for whole blood tests and tests requiring additional clearing buffer is also available.



Type	Description
Device 1	4 mm plastic cassette
Device 2	Special 5 mm cassette with 2 holes for whole blood tests and tests requiring additional clearing buffer
Device 3	5 mm plastic cassette
Device 4	8 mm plastic cassette
Device 5	3 mm plastic cassette
Device 9	5 mm plastic cassette with extra space between sample hole and window. Suitable for whole blood tests

Ordering Information

Kindly specify the device type and the quantity.

Components for Immunofiltration

IMMUNOFILTRATION MEMBRANES

mdi immunofiltration membranes are specially useful for making antibody detection tests and also for quantitative detection of proteins.

Types Available

Type CLW-040 is cast on cellulose paper. It is very sturdy to handle and the paper makes good contact with the absorbent. Available in sheets and strips of desired size.

Type CNJ is internally reinforced NC with an extremely uniform plain surface, and good for quantitative reflectance measurement by instruments. Available in reels slit to desired width.

Type	Typical Application
CLW-040, 0.3 µm/0.45µm/0.8 µm	HIV 1 and 2, HCV, other antibody tests, Microbial detection kits
CNJ, 0.45µm	Quantitative protein detection systems

What is special about mdi Immunofiltration Membranes

As with other membranes used in diagnostic assays, point to point uniformity and reproducibility from lot to lot are key requirements. This is particularly important when membranes act as support for quantitative assays.

mdi membrane type CNJ exhibits extraordinary point to point uniformity and reproducibility allowing production of high quality tests with a low coefficient of variation (CV) of the measured readings.

Technical Data

The reaction kinetics of Ag/Ab is governed by the flow rate of the membrane and its pore size. Bigger pore size will show faster flow rate. Membrane with slower flow exhibits higher sensitivity of the assay whereas fast flow membrane will have less nonspecific binding and results in a quicker test.

CLW-040, 0.45 µm is an optimised membrane for visual assays whereas for quantitative assays, 0.45 µm CNJ membrane is offered.

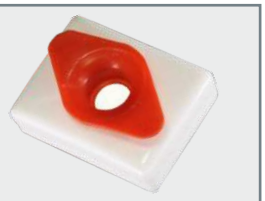
Ordering information

Please specify the membrane type, pore size, size of sheet/strips, and/or reels along with the quantity required.

PLASTIC HOUSING

Well designed snap-fit housing FT-12 with absorbent AP080 are available to make a complete immunofiltration system. The device uses eight (8) AP080 pads and can hold sample volume upto 4 ml.

Prefilter funnel (PF-12) and flow director funnels (F5) to fit the housing are also available. Prefilter funnel (PF-12) can also be used with a RBC filter to directly run whole blood tests.



FT-12 with PF-12

FT-12 with F-5

PF-12

F-5

Ordering Information

Kindly specify the number of plastic housings required.

Additionally, the type of funnel if required should also be mentioned.

Immunodiffusion Format

DIPSTICKS

mdi dipsticks for dot blot tests are convenient devices for conducting rapid enzyme immunoassays. These are particularly suited for semiquantitative analysis. These dipsticks have one or more membrane pads mounted on an inert plastic tab and are used for dot ELISA based on diffusion principle.

Types Available

Type DCN uses NC membrane and is most commonly used for protein spots. DCN can have one or more pads in the same dipstick.

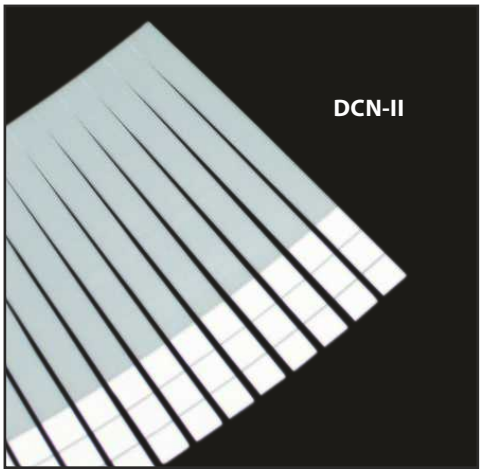
Type	Pad Size (mm)	Dipstick Length	No. of Pads
DCN-II	4	Normally 75 mm, Maximum 100 mm	Maximum 5
	5		
	6		

Application

The dipsticks find application in analysis of serum for diseases where multiple parameters in the patient serum have to be analysed at the same time.

Sizes Available

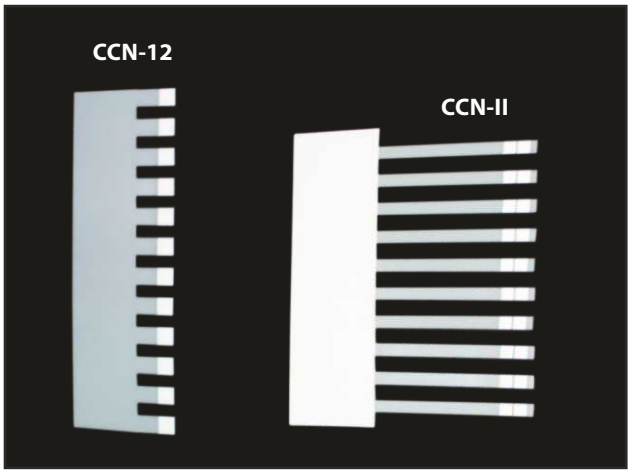
Normally 6 mm x 75 mm dipsticks with 6 mm square membrane pads are used. However, other size can be produced as specified.

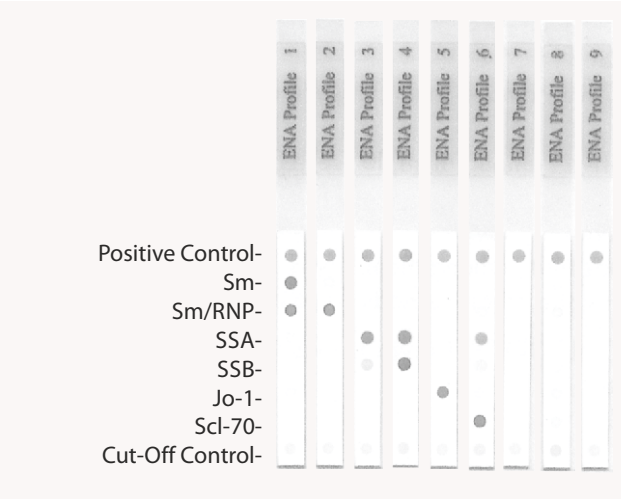


COMBS

Type CCN is a comb with 8 or 12 legs which fits into a normal ELISA plate. It allows 8 or 12 samples to be tested at the same time.

Type	Pad Size	Comb Size	Leg Spacing	No. of Pads
CCN-12 12 Leg	5 mm	104 x 35 mm	3.7 mm	1
CCN-8 8 Leg	5 mm	69 x 35 mm	3.7 mm	1
CCN-II, 10 Leg	4 mm	95 x 82 mm	5 mm	Max. 8





Ordering Information

To order specify the length, width, and number of membrane pads required in the dipsticks and/or combs.

Rapid Plasma Separation Device

Many Point of Care (POC) instruments require free plasma for the diagnostic tests to be conducted. This necessitates the removal of red blood cells from whole blood sample. Although centrifugation technique is commonly used, it requires sample to be sent to the lab. Some devices separate RBC from the whole blood but do not provide free plasma as it remains in the separation matrix only.

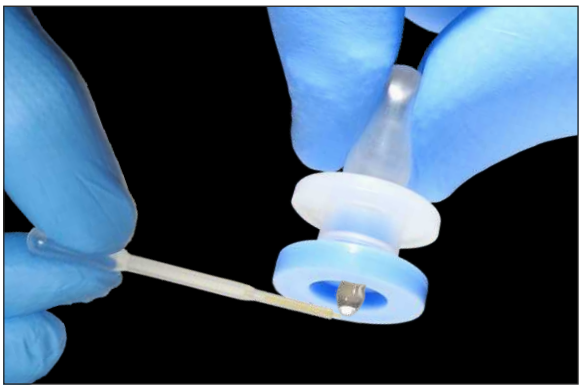
mdi PlasmaDrop Kit overcomes this problem and makes available a fixed volume plasma from whole blood in a few minutes for Biochemical, Immunological as well as Molecular Biology assays.

Principle

Whole blood sample is allowed to pass through an RBC retentive medium. Free plasma gets accumulated in a reservoir. By squeezing the device, plasma is driven out and collected in fixed volume dropper. The dropper is then used to deliver the free plasma to a point of care (POC) instrument/ device.

Apply finger prick blood on device

After ~5 minutes, fit the squeeze bulb



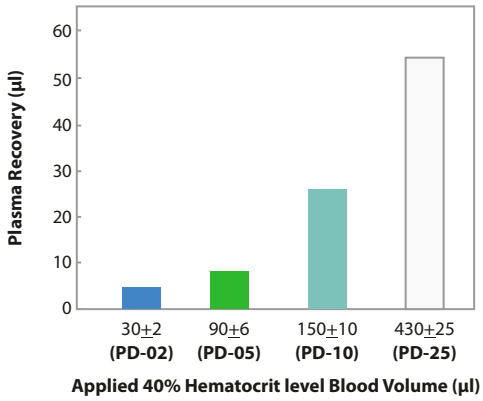
Press the squeeze bulb to get the plasma. Collect in fixed volume dropper

Guaranteed Performance even with 50% Hematocrit Level

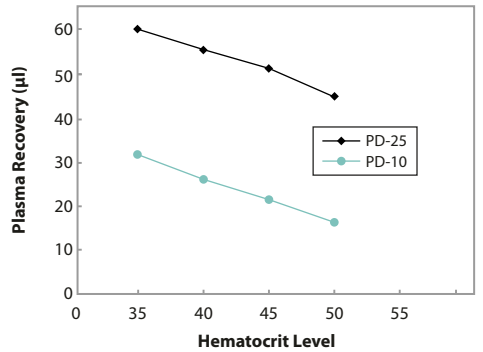
Type	Blood Applied	Fixed Plasma Collected
PD-02	1 drop (~ 30 µl)	2 µl
PD-05	3 drop (~ 90 µl)	5 µl
PD-10	140-160 µl	10 µl
PD-25	430 - 470 µl	25 µl

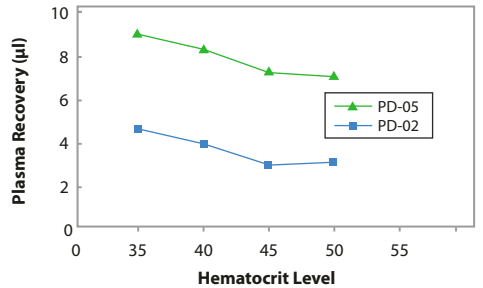
Performance Data

Effect of Blood Volume on liquid plasma recovery



Effect of Hematocrit Level on liquid plasma recovery





KINDLY NOTE: Rapid Plasma Separation System can be integrated with various micro-fluidic or other cartridges for Point of Care instruments. Please contact us at diagnostic@mdimembrane.com for your requirement.

Machines

Programmable Strip Cutter

SS Programmable Strip Cutter offered by **mdi** is a guillotine type programmable shear which can cut card or web stock into strips of desired width. This is run by an inbuilt microcomputer which can be easily programmed by a keypad and LCD display provided on display box. It is available in two models M-70 and M-100.

Specifcations

	M-70	M-100
Cutting Speed	Fixed	Variable
Cuts per Minute	80 strips	upto 200 strips
Key Pad	16 Key Touch Pad	16 Key Touch Pad
Size (LxBxH)	49cm x 34cm x 43cm	49cm x 34cm x 43cm
Voltage	220 V, 50 Hz or other	220 V, 50 Hz or other
Card Width	120 mm (Maximum)	120 mm (Maximum)
Width Range	2mm to 12mm	2mm to 12mm
Weight	38 Kg	38 Kg

Ordering Information

To order specify:
SS Programmable Strip Cutter Model M-100.
Please indicate the operating voltage.

Automatic Reagent Dispenser

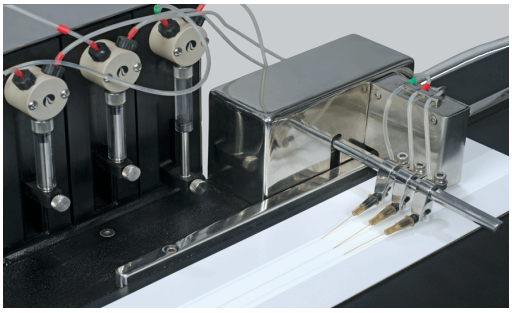
SS Automatic Reagent Dispenser Model PD-04-03 is a unique machine which will dispense precisely controlled reagent lines for one step rapid tests on membrane laminates for high volume production.

Specifications

Belt Speed	:	150 – 450 cm/min
Dispense Rate	:	0.4 – 4.0 µl/cm
Min. Working Volume	:	800 µl
Size	:	81 cm x 40 cm x 42 cm
Weight	:	33 Kg
Power	:	220 V, 0.6A, 50 Hz 110 V, 1.2A, 60 Hz
Maximum Line Width	:	3 mm
Minimum Line Width	:	0.3 mm

Features

1. Fully automatic, user friendly operation
2. Three delivery heads for printing one, two or three lines
3. Digitally programmable belt speed
4. Precise per cm reagent dispensing with positive displacement syringe pump
5. Very high throughputs
6. Blank laminates are detected photoelectrically
7. Printed laminates are removed from the other end of belt
8. Self priming to eliminate entrapped air
9. Extremely uniform, reproducible, and sharp printed lines
10. Big nozzle eliminates shear to avoid damage to proteins
11. No indentation even on softest membrane



Close View of Line Printing Process

Ordering Information

To order specify:
Automatic Reagent Dispenser Model PD-04-03.
Please specify the operating voltage.

Easypack Developer's Kits

mdi *Easypack* Developer's Kit is the starting point for those new to immunodiagnostic tests (lateral flow test, flow through test, immunodiffusion test, whole blood rapid test) as well as for the skilled in the art who want to select the best materials for the assay under development.

Easypack Membrane Kit

This kit consists of all materials necessary to make more than 3000 tests. Laminates of different pore size membranes, absorbent pads, sample pads, and release matrices are provided (details tabulated below) so that trials may be conducted for optimum results.

The *Easypack* Membrane Kit is offered in two variants:

1. *Easypack* Membrane Kit – Dipstick

   Kit for Dipstick Development

2. *Easypack* Membrane Kit – Device

   Kit for Device Development

Component of *Easypack* Membrane Kits		
Component	***Easypack* Membrane Kit (Dipstick)**	***Easypack* Membrane Kit (Device)**
Membrane Laminates	8 laminates each of 8 different types of NC membranes	
Plastic Backing	500 µm HIPS Backing	250 µm PVC Backing
Absorbent Pads	AP-045 and AP-080, 27 x 260mm - 32 nos. each	AP-080 and AP-110, 21 x 260mm - 32 nos. each
Release Matrix	PT-R5 and PT-R7 70 x 260 mm - 3 nos. each	PT-R5 and PT-R7 70 x 260 mm - 3 nos. each
Sample Pads	GFB-R4 and GFB-R7L 24 x 260 mm - 32 nos. each	GFB-R4 and GFB-R7L 13 x 260 mm - 32 nos. each
Cover Tapes	64 nos. sets	_____
Plastic Devices	_____	Device-3 - 100 nos.

Easypack Reagent Kit

Easypack Reagent Kit consists of standard reagents to make more than 1000 complete hCG tests. It is useful for putting together working lateral flow immunoassays and for getting familiar with the techniques.

1. Anti-hCG Antibody - 1ml (3 mg/ml)
2. Anti-βhCG Conjugate - 5 ml
3. Goat anti-mouse Ab (for control line) - 1ml (1mg/ml)

Easypack Packaging Kit

Once the developments are nearing completion, packaging materials for the test kit such as aluminium pouches, plastic droppers, plastic cassettes etc. can be ordered separately. The kit consists of the following:

1. Aluminium pouches - 1000 nos.
2. Plastic Droppers - 1000 nos.
3. Plastic cassettes - 1000 nos.
4. Dessicant (Silica Gel) - 1000 nos.

Easypack Blood Separation Membrane Kit

The kit has been designed to help select the best format suitable for your whole blood rapid test. The constituents of the kit are:

1. Type FR1(0.35), 15x15cm - 10 sheets
2. Type FR1(0.6), 15x15cm - 10 sheets
3. Type FR2 (0.7), 15x15cm - 10 sheets
4. Type WFR1, 3x30cm - 20 strips
5. Plastic Device-2 (two hole) - 100 Nos.
6. Plastic Device - 9 - 100 Nos

Ordering Information

To order for the kits, specify the name of kit and the quantity.

Easypack Developer's Kits

Easypack Immunofiltration Kit

mdi also offers a kit for new developers of flow through tests. The kit consists of membranes and devices for developing/making antibody detection tests and also for quantitative detection of protein. The kit components are:

1. Flow Through Device Type FT12/AP080, with absorbents - 250 Devices
2. Flow Director Funnel Type F5 - 250 Nos.
3. Membrane Type CLW-040-SH34, 0.3µ, 15x15cm - 4 Nos.
4. Membrane Type CLW-040-SH34, 0.45µ, 15x15cm - 4 Nos.
5. Membrane Type CLW-040-SH34, 0.8µ, 15x15cm - 4 Nos.
6. Absorbent Pad AP080, 20x30cm - 8 Nos.

Easypack Immunodiffusion Kit

The kit has following components. The immunodiffusion kit has been designed for the developers/manufacturers of rapid enzyme immunoassay.

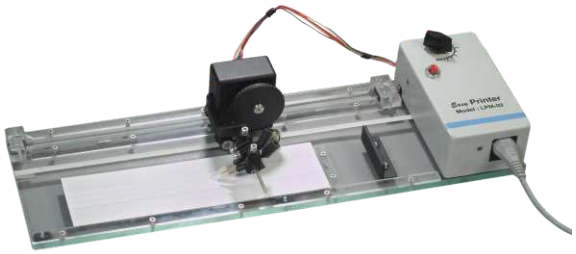
1. 6 mm Dipstick Type DCN-II, 1 Pad - 50 Nos.
2. 6 mm Dipstick Type DCN-II, 2 Pad - 50 Nos.
3. 6 mm Dipstick Type DCN-II, 5 Pad - 50 Nos.
4. 8 leg Combs Type CCN-8 - 25 Nos.
5. 12 leg Combs Type CCN-12 - 25 Nos.

Ordering Information

To order for the kits, specify the name of kit and the quantity.

Easy Printer

The dispensing of reagents has never been so simple and cost effective. The Easy Printer Model LPM-02 is the printer of choice for laboratory development of rapid assays. It is convenient not only for printing occasional lines with minimal reagent loss but due to in-built automation, can also be used for small pilot production.

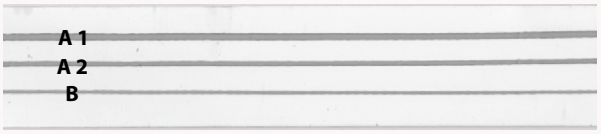


Features

1. Uniform dispensing of reagents results in good line quality
2. Two lines can be printed simultaneously
3. Provision of variable speed for controlled dispensing of reagents
4. A bigger and a smaller print needle for wider and thinner line width.
5. Auto-reverse facility makes the operation automatic
6. Pressure on the membrane is adjustable by a screw in the tip holder
7. Upto 300µl in holding tank allows printing of 10 laminates before refilling
8. Total recovery of unused reagents

Specifications

Maximum Print Length	:	30 cm
No. of Printing Heads	:	2
Min. Working Volume	:	50 µl
Voltage	:	220 V, 50 Hz 110 V, 60 Hz
Power	:	10 W
Weight	:	3.0 Kg
Dimension	:	47 x 16.5 x 11.5 cm
Shipping Carton	:	51 x 21 x 20 cm



Type	Print Needle Type
A1	Drawn with needle **Type A** at a slower speed
A2	Drawn with needle **Type A** at relatively faster speed than A1
B	Drawn with needle **Type B** at same speed as of A1

Ordering Information

To order specify:
Easy Printer Model LPM-02. Please indicate the operating voltage.

Filters

mdi Filters for Antibody and Gold Conjugate Filtration

mdi offers in-line filters and syringe filters for the filtration of small volume and high value products such as gold conjugate and antibodies. These are ideal for filtration of high value antibodies and reagents owing to very low protein binding.

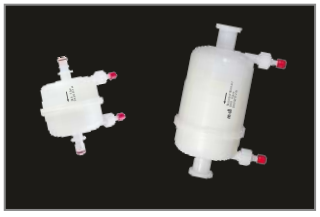
mdi IKT inline filters are compact devices and offer 'Zero' filtration losses as a unique built-in PTFE air vent allows passage of even the last milliliter of fluid through the filter as well as downstream tubing. Specially designed for relatively low volume, high value immuno-reagents.

mdi Capsule Filters for Serum and Buffer Filtration

These specially designed, ready to use, polyethersulfone membrane compact serial filtration capsule filters offer very low hold-up volumes to help minimize filtration losses. These offer enhanced throughput for difficult to filter biological solutions such as pure sera, serum solutions, as well as buffers.

mdi capsuringe offers an innovative capsule filter that can be used manually for small volume filtration directly with syringe.

mdi Filters for Buffer Clarification



mdi offers a wide range of Polypropylene Capsule filters for clarification applications. These capsule filters employ polypropylene filter media for wide chemical compatibility and high heat resistance.

These are available in a range of pore size, sizes and end connections to suit different process needs .

mdi Cartridge Filters for Haematology and Other Reagent Filtration

High flow rates, high throughput polyethersulfone membrane cartridge filters validated for bacterial retention. These are ideal for large volume filtration of biological solutions and reagents.

Transfer Membranes

mdi offers a wide range of binding membranes for western blots (Nitrocellulose and PVDF membranes), northern and southern blots (Nylon and positively charged Nylon membranes).

Special features

- High Signal- to-Noise ratio
- Minimal blow through
- Minimal background flourescence
- High binding capacity
- Superior handleability

Nucleic Acid Purification Kits

mdi offers innovative break through technologies for nucleic acid purification for research applications.

A wide range of validated kits are available for plasmid DNA, genomic DNA and RNA purification from a wide variety of samples such as mammalian cells and tissue (Blood tissue, plant tissue, bacterial and stools).

For detailed information on Filter products please ask for filter catalogs/visit our website:
www.mdimembrane.com

Frequently Asked Questions

Commercial

Question : How should I order? Who should I contact and how long does it take for material to arrive?
Answer : Orders may be placed by phone/Fax/email/mail directly to Sales at the address given on the back cover. The average lead time for ex-factory dispatch is 2-3 weeks. The average transit time is 5-10 days.

The material is shipped through FedEx or DHL Courier. Larger quantities are shipped by air freight. You need to specify your complete street address and port of discharge (for air freight). Any duties/taxes in the country of destination are the responsibility of consignee.

Question : How much is the freight for overseas shipments?
Answer : Membrane products are light weight and air freight charges usually vary between 3-10% of the value.

Question : I expect products from India to be cheaper. Are your membranes cheaper?
Answer : Ask for a quote. You may be pleasantly surprised.

Question : What are your production capacities?
Answer : **mdi** has been in business for more then 30 years. Several millions sq. ft. of membrane is produced every year. Capacities are always being expanded.

Quality

Question : How do you assure the quality of your products?
Answer : Quality is assured by adhering very strictly to specified, documented systems covering all aspects of membrane manufacture. Our quality management system is certified by UL-DQS, USA for ISO 9001 and ISO 13845 standards.

Question : In case of problem what support can I expect from mdi?
Answer : **mdi** will respond very quickly by assisting you in analysing the problem and isolating the source. All shipments have retained material. This retained material is crucial in identifying if the problem is coming from the membrane or not. Although very very rare, corrective action will follow including full replacement of the lot on priority if the problem is confirmed from the membrane.

Membranes

Question : What is different about mdi NC membrane compared to other brands?
Answer : Superior consistency and stability. Due to optimised surface chemistry and unique processing method **mdi** membranes are highly consistent, point to point as well as roll to roll.

Question : For lateral flow membranes, what is the significance of pore size?
Answer : Pore size is only a name designation. One manufacturer's pore size designation can be quite different from another's. Bigger pore size is designated for membranes with faster wicking rates.

Question : If pore size is only a name, how do you differentiate between different membranes?
Answer : The wicking time is an important parameter for lateral flow membranes. **mdi** membranes of designated pore size will exhibit highly repeatable wicking time.

Question : What is the difference between CNPF, CNPC and CNPH membranes?
Answer : CNPH and CNPC membranes are very high protein binding membranes and are helpful in achieving higher sensitivity in some assays. CNPF is a relatively low protein binding membrane. This choice of membranes helps achieve optimum assays.

Question : What is the shelf life of the membrane as received from mdi? Is there any precaution I should take in storing the membrane?
Answer : Properly stored, **mdi** NC membranes are stable for at least one year. Membrane should be kept away from high temperature and humidity. Whether in roll form or in laminate format, membranes must not be allowed to lie in the open for long periods.

Question : Do you have detergents/wetting agents in the membrane?
Answer : NC is a hydrophobic polymer. To be able to use the NC membrane successfully it is necessary to add a small amount of detergent or a combination of detergents. The amount is so small that it does not affect the binding properties of the membrane.

Question : Should I block the mdi membrane?
Answer : All **mdi** membranes exhibit stable wicking rates without blocking. It is possible to make many good assays without blocking. However, should there be a need to wet block the membrane for stabilizing the Ab, reducing nonspecific reaction, or improving the migration of conjugate particles, all **mdi** membranes can be blocked.

Question : I get broken lines while printing the reagent line and zones where membrane does not absorb the liquid. How can the problem be resolved?
Answer : If the NC membranes are allowed to stay in the open for a few days they tend to attract hydrophobic dust particles or other moieties which can cause above problem. Addition of 2-3% Isopropanol in the reagent formulation will help minimize above problem.

Frequently Asked Questions

Question : How much time should I wait for the Antigen/Antibody to bind on the membrane before an assay is run?
Answer : The binding of the protein to the NC membrane grows stronger as it is dehydrated more and more. Usually, at room temp, (20-30° C), the binding will reach a maximum in 3-5 days. For development, reasonable results can be expected with overnight drying at room temperature.

Question : The gold particles move very slowly and they do not clear after halfway up the membrane. Is this due to membrane?
Answer : The problem is in the chemistry of the conjugate, conjugate release pad, and the sample pad. Adding buffers to maintain pH at 7.4 and adding blocking agents such as PVP will help.

Question : Will serum migrate on mdi membranes?
Answer : Yes, serum and plasma migrate well on **mdi** membranes.

Question : I got a very faint shadow of false positive. I suspect the membrane. Please comment.
Answer : False positive is primarily due to nonspecific binding of the conjugate particles. Using bigger pore size membrane can help reduce this, usually at the cost of sensitivity. Addition of detergents in the sample pad can also help minimize it.

Question : My tests are not stable with time. Is the membrane to be suspected?
Answer : Membrane does not affect stability of the assay. It is related to the chemistry of the assay and many a times it improves by adding sucrose (0.5 - 1%) to the capture Antibody solutions.

Sample Pads

Question : How should I select a sample pad?
Answer : The sample pad should not bind proteins nonspecifically, should exhibit good flow characteristics, and have adequate volume capacity. Its thickness should be such that it fits in the test device.

Question : Are any additives added in the sample pad and why?
Answer : Sample pads may have many additives which a user can add to achieve desired results from the assay. The additives may be blocking agents for the membrane for rapid and uniform movement of conjugate particles, buffers to control the pH and improve specificity, detergents for improved flow and reduction of false positives.

Whole Blood Separator

Question : Why is a whole blood separator required?
Answer : Whole blood separator removes Red Blood Cells (RBC) to give free plasma so that analytes of interest may be detected directly from the blood sample without the need of centrifuge or clotting to get serum.

Question : What does a whole blood separator do in a lateral flow test?
Answer : Removal of RBC from blood is necessary for use of whole blood in lateral flow assays as RBC not only clog the membrane but can also hemolyse causing abortion of the test. **mdi** blood separators effectively stop RBC while allowing free plasma to migrate across the membrane with or without the driving buffer.

Question : How is blood separator used in a lateral flow test?
Answer : There are two ways in which whole blood test is accomplished in a lateral flow system.

a. By using a driving buffer supplied with the kit.
b. No buffer is used and plasma separated from whole blood itself migrates across the membrane to complete the test. Different blood separators are used for each case. The separators replace the normal sample pads in a lateral flow device.

Question : How much blood is required to be added in the whole blood test?
Answer : For assays with driving buffer, tests maybe made using as little as 5µl whole blood, whereas for tests without any buffer, 2-4 drops of blood is required.

Question : How much time does it take to complete the whole blood test?
Answer : A typical whole blood assay may take up to 10 minutes to complete.

Question : RBC tend to leak past most available separators. How is mdi separator system different from other brands?
Answer : Most blood separation systems rely on differential migration speeds of RBC and plasma in a matrix and when blood with high hematocrit is applied, the RBC leak past the separator onto the membrane. **mdi** blood separators virtually immobilize RBC where blood is applied and RBC do not go past the separator even with excess applied blood with high hematocrit.

mdi Quality

Quality Policy

Quality is built into **mdi** products and services by not only adhering to well designed quality systems to consistently produce high quality, internationally acceptable products but also by striving to incorporate superior performance parameters into all our products and services and provide our customers with a unique performance advantage in their application. Our quality policy provides a glimpse of our commitment:

"**mdi** strives to provide to its customers products and services of highest standards possible, consistently superior, and more satisfying than competing products and complying with quality management systems."

Stride Towards Excellence

At **mdi**, our mission is to constantly strive to achieve excellence in all our endeavors by establishing systems to create excellent products and services to fulfil the needs of our customers. To achieve this we

- Frequently compare our products with competing brands
- Simulate tests for functional use
- Develop easy-to-use innovative products

We are constantly working on improvements and welcome suggestions from our customers.

Guarantee

All **mdi** products are guaranteed and are backed by our

- Technical expertise and experience of over 40 years
- 'Special **mdi** processes' for consistency and repeatability
- Strict quality control and quality assurance regimen
- Certificate of Analysis accompanying all shipments

We have an unconditional replacement policy in case of any defects.

Quality and Services
UNCONDITIONAL GUARANTEE
Since 1976

WORLDWIDE EXPORTS

Other Literature available

mdi Laboratory Filtration Product Guide

mdi Biotech Product Guide

mdi Process Filtration Product Guide

www.mdimembrane.com

US Office

mdi Membrane Technologies INC.
75 Utley Drive STE 103
Camp Hill, PA 17011
Phone: +1-717-412-0943
Contact Person: Mr. Rohit Singhal
Email: rs@mdimembranetech.com
Website: www.mdimembranetech.com

For Diagnostic Queries Contact

Manoj Sharma
E-mail : diagnostic@mdimembrane.com
Mobile : + 91-97293 66221

Head Office

Advanced Microdevices Pvt. Ltd.

20-21, Industrial Area, Ambala Cantt-133 006, INDIA
Tel : +91-171-2699290, 2699471, + 91-9896394509
E-mail : info@mdimembrane.com

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