

# LIQUID SAMPLE PREPARATION TECHNOLOGY

## Membrane Filtration Cartridge System

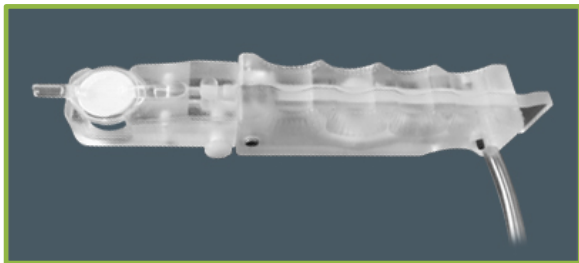
New innovations in sample preparation & in-vitro assays

### Enclosed-filtration devices and methods for in-line fluid handling to:

- ✓ Capture, remove, harvest and concentrate bacteria, cells, or particulates from fluids
  - ✓ Aspirate, collect, and pool filtered solutions, including aseptic processing
  - ✓ Conduct entire sample analyses and bioassays within enclosed filter cartridges
- **Save on labor, operational, and equipment costs**
  - **Increase productivity, process efficiency, and revenue**
  - **Reduce risks of sample-contamination, material wastage, and disposal costs**

### Technology

The improved membrane filtration (MF) liquid sample preparation technology offers new innovations in fluid-handling, sample preparations, and in-vitro assays. It is a novel system that combines use of a proprietary vacuum-based suction tool in conjunction with consumable filter cartridges containing porous hydrophilic membranes. The device enables aspiration of liquid into and through the easily interchangeable enclosed



membrane filter cartridges (MFC). The volume and rate of sample fluid processing with the system is user controllable via the device.



This enabling method markedly advances and broadens the applications which are addressable using enclosed MFCs. By solving a common limitation of enclosed filters in conventional in-line fluid systems, the suction tool enables – for the first time – multiple

aliquots of fluid(s), rinses, or sample-prep reagents to be sequentially processed in a controlled practical manner. Photonic BioSystems has eliminated the problem from air getting into the fluid path causing filtration blockage, due to air-lockup inside conventional closed cartridges.

The MFC system is versatile and can be diversified to provide highly effective and efficient processes for dealing with various types of fluid aspirations, filtration, separation of cellular or particulate from fluids, and samples preparations. The suction apparatus and MFCs can be used to perform manual operations by hand, or implemented in a robotized format to automate fluid handling systems for high sample-throughput in large labs, testing facilities or for industrial needs and to meet specialized process, multistep requirements.

***This device and method offers greater utility for MFC fluid handling over conventional processes. It is uniquely enabling for new assay and instrument developers and the creation of specialized assay applications.***

## Exemplary Sample-Prep Applications

- **Harvesting cell-culture fluids:**
  - when highly valuable to ensure the collected media sample is not contaminated
  - to minimize risk of fluid pooled from multiple sample vessels for efficacy getting batch co-contamination
  - to clarify or sterile filter aspirated fluid harvested directly into a sterile vessel
- **Filter process and collect a controlled definitive volume of sample fluid:**
  - controlled by the suction tool and collection vessel implementation
  - minimize contamination of containers and handling materials used for sample transport or measurement
- **Withdrawing small volumes of fluid out of reagent vessels, filtering, and then dispensing finally:**
  - to remove potential particulates or microbial contaminants from the reagent
  - uniquely dispense the filtered sample directly at the point of use e.g. into an assay vessel
  - a considerable benefit for controlling contamination risks in cell culture, microbial, and bioassay work

## Enclosed MFC Microbial Sample Prepare, Culture, and Analysis

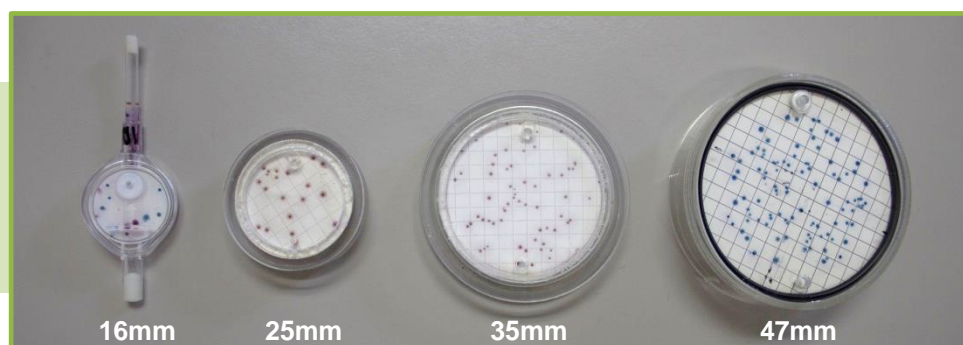
**Enclosed MFC and MFAC-** By utilizing the enclosed filter cartridges this technique offers distinct advantages. One critical to many applications is that the entire fluid path, and most importantly the filtration element, is protected with this system – it prevents exposure of the sample to the external environment and potential contaminations.

One fundamental improvement of enclosed cartridges over the conventional MF technique is the development of a proprietary self-contained Membrane Filter Assay Cartridge (MFAC) method for microbial testing or the bioassay of cells. The MFAC approach enables: sample collection, capturing and concentrating of organisms, rinsing (if required), aspirating culture media/reagents, incubation, and in situ analyses of organisms growth- all without opening the MFAC or exposing the sample to the external environment. This reduces the equipment, setup time, contamination risk, and technical skill required to prepare samples using the MF technique.

### Complete entire MF procedures – from sample collection to analysis – in one unitized device.

- All assay steps conducted *in situ* within the enclosed filter system:
  - harvest organisms, administer culture media, incubate, analyze culture test results
- Cultures can be fed
- Culture fluids can be harvested
- Organisms can be cultured on – or within - the filter matrix
- **Planktonic** cultures of organisms in fluid state is directly applicable

### Microbial colony growth using various 16-47mm size membrane Filter-Assay Cartridges



## Key Enablements for a Wide Variety of Uses

1. Fully enclosed filtration and culture system minimizes the risk of contamination enabling MF sample preparation and testing in the field (at sampling site) or in the lab without the need for a containment hood or clean environment.
2. Compatibility with different sizes, types, and configurations of filters and sampling varying fluid volumes (0.1 to >1,000mL).
3. A large variety of MF based sample preps and tests can be conducted with just one piece of equipment.
4. Back-flush extrication of material captured by the FC filtration.

### Collect, prepare and culture microbial samples without the requirement for:

- Filter funnels
- Sterilization of preparatory equipment
- Additional culture dishes and pads
- Membrane transfers manually
- Exposure to external environment

## Technology Advantages

Sample Prep Advantages	Benefits
<b>Aseptic sample collection</b>	<ul style="list-style-type: none"> <li>• Reduce operational costs and reduce false positives</li> </ul>
<b>Based on classic MF method</b>	<ul style="list-style-type: none"> <li>• Consistency with regulated procedures for membrane filtration</li> </ul>
<b>Eliminate in-line filter “air-locks”</b>	<ul style="list-style-type: none"> <li>• Enables new, practical applications, otherwise not feasible</li> </ul>
<b>Sample-volume flexibility 0.1 mL to &gt; 1,000 mL</b>	<ul style="list-style-type: none"> <li>• Reduce equipment/material costs by removing the need for separate/additional equipment to process varying sample volumes</li> <li>• Increase versatility and the process efficiency of FC applications</li> </ul>
<b>Controllable filtration volume:</b> <ul style="list-style-type: none"> <li>• Amount sample aspirated</li> <li>• Collected filtrate</li> </ul>	<ul style="list-style-type: none"> <li>• Precisely control uptake of a specified volume of sample fluid, depending on application/test requirement(s)</li> <li>• Increase productivity by automating volume-control</li> <li>• Meet regulatory compliance requiring specific sample size, e.g. 100 mL</li> </ul>
<b>Minimal technical skill required</b>	<ul style="list-style-type: none"> <li>• Reduce hiring and training costs</li> <li>• Reduce occurrence and cost of human-borne errors</li> <li>• Expand personnel pool for who can properly conduct MF testing</li> </ul>
<b>Compatible with 47mm, 35mm, 25mm, and 16mm membranes filters</b>	<ul style="list-style-type: none"> <li>• Continue use of 47mm membrane filters</li> <li>• Easily transition between different size membranes depending on application/test requirement(s)</li> <li>• Reduce equipment cost by only needing one piece of equipment for different diameter filters</li> </ul>
<b>Reduce volume of materials needed to filter sample</b>	<ul style="list-style-type: none"> <li>• Save on cost/test</li> <li>• Reduce operational costs by reducing the amount materials that need to be shipped, stored, decontaminated and disposed of</li> <li>• Provide customers w/ competitive cost/test pricing</li> </ul>



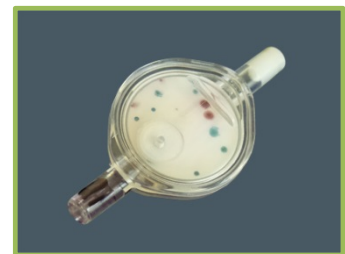
Micro & Bioassay Advantages	Benefits
Filter sample, capture organisms, rinse as needed, aspirate culture media/reagents, incubate, and analyze colony growth- <u>all</u> in enclosed culture system.	<ul style="list-style-type: none"> <li>• Reduce labor costs associated with sample preparation and processing</li> <li>• Reduce risk of filter and sample contamination by minimizing exposure to external environment</li> <li>• Eliminate manual operation of filter membrane transfer to another vessel for culture after filtration</li> <li>• Conduct testing in the field immediately upon sample collection</li> <li>• Increase revenue by offering in-the-field testing services</li> </ul>
Concentrate harvested organisms	<ul style="list-style-type: none"> <li>• Decrease assay time via concentration of the sample test constituents</li> </ul>
Microbial-barrier air vent	<ul style="list-style-type: none"> <li>• Minimize risk of contamination by keeping out airborne contaminants</li> </ul>
Enumerate & identify colony growth	<ul style="list-style-type: none"> <li>• Count colonies by eye manually or using or automated colony counters/analyzers</li> <li>• Pick isolated colonies from filter membrane for traditional biochemical confirmation and identification assays</li> </ul>

## Applications

This improved MF liquid sample preparation technology has extensive application in a variety of industries and subset markets.

Water	Medical	Sterility	Toxicity	Agriculture	Food/Beverage
<ul style="list-style-type: none"> <li>• Drinking</li> <li>• Source</li> <li>• Waste &amp; Discharge</li> <li>• Bottled</li> </ul>	<ul style="list-style-type: none"> <li>• Infection Control</li> <li>• Antibiotics sensitivity</li> <li>• Surveillance</li> </ul>	<ul style="list-style-type: none"> <li>• Pharma QA</li> <li>• Detoxification testing</li> <li>• Product testing</li> </ul>	<ul style="list-style-type: none"> <li>• Homeland security</li> <li>• Water</li> <li>• Pharma</li> <li>• Cosmetics</li> </ul>	<ul style="list-style-type: none"> <li>• Dairy</li> <li>• Feed QC</li> <li>• Biosecurity</li> <li>• Discharge</li> </ul>	<ul style="list-style-type: none"> <li>• Process QA, QC &amp; HACCP</li> <li>• Food testing</li> <li>• Milk/juice</li> <li>• Bioburden</li> </ul>

This platform technology can be deployed in a variety of configurations to meet application-specific requirements; the device shown is only one implementation of the technology designed specifically to DOD requirements. With numerous benefits over the conventional MF technique, Photonic BioSystems' liquid sample preparation technology is paving the way for a new gold standard in MF microbiological testing which will ensure the safety and health of our society for generations to come.



## Licensing Inquiries:

Please direct all licensing inquiries to:

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