



sartorius stedim
biotech

UniSart® Nitrocellulose Membranes The Substrate of Choice for Protein Assays



turning science into solutions

Sartorius Stedim Biotech – A Reliable Partner

Sartorius Stedim Biotech is a leading international provider of integrated solutions for the biopharmaceutical industry. With our extensive portfolio of products, technologies and services, we cover wide areas of the biopharmaceutical process chain, ranging from fermentation, cell cultivation, filtration and purification to media storage and transportation.

Being the first industrial manufacturer of nitrocellulose membranes, Sartorius Stedim Biotech has developed an unmatched expertise in the production of various high quality nitrocellulose matrices.

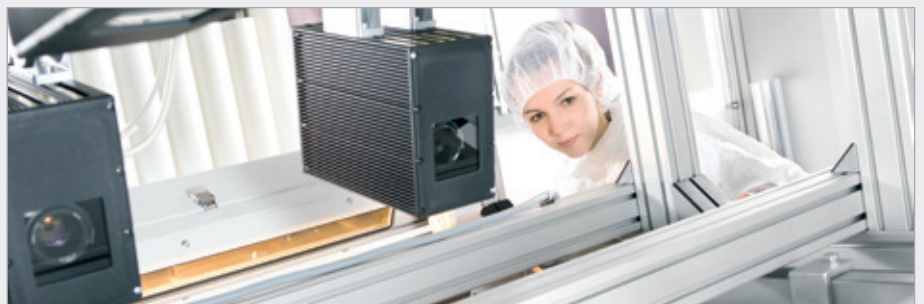
Sartorius Stedim Biotech is...



... Committed to the Industry

Sartorius Stedim Biotech is the partner for developers and manufacturers of protein tests based on nitrocellulose substrate.

Our company continuously seeks to improve the membrane portfolio to support our customers looking for a high quality, reliable and cost effective manufacturing of their assays and tests.





... Focused on Quality

Our products are developed, produced and distributed according to a Quality Management that is certified in compliance with ISO 9001.

All products must pass Sartorius Biotech's precisely defined in-house tests and therefore meet Sartorius Stedim Biotech's stringent quality control standards throughout all manufacturing steps.

... the Technology Leader

In-depth know-how in nitrocellulose membrane manufacturing as well as relevant application expertise are driving us to continuously improve our state-of-the-art manufacturing equipment, located in Göttingen, Germany.

This continuous thrive for improvement is resulting in a reliable supply of high quality nitrocellulose membranes, serving the demanding diagnostic and life science markets.

Nitrocellulose – The Substrate of Choice for Protein Assays

The popularity of the UniSart® nitrocellulose membranes as a major component of many rapid tests has been built on their prominent features.



Features & Benefits

- Availability on large Scale
- Wide Range of Applications
- High Protein Binding
- 3D Structure
The 3D microporous matrix allows liquids to flow in all directions
- High Consistency
High inter- and intra- lot consistency
- Excellent Performance
- Complete Traceability
- Reliable Supply
- Quality made in Germany



The UniSart® Product Portfolio



UniSart® CN Membranes for Lateral Flow Tests

When reliable capillary speed, homogenous thickness and defect free surface quality need to be combined to obtain high quality lateral flow tests, then the UniSart® CN 95, CN 110, CN 140, CN 150 and CN 180 are the membranes of choice.

Please find more details and ordering information on page 8.

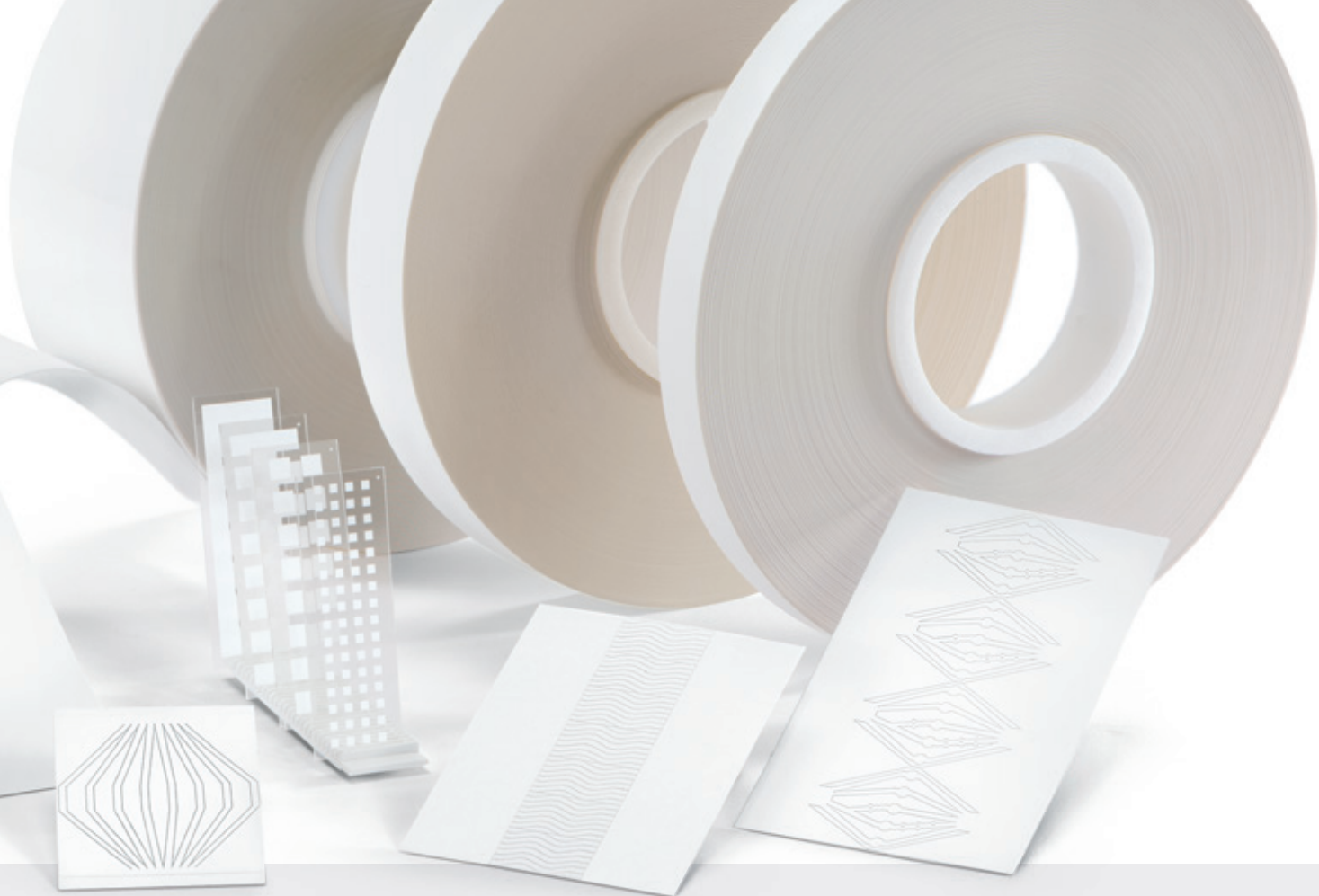


UniSart StructSure® Membranes for Multiplex Assays

These structured membranes have been developed through an innovative patterning process in order to better fulfill the need for rapid multiparameter tests.

Please find more information on page 14.





UniSart® CN Membranes for Blotting and Line Immuno-strips

This format is used when many parameters need to be assessed for a particular disease on patient serum. Accordingly, the nitrocellulose membrane is printed with many lines or spots of different recombinant antigens to detect the corresponding antibodies in patient blood.

Please find more details and ordering information on page 18.



UniSart® Microarray Slides

On a UniSart® microarray slide, the multiplicity of protein spots displayed in a sophisticated pattern allow to look for various molecular interactions simultaneously. Therefore, protein arrays, considerably accelerate the quest for new drug targets and disease markers.

Please find more details and ordering information on page 22.





UniSart® CN Membranes for Lateral Flow Tests

Membranes for Lateral Flow Tests

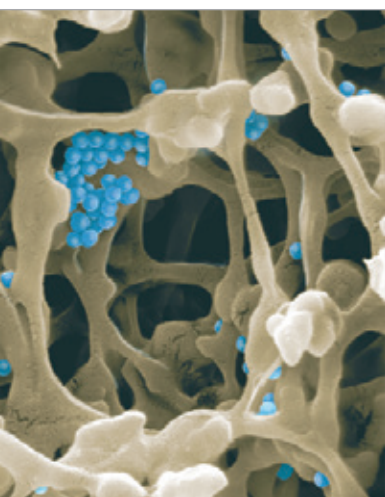
The UniSart® membranes with large pores have been designed to be the best substrate for the 3 billion and more rapid lateral tests manufactured and used every year around the world.

The role of the nitrocellulose in a lateral strip is highly critical. The membrane acts as the main motor of the test, drawing the samples and conjugates from one end of the strip to the other. Concurrently to their transport, the sample-conjugate complex can be captured by the reagents that are nested on the test and control lines. The UniSart® membranes have been developed to offer the features essential for highly reproducible readouts.

Although the affinity of the different molecules is a pivotal factor, the capillary speed and the surface quality of the membrane are also crucial parameters for a sensitive test. The UniSart® membranes have been engineered in order to show a clean and defined porous structure that leads to a consistent lateral wicking of samples and reagents. Their smooth and defect free surface allows for a consistent dispensing of sharp capture and control reagents lines.

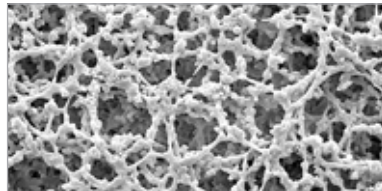
New state of the art casting machines enable the production of large batches of our different UniSart® membranes with high consistency. From many square meters of one batch down to the few square centimeters of a lateral strip, our stringent QC and labelling allow for a consistent membrane with a precise traceability.

The UniSart® membranes will perfectly fit all diagnostic manufacturer production needs from thousand strips on manual cards to million strips on reel to reel equipment. All production steps including laminating, dispensing, drying, blocking, assembling and packaging are considerably improved when UniSart® membranes are used as revealed by the absolute final yields.

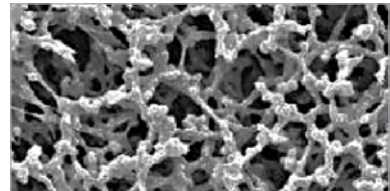




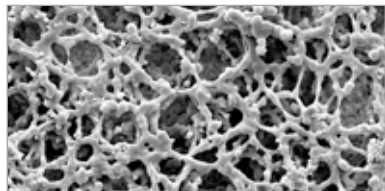
SEM's



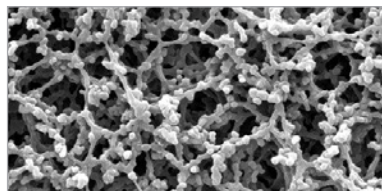
CN 140



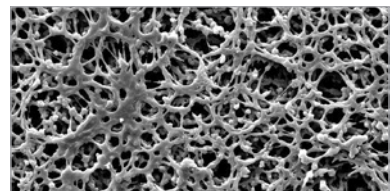
CN 95



CN 150



CN 110



CN 180



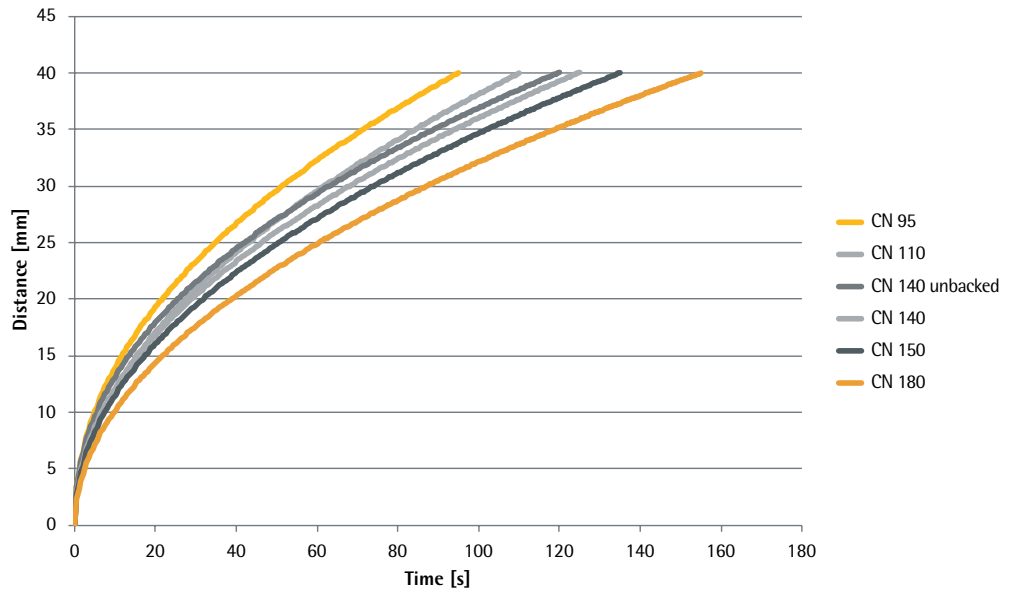
Specifications & Characteristics

UniSart®	CN 95 backed	CN 110 backed	CN 140 unbacked	CN 140 backed	CN 150 backed	CN 180 backed
Membrane material	cellulose nitrate	cellulose nitrate	cellulose nitrate	cellulose nitrate	cellulose nitrate	cellulose nitrate
Backing	100 µm polyester, clear	100 µm polyester, clear	none	100 µm polyester, clear	100 µm polyester, clear; 100 µm polyester, white	100 µm polyester, clear
Thickness (µm)	240 – 270	185 – 215	120 – 160	225 – 255	240 – 280	225 – 255
Capillary speed down web, purified water (s/40 mm)	65 – 115	90 – 130	90 – 150	95 – 155	90 – 180	135 – 175
Visual appearance	All UniSart® membranes offer a white, flat and smooth surface, free of macroscopic defects and foreign matter. They are all 100% inspected by backlight inspection.					
Wettability	Precise amount of anionic surfactant allows for fast wetting					



UniSart® Diagnostic Membranes

Capillary speed graph





Choose the Best Membrane for Your Application

UniSart®	CN 95 backed	CN 110 backed	CN 140 unbacked	CN 140 backed	CN 150 backed	CN 180 backed
Backing	100 µm clear	100 µm clear	none	100 µm clear	100 µm clear 100 µm white	100 µm clear
Background clearing	very fast	very fast	fast	fast	fast	medium
Time-to-signal	fast	medium	medium	medium	medium	medium
Quick response tests	most suitable	Suitable, depending on migration distance	Suitable, depending on migration distance	Suitable, depending on migration distance	Suitable, depending on migration distance	Suitable, depending on migration distance
Sensitivity	good	very good	very good	very good	very good, white backing perfectly suitable for immunofluorescent readout	very high
Viscous samples	very good	good	good	good	good	medium
Particle loaded samples	very good	good	good	good	good	medium
Backing as barrier against card glue	yes	yes	no, cards need to be selected carefully	yes	yes	yes
Contact dispensing equipment	suitable	suitable	suitable	suitable	suitable	suitable
Non- contact dispensing equipment	suitable	suitable	suitable	suitable	suitable	suitable
Reel- to- reel manufacturing	suitable	suitable	needs careful handling	suitable	suitable	suitable

Roll Specification

Plastic roll core	76.8 mm; (3")
Certificate of analysis	provided with each delivery
Membrane width	17 – 300 mm (+ – 0.5 mm)

Membrane wound with yellow interleaving protection paper between the membrane layers.

Ordering Information

UniSart® Membrane	Polyester Backing	Width [in mm]	Length [in m]	Max. Splices	Units Box	Catalog Number
CN 95 backed						
CN 95	100 µm clear	20	50	0	5 rolls	1UN95ER050020WSB
CN 95	100 µm clear	25	50	0	5 rolls	1UN95ER050025WSB
CN 95	100 µm clear	30	50	3	5 rolls	1UN95ER050030--B
CN 95	100 µm clear	20	100	3	1 roll	1UN95ER100020NT
CN 95	100 µm clear	22	100	3	5 rolls	1UN95ER100022NTB
CN 95	100 µm clear	25	100	1	5 rolls	1UN95ER100025KSB
CN 95	100 µm clear	25	100	3	5 rolls	1UN95ER100025NTB
CN 95	100 µm clear	28	100	3	5 rolls	1UN95ER100028NTB
CN 95	100 µm clear	30	100	3	5 rolls	1UN95ER100030--B
CN 95	100 µm clear	35	100	3	5 rolls	1UN95ER100035NTB
CN 95	100 µm clear	40	100	0	1 roll	1UN95ER100040WS
CN 95	100 µm clear	70	100	0	1 roll	1UN95ER100070WS
CN 110 backed						
CN 110	100 µm clear	20	100	3	5 rolls	1UN11ER100020NTB
CN 110	100 µm clear	25	100	3	1 roll	1UN11ER100025NT
CN 110	100 µm clear	25	100	3	5 rolls	1UN11ER100025NTB
CN 140 unbacked						
CN 140	none	20	50	3	5 rolls	1UN14AR050020--B
CN 140	none	25	50	3	5 rolls	1UN14AR050025--B
CN 140	none	20	100	3	5 rolls	1UN14AR100020NTB
CN 140	none	20	100	0	5 rolls	1UN14AR100020WSB
CN 140	none	25	100	3	5 rolls	1UN14AR100025NTB
CN 140	none	25	100	0	5 rolls	1UN14AR100025WSB
CN 140	none	35	100	3	5 rolls	1UN14AR100035NTB
CN 140	none	40	100	3	1 roll	1UN14AR100040NT
CN 140	none	270	100	3	1 roll	1UN14AR100270NT





UniSart® Membrane	Polyester Backing	Width [in mm]	Length [in m]	Max. Splices	Units Box	Catalog Number
CN 140 backed						
CN 140	100 µm clear	20	50	3	5 rolls	1UN14ER050020--B
CN 140	100 µm clear	25	50	3	5 rolls	1UN14ER050025--B
CN 140	100 µm clear	25	50	0	5 rolls	1UN14ER050025WSB
CN 140	100 µm clear	18	100	3	5 rolls	1UN14ER100018NTB
CN 140	100 µm clear	20	100	3	1 roll	1UN14ER100020NT
CN 140	100 µm clear	20	100	3	5 rolls	1UN14ER100020NTB
CN 140	100 µm clear	25	100	3	1 roll	1UN14ER100025NT
CN 140	100 µm clear	25	100	3	5 rolls	1UN14ER100025NTB
CN 140	100 µm clear	28	100	3	5 rolls	1UN14ER100028NTB
CN 140	100 µm clear	35	100	3	5 rolls	1UN14ER100035NTB
CN 140	100 µm clear	40	100	0	5 rolls	1UN14ER100040WSB
CN 140	100 µm clear	70	100	0	1 roll	1UN14ER100070
CN 140	100 µm clear	270	100	3	1 roll	1UN14ER100270NT
CN 150 backed						
CN 150	100 µm clear	20	50	3	5 rolls	1UN15LR050020NTB
CN 150	100 µm clear	25	50	3	5 rolls	1UN15LR050025NTB
CN 150	100 µm clear	20	100	3	5 rolls	1UN15LR100020NTB
CN 150	100 µm clear	25	100	3	1 roll	1UN15LR100025NT
CN 150	100 µm clear	25	100	3	5 rolls	1UN15LR100025NTB
CN 150	100 µm white	25	50	0	5 rolls	1UN15WR050025WSB
CN 150	100 µm white	25	100	3	1 roll	1UN15WR100025NT
CN 150	100 µm white	25	100	3	5 rolls	1UN15WR100025NTB
CN 180 backed						
CN 180	100 µm clear	20	100	3	5 rolls	1UN18ER100020NTB
CN 180	100 µm clear	25	100	3	1 roll	1UN18ER100025NT
CN 180	100 µm clear	25	100	3	5 rolls	1UN18ER100025NTB

Customized dimensions of UniSart® CN membranes are also available upon request.

For further information and customized dimension please contact us:
 UniSart@sartorius-stedim.com



UniSart StructSure® Membrane

The innovative way to build your own multiparameter assay on nitrocellulose membrane with microfluidic design.

Up to now, the features of nitrocellulose membranes have been essentially exploited in simple longitudinal strip or vertical flow through devices where the membrane is limited to simple rectangular or circular shape.

Sartorius Stedim Biotech has now developed a new technology to engraving different patterns into a nitrocellulose membrane. This innovative process leads to the creation of a hydrophobic barrier delineating the membrane zones. The remaining membrane stays fully functional.

Such a UniSart StructSure® membrane can act like a microfluidic device, the pump function being fulfilled by the natural capillary force of the membrane and the liquid being conveyed and restricted within a given path as the hydrophobic trenches prevent any overflow of the liquid. Multiple lanes network with separate reaction and mixing zones or complex lane network with joint reaction zones can all be created.

The UniSart StructSure® membrane can be produced and handled in a way compatible with the existing rapid test equipment. Moreover, various UniSart® nitrocellulose membranes used in lateral flow application are compatible with this innovative process.





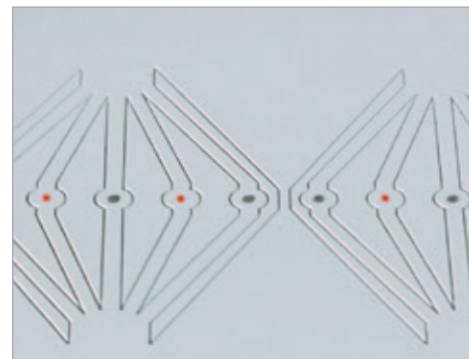
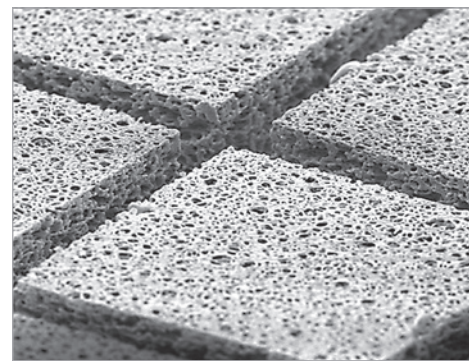
Multiparameter Lateral Flow Strip

To fulfill the needs for multiplex readout while keeping the simple rapid test format, manufacturers have developed lateral flow tests with manifold capture line across the strip.

These strips have a limited number of lines due to drawbacks like the decreasing of capillary flow speed with increasing distance from the origin, the modification of the sample after passage through the multiple lines and finally a loss of sensitivity with the depletion of conjugates.

With the UniSart StructSure[®] membrane, a new generation of lateral flow strips can be created.

As shown in the example here included, a lateral flow membrane is designed with individual isomorphic lanes, each leading to separate test and control zones. In addition to enabling the positioning of individual reaction zones, the channeling of the liquid also has a positive impact on the generated signal intensity. Indeed, the hydrophobic barriers are likely to restrict the side flow of the reagents. UniSart StructSure[®] is currently available on a customized basis.



Structure engraved in UniSart[®] membrane showing a clear cut between the erased and the remaining nitrocellulose membrane zones.

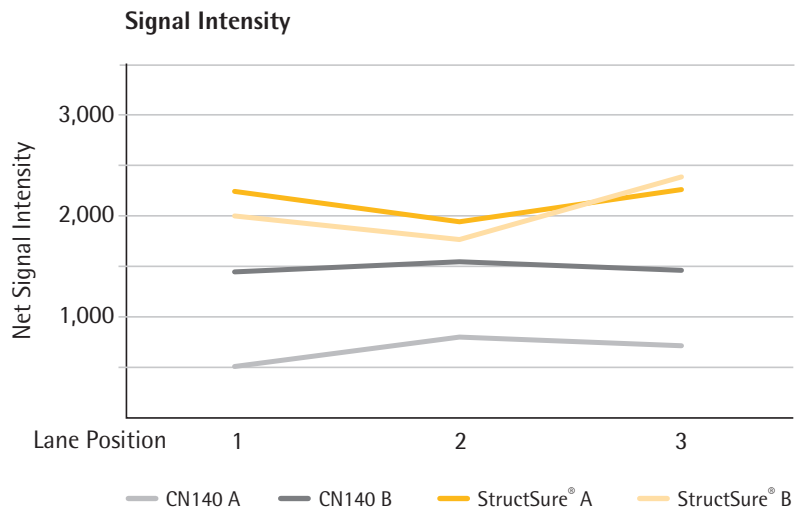
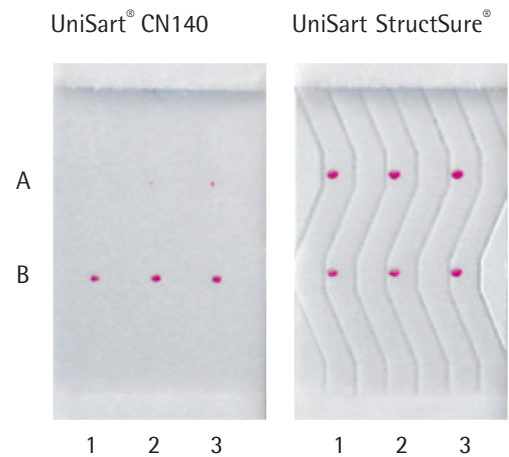


Example n°1

The lateral flow strip prepared with the UniSart® membrane confirms that a significant decreased signal intensity is observed on capture spots positioned behind a first row of spots with the same capture reagents. This decrease is largely due to the loss of conjugate after the reaction on the first row.

In contrast, on the strip build with a UniSart StructSure® membrane, the downstream capture spots are showing the same signal intensity as the first row of spots. Thanks to the isomorphic lanes, the second row of capture spots has received the same amount of sample and conjugate as the first row.

- Significant decreased signal intensity on capture spots of row A compared to row B on UniSart® CN 140 membrane
- Capture spots show similar signal intensity on both rows with a UniSart StructSure® membrane

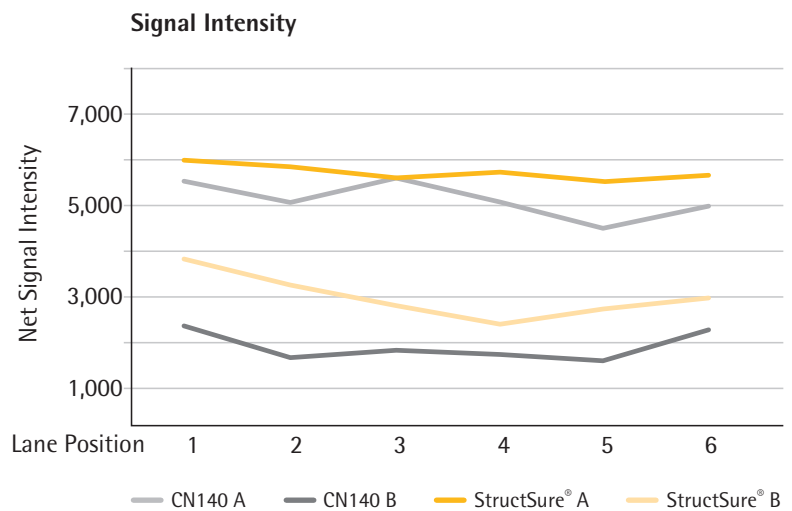
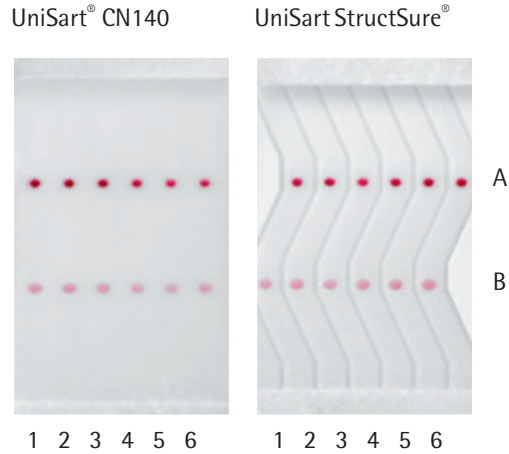




Example n°2

In this second example, the test spots are in the first row and the control spots are in the second row of the strips. The capture spots positioned on the UniSart StructSure® membrane are showing increased intensity compared to the ones on the UniSart® membrane. Indeed, the restrictions in the liquid flow brought by the addition of individual lanes are assisting the binding of the conjugated particles on the reaction spots.

- Signal intensity increased in individual channel vs. inherent membrane
- Signal intensity homogenous in all 6 channels of UniSart StructSure® membrane
- The membrane zones that are individually served with native reagents facilitate a high quality readout for multiple parameters



If you have a new product that contains multiparameter readouts, we will be glad to realize the substrate for your needs.

Contact us: UniSart@sartorius-stedim.com



UniSart[®] Membranes for Immuno-strips and Blotting

Immuno-strips

Line or dot blot strips are widely used for in vitro diagnostic tests. Many infectious diseases generate a complex immune response and require an antibody profiling of the patient serum. To do so, the different immuno-dominant antigens have to be applied in line or dots onto a uniform binding substrate. Today, long after the first membrane was used in blotting, the nitrocellulose membrane is still the best substrate for proteins.

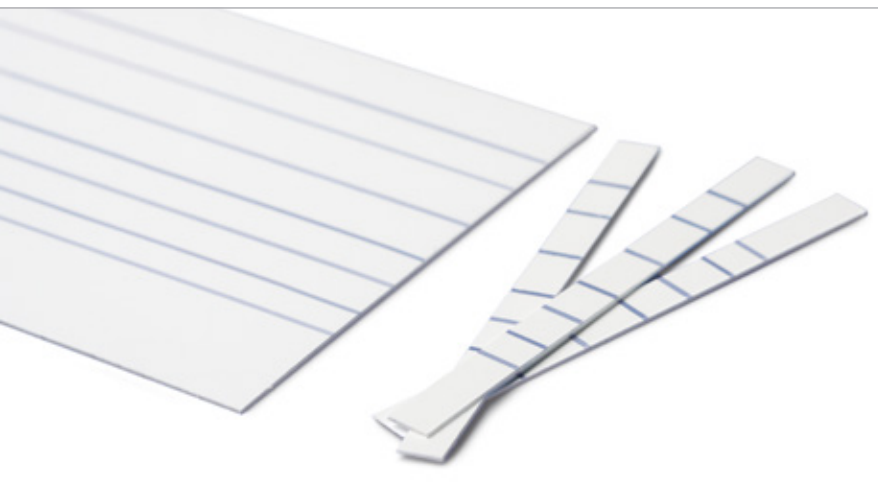
The UniSart[®] 0.22 μm and 0.45 μm nitrocellulose membranes have been designed to show exceptional consistency in IVD blot strips.

Blotting

The UniSart[®] 0.22 μm and 0.45 μm membranes are well adapted to all protein blotting systems including electro transfer, semi-dry, vacuum or simple capillary blotting. They can be easily cut to the desired dimensions. Under the electrical field and the capillary drive, proteins move out of the gel into the UniSart[®] membrane which captures them instantly.

The staining of the transferred proteins can easily be done with methods like Ponceau S or SyproRuby staining. After protein transfer, the UniSart[®] nitrocellulose can be processed according to standard immunostaining protocols.

The antibody-antigen complex can be revealed on the membrane with different detection methods based on colorimetric, chemiluminescent and fluorescent signals. The label can be conjugated to specific molecules or even particles, similar to the one used in lateral flow immunoassays. Due to the production process, the non-supported nitrocellulose membranes like the UniSart[®] 0.22 μm and 0.45 μm , always present two different surfaces, the air and belt side. Each side shall be first evaluated to select the one of choice.

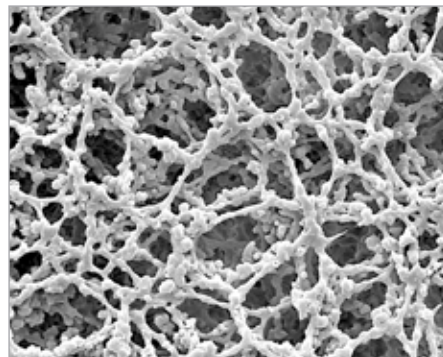
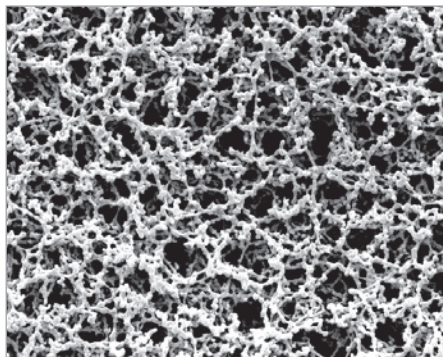




Line and Dot Printing

Today, most markers of interest can be generated through recombinant techniques in a pure state and large quantities. Consequently, these proteins can easily be dispensed in line or dots onto the membrane rather than to be transferred from a gel. The smooth surface of the UniSart® 0.22 μm and 0.45 μm allows for an easy dispensing either with contact tips or non-contact nozzles, allowing for sharp lines or spots.

The UniSart® 0.22 μm and 0.45 μm membranes show an optimized structure for blotting. The small pore size membranes allow for a high protein binding capacity onto the sponge like 3D matrix. Furthermore, the high ratio of pores allow for a fast flow through the membrane.



Scan Electron Microscope photo of the 0.22 μm membrane and 0.45 μm (@ 4000x)

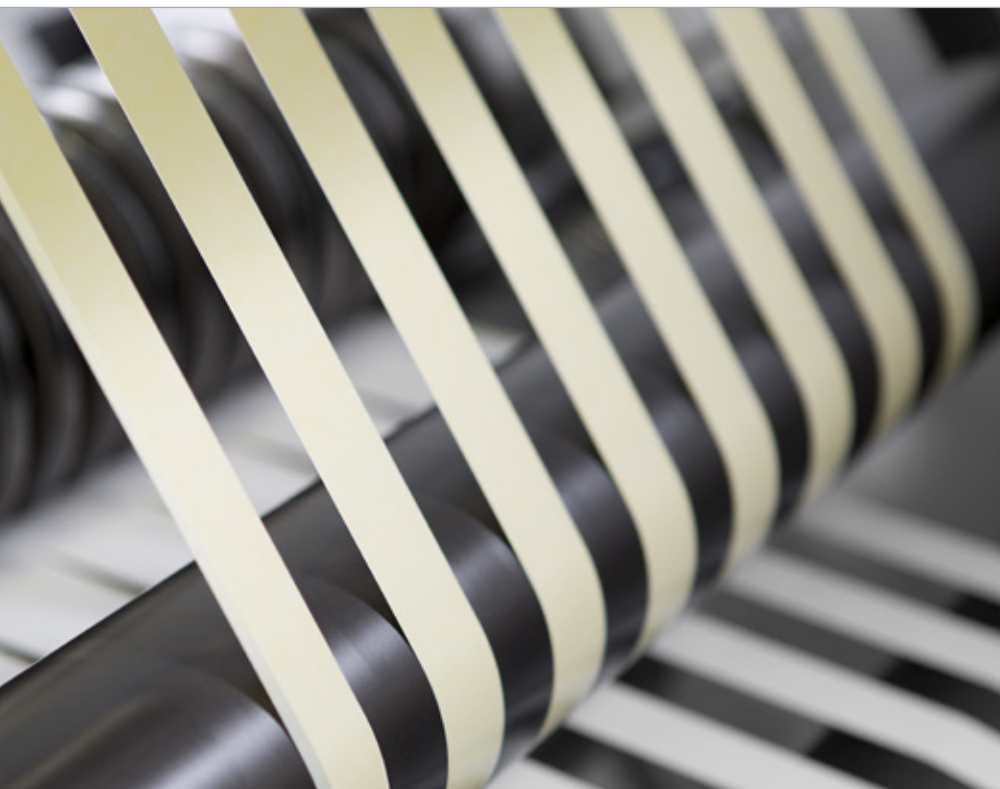


Typical Parameter Value of the UniSart® 0.22 µm and 0.45 µm

UniSart® Blotting Membrane	0.22 µm	0.45 µm
Flow rate for water [ml/(min. cm ² bar)]	27	70
Bubble point with water [bar]	4.4	2.4
Extractable content in water [%]	< 1	< 1
Thickness [µm]	120	130
Burst pressure [bar]	0.8	0.2
Wetting with water [secs]	< 1	< 1

Membrane wound with yellow interleaving protection paper between the membrane layers.

UniSart StructSure® membranes can also be designed on small pore size nitrocellulose to create multiplex blot cards to better distinguish each test zone.





Ordering Information

UniSart® CN Blotting Membrane	Backing Polyester	Width [in mm]	Length [in m]	Max. Splices	Units Box	Catalog Number
0.45 µm	none	300	50	3	1 roll	11306-----77
0.2 µm	none	140	0.18	n a	200	11327-140-180--S
0.2 µm	none	110	0.16	n a	100	11327-160-110--N
0.2 µm	none	64.5	50	3	1 roll	11327-----184
0.2 µm	none	160	50	3	1 roll	11327-----185
0.2 µm	none	230	0.22	n a	100	11327-230-220--N
0.2 µm	none	480	0.13	n a	500	11327-480-130--Q
0.2 µm	none	300	50	3	1 roll	11327-----77

Customized dimensions of UniSart® CN membranes are also available upon request.

For further information please contact us:
UniSart@sartorius-stedim.com

UniSart® Microarray Slides

UniSart® Microarray slides are engineered for consistent protein microarrays.

UniSart® Microarray slides

For the new generation of protein arrays, Sartorius has developed glass slides coated with a thin microporous nitrocellulose membrane.

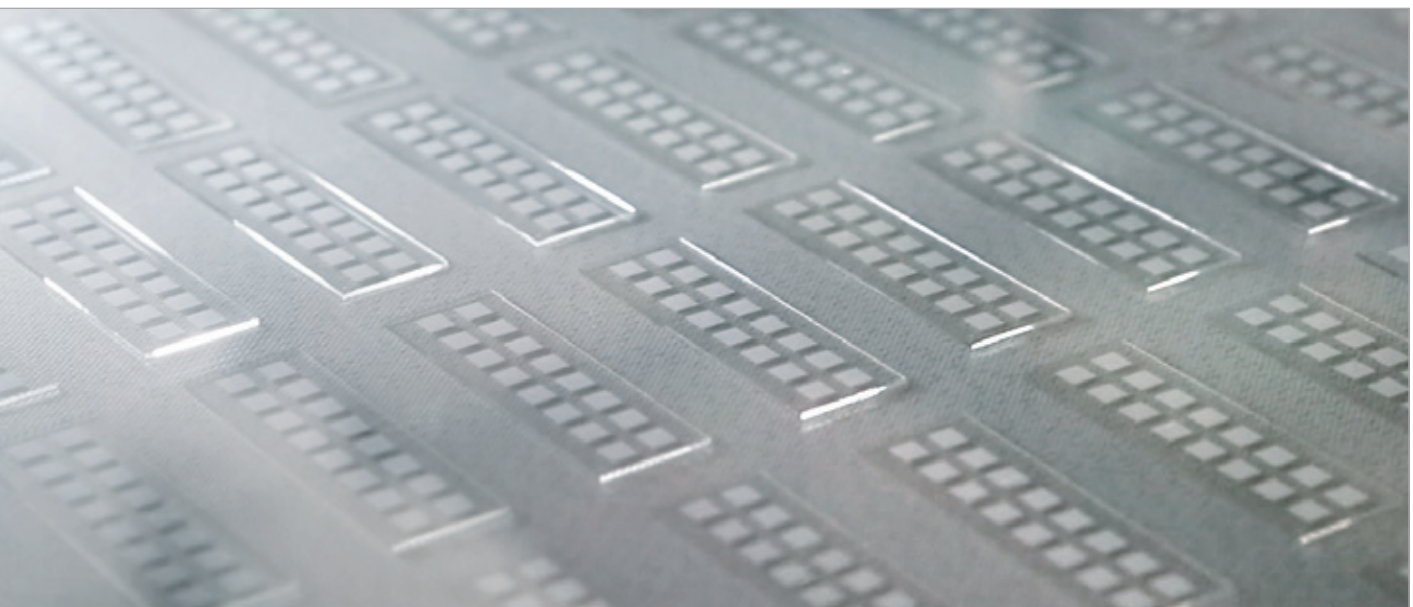
Nitrocellulose membranes are the substrate of choice when it comes to protein-based assays. Widely used in electrophoresis blotting techniques and new rapid diagnostic immunoassays, the classical nitrocellulose membranes needed to be reengineered to best fit the protein array applications.

The UniSart® Microarray slides have an optimized nitrocellulose membrane with

- a high signal to noise ratio (>50) at very low protein concentrations (pg-fg)
- a very low background of the native array slide
- a perfect spot geometry

The inherent nitrocellulose properties like: a fast protein attachment without additional chemistry and a good preservation of functional structure as well as a high protein binding capacity per μm^2 add to the advantages of this particular substrate.

Modified glass surface has become the most widely used substrate for nucleic DNA arrays. However, proteins are very different from nucleic acids. They are heterogeneous with limited stability while DNAs are uniform and stable. Proteins easily lose their activity through denaturation and dehydration as DNAs keep their activity even when denatured. In addition, protein chemistry is more complex with limited amplification methods available. All these differences support the needs of an alternative solid substrate for protein-based arrays.





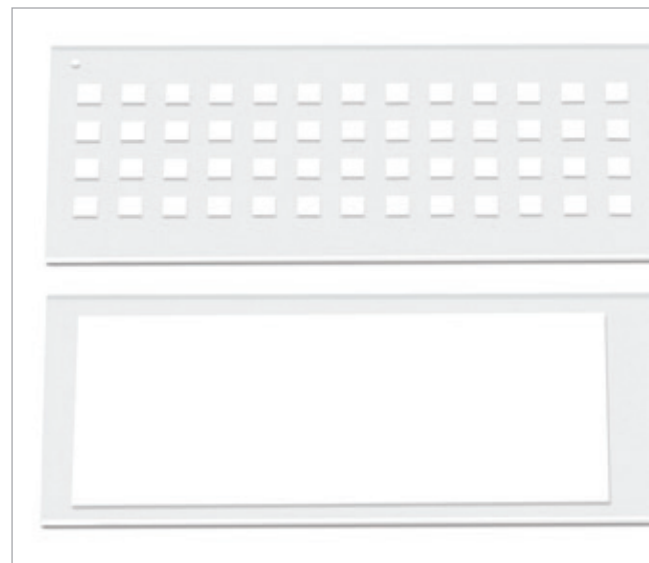
The UniSart® Microarray slides have been designed to be the best substrate for protein array application like:

**Forward Protein Array
(or Capture Protein Array)**

Small amount of pure known proteins are spotted onto the slide. More than 15 000 active spots can be created. Once placed in contact with one sample, it will allow for the simultaneous reaction of the sample with all the spotted molecules.

**Reverse Phase Protein Array
(or Lysate Protein Array)**

In a reverse phase protein microarray, multiple micro volume of cell lysate, tissue samples or even body fluids are spotted onto the slide. The reverse phase array is then incubated against one single specific marker, usually a high quality antibody.



After several years of development, a new manufacturing process has been designed. This new validated robotic equipment enables manufacturing the new UniSart® Microarray slides with an unmatched membrane consistency.

The new production process brings the following advantages:

- Tightest thickness specification with $\pm 1 \mu\text{m}$ maximum variation. A constant thickness will allow for an homogeneous membrane structure and thus a uniform protein binding and spot morphology.
- Consistent and larger batches. The new process enables the production of NC-coated slides on a continuous mode. This offers the guaranty for better intra- and inter lot consistency.



Specifications

Glass slide

Dimensions are the industrial standard in order to fit with instruments used by the microarray society.

Material: borosilicate glass

Dimension:

Thickness: $1 \text{ mm} \pm 50 \mu\text{m}$

Length: $75.6 \text{ mm} \pm 50 \mu\text{m}$

Width: $25.0 \text{ mm} \pm 50 \mu\text{m}$

Membrane pad

Material: Nitrocellulose

Thickness in μm : $12.5 \mu\text{m} \pm 2.5$

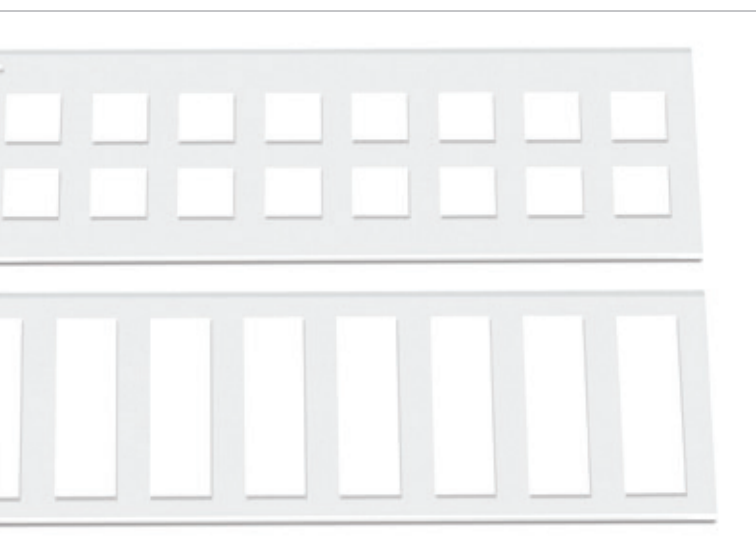
Wetting time ($2 \mu\text{l}$ test solution): 180 s

Cleanness:

Slides are 100 % visually inspected and show a white membrane, free of macroscopic defects, without visible marks, stains, dust or foreign matter.

Pad dimension:

according format, tolerance $\pm 0.2\text{mm}$





Ordering Information

Description

UniSart® Microarray slide with one nitro-cellulose membrane pad 51 mm on 21 mm or 60 mm on 21 mm and a bar code label, box of 25 slides

Catalog Number
2UNY2GW060021M

Description

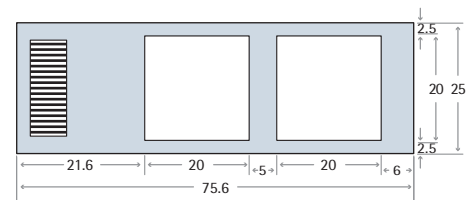
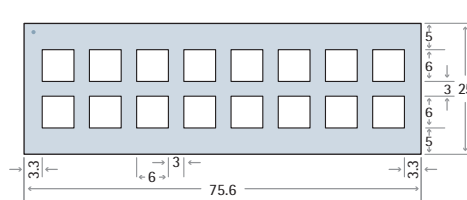
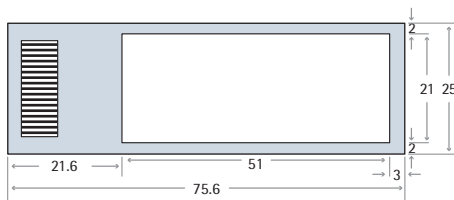
UniSart® Microarray slide with 16 nitrocellulose membrane pads 6 mm on 6 mm, box of 25 slides

Catalog Number
2UNY2GW00600616G

Description

UniSart® Microarray slide with two nitrocellulose membrane pads 20 mm on 20 mm and one bar code label, box of 25 slides

Catalog Number
2UNY2GW020020M2G



UniSart® Microarray Slide with Custom Pad

Various custom pads can be easily produced with the new manufacturing process. Pads can be of any size within the limit of the standard glass slide or within the 96 platze size.

Ask us for prototypes and a quote for minimum quantities:

UniSart@sartorius-stedim.com

UniSart® Nitrocellulose

Storage, Handling and Shelf Life

Storage and Handling

Keep away from open fire, any sources of heat, light and chemical vapours of any kind. Constant temperatures between 15 – 25°C and a relative humidity of maximum 60% are best for storage and handling of the membrane. Very dry or humid storage conditions might alter the wettability and handling properties of the membrane. This change is only temporarily and can be overcome by conditioning the membrane at rel. humidity between 40 – 60% for approx. 12 hours before processing the membrane.

After unpacking the membrane, please avoid any direct contact to the membrane. Please also avoid any direct contact of the membrane to materials that have the potential to release chemicals or additives into the membrane (e.g. cardboard, plastic ...). Adsorption or absorption of such substances may alter the membrane properties like wettability. Nitrocellulose membranes are highly flammable. Always keep the membrane separated by the interleaving paper as originally supplied. A material safety data sheet accompanies each shipment of material. Please make sure that the membrane is always handled according to local laws.

Shelf Life Information

For UniSart® nitrocellulose-based substrates, the shelf life is:

- UniSart® Membranes for Lateral Flow: 3 years after manufacturing
- UniSart® Membranes for Line Blot or Blotting Application: 3 years after manufacturing
- UniSart StructSure® Membranes: 3 years after manufacturing
- UniSart® Microarray Slides: 1 year after manufacturing

The shelf life is clearly labelled as “use before” or “expiry date” on each Certificate of Analysis. The certificate accompanies each box of product. The shelf life is only guaranteed for originally packed material. Once the UniSart® Membrane | Microarray slide has been built into an OEM device or has been altered in any way, it is highly recommended that the manufacturer of such devices determines the shelf life of the final device.





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