



Certified Pure Porex™ Materials and Filters

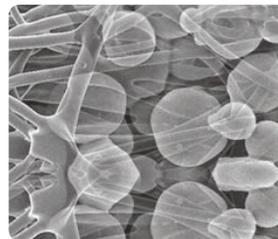
Life Sciences | Clinical Sciences | Medical Devices



Comprehensive Technical Performance and Media Certification Program*

- Non Cytotoxic
- Non Hemolytic
- Clinical Laboratory Methodology Compatibility
- Heavy Metal and Inorganic Element Non Interference
- Filter Media Purity
- 99.9% Bacterial Aerosol Filtration Efficiency

Think Pure. Think Porex.



Known for its innovative solutions, Porex brings a wealth of experience to the design and manufacture of porous plastics, porous polymeric fibers, porous glass fiber media, porous composites, functionalized porous media, bio-activated porous media and other high performance porous materials.

Rigorously tested by third-party analytical, clinical and life cycle microbiology laboratories, Certified Pure Porex Materials and Filters help meet the requirements for developing complex and demanding healthcare and life science products. In addition to product innovation, Porex now offers the advantages and peace of mind provided using certified filtration, venting, separation and wicking products.



Certified Pure Porex™ Materials and Filters

Life Sciences | Clinical Sciences | Medical Devices

The best results come from the best materials.

Optimal results demand quality media. Certified Pure Porex Materials and Filters were rigorously tested by third-party analytical, clinical and life cycle microbiology laboratories to help insure performance, accuracy and reproducibility in demanding healthcare and life science applications. The Pure Porex™ Certification designation substantiates the following for critical Porex healthcare and life science products.*

- Filter Media Purity
- No Heavy Metal Interference
- No Other Inorganic Element Interference
- Clinical Laboratory Methodology Compatibility

Hemocompatibility

Various Porex materials and filters were tested by an independent, life cycle microbiology laboratory using Modified ASTM F 756-08 Hemolysis (Direct Contact Method) GLP with human blood to determine the hemolytic index and hemolytic grade.

The tested Porex materials and filters were shown to be non-hemolytic with a hemolytic index ranging from 0.00% to <0.75%.*

Cytotoxicity

Independent, life cycle microbiology laboratory testing using ISO 10993-5 MRM (Minimal Essential Media) Elution, GLP Compliant test method.*

Extracts of various Porex material and filters were added to cell monolayers and incubated. The cell monolayers were examined and scored based on the degree of cellular destruction. No cell lysis or intracytoplasmic granules reported.

Bacterial Aerosol Filtration Efficiency

Porex tested various materials using test methods that conform to ASTM F2102 to determine the bacterial filtration efficiency (BFE) of these materials using a ratio of bacterial challenge counts to sample effluent counts in order to determine a percent BFE (BFE %). These tests were conducted at an independent, outside laboratory located in the United States.*

Test results showed the following materials had a BFE of >99.9%.**

Material	Pore Size	Thickness
Self-Sealing Plug	7-10 µm	5 mm
Super Filter Plug	7-10 µm	5 mm
Super Filter Sheet	7-10 µm	3.4 mm
Super Absorbent Sheet	16-19 µm	2.5 mm
PTFE Sheet	10 µm	1 mm

Due to the differences in applications and operating conditions, Porex recommends that customers undertake their own appropriate tests to determine the performance of Certified Pure Porex Materials and Filters specific to the application and test condition.

* Data on file and available on request.

** A culture of Staphylococcus Aureus diluted in 1.5% peptone water (PEPW) to produce a challenge titer capable of delivering 2200 ± 500 CPU per test sample.



The Pure Porex Certification substantiates Porex® Filters and Materials for filter purity, no material additives or contaminants, no heavy metal or inorganic element interference, clinical laboratory methodology compatibility and 99.9% bacterial aerosol filtration efficiency.



Porex Corporation
500 Bohannon Road, Fairburn, GA 30213 USA
T. +1 770 964 1421 F. +1 770 969 0954
info.porex.amrs@filtrationgroup.com

porex.com

Porex Technologies GmbH
Strangenhäuschen 30, 52070 Aachen, Germany
T. +49 241 910525-0 F. +49 241 910525-16
info.porex.emea@filtrationgroup.com

800.241.0195

Porex Technologies Sdn Bhd
Lot P.T. 74, Jalan Hulu Tinggi 26/6, Seksyen 26, Sektor A
Hicom Industrial Park, 40400 Shah Alam, Selangor Malaysia
T. +603 5191 3308 F. +603 5192 3308
info.porex.apac@filtrationgroup.com