

ReadyToProcess ULTA normal flow filter capsules and assemblies

READYTOPROCESS

Cytiva's ReadyToProcess™ normal flow filter capsule assemblies are disposable normal flow filters designed for laboratory through process scale processing, with typical volumes ranging from a few hundred milliliters to 1000 L of solution.

Five ReadyToProcess normal flow filter capsules are presently being offered:

- ReadyCircuit™ ULTA™ SG Capsule Assembly: provides sterile filtration of biopharmaceutical solutions
- ReadyCircuit ULTA HC Capsule Assembly: for effective sterile filtration of difficult-to-filter biopharmaceutical and diagnostic solutions
- ReadyCircuit ULTA CG Capsule Assembly: for controlling bioburden and particle retention in a wide variety of pH ranges and feed streams
- ReadyCircuit ULTA GF Capsule Assembly: for effective prefiltration/clarification of biopharmaceutical solutions
- ReadyCircuit ULTA MR Capsule Assembly: for efficient filtration of mycoplasma from cell culture media

ReadyToProcess normal flow filter capsules are preconditioned at the factory and ready-to-use. Critical features include:

- Low total organic carbon (TOC)
- Minimal or no rinse-out needed prior to use
- Gamma irradiated and biostable
- Endotoxin free



Fig 1. ReadyToProcess normal flow filter capsule.

ReadyToProcess

ReadyToProcess ULTA normal flow filter capsules are part of the ReadyToProcess product platform, a suite of products designed to bring a comprehensive offering of ready-to-use cell culture, purification, and fluid management products such as:

- ReadyToProcess cross flow and normal flow filters
- ReadyToProcess columns and ÄKTA™ ready automated chromatography systems
- WAVE Bioreactor™ and Cellbag™ bioreactor chambers
- ReadyCircuit bioprocess containers and tubing assemblies
- ReadyKart hardware and portability solutions
- ReadyMate™ Disposable Aseptic Connectors

ULTA Pure SG capsules

Pleated capsules with Sterilizing Grade Polyethersulphone Membranes, ULTA Pure SG utilizes the unique properties of a patented microbially retentive polyethersulphone membrane to provide sterile filtration to meet the specific needs of the pharmaceutical industry.

Features

- 0.2 micron polyethersulphone membrane
- Microbially retentive and validated to ASTM F838-83 methodology
- Asymmetrical pore structure resulting in high throughputs and flow rates
- Low chemical and protein binding characteristics
- Wide range of chemical compatibility with low extractable levels

ULTA Pure HC capsules

Pleated capsules with Polyethersulphone Membranes, ULTA Pure HC capsule filters provide sterile filtration and have been specifically designed for the effective and economical processing of difficult to filter solutions often associated with biopharmaceutical and diagnostics production.

Features

- 0.6/0.2 micron polyethersulphone membrane
- Microbially retentive and validated to ASTM F838-83 methodology
- Optimized membrane configuration allows up to ten times the throughput
- Integral prefilter layer can condense filter trains for greater processing economy
- Fully validated and integrity testable membrane for assurance of sterility
- Low adsorption of proteins for minimal loss of expensive pharmaceutical product

ULTA Prime CG capsules

Pleated capsules with Polyethersulphone Membrane, ULTA Prime CG filter capsules are specifically designed for consistently controlling bioburden and particle retention in a variety of pH ranges and feed streams. The pleated polyethersulfone (PES) membrane combined with thermalbonded construction, in both capsule and cartridge formats, ensures low extractables.

Features

- Bioburden control to 5 logs
- Broad pH compatibility
- High flow, low pressure drop
- Exceptional price performance

ULTA Prime GF capsules

Features

- Micron rating range from 0.6 to 10 micron
- High capacity filter media giving microbial retention
- Thermal bonded construction
- High filtration area

Typical applications

- Final sterile filtration of biopharmaceutical solutions
- Bioburden reduction
- Column guard: reducing bioburden and particulates before chromatography columns
- Prefiltration of media, buffer, and water
- Serum and tissue culture media clarification
- Disposable laboratory prefiltration

ULTA Pure MR capsules

Pleated capsules with Mycoplasma Retentive Polyethersulphone Membranes, ULTA Pure MR filters have been specifically designed for fast, effective and economical removal of mycoplasma from cell culture media in the biopharmaceutical industry.

Features

- Integral prefilter layer increases throughput for reduction of filter trains
- Exceptional flow rates for quick processing of cell culture media
- A typical LRV of > 10 for *Acholeplasma laidlawii* for effective mycoplasma control
- Validated and integrity testable for sterility

Biological safety

Materials conform to the relevant requirements of 21CFR Part 177 and current USP Plastics Class VI - 121°C and ISO10993 equivalents.

Non-volatile extractables (NVE)

Total NVEs extracted in the first 5 liter flush of WFI for a 10 in equivalent pre-autoclaved device is < 6 mg.

Oxidizable substances

ULTA normal flow filter capsule assemblies meet current USP quality standards for oxidizable substances.

TOC/Conductivity

The effluent quality from a 10 in equivalent ULTA normal flow filter capsule assemblies conforms to the requirements of USP 28<643>(TOC) and USP 28<645> (conductivity) following a 3 liter flush.

Endotoxins

Aqueous extracts from the ULTA normal flow filter capsule assemblies contain < 0.25 Eu/mL when tested in accordance with the standard LAL test.

Retention characteristics

ULTA SG, ULTA MR, and ULTA HC capsule assemblies are validated to give an LRV of at least 7 when challenged with *Brevundimonas diminuta* in accordance with methods specified in ASTM F838-05 (107 organisms/cm² minimum). Typical in-house challenge levels are in the order of 10¹¹ per 10 in module.

Sterility

Each ReadyToProcess normal flow filter capsule assembly is sterile for all fluid contact surfaces (per ISO 11137).

Integrity test specifications

All filters are flushed with pharmaceutical grade purified water prior to packaging. They are integrity testable (except ULTA Prime GF capsules), see Table 1.

Table 1. Integrity test parameters for sterile filters and bioburden reduction filters

	Pore size (microns)	ITΔP (barg)	Diffusional flow specification (sccm)							Bubble point (barg)
			2 in	4 in	6 in	5 in	10 in	20 in	30 in	
ULTA Prime CG	0.6/0.2	1.70	1.2	2.9	6.0	7.4	16.0	32.0	48.0	2.48
ULTA Pure SG	0.22	2.80	1.2	2.9	6.0	7.4	16.0	32.0	48.0	3.38
ULTA Pure HC	0.6/0.22	2.80	1.4	3.2	6.7	8.4	18.0	36.0	54.0	3.38
ULTA Pure MR	0.1	4.80	2.2	4.6	9.3	11.5	24.2	48.4	72.6	2.36

Capsule flow rates

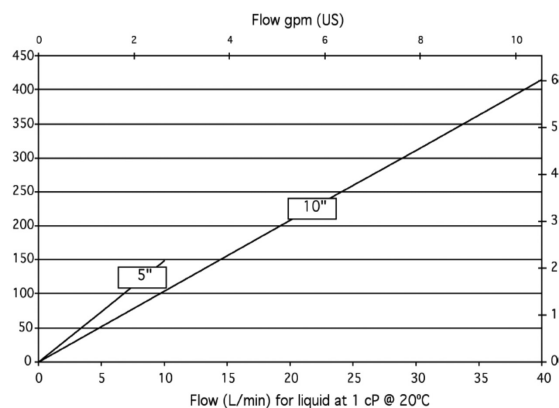


Fig 1. ULTA Pure SG: Average water flow characteristics for large capsules.

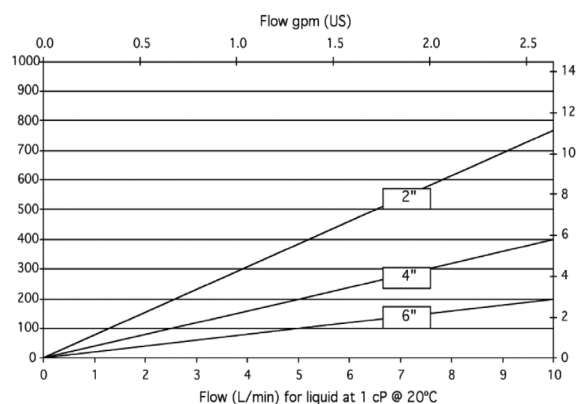


Fig 2. ULTA Pure SG: Average water flow characteristics for small capsules.

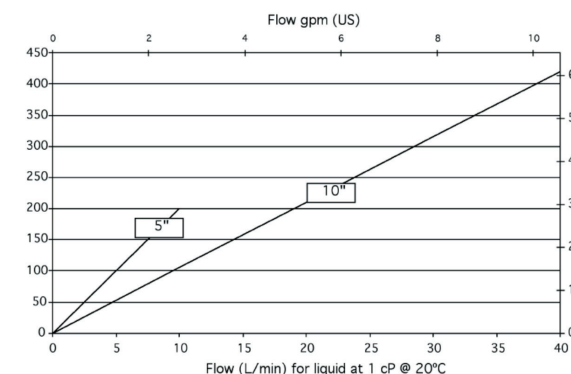


Fig 3. ULTA Pure HC: Average water flow characteristics for large capsules.

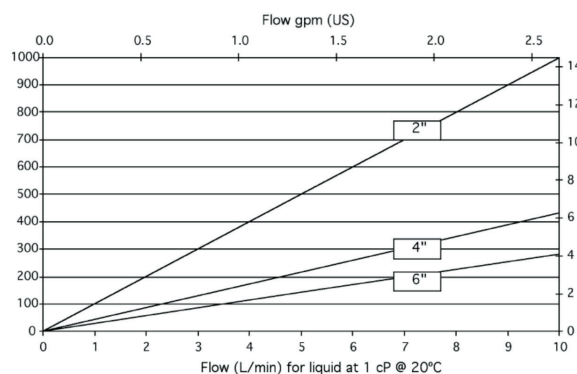


Fig 4. ULTA Pure HC: Average water flow characteristics for small capsules.

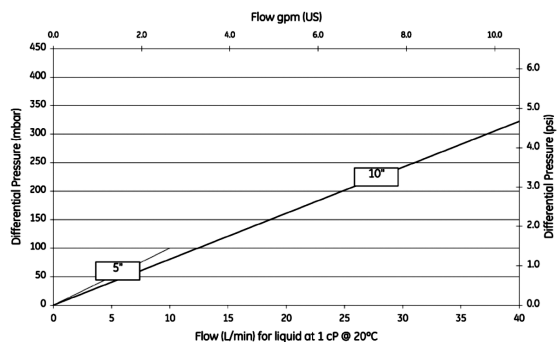


Fig 5. ULTA Prime CG: Average water flow characteristics for large capsules.

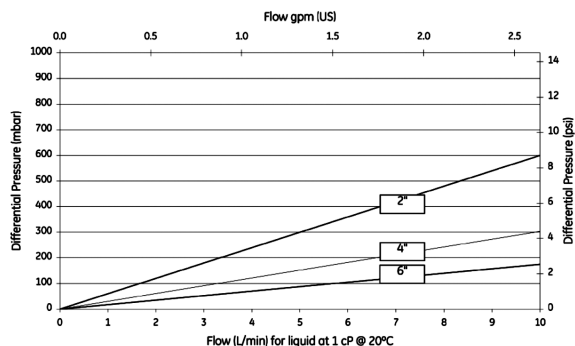


Fig 6. ULTA Prime CG: Average water flow characteristics for small capsules.

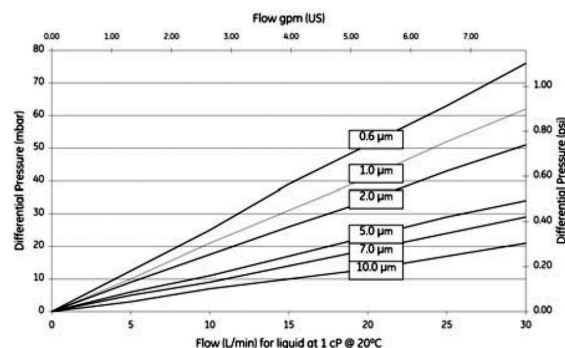


Fig 7. ULTA Prime GF: Average water flow characteristics for 10 in capsules.

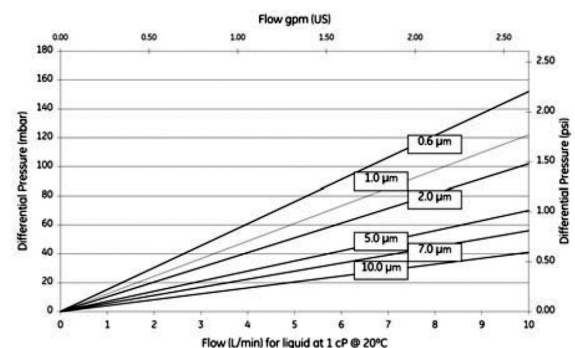


Fig 8. ULTA Prime GF: Average water flow characteristics for 4 in capsules.

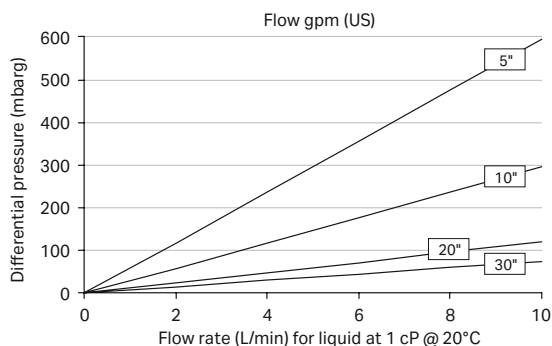


Fig 9. ULTA Pure MR: Average water flow characteristics for large capsules.

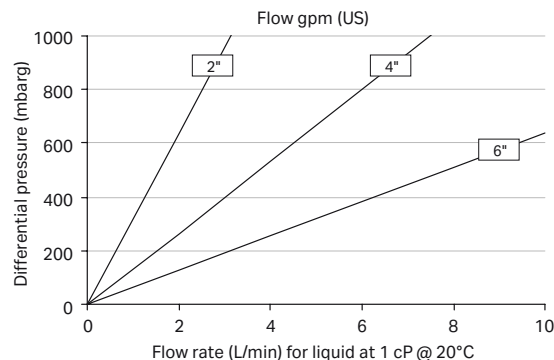


Fig 10. ULTA Pure MR: Average water flow characteristics for small capsules.

Operating and technical specifications

Maximum recommended operating conditions

Large Capsule Assemblies with Readymate (5 in, 10 in, 20 in, 30 in capsules)	5.5 barg (79 psi) at 25°C (77°F)
Small Capsule Assemblies with C-Flex® tubing and ReadyMate (2 in, 4 in, 6 in capsules)	1 barg (14.5psi) at 25°C (77°F)

Area specifications

	Pore size (microns)	Mean surface area (m ²)						
		2 in	4 in	6 in	5 in	10 in	20 in	30 in
ULTA Prime GF	0.6	0.045	0.095	0.19	0.27	0.56	1.12	1.68
	1.0	0.045	0.095	0.19	0.24	0.51	1.01	1.52
	2.0	0.045	0.095	0.19	0.24	0.51	1.01	1.52
	5.0	0.045	0.095	0.19	0.26	0.53	1.07	1.60
	7.0	0.036	0.076	0.15	0.20	0.42	0.83	1.25
	10.0	0.036	0.076	0.15	0.20	0.42	0.83	1.25
ULTA Prime CG	0.6/0.2	0.047	0.10	0.21	0.26	0.55	1.10	1.65
ULTA Pure SG	0.2	0.047	0.10	0.21	0.26	0.55	1.10	1.65
ULTA Pure HC	0.6/0.2	0.047	0.10	0.21	0.26	0.55	1.10	1.65
ULTA Pure MR	0.1	0.047	0.10	0.19	0.24	0.50	1.00	1.50

Materials of construction

	ULTA HC	ULTA SG	ULTA CG	ULTA MR	ULTA GF
Filtration membrane	Polyethersulphone	Polyethersulphone	Polyethersulphone	Polyethersulphone	Glass Borosilicate glass microfiber
Prefiltration membrane	Polyethersulphone	N/A	Polyester	Polyethersulphone	N/A
Upstream support	Polyester	Polyester	Polyester	Polypropylene/ Polyester	Polyester
Downstream support	Polyester	Polyester	Polyester	Polyester	Polyester
Inner core	Polypropylene	Polypropylene	Polypropylene	Polypropylene	Polypropylene
Sleeve	Polypropylene	Polypropylene	Polypropylene	Polypropylene	Polypropylene
Small capsule body (2 in, 4 in, 6 in)	Nylon	Nylon	Nylon	Nylon	Nylon
Large capsule body (5 in, 10 in, 20 in, 30 in)	Polypropylene	Polypropylene	Polypropylene	Polypropylene	Polypropylene
Capsule vent seals	Silicone	Silicone	Silicone	Silicone	Silicone
Cartridge end caps	Nylon	Nylon	Nylon	Nylon	Nylon
Cartridge end cap insert (5 in, 10 in, 20 in, 30 in)	316 stainless steel	316 stainless steel	316 stainless steel	316 stainless steel	316 stainless steel
Cartridge O-rings (5 in, 10 in, 20 in, 30 in)	Silicone or EPDM	Silicone or EPDM	Silicone or EPDM	Silicone or EPDM	Silicone or EPDM

Ordering information

ULTA normal flow filter capsule assemblies

Code number	Description	Expanded description
12-4100-58	1XCG9202 2×0.5 FT CF RM	ULTA Prime CG 0.2 µm 2 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4100-59	1XCG9204 2×0.5 FT CF RM	ULTA Prime CG 0.2 µm 4 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4100-60	1XCG92H1 2× RM	ULTA Prime CG 0.2 µm 5 in capsule filter terminating with ReadyMate connectors.
12-4100-61	1XCG9206 2×0.5 FT CF RM	ULTA Prime CG 0.2 µm 6 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4100-62	1XCG9210 2× RM	ULTA Prime CG 0.2 µm 10 in capsule filter terminating with ReadyMate connectors.
12-4100-63	1XCG9220 2× RM	ULTA Prime CG 0.2 µm 20 in capsule filter terminating with ReadyMate connectors.
12-4100-64	1XCG9230 2× RM	ULTA Prime CG 0.2 µm 30 in capsule filter terminating with ReadyMate connectors.
12-4100-65	1XGF9602 2×0.5 FT CF RM	ULTA Prime GF 0.6 µm 2 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4100-66	1XGF9604 2×0.5 FT CF RM	ULTA Prime GF 0.6 µm 4 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4100-67	1XGF96H1 2× RM	ULTA Prime GF 0.6 µm 5 in capsule filter terminating with ReadyMate connectors.
12-4100-68	1XGF9606 2×0.5 FT CF RM	ULTA Prime GF 0.6 µm 6 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4100-69	1XGF9610 2× RM	ULTA Prime GF 0.6 µm 10 in capsule filter terminating with ReadyMate connectors.
12-4100-70	1XGF9620 2× RM	ULTA Prime GF 0.6 µm 20 in capsule filter terminating with ReadyMate connectors.
12-4100-71	1XGF9630 2× RM	ULTA Prime GF 0.6 µm 30 in capsule filter terminating with ReadyMate connectors.
12-4100-72	1XGF0102 2×0.5 FT CF RM	ULTA Prime GF 1 µm 2 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4100-73	1XGF0104 2×0.5 FT CF RM	ULTA Prime GF 1 µm 4 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4100-74	1XGF0106 2×0.5 FT CF RM	ULTA Prime GF 1 µm 6 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4100-75	1XGF01H1 2× RM	ULTA Prime GF 1 µm 5 in capsule filter terminating with ReadyMate connectors.
12-4100-76	1XGF0110 2× RM	ULTA Prime GF 1 µm 10 in capsule filter terminating with ReadyMate connectors.
12-4100-77	1XGF0120 2× RM	ULTA Prime GF 1 µm 20 in capsule filter terminating with ReadyMate connectors.
12-4100-78	1XGF0130 2× RM	ULTA Prime GF 1 µm 30 in capsule filter terminating with ReadyMate connectors.
12-4100-79	1XGF0202 2×0.5 FT CF RM	ULTA Prime GF 2 µm 2 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4100-80	1XGF0204 2×0.5 FT CF RM	ULTA Prime GF 2 µm 4 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4100-81	1XGF0206 2×0.5 FT CF RM	ULTA Prime GF 2 µm 5 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4100-82	1XGF02H1 2× RM	ULTA Prime GF 2 µm 6 in capsule filter terminating with ReadyMate connectors.
12-4100-83	1XGF0210 2× RM	ULTA Prime GF 2 µm 10 in capsule filter terminating with ReadyMate connectors.
12-4100-84	1XGF0220 2× RM	ULTA Prime GF 2 µm 20 in capsule filter terminating with ReadyMate connectors.
12-4100-85	1XGF0230 2× RM	ULTA Prime GF 2 µm 30 in capsule filter terminating with ReadyMate connectors.
12-4100-86	1XGF0502 2×0.5 FT CF RM	ULTA Prime GF 5 µm 2 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4100-87	1XGF0504 2×0.5 FT CF RM	ULTA Prime GF 5 µm 4 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4100-88	1XGF05H1 2× RM	ULTA Prime GF 5 µm 5 in capsule filter terminating with ReadyMate connectors.
12-4100-89	1XGF0506 2×0.5 FT CF RM	ULTA Prime GF 5 µm 6 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.

ULTA normal flow capsule assemblies (continued)

Code number	Description	Expanded description
12-4100-90	1XGF0510 2× RM	ULTA Prime GF 5 µm 10 in capsule filter terminating with ReadyMate connectors.
12-4100-91	1XGF0520 2× RM	ULTA Prime GF 5 µm 20 in capsule filter terminating with ReadyMate connectors.
12-4100-92	1XGF0530 2× RM	ULTA Prime GF 5 µm 30 in capsule filter terminating with ReadyMate connectors.
12-4100-93	1XHC9202 2×0.5 FT CF RM	ULTA Prime HC 0.6/0.2 µm 2 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4100-94	1XHC9204 2×0.5 FT CF RM	ULTA Prime HC 0.6/0.2 µm 4 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4100-95	1XHC92H1 2× RM	ULTA Prime HC 0.6/0.2 µm 5 in capsule filter terminating with ReadyMate connectors.
12-4100-96	1XHC9206 2×0.5 FT CF RM	ULTA Prime HC 0.6/0.2 µm 6 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4100-97	1XHC9210 2× RM	ULTA Prime HC 0.6/0.2 µm 10 in capsule filter terminating with ReadyMate connectors.
12-4100-98	1XHC9220 2× RM	ULTA Prime HC 0.6/0.2 µm 20 in capsule filter terminating with ReadyMate connectors.
12-4100-99	1XHC9230 2× RM	ULTA Prime HC 0.6/0.2 µm 30 in capsule filter terminating with ReadyMate connectors.
12-4101-00	1XSG9202 2×0.5 FT CF RM	ULTA Prime SG 0.2 µm 2 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4101-01	1XSG9204 2×0.5 FT CF RM	ULTA Prime SG 0.2 µm 4 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4101-02	1SG92H1 2× RM	ULTA Prime SG 0.2 µm 5 in capsule filter terminating with ReadyMate connectors.
12-4101-03	1XSG9206 2×0.5 FT CF RM	ULTA Prime SG 0.2 µm 6 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4101-04	1XSG9210 2× RM	ULTA Prime SG 0.2 µm 10 in capsule filter terminating with ReadyMate connectors.
12-4101-05	1XSG9220 2× RM	ULTA Prime SG 0.2 µm 20 in capsule filter terminating with ReadyMate connectors.
12-4101-06	1XSG9230 2× RM	ULTA Prime SG 0.2 µm 30 in capsule filter terminating with ReadyMate connectors.
29-0962-39	1MR9102 2×0.5 FT CF RM	ULTA Pure MR 0.1 µm 2 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate DAC.
29-0967-72	1MR9104 2×0.5 FT CF RM	ULTA Pure MR 0.1 µm 4 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate DAC.
29-0967-85	1MR91H1 2× RM	ULTA Pure MR 0.1 µm 5 in capsule filter terminating with ReadyMate DAC.
29-0967-94	1MR9106 2×0.5 FT CF RM	ULTA Pure MR 0.1 µm 6 in capsule filter and 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate DAC.
29-0967-98	1MR9110 2× RM	ULTA Pure MR 0.1 µm 10 in capsule filter terminating with ReadyMate DAC.
29-0968-02	1MR9120 2× RM	ULTA Pure MR 0.1 µm 20 in capsule filter terminating with ReadyMate DAC.
29-0968-05	1MR9130 2× RM	ULTA Pure MR 0.1 µm 30 in capsule filter terminating with ReadyMate DAC.

ULTA normal flow filter capsule assemblies — cell harvest filter trains

12-4102-45	1XGF0502 1XCG9202 2×0.5ft C RM	ULTA Prime GF 5 µm 2 in capsule filter and ULTA Prime CG 0.2 µm 2 in capsule filter with 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4102-46	1XGF05H1 1XCG9206 1×0.5ft C RM	ULTA Prime GF 5 µm 5 in capsule filter and ULTA Prime CG 0.2 µm 6 in capsule filter with 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4102-47	1XGF0510 1XCG92H1 2× RM	ULTA Prime GF 5 µm 10 in capsule filter and ULTA Prime CG 0.2 µm 5 in capsule filter terminating with ReadyMate connectors.
12-4102-48	1XGF0520 1XCG9210 2× RM	ULTA Prime GF 5 µm 20 in capsule filter and ULTA Prime CG 0.2 µm 10 in capsule filter terminating with ReadyMate connectors.
12-4102-51	1XGF0502 1XHC9202 2×0.5ft C RM	ULTA Prime GF 5 µm 2 in capsule filter and ULTA Prime HC 0.6/0.2 µm 2 in capsule filter with 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4102-52	1XGF05H1 1XHC9206 1×0.5ft C RM	ULTA Prime GF 5 µm 5 in capsule filter and ULTA Prime HC 0.6/0.2 µm 6 in capsule filter with 6 in (152 mm) of C-Flex 374 tubing terminating with ReadyMate connectors.
12-4102-53	1XGF0510 1XHC92H1 2× RM	ULTA Prime GF 5 µm 10 in capsule filter and ULTA Prime HC 0.6/0.2 µm 5 in capsule filter terminating with ReadyMate connectors.
12-4102-54	1XGF0520 1XHC9210 2× RM	ULTA Prime GF 5 µm 20 in capsule filter and ULTA Prime HC 0.6/0.2 µm 10 in capsule filter terminating with ReadyMate connectors.

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