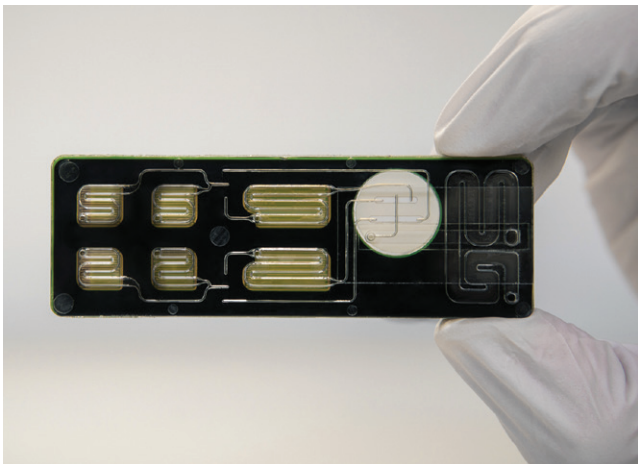
GORE® Microfiltration Media
In-Vitro Diagnostic
Applications

DEVELOP MOLECULAR DIAGNOSTIC (MDx) PANELS WITH CONSISTENT AND PRECISE FLUID MOVEMENT

GORE® Microfiltration Media help design engineers and program managers of Original Equipment Manufacturers (OEMs) and Contract Development Manufacturing Organizations (CDMOs) of diagnostics equipment and consumables to develop molecular diagnostic (MDx) panels with consistent and precise fluid movement thus enabling accurate and reliable test results. Unlike other filter or vent options Gore's vent solutions are engineered to work with aggressive reagents and solvents giving more degrees of freedom in cartridge design enabling the most cost-effective designs.



Microfluidic chip component within a Diagnostic panel vented with Gore Microfiltration Media.

Reliable real-time intelligence has never been more critical in healthcare. 70% of clinical decisions are made from in-vitro diagnostics (IVD) test results.[1,2] Molecular Diagnostics (IVD) equipment and consumables are the fastest growing segment of the broader diagnostics market.[3] There is a strong desire to determine a patient's disease during an office or clinic visit at the point-of-care (POC). If the disease can be identified during the visit tremendous benefits in healthcare can be achieved. Growth is driven by:

- Expanding beyond infectious diseases to reproductive health and cancer
- Discovery of genetic biomarkers with proven clinical utility
- Increased adoption of genetic-based diagnostic tests
- Expansion of reimbursement programs to include a greater number of approved MDx tests
- Miniturization of MDx devices
- Decreased costs for MDx tests

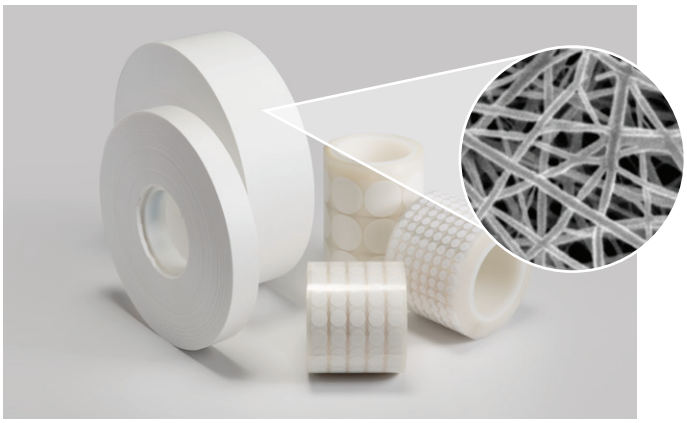
1. https://www.cdc.gov/csels/dls/strengthening-clinical-labs.html
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5759162/
3. Molecular diagnostics 2020-2030 Technologies, markets and forecast, IDTechEx Research

Together, improving life

Key Features and Benefits

- Flexible form factors for easy integration into Diagnostic consumable cartridges
  - – Cut Parts
  - – Roll Goods
- Application Engineering support for ease of integration
- Variety of engineered materials to achieve optimum ratio of airflow (pressure equalization) to liquid barrier properties.
- Scalable from bench scale prototypes to high volume production
- Certificate of compliance supplied with each shipment
- Typical Physical Properties:
  - – Pore Size: 0.45 um
  - – Airflow: 24 L/hr/2.99 cm^2 (normalized to 0 °C and 12 mbar pressure drop)
  - – Thickness: 0.19 mm, (0.007 inches)
  - – Water Entry Pressure: 294 kPA, (43 psi)
    - • Maintains barrier properties under pressure with various liquids
    - • Allows airflow after exposure to liquid
  - – Oil Rating minimum 6

Unique Filter Membrane



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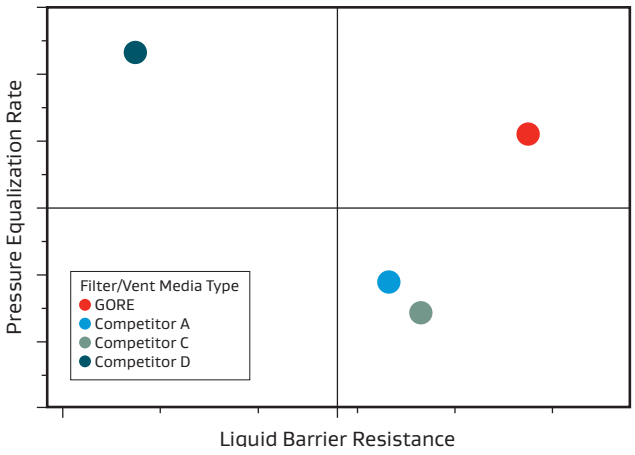
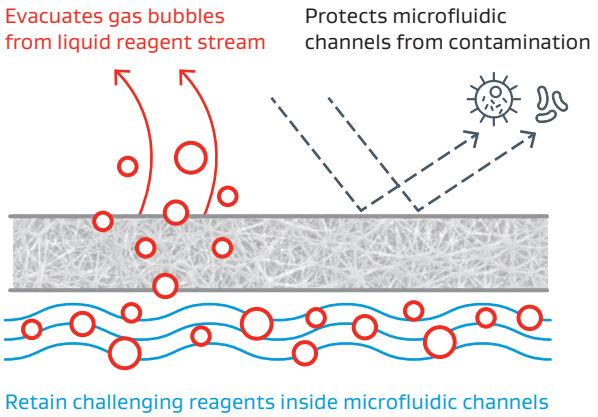
Performance summary vs competition



Gore Diagnostic Media provides the optimal combination of pressure equilization rate and resistance to aggressive liquids which may enable optimized microfluidic designs (ex. More analytes per unit area, allow the use of low surface energy reagents, etc.)

Key Features



Operating Conditions

Thermal Resistance to handle temperature cycles ambient to 100 °C

Chemical resistance to handle wash buffers and typical diagnostic reagents.

Regulatory Compliance

- GORE® Microfiltration Media are manufactured following the applicable material quality and regulatory requirements.
- Please contact Gore for current applicable compliance statements

Quality Statement

- GORE Microfiltration Media are manufactured following the applicable material quality requirements, including relevant Good Manufacturing Processes as defined in the Gore PharmBIO quality system which is certified to ISO 13485.
- Each produced lot is controlled according to agreed specification and lot data can be provided with a Certificate of Analysis.
- For quality control information: contact GORE for more information.

Controlled Environment

- Assembly operations, final inspection, and packaging for GORE Microfiltration Media are conducted in a cleanroom environment that employs a non-viable particulate monitoring program consistent with particle levels as defined for ISO 8 designation.

Gore PharmBIO Products

Our technologies, capabilities, and competencies in fluoropolymer science are focused on satisfying the evolving product, regulatory, and quality needs of pharmaceutical and bioprocessing customers, and medical device manufacturers. The products in the Gore PharmBIO Products' portfolio, are tested and manufactured under stringent quality systems. These high-performance products provide creative solutions to our customers' design, manufacturing, and performance-in-use needs.

All technical information and advice given here is based on our previous experiences and/or test results. We give this information to the best of our knowledge, but assume no legal responsibility. Customers are asked to check the suitability and usability of our products in the specific applications, since the performance of the product can only be judged when all necessary operating data is available. Gore's terms and conditions of sales apply to the purchase and sale of the product.

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