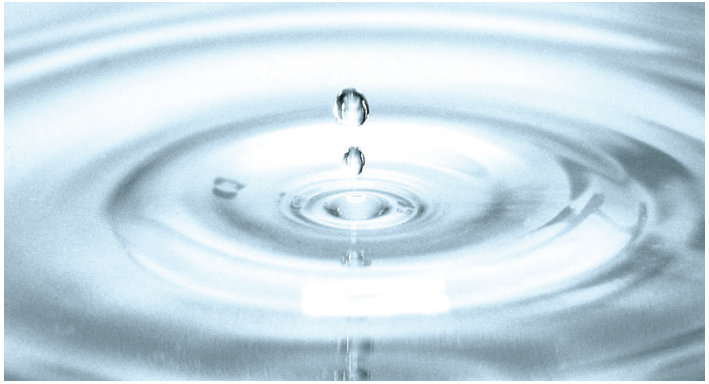
Guideline Landscape

Quality Control



Environmental | Water Testing

Pharma | Biotech

Watertesting according to current standards & regulations
Membranefilteroverview for accredited laboratories

Guideline Landscape Water

All gridded 0.45 µm Sartorius filters are ISO7704 conform

Correct choice of pore size as defined by the respective ISO for each analysis listed

ISO 7704:1985 QC filters „how to release membrane-filters" has to be used for all filter releases

Organism	Guideline	Filter per guideline	Sartorius
Enterococci	ISO 7899-2:2000	0.45 µm	✓
E. Coli	ISO DIS 9308-1:2012	0.45 µm Cellulose-Esters, every lot to be tested according to ISO 7704	✓
Legionella	ISO WD 11731:2012	0.22–0.45 µm black Cellulose Nitrate membranes	✓
Clostridium perfringens	ISO DIS 14189:2013	0.45 µm	✓
Pseudomonas aeruginosa	ISO 16266:2006	0.45 µm	✓
Campylobacter	ISO 17995:2005	0.45 µm; CE	✓
Salmonella	ISO 19250:2010	0.45 µm	✓
anaerobes (Clostridia)	ISO 6461-2:1986	0.2 µm	✓
Bacteriophages	ISO 10705 part 1-4	0.2 µm	✓

Test organism	Sartorius Filter Dispenser – ready filter	Single sterile membranes
Enterococci E. Coli	114H6Z-47----SCM (white) 138H6Z-47----SCM (green)	114H6--47----ACN (white) 138H6--47----ACN (green)
Legionella	130H6Z-47----SCM (black)	130H6--47----ACN (black)
Clostridium perfringens	138H6Z-47----SCM (green) 114H6Z-47----SCM (white)	138H6--47----ACN (green) 114H6--47----ACN (white)
Pseudomonas aeruginosa	114H6Z-47----SCM (white)	114H6--47----ACN (white)
Campylobacter	114H6Z-47----SCM (white)	114H6--47----ACN (white)
Salmonella	114H6--47----SCM (white)	114H6--47----ACN (white)
anaerobes (Clostridia)	11407Z -47-----SCM (white)	11407--47----ACN (white)
Bacteriophages	11407Z-47----SCM (white)	11407--47----ACN (white)

Appendix: guideline passages

ISO 7704:1985 (membrane filter)

5. Apparatus

5.2 Sterile membrane filters
A thin non-fibrous filtration medium for liquids and gases, having a mean pore size larger than 0.01 µm in diameter, on which particles larger than the rated pore size are retained at or near the delivery surface when suction or pressure is applied.

8. Membrane filter
The membrane filters shall be sterile.

ISO 8199:2005 (Enumeration)
With membranes of mean pore size 0.45 µm, it may be possible to filter several litres of such water through a single membrane, and so achieve a high level of test sensitivity. For some organisms (like Legionella), however, filtration through a membrane with a mean pore size of 0.2 µm may be necessary.

ISO 7899-2:2000 (Enterococci)
Sterile membrane filters, nominal pore size 0.45 µm.

The quality of membrane filters may vary from brand to brand or even from batch to batch. It is therefore advisable to check the quality on a regular basis according to ISO 7704.

ISO 11731-2:2012 (Legionella)

5. Apparatus and glassware

5.5 Polycarbonate membrane filters

5.6 Black Membrane filters
Polycarbonate membrane filters diameter 47 mm to 142 mm with rated pore sizes of 0.2 µm.

Black membrane filters from cellulose nitrate or mixed cellulose ester, diameter 47 mm to 50 mm with rated pore sizes of 0.22 µm or 0.45 µm. Note – This type of membrane filters are used for direct placing on to the culture media after filtration. Filters shall be evaluated prior to use in accordance with ISO 7704.

ISO 9308-1:2012 (E.Coli & Coliforme)

5. Apparatus and glassware

5.5 Membrane filters
Membrane filters, composed from cellulose esters, usually about 47 mm or 50 mm in diameter, with filtration characteristics equivalent to a rated nominal pore diameter of 0.45 µm and, preferentially, with grids.

The filters shall be free from growth-inhibiting or growth-promoting properties and the printing ink used for the grid shall not affect the growth of bacteria. If not obtained sterile, they shall be sterilized according to the manufacturer's instructions.

Every batch of membranes shall be tested for its suitability for the test according to ISO 7704 especially since the use of different brands of filters may result in different recovery and colour development.

ISO 16266:2006
(Pseudomonas aeruginosa)

6. Apparatus and glassware

6.4 Sterile membrane filters
Sterile membrane filters, with nominal pore size of 0.45 µm. Check filters on a regular basis as specified in ISO 7704.

ISO 6461-2:1986 (Anaerobes | Clostridia)

7. Apparatus and glassware

7.9 Sterile membrane filters
Sterile membrane filters, nominal pore size 0.2 µm.

Note – The quality of membrane filters may vary from brand to brand or even from batch to batch. It is therefore advisable to check the quality on a regular basis according to ISO 7704.

ISO 10705, part 1-4 (Bacteriophages)
Only membranes defined for de-contamination purposes

ISO DIS 14189:2013
(Clostridium perfringens)

5. Apparatus and glassware

5.3 Sterile membrane filters
Sterile membrane filters, nominal pore size 0.45 µm.

The quality of membrane filters may vary from brand to brand or even from batch to batch. It is therefore advisable to check the quality on a regular basis.

ISO 17995:2005 (Campylobacter)

5. Apparatus

5.3 Membrane filters
Sterile membrane filters made from cellulose ester with a diameter of 45 mm to 50 mm and a pore size of 0.45 mm. Similar filters with a pore size of 0.22 µm are recommended for sterilization of supplements.

ISO 19250:2010 Salmonella

5. Apparatus

5.5 Sterile membrane filters
Sterile membrane filters, with a nominal pore size of 0.45 µm. Note – The quality of membrane filters may vary from brand to brand or even from batch to batch. It is therefore advisable to check the quality on a regular basis according to ISO 7704.

ISO 11133:2015
(Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media)

7.3 Testing of culture media used for membrane filtration

The quality of the membrane filters used shall be previously evaluated to demonstrate their suitability for use.

See ISO 7704.

To test the performance of a culture medium for use in membrane filtration, use working cultures and inocula as described in 5.3.2. Inoculate the suspension medium e.g: dilution fluid, sterile water, with a suitable inoculum level given in 5.3.2.5

Filter the liquid according to the requirements of the specific standard. Place the membrane on the surface of the agar under test. Inoculate sufficient membranes | plates to obtain a total of approximately 100 cfu for productivity testing. Repeat with a new membrane and place the second membrane on the surface of the reference medium, using dilutions if required for selectivity testing. Incubate the plates according to the specific standard.

Repeat the process each time the batch of membranes changes as well as each new batch of medium.

If necessary, to evaluate the influence of the membrane on the result also spread the test inoculum onto the test medium and reference medium without the membranes.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