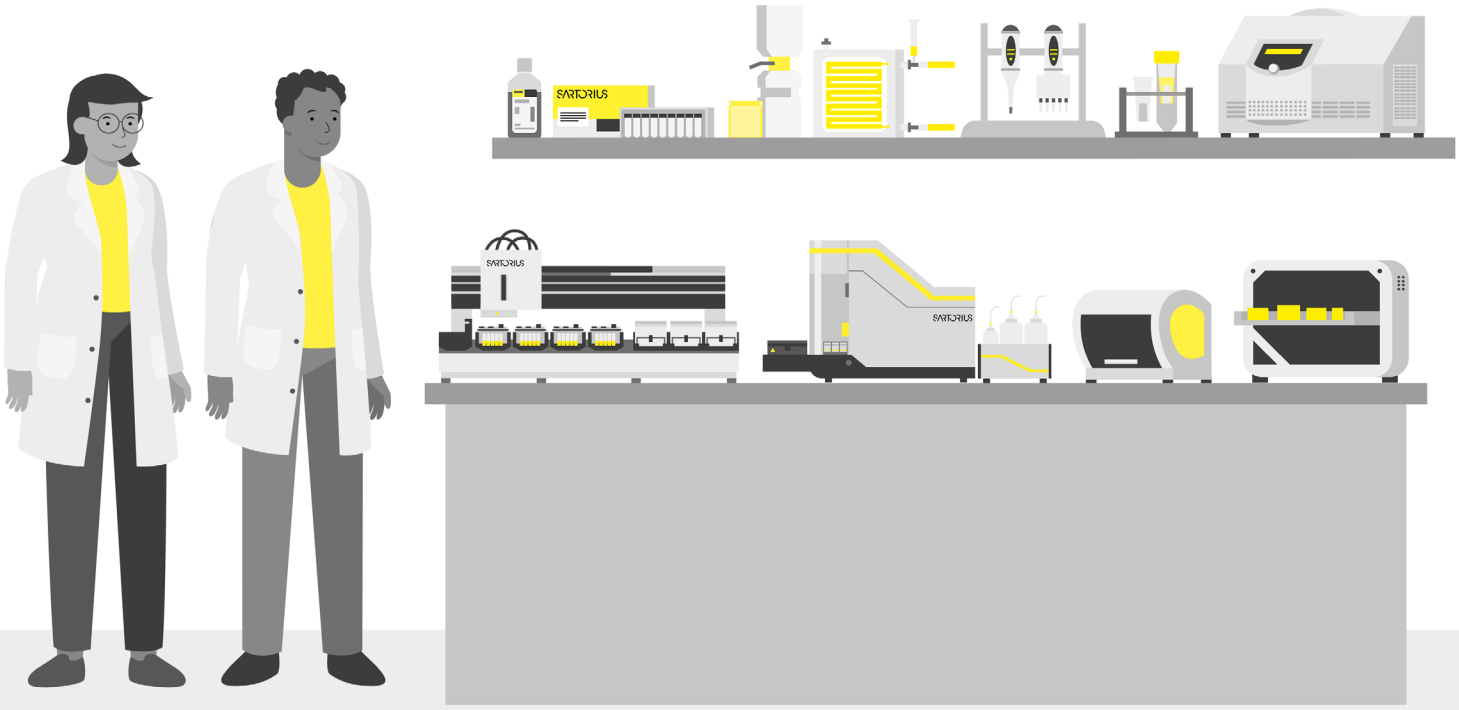

Sartorius T-Cell Screening Solution

Data Sheet Collection

SARTORIUS

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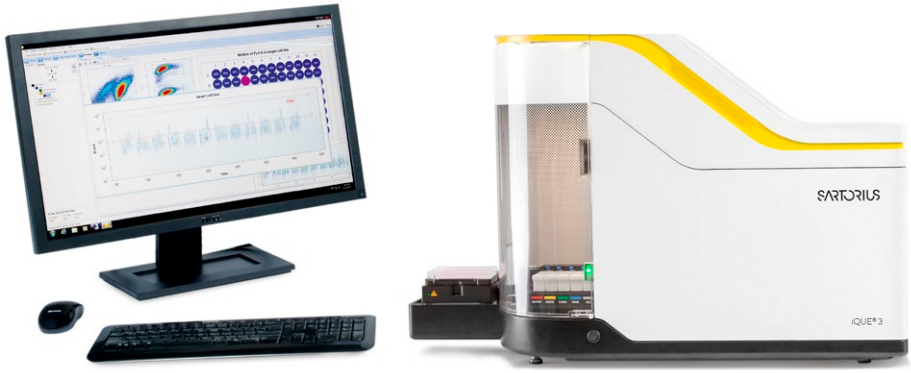
Technical Specifications

iQue® 3

Faster, Smarter, Flow Cytometry

Advanced High Throughput Flow Cytometry Solution Speeds Up Your Entire Workflow



The iQue® 3 Platform is the most advanced flow cytometry platform—with a focus on speed from setup, to acquisition and analysis. It combines a patented sampling method, which allows for the fastest sample acquisition in the industry. It has the ability to handle 96, 384, or 1536-well plates, and enables continuous plate loading through connection with any automation system. The Enhanced Rinse Station (ERS) provides continuous monitoring of liquid levels to ensure sufficient volumes prior to each run.

When used with the pre-configured iQue® reagent kits, samples can be analyzed instantly through the use of customizable templates following acquisition.

The included iQue Forecyt® Software enables dynamic data visualizations with an ease of use that allows all users to identify samples of interest without having to export to multiple software packages.

The iQue® Advantage

Speed

- Faster plate processing, minutes, not hours
- Mix and read samples
- Faster time to results

Miniaturization

- Consumes less reagents
- Conserves precious cells
- Saves money

Content

- Rich, multiplexed, per-cell content
- Cell and beads together
- Secreted protein analysis

Usability

- Automated workflow
- Validated reagents
- Easiest software you will ever love

Insight

- Link information
- Run scenarios
- Create knowledge
- Make decisions

iQue® 3 Platform

The iQue® 3 Platform is an integrated instrument, software and reagent system that enables rapid, high content, multiplexed analysis of cells and beads in suspension. Our unique, software-assisted automation and experiment-based analyses deliver the deep insight needed to answer complex biological questions.

The iQue® 3 BR (Blue-Red laser configuration) is a phenotypic screening and profiling workhorse that is ideal for applications that require up to 6-color detection, including antibody and biologics discovery, cell health assessment, secreted protein analysis using iQue® Qbead-based assays, and many more applications. Our platform delivers the iQue Forecyt® Software Workflow Advantage: a single data management workflow from input to output, which means you work faster and work smarter—not harder.

Content is king with the iQue® 3 VBR and VYB (Violet-Blue-Red and Violet-Yellow-Blue laser configurations). Three-laser systems offer up to 13-color detection and are ideal for functional and phenotypic applications that demand more choice and flexibility in experimental design. These systems combine high performance multi-color analysis with the iQue Forecyt® Software Workflow Advantage making them hands-down the choice of scientists in immune-based drug discovery, immuno-oncology, and cell therapy applications.

The iQue® 3 HD (Blue-Red laser configuration) provides the ultimate assay miniaturization and is the only high content, per-cell, 1536-well capable suspension screener available.

iQue® 3 Technical Specifications

	iQue® 3 Configuration	Blue and Red		Violet, Blue and Red			Violet, Yellow and Blue		
Detectors	**Lasers**	**488 nm**	**640 nm**	**405 nm**	**488 nm**	**640 nm**	**405 nm**	**561 nm**	**488 nm**
	445/45 nm			■			■		
	530/30 nm	■		■	■		■		■
	572/28 nm	■		■	■				
	586/20 nm						■	■	
	615/24 nm			■	■				
	615/20 nm						■	■	■
	660/20 nm						■	■	■
	675/30 nm	■	■	■	■	■			
	780/60 nm	■	■	■	■	■	■	■	
	Forward light scatter (relative size)	■			■			■	
	Side light scatter (relative granularity)	■			■			■	
Optical	Fluorescence sensitivity	FITC < 75 MESF; PE < 50 MESF; APC < 20 MESF							
	Minimum particle size detection	0.5 µm							
	Cell detection rate	Up to 35,000/second							
	Dynamic range of detection*	> 7 decades							
	* This wide dynamic range and a Zoom function permit operation of the system without user adjustments of the voltage or gain of the detectors.								
Sampling	Plate compatibility	96-well, 384-well or 384-well, 1536-well (iQue® 3 HD BR)							
	Sampling	Continuous air-gap delimited							
	Minimum assay volume requirements	10 µL							
	Minimum sample aspiration	1 µL							
	Minimum plate sampling time*	< 5 minutes | 96 wells		< 20 minutes | 384 wells					
	Carryover	< 2% for typical no-wash assays. Actual amounts are cell and assay dependent and are easily managed by including interwell rinses to reduce carryover to < 0.1%							
	Automated plate shaker	Up to 3,000 rpm (Up to 5000 rpm on iQue® 3 HD BR)							
	Features	▪ Foil-sealed plate processing ▪ Volumetric cell counting (< 10% CV)							
	* The time required for sampling plates is both sample type and experiment dependent. A range of well-sampling times can be designated from 0.5 seconds–minutes.								
Enhanced Rinse Station	Features	▪ Reduces evaporation ▪ Monitors fluid levels			▪ Automated QC bead vortexing				
iQue Forecyt® Software	Features	▪ Auto compensation ▪ Real-time whole-plate data analysis ▪ Dynamic linked gating ▪ Interactive heat maps, profile maps			▪ Cross plate analysis ▪ Export files in FCS, CSV or iQue Forecyt® formats ▪ Customizable PDF data report ▪ iQue Forecyt® Enterprise Edition compatible				
Operational	Computer workstation, Windows compatible	Xeon processor, dual 256 GB SSD (RAID 0), 16 GB RAM, 27" monitor 2560 x 1400							
	Weight (less computer)	205 lbs, 93 kg							
	Dimensions	39" W x 25" D x 26" H | 99 cm W x 63 cm D x 66 cm H							
	Power requirements	100 | 115 | 230 VAC, 50-60 Hz							
	Environment requirements	Temperature: 15–32° C (59–90° F), Relative humidity: 80% maximum							
	Features	▪ CE labeled ▪ 21 CFR logging option compatible			▪ Robotic integration option compatible ▪ iQue® Qmax refill module option compatible				

iQue® technology is protected by the following patents and other patents pending:
6,890,487, 6,878,556, 7,368,084, 7,842,244, 8,021,872, 8,268,571, 8,637,261, 8,823,943, 9,012,235, D,722,515

Learn why iQue® is the choice of leaders in Immuno-Oncology, Antibody Discovery and Immune Target Screening at: **www.sartorius.com/ique**

SARTORIUS

Product Datasheet

Octet® RH96 System

Accelerate Your Label-free Workflow

Key Features

- 96-well plate quantitation in 2 minutes
- 32 x 32 epitope binning in less than 8 hours
- Full plate off-rate ranking in minutes, not hours
- Simultaneously reads 8, 16, 32, 48 or 96 wells

Overview

The Octet® RH96 instrument monitors up to 96 biosensors simultaneously, enabling label-free detection for protein quantitation and kinetic characterization at unmatched speed. The system's ability to read 8, 16, 32, 48 or 96 wells in parallel lets you tailor your assay design to maximize analytical throughput or sensitivity. Rapid whole-plate detection is accomplished using the 96 biosensor mode, providing either quantitation data for 96 samples in as little as 2 minutes or full plate kinetic screening in minutes instead of hours. The 8 and 16 biosensor modes provide high sensitivity for measuring small molecule binding interactions or protein quantitation

down in a simple one-step assay to 50 ng/mL. The 32 or 48 biosensor modes enable larger complex assays such as epitope binning or multi-step quantitation to be analyzed in the shortest amount of time. Key applications that leverage the unique strengths of the Octet® RH96 system include epitope binning experiments, off-rate ranking, and titer determination.

Epitope Binning

Analysis of epitope binning matrices can be completed in record time, with 32 x 32 in less than 8 hours and larger studies over a day. Powerful epitope binning analysis software enables easy visualization of data sets and provides a flexible data matrix that can accommodate a variety of cross-blocking formats (Figure 1).

Protein Concentration Determination

Use of the 32, 48, or 96 biosensor modes enable fast, whole-plate titer determinations, and provides design flexibility for multi-step quantitation assays, including host cell proteins (HCP) and residual protein A contaminant testing.

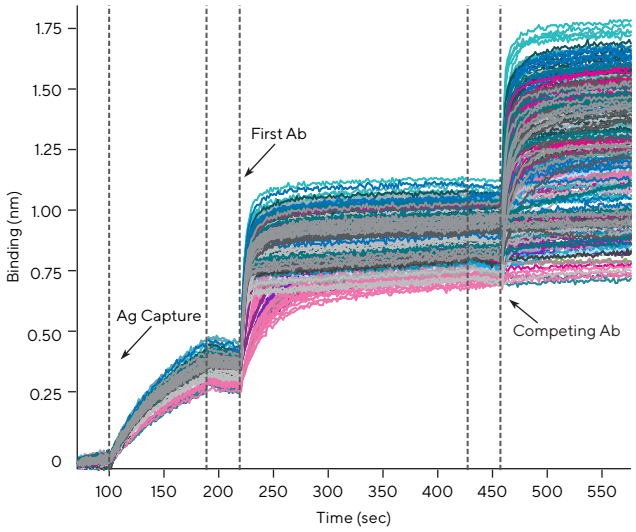


Figure 1: Epitope binning of 32 x 32 purified mAbs using the 32 biosensor mode, performed in 14 hours.

Octet® RH96 System Specifications*

Technical Information and Specifications	
Detection technology	Bio-Layer Interferometry (BLI) based on fiber optic biosensors
Information provided	▪ Yes/No binding ▪ Kinetic and affinity analysis (k_{obs}, K_a, k_d, K_D) ▪ Specific and selective detection of molecules, even in crude samples ▪ Relative and absolute quantitation (using a standard curve) of specific proteins in crude matrices or purified samples
Data presentation	▪ In the form of real-time kinetic binding and fitted results plots/graphs ▪ Concentration data analysis including calibration curves and output of tabulated concentration data ▪ Tabulated kinetic data ▪ Epitope binning and cross-blocking matrices and trace overlays ▪ Customized reports in PDF format
Automation	Robot compatible, microplate and biosensor tray loading
Sample types	Proteins, antibodies, peptides, DNA, RNA, liposomes, bacterial cells, viruses, mammalian cells, small molecules in various media including serum, buffers containing DMSO, periplasmic fractions, untreated cell culture supernatants, and crude cell lysate
Sample plate	2 positions; standard, 96-well and 384-well black, flat bottom microplates and 384 tilted-well microplate
Sample volume	40–100 uL/well (384TW microplate); 80–130 µL/well (384-well microplate); 180–220 µL/well (96-well microplate) Nondestructive testing, easily recoverable
Orbital flow capacity	Static or 100–1500 rpm
Analysis temperature	Ambient + 4°C to 40°C, in 1°C increments
Sample refractive index	Minimally affected by refractive index changes

Instrument	
Dimensions (H x W x D)	30.1 in x 31.5 in x 31.5 in (77 cm x 80 cm x 80 cm)
Weight	200 lbs (90.7 kg)
Power	100–240 V AC, 5.0–2.0 A, 50/60 Hz, single phase/195 W (240 W peak)

Data Handling and Storage	
PC operating system	▪ Windows® 10 Professional, 64-bit ▪ Windows 7 Professional, 64-bit ▪ Windows 7 Professional, 32-bit
Interfaces	RS232, USB

Compliance	
Safety standards	CE, Nemko

Kinetics	
Workflow	Up to 96 assays in parallel, up to 96 assays in two 96-well microplates and 384 assays in two 384-well microplates
Analysis time per sample	Real-time kinetic binding experiments from five minutes to 4 hours
Association rate constant (k_a)	10^1 to 10^7 M^{-1} s^{-1}
Dissociation rate constant (k_d)	10^{-6} to 10^{-1} s^{-1}
Affinity constant (k_D)	1 mM to 10 pM
Molecular weight detection	> 150 Da (8–16 biosensors), > 5000 Da (32–96 biosensors)
Baseline noise (RMS)***	< 4 pm (8–16 biosensors); < 8 pm (32–96 biosensors)
Baseline drift***	< 0.1 nm/hour

Quantitation	
Workflow	Up to 96 assays in parallel, up to 96 assays per 96-well microplate and 384 assays per 384-well microplate
Analysis time per sample	hIgG quantitation 2 minutes for 96 samples in a 96-well microplate, 9 minutes for 384 samples in a 384-well microplate
Quantitation range	32–96 biosensors: 0.1–100 µg/mL of hIgG at 1000 rpm**; 1.0–700 µg/mL at 400 rpm 8–16 biosensors: 0.05–300 µg/mL of hIgG at 1000 rpm**; 0.5–2000 µg/mL at 400 rpm
Precision range	**CV < 10%**

*All specifications are subject to change without notice.
**5-minute assay.
***Baseline drift and noise is measured at 30 °C in 384 TW microplates

Ordering Information

Part No.	UOM	Description
OCTER-RH96	System	Includes Octet® RH96 instrument, desktop computer, LCD monitor, accessory kit, and one-year warranty.
OCTET-RH96-GXP	System	Includes Octet® RH96 instrument, Latest Octet CFR Part 11 Software, Software Validation Package, IQOQ Kit/Manual, IQOQ Service and 2 PMOQ Services.

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Phone +1 888 OCTET 75
Or +1 650 322 1360

For further contacts, visit
www.sartorius.com/octet-support

PN-3016 Rev E

SARTORIUS

Simplifying Progress

Introducing the Incucyte® SX5 Live-Cell Analysis System

More Colors. More Insights. More Possibilities.

Leading the Way With Living Cells

See more information in every sample and explore more applications. Leverage up to 5 different fluorescence channels, up to 3 at a time, for long term timelapse experiments.

Protect Your Cells

Patent-pending 3-color optical module includes a long wavelength, low phototoxicity Near IR channel and reagents designed for long term live-cell experiments.

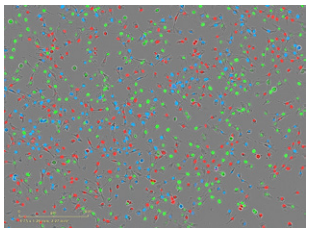
Go Where Your Research Takes You

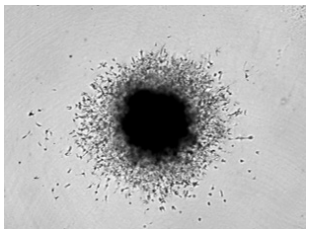
Study complex immune-tumor cell interactions, synaptic activity in neuronal co-cultures, metabolism in cancer cells, and much more—with a single platform.

Improve Productivity

Enjoy walk-away convenience as images are automatically acquired and analyzed in microplate format, up to six in parallel.

The Incucyte SX5 Live-Cell Analysis System offers more channels, more reagents and more purpose-built software for more applications—allowing you to derive deeper, physiologically relevant information about your cells. Never miss powerful insights again, with the Incucyte SX5 Live-Cell Analysis System, Software, Reagents, and Consumables.





Dedicated to Living Cells

- Up to 5 different fluorescence channel options
- Multiplex HD Phase with up to 3 fluorescence channels at a time (Green/Orange/Near IR)
- 4x, 10X, and 20X lenses on an automated turret
- Purpose-built software modules, reagents and consumables for turnkey applications

Support for Multiple Users

- Support for 3 interchangeable vessel trays and over 600 vessels, up to 6 microplates in parallel
- Remote, networked access with unlimited, free licenses

See What You Can Do With the Incucyte Live-Cell Analysis System!

Cell Health & Proliferation
Proliferation & Cell Counting
Cell Cycle
Apoptosis
Cytotoxicity
Viability
Mitochondrial Membrane Potential NEW!
ATP Metabolism NEW!

Cell Function
Immune Cell Killing
Antibody Internalization
Immunocytochemistry
Phagocytosis
Neurite Dynamics
Neuronal Activity
Angiogenesis

3D Cell Models
Spheroid Growth & Viability
Spheroid Invasion

Cell Movement & Morphology
Chemotaxis Migration & Invasion
Scratch Wound Migration & Invasion

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SARTORIUS

Product Datasheet

Picus® & Picus® Nxt Electronic Pipettes

The Most Sophisticated and Ergonomic Pipettes Ever!

Product Information

Sartorius Picus® & Picus® Nxt are the most sophisticated and ergonomic electronic pipettes on the market. These exceptionally compact and lightweight pipettes have been specially designed to ease the user's workload and to protect the user from repetitive strain injury (RSI).

Description

The Picus family pipettes are kind to your hand with unbeatable ergonomic design that ensures reliable and repeatable experiment results. Repeatable pipetting results are guaranteed with the electronic piston control and brake, raising all users to expert level. Picus® Nxt provides distinct advantages for highly regulated laboratories.

Features

Picus® & Picus® Nxt

- Highest level of ergonomics provided by the uniquely low weight, light electronic tip ejection and comfortable handle design
- Extensive range of pipetting modes reduces the needed pipetting steps and speeds up work
- Electronic brake and piston control system provide outstanding accuracy and repeatability of pipetting results, independent of the user
- Intuitive user interface in five language options: English, French, German, Russian and Chinese, enables ease of use
- Adjustment wheel offers extremely fast volume setting and menu navigation
- Optiload enables perfect tip sealing for accurate delivery from each channel
- Safe-Cone Filters prevent the risk of contamination cost-effectively
- Microwell plate tracker guides the user to pipette into the correct wells
- Calibration adjustment in 1, 2 or 3 points

Picus® Nxt

- Certificate of accredited 3-point calibration (per ISO 17025 and ISO 8655) delivered with the product at no extra charge
- User programmable pipetting protocols enable the storage of three frequently needed pipetting workflows; easily activated when needed.
- 2-level password protection for stored programs to prevent unauthorized changes (optional)
- Pipette locking, e.g. in case of contamination, increases lab safety by disabling the pipette from use.
- Service and calibration reminders help the users to remember important service dates.
- Repeated blow-out helps to dispense the last droplets of e.g. viscous liquids

Applications

- PCR and other DNA/RNA techniques
- ELISA
- Protein analysis
- Cell culture

Applications

Fully electronic liquid handling in the volume range of 0.2 µL to 10 mL.

Technical Date

Techncal Specifications	
Rechargeable battery	Li-Polymer with protection circuit
Charging time	Approx. 1 hour
Charger	Universal charger with EU, US|JPN, UK, CHN, AUS and KOR plugs
Weight	100 g (1-ch, 300 µL) 160 g (8-ch, 300 µL)
Length	210 mm (1-ch, 300 µL) 216 mm (8-ch, 300 µL)
Number of pipetting cycles	>1,000
Volume range	1-ch: 0.2 – 10,000 µL 8- & 12-ch: 0.2 – 1200 µL
Pipetting modes	Picus®: 8 + 6 | Picus® Nxt: 9 + 7
DC-motor concept	Electronic piston control Electronic brake
Memory places	Picus®: 10 | Picus® Nxt: 3* + 10
Tip ejection	Electronic
Spring loaded tip cones	Optiload feature in multichannel models
Filters	Safe-Cone Filters in all models >10 µL
Autoclavable lower parts**	121 °C, 20 min, 1 bar
Charging Stands, available separately	Charging Stand for 1 pipette, Charging Carousel for 4 pipettes
Warranty	2 years, possibility for 1 year extended warranty

* For Protocols
** Excluding 1200 µL multichannel models

Pipetting Modes	Advanced Functions
Pipetting	Tracker, Mixing, Counter, Repeated Blow-out*
Reverse Pipetting	Tracker, Counter, Excess Volume Adjustment
Manual Pipetting	Repeated Blow-out*
Multi-Dispensing	Tracker, Excess Volume Adjustment, Auto-Dispensing
Diluting	Mixing, Repeated Blow-out*
Sequential Dispensing	Excess Volume Adjustment
Multi-Aspiration	Repeated Blow-out*
Titrate	Fast Dispensing
Protocol*	All additional modes

* Advanced function, Repeated Blow-out, and pipetting mode, Protocol, are only available in Picus® Nxt models.

Ordering Information

Picus® Nxt	Picus®	Channels	Volume Range (µL)	Increment (µL)	Test Volume (µL)	Mode[P|D]	Systematic Error[N] Limit ± (%)	(µL)	Random Error[N] Limit (%)	(µL)
LH-745021	735021	1	0.2 – 10	0.01	10	P	1.0	0.100	0.4	0.040
					5	P	1.2	0.060	0.7	0.035
					1	P	3.0	0.030	2.0	0.020
					0.2	P	17.5	0.035	10	0.020
					1	D	6.0	0.060	7.0	0.070
LH-745041	735041	1	5 – 120	0.10	120	P	0.5	0.60	0.15	0.18
					60	P	0.7	0.42	0.2	0.12
					12	P	2.0	0.24	1.0	0.12
					5	P	5.5	0.275	2.5	0.125
					12	D	4.0	0.48	4.0	0.48
LH-745061	735061	1	10 – 300	0.20	300	P	0.5	1.50	0.15	0.45
					150	P	0.6	0.90	0.2	0.30
					30	P	1.5	0.45	0.8	0.24
					10	P	5.0	0.50	2.4	0.24
					30	D	3.0	0.90	3.0	0.90
LH-745081	735081	1	50 – 1,000	1.00	1,000	P	0.45	4.5	0.15	1.5
					500	P	0.6	3.0	0.2	1.0
					100	P	2.0	2.0	0.5	0.5
					50	P	4.0	2.0	1.0	0.5
					100	D	2.5	2.5	2.0	2.0
LH-745101	735101	1	100 – 5,000	5.00	5,000	P	0.5	25	0.15	7.5
					2,500	P	0.7	17.5	0.2	5
					500	P	1.6	8	0.4	2
					100	P	8.0	8	2.0	2
					500	D	2.4	12	2.4	12
LH-745111	735111	1	500 – 10,000	10.00	10,000	P	0.6	60	0.2	20
					5,000	P	0.9	45	0.3	15
					1,000	P	3.0	30	0.6	6
					500	P	7.0	35	1.2	6
					1,000	D	4.0	40	2.4	24
LH-745321	735321	8	0.2 – 10	0.01	10	P	1.2	0.120	0.5	0.050
LH-745421	735421	12			5	P	1.5	0.075	0.8	0.040
					1	P	4.0	0.040	3.0	0.030
					0.2	P	25.0	0.050	15.0	0.030
					1	D	12.0	0.120	15.0	0.150
LH-745341	735341	8	5 – 120	0.10	120	P	0.6	0.72	0.3	0.36
LH-745441	735441	12			60	P	0.8	0.48	0.4	0.24
					12	P	2.5	0.30	1.67	0.20
					5	P	6.0	0.30	4.0	0.20
					12	D	4.5	0.54	8.0	0.96
LH-745361	735361	8	10 – 300	0.20	300	P	0.6	1.80	0.2	0.60
LH-745461	735461	12			150	P	0.8	1.20	0.3	0.45
					30	P	2.33	0.70	1.0	0.30
					10	P	8.0	0.80	3.0	0.30
					30	D	3.33	1.00	6.0	1.80
LH-745391	735391	8	50 – 1,200	1.00	1,200	P	0.6	7.2	0.2	2.4
LH-745491	735491	12			600	P	1.0	6.0	0.3	1.8
					120	P	2.5	3.0	1.0	1.2
					50	P	8.0	4.0	2.4	1.2
					120	D	3.33	4.0	3.33	4.0

[N] Note: The listed systematic and random error values can be achieved only under strictly controlled conditions during type test per ISO 8655. The best compatibility is achieved when combining Sartorius pipettes and Sartorius tips. The systematic error and random error results, in tests, have been achieved using Sartorius Optifit tips at factory default speed settings. Due to the continuous product development by Sartorius, the systematic and random error values are subject to change without prior notice.

[P] P = Pipetting Mode

[D] D = Multi-dispensing mode. The listed systematic and random error values are of 10 measurements at 10 % of the nominal volume.

All pipettes are supplied with a universal charger (EU, UK, US | JPN, KOR, AUS and CHN plugs)

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Toll-free +1 800 635 2906

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Laippatie 1
00880 Helsinki
Phone +358 9 755 951

For further contacts, visit
www.sartorius.com

Status: 10 | 2020

SARTORIUS

Product Datasheet

Sartoclear Dynamics® Lab V

For simultaneous clarification and sterile filtration of >15 mL to 1 L mammalian cell cultures in one step

Benefits

- Clarify high-density mammalian cell culture in minutes
- Out-of-the-box solution
- Fast and effortless
- No need for centrifugation

Product Information

Sartoclear Dynamics® Lab V kits are designed for simultaneous clarification and sterile filtration of > 15 mL to 1 L of mammalian cell culture broth to prepare samples for subsequent downstream processing steps, such as protein purification and concentration. The convenient kits combine pouches of filter aid for clarification and vacuum filtration units for sterile filtration.

High Filtration Performance
Sartoclear Dynamics® Lab V kits have been designed for cell harvesting of mammalian cell cultures, such as CHO, HEK, hybridomas and many others, with high cell densities.

Clarification Using Body Feed Filtration
Inspired by the plasma industry, Sartoclear Dynamics® Lab is based on the principle of body feed filtration using diatomaceous earth (DE) as a filter aid. DE is a highly porous, insoluble material used as a spacer between solid particles. While these particulate solids are entrapped in a cake that builds up on the filter, liquid along with the dissolved target substances can easily flow through this filter cake by passing through the porous structure of the DE particles.

Filtration with the Membrane of Choice: Polyethersulfone
Sartoclear Dynamics® Lab products are available either with a 0.22 or 0.45 µm polyethersulfone which have been developped and manufactured by Sartorius at its own facilities.

Both membranes provide fastest flow rates due to their asymmetric structure and ensure lowest protein binding as well as extractable. Therefore, they are the membranes of choice for cell culture harvesting applications.

14 Kits to Cover a Range of Volumes and Cell Densities
Fourteen kits are available to meet all your needs based on your filtration volume and the cell density of your mammalian cell cultures.

Technical Specifications

Typical Results

Cell Type	Cell Density	Viability	Monoclonal Antibody (mAb) Concentration Before Filtration	Monoclonal Antibody (mAb) Concentration After Filtration	Recovery Rate	Turbidity
CHO	14.46×10^6 cells/mL	85.2%	5.2 g/L	5.15 g/L	99%	18 NTU
HEK	8×10^6 cells/mL	70%	0.035 g/L	0.034 g/L	97%	8 NTU

Clarification

Pouches of filter aid

Diatomaceous Earth (DE)	1 g, 5 g or 10 g highly pure diatomaceous earth, (Celpure® C300 – pharmaceutical grade)*, mixed with water in a ratio of 1 DE : 1.25 ultrapure water
	Dust-free, gamma irradiated

* Celpure® is a trademark of Advanced Minerals

Filtration

Vacuum filtration units with receiver flasks (Sartolab® RF 150 - 1000)

Funnel, dust cover, receiver bottles	Polystyrene (PS)
Funnel adapter, tubing connector, cap	High Density Polyethylene (HDPE)
Filter material	0.22 µm polyethersulfone
Packaging	Single-packaged, sterile

Vacuum filtration units with conical tube (Sartolab® RF 50)

Funnel, dust cover	Polystyrene (PS)
Funnel adapter, tubing connector, cap	High Density Polyethylene (HDPE)
Conical tube	Polypropylene
Filter material	0.22 µm polyethersulfone (order no. 180E01) 0.45 µm polyethersulfone (order no. 180F01)
Packaging	Single-packaged, sterile

Each Sartoclear Dynamics® Lab V kit is comprised of pouches of filter aid and vacuum filtration units (Sartolab® RF) that match your needs. Find the right kit in just two easy steps:
1. Determine the volume range of your sample to be filtered.
2. Then reference it to the cell density of your cell culture.

Volume*	Cell Density* < 5 million cells/mL	Cell Density* 5 – 10 million cells/mL	Cell Density* 10 – 20 million cells/mL
≤ 50 mL	SDLV-0050-01E0-2	SDLV-0050-02E0-2	
≥ 50 – 150 mL	SDLV-0150-02E0-E	SDLV-0150-05E0-2	
150 – 250 mL	SDLV-0250-05E0-2	SDLV-0250-10E0-2	
250 – 500 mL	SDLV-0500-05E0-2	SDLV-0500-10E0-2	SDLV-0500-20E0-E
500 – 1000 mL	SDLV-1000-10E0-2	SDLV-1000-20E0-E	SDLV-1000-40E0-E

Two Sartoclear Dynamics® Lab V50 kits are available for the filtration with a 0.45 µm PES membrane:

Volume	Cell Density* < 5 million cells/mL	Cell Density* > 5 million cells/mL
≤ 50 mL	SDLV-0050-01F0-2	SDLV-0050-02F0-2

* Tested with CHO cell lines with a cell viability of approx. 85%

Ordering Information

Sartoclear Dynamics® Lab V50 Kits – 0.22 µm PES

Order Number	Description	Quantity
SDLV-0050-01E0-2	Sartoclear Dynamics® Lab V, 50 mL, 1 g Filtration of up to 50 mL with 1 g of DE per unit Contents: 1 × 180E01---------2 (24 × Sartolab® RF 50, 0.22 µm PES) 1 × SDLKG-01.0-----2 (24 × pouches of filter aid, 1 g)	24
SDLV-0050-02E0-2	Sartoclear Dynamics® Lab V, 50 mL, 2 g Filtration of up to 50 mL with 2 g of DE per unit Contents: 1 × 180E01---------2 (24 × Sartolab® RF 50, 0.22 µm PES) 2 × SDLKG-01.0-----2 (48 × pouches of filter aid, 1 g)	24

Sartoclear Dynamics® Lab V50 Kits – 0.45 µm PES

Order Number	Description	Quantity
SDLV-0050-01F0-2	Sartoclear Dynamics® Lab V, 50 mL, 1 g Filtration of up to 50 mL with 1 g of DE per unit Contents: 1 × 180F01---------2 (24 × Sartolab® RF 50, 0.45 µm PES) 1 × SDLKG-01.0-----2 (24 × pouches of filter aid, 1 g)	24
SDLV-0050-02F0-2	Sartoclear Dynamics® Lab V, 50 mL, 1 g, Filtration of up to 50 mL with 2 g of DE per unit Contents: 1 × 180F01---------2 (24 × Sartolab® RF 50, 0.45 µm PES) 2 × SDLKG-01.0-----2 (48 × pouches of filter aid, 1 g)	24

Sartoclear Dynamics® Lab V150 Kits

Order Number	Description	Quantity
SDLV-0150-02E0-E	Sartoclear Dynamics® Lab V, 150 mL, 2 g Filtration of up to 150 mL with 2 g of DE per unit Contents: 1 × 180E02---------E (12 × Sartolab® RF 150, 0.22 µm PES) 1 × SDLKG-01.0------2 (24 × pouches of filter aid, 1 g)	12
SDLV-0150-05E0-2	Sartoclear Dynamics® Lab V, 150 mL, 5 g Filtration of up to 150 mL with 5 g DE per unit Contents: 2 × 180E02---------E (24 × Sartolab® RF 150, 0.22 µm PES) 1 × SDLKG-05.0------2 (24 × pouches of filter aid, 5 g)	24

Sartoclear Dynamics® Lab V250 Kits

Order Number	Description	Quantity
SDLV-0250-05E0-2	Sartoclear Dynamics® Lab V, 250 mL, 5 g Filtration of up to 250 mL with 5 g of DE per unit Contents: 2 × 180E03---------E (24 × Sartolab® RF 250, 0.22 µm PES) 1 × SDLKG-05.0-----2 (24 × pouches of filter aid, 5 g)	24
SDLV-0250-10E0-2	Sartoclear Dynamics® Lab V, 250 mL, 10 g Filtration of up to 250 mL with 10 g of DE per unit Contents: 2 × 180E03---------E (24 × Sartolab® RF 250, 0.22 µm PES) 1 × SDLKG-10.0-----2 (24 × pouches of filter aid, 10 g)	24

Sartoclear Dynamics® Lab V500 Kits

Order Number	Description	Quantity
SDLV-0500-05E0-2	Sartoclear Dynamics® Lab V, 500 mL, 5 g Filtration of up to 500 mL with 5 g DE per unit Contents: 2 × 180E04---------E (24 × Sartolab® RF 500, 0.22 µm PES) 1 × SDLKG-05.0-----2 (24 × pouches of filter aid, 5 g)	24
SDLV-0500-10E0-2	Sartoclear Dynamics® Lab V, 500 mL, 10 g Filtration of up to 500 mL with 10 g DE per unit Contents: 2 × 180E04---------E (24 × Sartolab® RF 500, 0.22 µm PES) 1 × SDLKG-10.0-----2 (24 × pouches of filter aid, 10 g)	24
SDLV-0500-20E0-E	Sartoclear Dynamics® Lab V, 500 mL, 20 g Filtration of up to 500 mL with 20 g of DE per unit Contents: 1 × 180E04---------E (12 × Sartolab® RF 500, 0.22 µm PES) 1 × SDLKG-10.0-----2 (24 × pouches of filter aid, 10 g)	12

Sartoclear Dynamics® Lab V1000 Kits

Order Number	Description	Quantity
SDLV-1000-10E0-2	Sartoclear Dynamics® Lab V, 1,000 mL, 10 g Filtration of up to 1 L with 10 g of DE per unit Contents: 2 × 180E05---------E (24 × Sartolab® RF 1000, 0.22 µm PES) 1 × SDLKG-10.0-----2 (24 × pouches of filter aid, 10 g)	24
SDLV-1000-20E0-E	Sartoclear Dynamics® Lab V, 1,000 mL, 20 g Filtration of up to 1 L with 20 g of DE per unit Contents: 1 × 180E05---------E (12 × Sartolab® RF 1000, 0.22 µm PES) 1 × SDLKG-10.0-----2 (24 × pouches of filter aid, 10 g)	12
SDLV-1000-40E0-E	Sartoclear Dynamics® Lab V, 1,000 mL, 40 g Filtration of up to 1 L with 40 g of DE per unit Contents: 1 × 180E05---------E (12 × Sartolab® RF 1000, 0.22 µm PES) 2 × SDLKG-10.0-----2 (48 × pouches of filter aid, 10 g)	12

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Product Datasheet

Vivaflow®

Unique, plug and play laboratory crossflow cassettes

Benefits

- Rapid sample processing, with ready-to-use cassettes operated by a standard peristaltic pump
- Plug and play simplicity, thanks to the unique flip-flow channels that ensure optimal flux
- Flexible and modular scalability, with a broad choice of membrane, MWCO and single or multi use options for samples up to 5 L

Product Overview

Vivaflow® brings the benefits of tangential flow filtration to research and development laboratories. Operated with a standard peristaltic pump, these ready-to-use cassettes eliminate the cost and complexity of process-scale systems. Ideal for the ultrafiltration and diafiltration of 0.1 to 5 L samples, the unique flip-flow channel design provides plug and play convenience, ensuring optimal crossflow velocities for fast concentration

Product Information

The Vivaflow® range offers a choice of crossflow devices for scientists who need to reliably concentrate or re-buffer aqueous samples with initial volumes of up to 5 L. Unlike other crossflow cassettes on the market, Vivaflow® is a dedicated laboratory product that meets the demand for ease of use without requiring additional, non-standard equipment or significant process optimization. A choice of devices, operated with a standard peristaltic pump, achieve optimal results for every ultrafiltration need:

Vivaflow® 50 is a modular, single use cassette. With its unique interlocking design and optional stand, up to 6 cassettes are conveniently connected in series and parallel to suit the sample volume and achieve the desired processing speed. With no requirement for cleaning, Vivaflow® 50 is ready-to-use and eliminates the risk of sample cross-contamination. This is the ideal choice for the concentration or buffer exchange of 0.1 to 3 L samples.

Vivaflow® 50R is the most compact crossflow cassette to feature Sartorius' unique, low-binding Hydrosart® membrane. Therefore, it is the ideal choice for the concentration of high value samples, such as viruses and antibodies. For sample volumes up to 1 L, two cassettes may be operated in parallel, and with a robust cleaning procedure, can be reused multiple times.

Vivaflow® 200, like Vivaflow® 50R, is a multi-use cassette. It is offered with a choice of PES or Hydrosart® membranes and a broad range of MWCO options. This enables convenient scale up from the smaller Vivaflow® 50 and 50R cassettes, whilst ensuring suitability for all target molecule types. For sample volumes up to 5 L, two cassettes may be operated in parallel.

Applications

Vivaflow® cassettes lend themselves to a multitude of ultrafiltration applications whenever larger sample volumes need to be concentrated, desalinated or buffer exchanged in a research or process development laboratory environment.

Typical applications include:

- Recombinant protein (e.g. mAb) concentration or diafiltration in biopharmaceutical research
- Virus and virus-like particle (VLP) clarification, concentration or diafiltration from cell culture and environmental samples
- Isolation and concentration of viruses and viral nucleic acids from wastewater
- Concentration, diafiltration or free drug removal in nanoparticle research
- Concentration of environmental samples prior to trace metals analysis

Technical Data

	Vivaflow® 50	Vivaflow® 50R	Vivaflow® 200
Materials of construction			
Main housing	Polycarbonate	Acrylic	Acrylic
Flow channel	TPX (PMP)	Acrylic	Acrylic
Membrane support	TPX (PMP)	Polypropylene	Polypropylene
Membrane seals and O rings	Silicone	Silicone	Silicone
Pressure indicator	Not included*	Polypropylene, SS** spring	Polypropylene, SS** spring
Flow restrictor	Polypropylene	Polypropylene	Polypropylene
Fittings	Nylon	Nylon	Nylon
Tubing	PVC (medical grade)	PVC (medical grade)	PVC (medical grade)

Dimensions			
Overall L | H | W	107 | 84 | 25 mm	100 | 100 | 24 mm	126 | 138 | 38 mm
Channel W | H	15 mm | 0.3 mm	7.5 | 0.4 mm	10 mm | 0.4 mm
Active membrane area	50 cm^2	50 cm^2	200 cm^2
Min. recirculation volume	< 10 mL	< 10 mL	< 20 mL
Hold-up volume, cassette	1.5 mL	1.7 mL	5.3 mL
Non-recoverable hold-up	< 0.5 mL	< 0.5 mL	< 1 mL

Operating Conditions			
Pump flow rate	200–400 mL/min	200–400 mL/min	200–400 mL/min
Maximum pressure	3 bar (45 psi)	4 bar (60 psi)***	4 bar (60 psi)***
Maximum temperature	60°C	60°C	60°C

* Pressure indicator is available separately (Order no. VFA020) as an optional accessory for Vivaflow® 50

** SS = stainless steel

*** Pressure drop across inlet | outlet = 0.5 bar (7 psi)

Working Principle

Vivaflow® cassettes contain an ultrafiltration membrane over which a sample is recirculated using a peristaltic pump (Figure 1). The thin channel flip-flow path provides high crossflow velocities with minimal pump speed requirements of 200 – 400 mL/min. A flow restrictor included with each cassette generates the optimal transmembrane pressure for concentration | diafiltration of the sample, whilst the filtrate is collected in a separate vessel. Ultrafiltration can be stopped as soon as the desired volume is reached by simply turning off the pump.

A single 50 cm^2 cassette typically reduces 500 mL to 15 mL in less than 50 min. Virtual total recovery of the retentate is achieved with a single rinse.

Convenient Diafiltration

The optional diafiltration reservoir (order number VFA006) makes both concentration and diafiltration with Vivaflow® exceptionally convenient. A sample is first concentrated to the desired volume, then a length of tubing placed into a separate vessel containing the exchange buffer is connected to the reservoir (Figure 2). Airtight sealing in the lid of the diafiltration reservoir enables constant volume buffer exchange. As the original buffer continues to permeate the ultrafiltration membrane, it is replaced with an equal volume of the exchange buffer, thereby limiting the need for large buffer volumes, and avoiding sample dilution.

Figure 1

Ultrafiltration with Vivaflow®

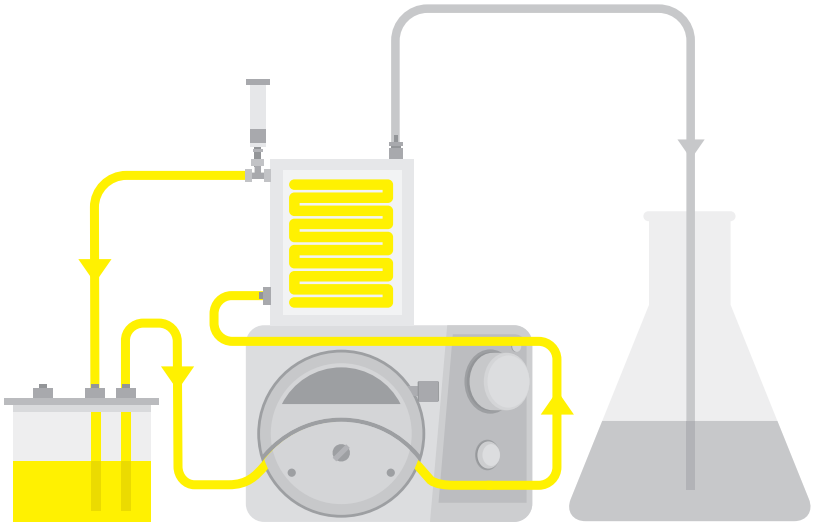
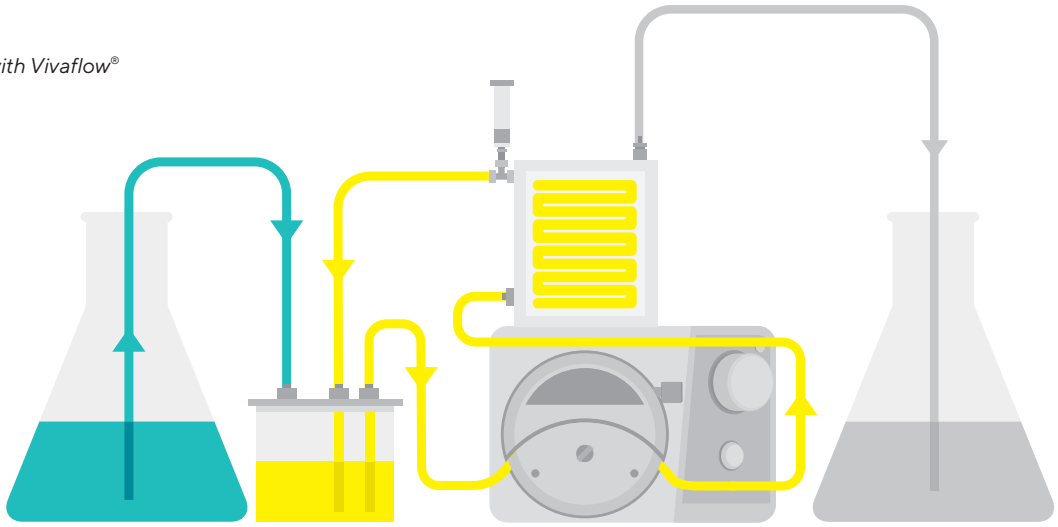


Figure 2

Diafiltration with Vivaflow®



Components for Operating One to Six Vivaflow® 50 Cassettes

The modular design of Vivaflow® 50 enables the operation of multiple cassettes in series and parallel (Figure 3 and Table 1). This increases the maximum throughput to up to 3 L and accelerates processing speed in proportion to the membrane area (Figure 4).

Figure 4

Precise scale-up in process speed when using one to four Vivaflow® 50 cassettes.

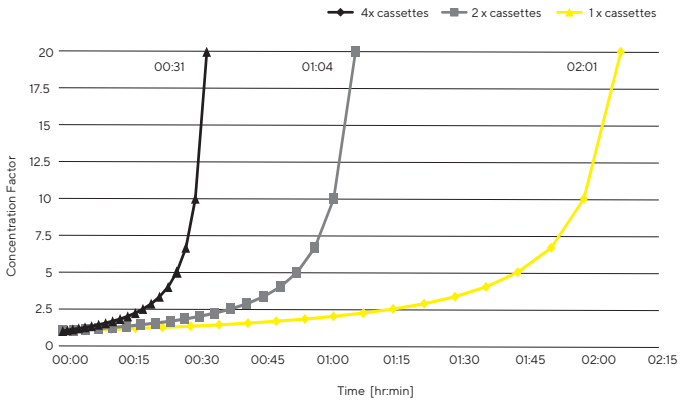


Figure 3

System components for operating multiple Vivaflow® 50 cassettes.

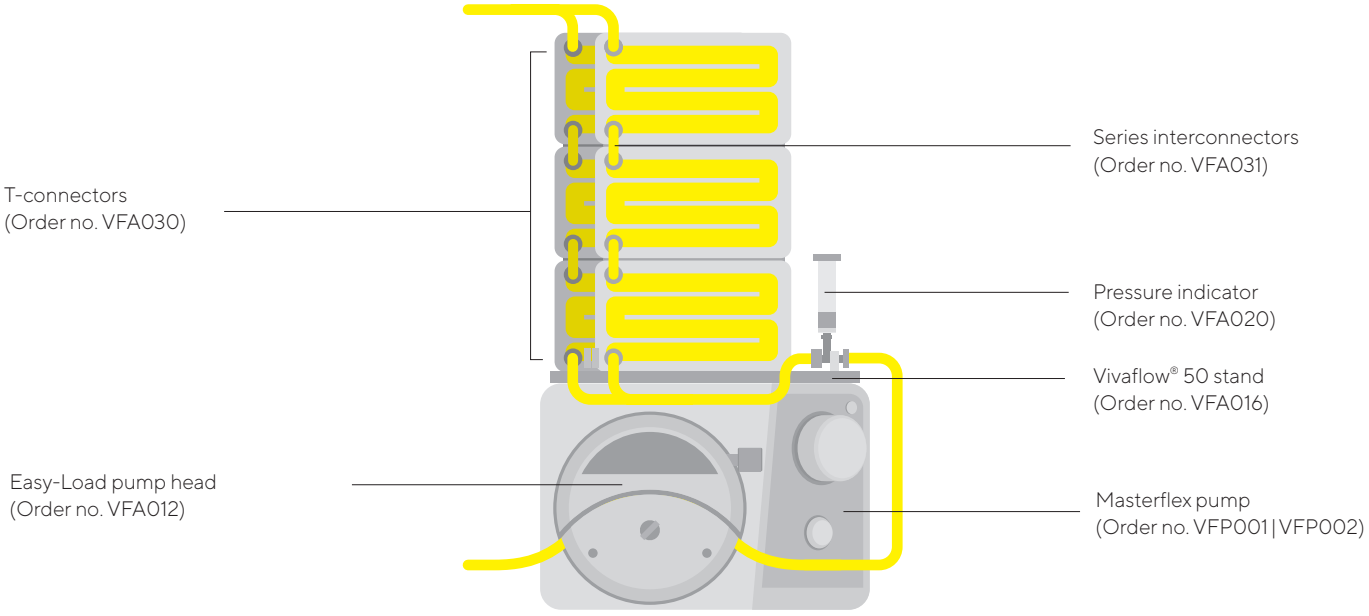


Table 1

Sample capacities and system components for operating Vivaflow® 50 cassettes

		1x VF 50	2x VF 50	3x VF 50	4x VF 50	5x VF 50	6x VF 50
Operating Mode		**Single**	**Series**	**Series**	**Series and parallel**	**Series and parallel**	**Series and parallel**
Sample Volume		**0.1 – 0.5 L**	**0.5 – 1 L**	**1 – 1.5 L**	**1.5 – 2 L**	**2 – 2.5 L**	**2.5 – 3 L**
Masterflex pump	VFP001 | VFP002*	1	1	1	1	1	1
Easy-Load pump head - size 16	VFA012	1	1	1	1	1	1
Pressure indicator	VFA020	optional	1	1	1	1	1
Series interconnectors	VFA031	-	(1)**	(2)**	(2)**	(3)**	(3)** + 1
T-connectors (x2)	VFA030	-	-	-	1	1	1
Vivaflow® 50 stand	VFA016	optional	1	1	1	1	1

* VFP001 line voltage = 240 V; VFP002 line voltage = 115 V
** One series interconnector is supplied with each pack of 2x cassettes

Components for Operating One or Two Vivaflow® 50R | 200 Cassettes

The maximum throughput of Vivaflow® 50R | 200 can also be increased and processing time reduced by adding a second cassette to the setup (Figure 5 and Table 2).

Figure 5

System components for operating two Vivaflow® 50R | 200 cassettes

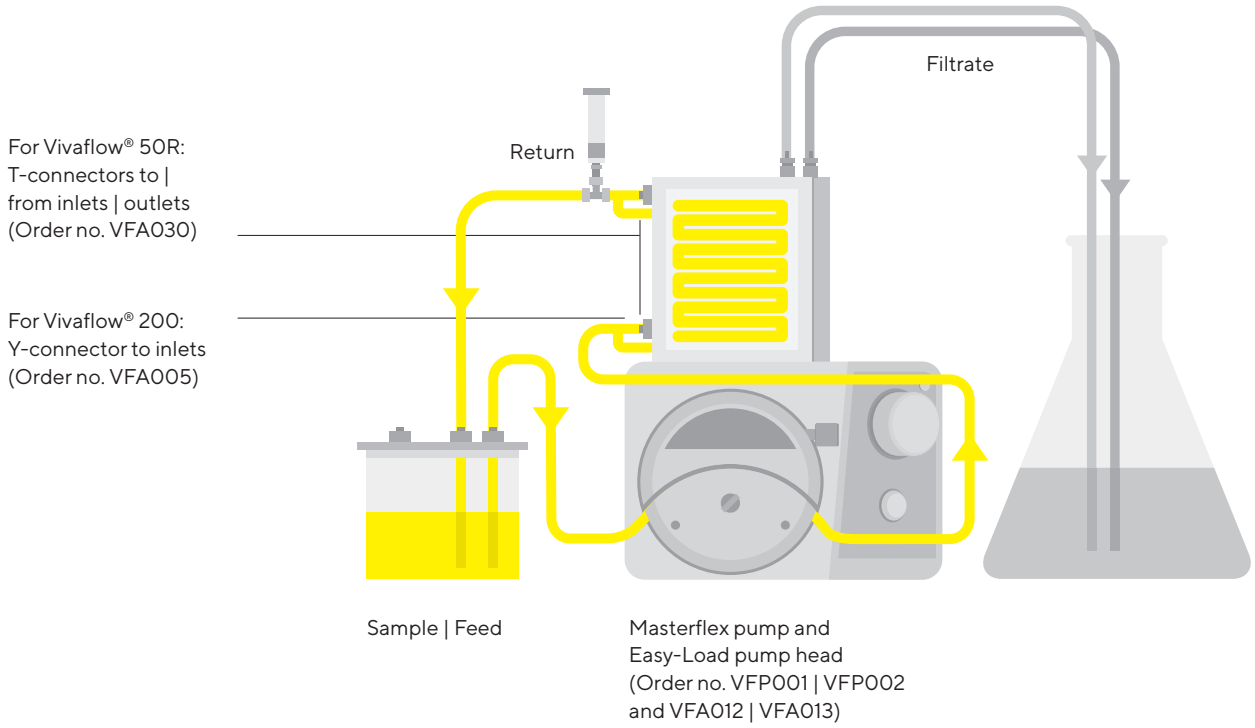


Table 2

Sample capacities and system components for operating Vivaflow® 50R | 200 cassettes

		1x VF 50R	2x VF 50R	1x VF 200	2x VF 200
Operating Mode		**Single**	**Parallel**	**Single**	**Parallel**
Sample Volume		**0.1 – 0.5 L**	**0.5 – 1 L**	**0.5 – 2.5 L**	**2.5 – 5 L**
Masterflex pump	VFP001 | VFP002 *	1	1	1	1
Easy-Load pump head - size 16	VFA012	1	1	1	-
Easy-Load pump head - size 16	VFA013	-	-	-	1
Pressure indicator	VFA020	(1)**	(1)**	(1)**	(1)**
Y-connector	VFA005	-	-	-	1
T-connectors (x2)	VFA030	-	1	-	-

* VFP001 line voltage = 240 V; VFP002 line voltage = 115 V

** One pressure indicator is supplied with each pack of 1x cassette

Performance

Performance Characteristics for Vivaflow® 50

	Time to concentrate up to 20x at 3 bar inlet pressure, 20°C			
	One Cassette	Three Cassettes		
	250 mL Initial Volume	1 L Initial Volume	Recovery (Direct)	Recovery (10 mL Rinse)
BSA, 1.0 mg/mL (66,000 MW)				
5,000 MWCO PES	34 min	49 min	96%	> 99%
10,000 MWCO PES	22 min	32 min	94%	> 99%
30,000 MWCO PES	22 min	32 min	92%	99%
50,000 MWCO PES	20 min	29 min	92%	98%
γ Globulins, 1.0 mg/mL (150,000 MW)				
100,000 MWCO PES	43 min	62 min	92%	98%
100,000 MWCO RC	40 min	58 min	92%	98%
Yeast, 1.0 mg/mL (*S. cerevisiae*)				
0.2 µm PES	33 min	47 min	92%	98%

Performance Characteristics for Vivaflow® 50R

	Time to concentrate up to 20x at 3 bar inlet pressure, 20°C			
	250 mL Initial Volume	Average Flux	Recovery (Direct)	Recovery (25 mL Rinse)
Lysozyme, 0.25 mg/mL (14,000 MW)				
5,000 MWCO Hydrosart®	70 min	3.4 mL/min	96%	98%
10,000 MWCO Hydrosart®	23 min	10.3 mL/min	94%	96%
BSA, 1.0 mg/mL (66,000 MW)				
10,000 MWCO Hydrosart®	24 min	9.9 mL/min	98%	> 99%
30,000 MWCO Hydrosart®	15 min	15.8 mL/min	97%	> 99%
γ Globulins, 1.0 mg/mL (150,000 MW)				
100,000 MWCO Hydrosart®	46 min	5.2 mL/min	97%	> 99%
	Time to concentrate 1 L BSA (1 mg/mL) at 3 bar inlet pressure with 10,000 MWCO Hydrosart®			
One Vivaflow® 50R Cassette	95 min	10.0 mL/min	98%	> 99%
Two Vivaflow® 50R Cassettes	48 min	19.8 mL/min	98%	> 99%

Performance Characteristics for Vivaflow® 200

	Time to concentrate up to 20x at 3 bar inlet pressure, 20°C			
	1 L Initial Volume	**Average Flux**	**Recovery (Direct)**	**Recovery (25 mL Rinse)**
Lysozyme, 0.25 mg/mL (14,000 MW)				
2,000 MWCO Hydrosart®	160 min	6 mL/min	97%	> 99%
3,000 MWCO PES	180 min	5 mL/min	97%	> 99%
BSA, 1.0 mg/mL (66,000 MW)				
5,000 MWCO PES	29 min	33 mL/min	98%	> 99%
5,000 MWCO Hydrosart®	70 min	14 mL/min	98%	> 99%
10,000 MWCO PES	23 min	41 mL/min	96%	> 99%
10,000 MWCO Hydrosart®	35 min	27 mL/min	98%	> 99%
30,000 MWCO PES	25 min	38 mL/min	96%	99%
30,000 MWCO Hydrosart®	20 min	48 mL/min	96%	> 99%
50,000 MWCO PES	22 min	43 mL/min	96%	98%
γ Globulins, 1.0 mg/mL (average 150,000 MW)				
100,000 MWCO PES	54 min	18 mL/min	96%	99%
100,000 MWCO Hydrosart®	45 min	21 mL/min	96%	99%
Yeast, 1.0 mg/mL (*S. cerevisiae*)				
0.2 µm PES	11 min	86 mL/min	92%	98%
	Time to concentrate dilute solute from 1 L initial volume at 3 bar inlet pressure with 10,000 MWCO PES			
BSA, 0.001 mg/mL	18 min	52 mL/min	90%	98%
BSA, 0.01 mg/mL	20 min	47 mL/min	92%	98%
BSA, 0.1 mg/mL	21 min	45 mL/min	94%	99%
	Time to concentrate BSA (1 mg/mL) from 5 L initial volume at 3 bar inlet pressure with 10,000 MWCO PES			
BSA, 1.0 mg/mL	67 min	70 mL/min	97%	> 99%

Ordering Information

	Quantity	Order No.
Vivaflow® 50 (includes 2x cassettes with filtrate tube, size 16 peristaltic tubing, flow restrictor and fittings, and 1x series interconnector)		
3,000 MWCO PES	2	VF05P9
5,000 MWCO PES	2	VF05P1
10,000 MWCO PES	2	VF05P0
30,000 MWCO PES	2	VF05P2
50,000 MWCO PES	2	VF05P3
100,000 MWCO PES	2	VF05P4
1,000,000 MWCO PES	2	VF05P6
0.2 µm PES	2	VF05P7
100,000 MWCO RC	2	VF05C4
Vivaflow® 50 complete system		
Pump (240 V), Easy-Load pump head (size 16), tubing, 500 mL sample|diafiltration reservoir, cassette stand, pressure indicator, T connectors and series interconnectors	1	VFS502
Pump (115 V), Easy-Load pump head (size 16), tubing, 500 mL sample|diafiltration reservoir, cassette stand, pressure indicator, T-connectors and series interconnectors	1	VFS504
Vivaflow® 50R (includes 1x cassette, filtrate tube, size 16 peristaltic tubing, flow restrictor and fittings, and 1x pressure indicator)		
5,000 MWCO Hydrosart®	1	VF05H1
10,000 MWCO Hydrosart®	1	VF05H0
30,000 MWCO Hydrosart®	1	VF05H2
100,000 MWCO Hydrosart®	1	VF05H4
Vivaflow® 200 (includes 1x cassette, filtrate tube, size 16 peristaltic tubing, flow restrictor and fittings, and 1x pressure indicator)		
3,000 MWCO PES	1	VF20P9
5,000 MWCO PES	1	VF20P1
10,000 MWCO PES	1	VF20P0
30,000 MWCO PES	1	VF20P2
50,000 MWCO PES	1	VF20P3
100,000 MWCO PES	1	VF20P4
0.2 µm PES	1	VF20P7
2,000 MWCO Hydrosart®	1	VF20H9
5,000 MWCO Hydrosart®	1	VF20H1
10,000 MWCO Hydrosart®	1	VF20H0
30,000 MWCO Hydrosart®	1	VF20H2
100,000 MWCO Hydrosart®	1	VF20H4

	Quantity	Order No.
Vivaflow® 50R | 200 complete system		
Pump (240 V), Easy-Load pump head (size 16), tubing and 500 mL sample|diafiltration reservoir	1	VFS202
Pump (115 V), Easy-Load pump head (size 16), tubing and 500 mL sample|diafiltration reservoir	1	VFS204
Vivaflow® accessories		
Masterflex Economy Drive variable speed peristaltic pump (230 V)		VFP001
Masterflex Economy Drive variable speed peristaltic pump (115 V)		VFP002
500 mL sample and|or diafiltration reservoir		VFA006
Masterflex Easy-Load pump head – size 16		VFA012
Masterflex Easy-Load pump head – size 15		VFA013
Vivaflow® 50 stand		VFA016
Pressure indicator (1–3 bar)		VFA020
Vivaflow® 50 accessories for operating 2-6 cassettes		
T-connectors for running 2 stacks	2	VFA030
Series interconnectors	6	VFA031
Pressure indicator (1–3 bar)	1	VFA020
Vivaflow® 50R accessories for operating 2 cassettes		
T-connector	2	VFA030
Vivaflow® 200 accessories for operating 2 cassettes		
Y-connector (size 15 to 2 x size 16, Luer fittings)	1	VFA005
Masterflex Easy-Load pump head – size 15	1	VFA013

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Product Datasheet

Vivaspin® Turbo 4 and 15 PES and RC

Enabling the fastest sample concentration with highest recoveries

Benefits

- Complete Recoveries
- Fastest Concentrations
- Highest Chemical Resistance
- Unique PES and RC Device Range
- Optimal Sample to Membrane Compatability

Product Information

Vivaspin® Turbo 4 and 15 PES and RC centrifugal concentrators offer the optimal solution to any concentration or buffer exchange application with their broad range of MWCOs and unique membrane choice.

Highest flow rates are achieved due to their twin vertical membranes which minimize protein polarization and subsequent fouling of the membrane. Additionally, their sleek internal profile ensures maximum process speeds right down to the last 100 µL.

Working Principle
Centrifugation provides the vector to clear solvent and micro molecules through an ultrafiltration membrane to separate macromolecular species and solvents primarily on the basis of size. It is particularly appropriate for the concentration of macromolecules and can also be used to purify molecular species or for solvent exchange. Ultrafiltration is a non denaturing method that is more efficient, flexible and gentle than alternative processes.

High Performance
In a single spin, 4 or 15 mL solutions can be concentrated up to 150×. Samples can be typically concentrated in 10–30 minutes with macromolecular recoveries in excess of 90%.

Optimized Design for Fastest Concentration Results
The Vivaspin® Turbo's optimized design, its sleek internal profile, ensures maximum process speeds right the way down to the last few micro liters. The UV and ultrasonic joining technologies allow for a smooth joint transition between membrane and plastic housing, allowing all of your valuable sample to be collected into the unique pipette friendly dead stop pocket.

The ultimate in centrifugal ultrafiltration technology:

- Sleek internal design: Ensures maximum process speed for the complete filtration
- Large twin vertical membranes: A fouling of the membrane is avoided due to minimized protein polarization.
- Unique angular dead stop pocket: The dead stop pocket in both Vivaspin® Turbo 4 & 15 is easy to access with standard 200 µL pipette tips due to its patent pending angular design. It eliminates the risk of the sample running to dryness while allowing highest recovery of the concentrate.

Optimized Choice of Materials for High Chemical Compatibility
The combination of Polyethersulfone (PES) | Regenerated Cellulose (RC), Polystyrene and Polypropylene (PP) allows sterilization and depyrogenization of the Vivaspin® Turbo units.

PES membranes are preferred for their low fouling characteristics, exceptional flux and broad pH range compatibility.

RC membranes offer a neutral membrane charge and broad chemical compatibility well suited to general sample types.

Applications

Sample preparation
- Sample (protein, lipid, exosomes, virus, nanoparticle, macromolecule) concentration
- Desalting | dialysis
- Buffer exchange

Your sample is often the result of several months of research. Your sample is valuable, and the Vivaspin® Turbo range provides highest recovery.

Summary
For scientists and lab technicians who need to quickly and safely concentrate a wide range of biological samples of 2 mL to 15 mL initial volume up to 150 fold, Sartorius offers the Vivaspin® Turbo 4 and 15 PES and RC ultrafilters.

Unlike competitive ultrafiltration units, Vivaspin® Turbo units are equipped with an angular dead stop pocket, that enables reproducible and complete recoveries, while being the fastest in the market.

Now with the choice between both PES and RC membrane variants, the Vivaspin® Turbo range enables users to choose the best membrane for their target, in the same super-fast device.

Technical specifications

		Vivaspin® Turbo 4 PES	Vivaspin® Turbo 15 PES	Vivaspin® Turbo 15 RC
Materials	Body	Styrene butadiene copolymere	Styrene butadiene copolymere	Styrene butadiene copolymere
	Filtrate vessel	Polypropylene	Polypropylene	Polypropylene
	Concentrator cap	Polypropylene	Polypropylene	Polypropylene
	Membrane	Polyethersulfone (PES)	Polyethersulfone (PES)	Regenerated Celloluse (RC)
Dimensions	Total length (concentrator insert)	75.5 mm	77 mm	77 mm
	Total length (in tube with cap)	122.5 mm	118 mm	118 mm
	Diameter (concentrator insert)	14.6 mm	27 mm	27 mm
	Active membrane area	3.2 cm^2	7.2 cm^2	8.1 cm^2
	Hold up volume of membrane	<10 µL	<10 µL	<10 µL
	Dead stop volume in swing out	40 µL	100 µL	100 µL
	Dead stop volume in fixed angle	30 µL	60 µL	60 µL
Concentrator capacity	Swing bucket rotor	4 mL	15 mL	15 mL
	Fixed angle rotor (25°)	4 mL	9 mL	9 mL
Maximum speed 3 kDa – 50 kDa	Swing bucket rotor	4,000 × g	4,000 × g	4,000 × g
	Fixed Angle rotor (25°)	7,500 × g	4,000 × g	6,000 × g
Maximum speed 100 kDa	Swing bucket rotor	3,000 × g	2,000 × g	3,000 × g
	Fixed Angle rotor (25°)	5,000 × g	2,000 × g	6,000 × g
Sterilization	ETO or 70% EtOH			
Removal of endotoxins [Depyrogenization]	Flushing with 1N NaOH*			

* PES variants only

Performance Characteristics

Vivaspin® Turbo 4 PES

Time to concentrate up to 30× [min.] at 20°C and solute recovery %				
Rotor	Swing bucket		Fixed angle (25°)	
Centrifugal speed	4,000 × g		7,500 × g	
Start volume	4 mL		4 mL	
	Min.	Rec.	Min.	Rec.
Cytochrome c* (12,400 MW) 3 MWCO PES	60	98	80	96
Lysozyme* (14,300 MW) 3 MWCO PES	65	95	70	93
Cytochrome c* (12,400 MW) 5 MWCO PES	40	95	50	94
Lysozyme* (14,300 MW) 5 MWCO PES	50	94	60	92
α-Chymotrypsin** (25,000 MW) 10 MWCO PES	10	95	8	95
BSA** (66,000 MW) 10 MWCO PES 30 MWCO PES	10 8	98 96	7 6	97 97
IgG** (160,000 MW) 30 MWCO PES 50 MWCO PES 100 MWCO PES****	18 16 17	94 93 94	13 12 13	92 90 92

Vivaspin® Turbo 15 PES

Time to concentrate up to 20× [min.] at 20°C and solute recovery %				
Rotor	Swing bucket		Fixed angle (25°)	
Centrifugal speed	4,000 × g		4,000 × g	
Start volume	15 mL		9 mL	
	Min.	Rec.	Min.	Rec.
Cytochrome c* (12,400 MW) 3 MWCO PES	61	98%	86	97%
Lysozyme* (14,300 MW) 3 MWCO PES	56	98%	87	97%
Cytochrome c* (12,400 MW) 5 MWCO PES	30	98%	50	98%
Lysozyme* (14,300 MW) 5 MWCO PES	33	96%	50	96%
α-Chymotrypsin** (25,000 MW) 10 MWCO PES	10	95%	10	95%
BSA** (66,000 MW) 10 MWCO PES 30 MWCO PES	10 8	99% 98%	10 10	99% 98%
IgG** (160,000 MW) 30 MWCO PES 50 MWCO PES 100 MWCO PES***	23 20 30	95% 94% 92%	17 15 16	95% 94% 92%

Vivaspin® Turbo 15 RC

Time to concentrate up to 20× [min.] at 20°C and solute recovery %				
Rotor	Swing bucket		Fixed angle (25°)	
Centrifugal speed	4,000 × g		7,500 × g	
Start volume	15 mL		9 mL	
	Min.	Rec.	Min.	Rec.
Lysozyme* (14,300 MW) 5 MWCO PES	23	94%	25	92%
α-Chymotrypsin** (25,000 MW) 10 MWCO PES	7	93%	9	92%
BSA** (66,000 MW) 10 MWCO PES 30 MWCO PES	8 4	94% 96%	10 4	98% 93%
IgG** (160,000 MW) 50 MWCO PES 100 MWCO PES****	17 18	95% 89%	12 11	96% 89%

* 0.25 mg/mL
** 1 mg/mL
*** 3,000 g centrifugal speed
**** 3,000 g swing-out | 5,000 g fixed angle
***** 3,000 g swing-out | 4,000 g fixed angle

Ordering Information

Vivaspin® Turbo 4 and 15 centrifugal concentrators, disposable ultrafiltration units, for processing sample volumes of 2 – 4 mL and 15 mL, Polyethersulfone UF membrane.

Vivaspin® Turbo 4 PES

Cut off	Quantity	Order no.
3,000 MWCO	25	VS04T91
3,000 MWCO	100	VS04T92
5,000 MWCO	25	VS04T11
5,000 MWCO	100	VS04T12
10,000 MWCO	25	VS04T01
10,000 MWCO	100	VS04T02
30,000 MWCO	25	VS04T21
30,000 MWCO	100	VS04T22
50,000 MWCO	25	VS04T31
50,000 MWCO	100	VS04T32
100,000 MWCO	25	VS04T41
100,000 MWCO	100	VS04T42

Vivaspin® Turbo 15 PES

Cut off	Quantity	Order no.
3,000 MWCO	12	VS15T91
3,000 MWCO	48	VS15T92
5,000 MWCO	12	VS15T11
5,000 MWCO	48	VS15T12
10,000 MWCO	12	VS15T01
10,000 MWCO	48	VS15T02
30,000 MWCO	12	VS15T21
30,000 MWCO	48	VS15T22
50,000 MWCO	12	VS15T31
50,000 MWCO	48	VS15T32
100,000 MWCO	12	VS15T41
100,000 MWCO	48	VS15T42

Vivaspin® Turbo 15 RC

Cut off	Quantity	Order no.
5,000 MWCO	12	VS15TR11
5,000 MWCO	48	VS15TR12
10,000 MWCO	12	VS15TR01
10,000 MWCO	48	VS15TR02
30,000 MWCO	12	VS15TR21
30,000 MWCO	48	VS15TR22
50,000 MWCO	12	VS15TR31
50,000 MWCO	48	VS15TR32
100,000 MWCO	12	VS15TR41
100,000 MWCO	48	VS15TR42

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Toll-free +1 800 635 2906

Status: 07|2020

Ambr® 15 Cell Culture Generation 2

Technical Specification

Scope
Automated high throughput microscale bioreactor system for cell culture applications.

Monitoring and control of 24 or 48 cultures in parallel at 10 - 15 mL working volumes.

Comprising single-use microbioreactor vessels, automated workstation, laptop and software.

Recommended Working Space

System dimensions excluding laptop computer and system options.
Refer to Building Services Specification for detailed drawings.

Ambr® 15 Cell Culture, 24 microbioreactor system

Width (small tip bin)	Width (large tip bin)	Depth	Height
780mm	915 mm	530 mm	665 mm
31 "	36"	21 "	26"

Ambr® 15 Cell Culture, 48 microbioreactor system

Width (small tip bin)	Width (large tip bin)	Depth	Height
1270mm	1405 mm	530 mm	665 mm
50"	55"	21 "	26"

System operating parameters

Number of microbioreactors	24 or 48 (2 or 4 stations of 12)
Agitation speed	150 – 2500 rpm
Culture temperature (standard)	33 – 40°C ± 0.5°C (+ 8°C above ambient)
Culture temperature (cooled)	20 - 40°C ± 0.5°C
Temperature shift rate	≥ 5°C per 30 mins
pH set point range	6.5 – 7.5
pH monitoring range	6.0 – 8.0
pH monitoring accuracy	± 0.1 pH units
DO (% air saturation) monitoring range	0 – 200%
DO monitoring accuracy	±2% @ 100%
Maximum air or total gas flow	1 mL/min
Disposable tip sizes	1 mL and 5 mL tips

Pipette based liquid handling:

1 mL tip	± 5% from 20 µL – 50 µL	± 2% from 50 µL – 900 µL
5 mL tip	± 2% from 0.5 mL – 1 mL	± 1% from 1 mL – 4 mL

Rapid Vessel Drain operating parameters

Passage culture minimum volume remaining	2.5 mL	
Passage culture precision	± 5% @ 2.5 mL	± 1% @ 6 mL
Rapid vessel drain minimum volume remaining	0 mL	
Rapid vessel drain precision	± 5% @ 2.5 mL	± 1% @ 6 mL

Labware deck positions

	Flexible	Plate	Cooled plate
Ambr® 15 Cell Culture 24 microbioreactor system	6	2	0
Ambr® 15 Cell Culture 24 microbioreactor system cooled	6	1	1
Ambr® 15 Cell Culture 48 microbioreactor system	9	4	0
Ambr® 15 Cell Culture 48 microbioreactor system cooled	9	2	2

Deck positions for maximum plates

	24	24C	48	48C
Plate locations	5	4	10	8
Chilled plate locations	0	1	0	2
Plate lids (multiple locations can be defined)	1	1	1	1
1 or 5 mL pipette tip box (5 mL tip box cannot be defined in front of a 1 mL tip box)	1	1	1	1
Tip box lid (multiple locations can be defined)	1	1	1	1

Deck positions for maximum pipette tips

	24	24C	48	48C
Plate locations	1	1	2	2
Chilled plate locations	0	1	0	2
Plate lids (multiple locations can be defined)	1	1	1	1
1 or 5 mL pipette tip box (5 mL tip box cannot be defined in front of a 1 mL tip box)	5	4	9	7
Tip box lid	1	1	1	1

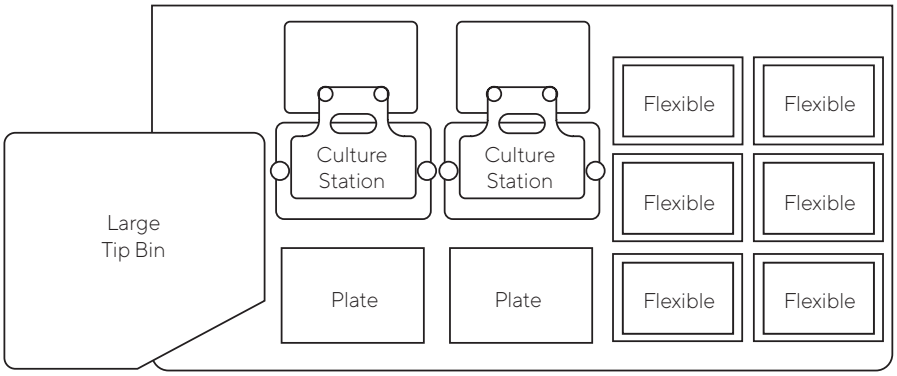
Microbioreactor vessel

Construction material	Polycarbonate, polyethylene
Internal dimensions (L x W x H)	28.0 x 14.6 x 59.7 mm
Total volume	18 mL
Working volume	10 – 15 mL
pH monitoring technology	Fluorescence based spot
DO monitoring technology	Fluorescence based spot
Impeller type	Pitched blade
Diameter	11.4 mm
Power number	2.15
KLa (sparged vessels, 13 mL DI water, 1500 rpm, gassing @ 1 mL/min)	17.6 per hour

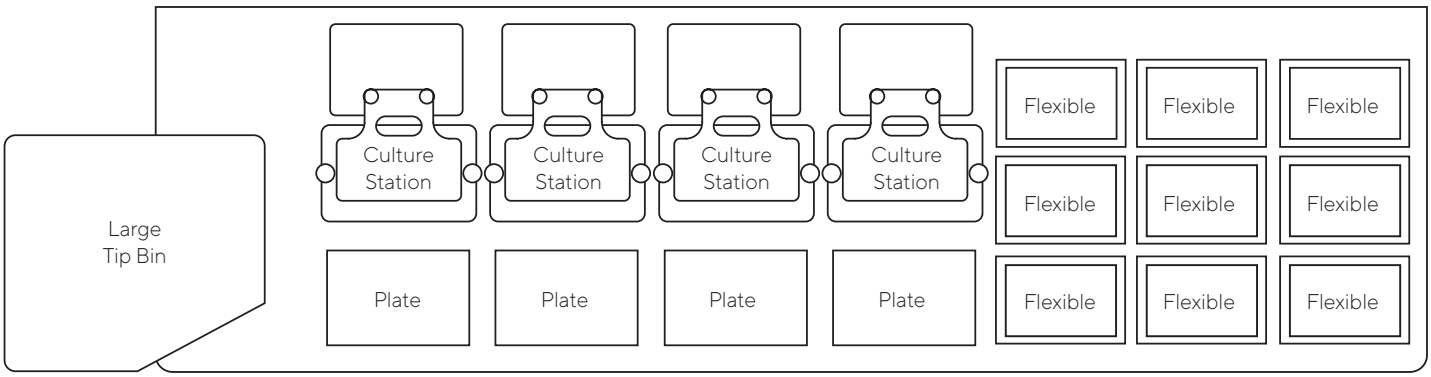
Note: All information is correct at time of publication, but Sartorius reserves the right to make alterations due to technical enhancements or other changes.

Ambr® 15 Cell Culture Generation 2 Deck Layouts

Ambr® 15 Cell Culture 24 microbioreactor system



Ambr® 15 Cell Culture 48 microbioreactor system



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DIR: 2475299-000-02
Status: 05 | 2020

MODDE®

Design of Experiments solution

Simplifying Progress

SARTORIUS

Create the knowledge you need more efficiently

The more efficient your Design of Experiments (DOE) solution, the faster you can get products to market. MODDE® is an innovative DOE solution from Sartorius Stedim Data Analytics. Its straightforward graphical interface and support for data analytics lets you interpret your results with confidence. With over 30 years of experience in data analytics, MODDE gives you the insight to set up your experiment and get it right from the start.

What does MODDE offer?

MODDE is a lot more than just DOE software. It also provides a quality analysis on your decisions and looks at the risks - warning you about critical settings and guiding you towards more robust conclusions. It will:

- Reduce the number of required experiments
- Guide you through the set-up of your experiment
- Provide confidence in your data handling
- Help you make better decisions
- Integrate with your systems
- Meet your quality goals

Who is using MODDE?

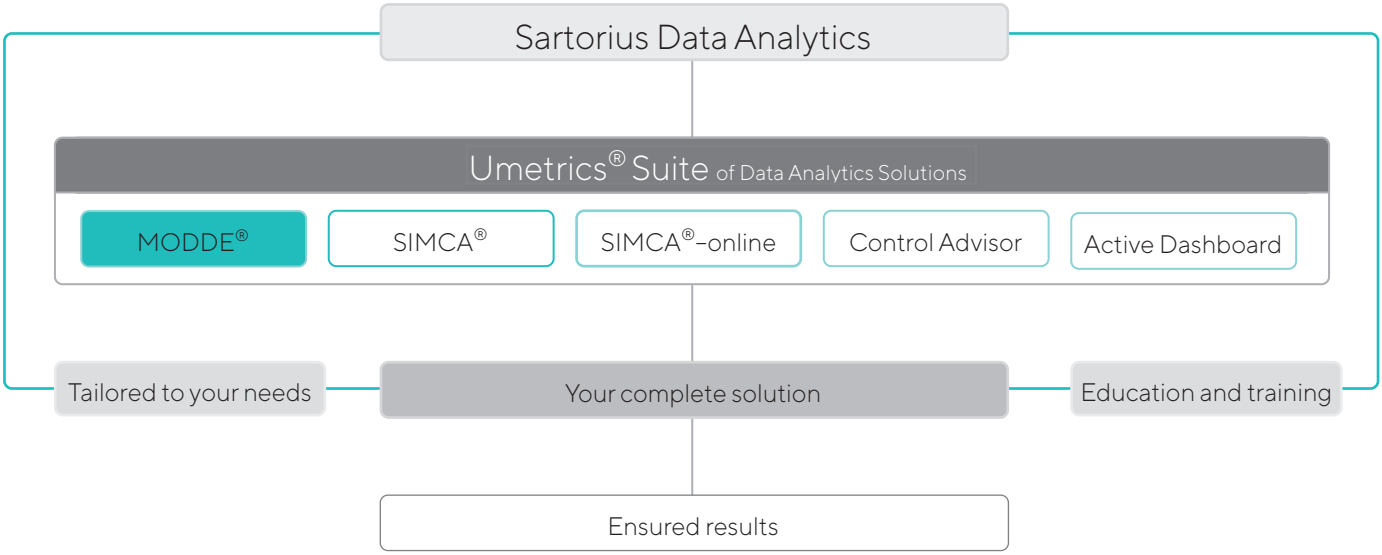
MODDE is helping companies in many different industries to design more effective experiments and create more effective strategies for tackling process problems. For instance:

- In pharma and biopharma, there are a wide variety of aspects to consider when determining the correct tablet formulation. These include how the drug dissolves, its hardness and how it is administered, which can now be addressed with MODDE's advanced formulation DOE toolbox.
- In manufacturing there needs to be a careful balance between productivity and quality. MODDE helps producers use DOE to maximize production quality through applications like robust optimization - where MODDE has the best available tools.

MODDE at a glance:

- Automated analysis wizard
- Robust optimum identification
- Interactive setpoint analysis with risk estimate
- Design Space visualization
- Generalized subset designs
- Stability testing design setup

More than Software



Our complete solution includes everything you need through the whole process and provides results quickly.

As our customer, you'll have access to supporting documents, templates, training and consultation to address your specific business challenges. Our courses and webinars help over a thousand people every year develop expertise and confidence in data analytics.

> "The Umetrics® Suite simplifies the entire process of handling, analyzing and managing our data.

A complete suite for business growth

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- SIMCA®
  Multivariate Data Analysis Solution to help you see what others don't
- SIMCA®–online
  Online – Real-time process monitoring to maintain product quality
- Control Advisor
  Predictive capabilities to be able to forecast the output
- Active Dashboard
  Interactive performance insight

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We help organizations grow. The Umetrics® Suite of Data Analytics Solutions helps you harness the wealth of data within your organization. Our expertise in data analytics can help you identify vital elements to improve the results of your research, development and manufacturing processes. With improved process understanding and more consistent product quality, you'll be able to reduce risk, get to market faster, and grow your business. Our complete solution encompasses software, training, support and project management. And as part of Sartorius, a global company with more than 7,000 employees, we give you the backing of an international presence.

Experience the benefits for your business today
Find out how our solutions can help your business to grow, whatever industry you are in.

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MODDE®-product-leaflet-EN-B-00003-Sartorius

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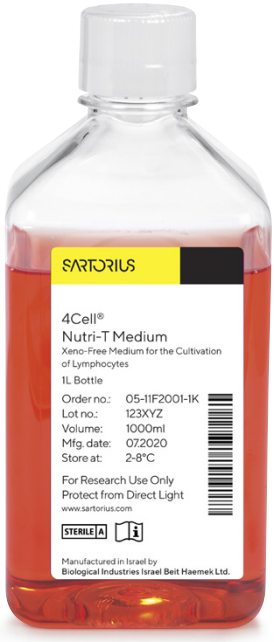
Product Datasheet

4Cell® Nutri-T Medium

A Xeno-Free, Serum-Free Medium for the Cultivation of Lymphocytes Offering Superior Performance and Flexibility



Product Information

4Cell® Nutri-T Medium: A Solution Without Serum
Cell-based immunotherapy is at the forefront of advanced cancer treatments. The most common cell-based immuno-therapies to date are T cell therapies (mainly CAR-Ts and TILs). Cells being used for immunotherapy are commonly cultured in media supplemented with human serum. The use of serum introduces further variability into the process due to donor-to-donor variation, which leads to inconsistent cell growth and characteristics. Eliminating serum simplifies the process, lowers the regulatory risk, and reduces the associated logistical burden. Nutri-T eliminates this need for serum addition by substituting serum's critical components with specific proteins, lipids, and other small molecules.

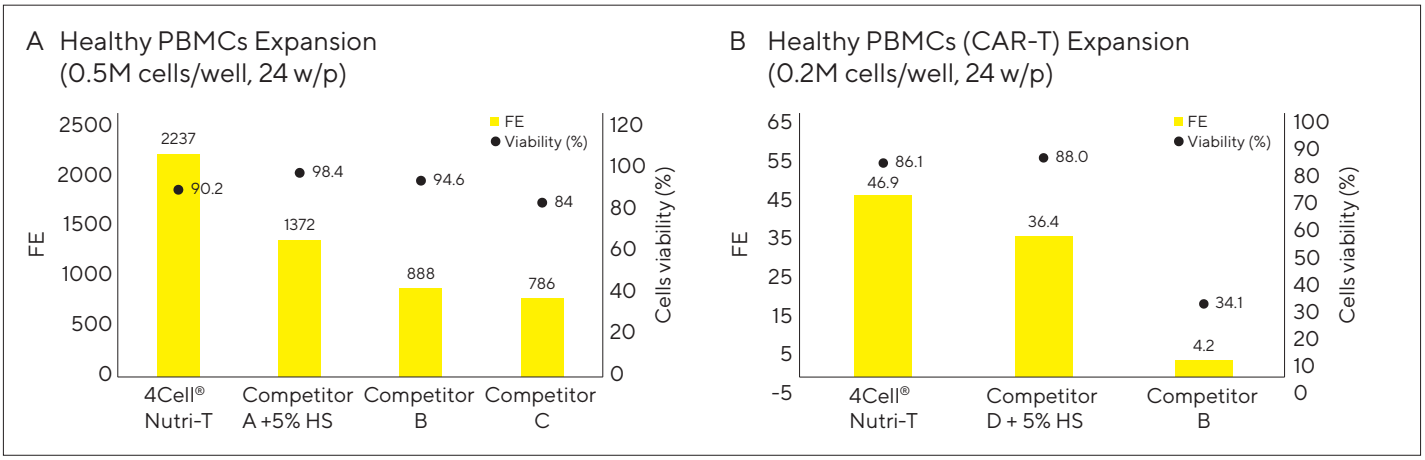
Product Snapshot

- Xeno-free
- Serum-free. No need to add serum
- ISO13408 Regulatory Compliance
- Research use only
- Developed using actual cancer patient cells
- Excellent performance for PBMCs, TILs, CAR-T
- Excellent performance at low initial seeding densities

4Cell® Nuti-T Cell Medium: Advancing Research and Clinical Applications

4Cell® Nutri-T is the ideal medium to use in the development and scale-up of cell-based therapeutic applications in the field of immune-oncology. Nutri-T is a xeno-free formulation demonstrating consistent and accurate results for both healthy donors (Fig. 1) and patient-derived (Fig. 2) T cells, without serum supplementation.

Figure 1: Nutri-T is Superior to Competitor Media in Expansion of Healthy PBMCs (With and Without CAR-T Transduction) at Multiple Seeding Densities



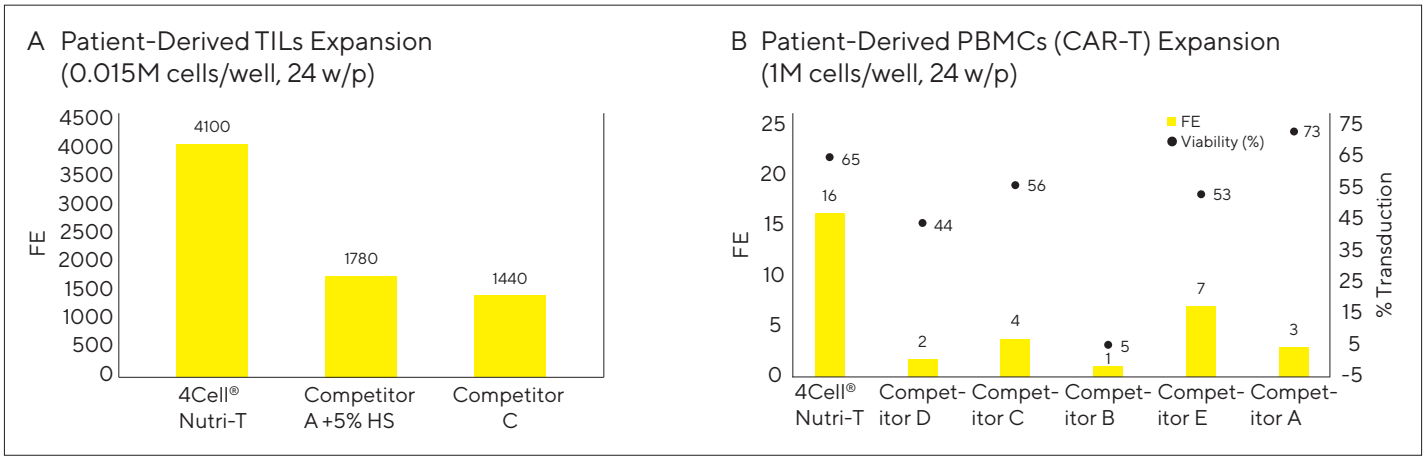
(A) 0.5M healthy donor PBMCs were seeded in 24w plates (2 ml media/well). Cells were activated with TransAct 1:100 and 600 IU/ml IL-2. Cells were split and media renewed every 2 – 3 days. Fold expansion (FE) and cell viability were measured at Day 11.

(B) 0.2M PBMCs from healthy donors were seeded in 24w plates (2 ml media/well). Cells were activated with TransAct 1:100 and 600 IU/ml IL-2. 24 h. After seeding cells were transduced with a lentiviral vector expressing an EGFR-CAR-T. Cells were split and media renewed every 2 – 3 days. FE and cell viability were measured at Day 11.

4Cell® Nutri-T Medium: Excellent Performance With Patient-Derived Cancer T Cells

Most of the currently available xeno-free media for T cells have been validated only on cells isolated from healthy donor derived PBMCs, or healthy CAR-T manipulated cells. 4Cell® Nutri-T was developed in collaboration with the highly accredited Ella Lemelbaum Institute for Immuno-Oncology at Sheba Medical Center, Israel. The Sheba partnership allows Sartorius access to clinical, patient-derived TILs and T cells. This unique development platform resulted in 4Cell® Nutri-T medium exhibiting excellent performance even with clinical condition cells at low initial seeding concentrations (Fig. 2).

Figure 2: Nutri-T is Superior to Competitor Media in Expansion of Patient-Derived Cancer Cells for Both TILs and CAR-T Processes



(A) TILs were isolated from a melanoma patient. 15,000 cells were seeded in a 24 well plate (2 ml/well) with PBMCs (1:100). Cells were activated with IL-2 (3,000 IU/ml) and OKT-3 (50 ng/ml). 2 ml and 4 ml of fresh medium + IL2 were added at days 5 and 7 respectively (total volume of 8 ml). Fold expansion was measured at 14 days. Inherent variations among primary T lymphocyte donor populations may result in varying outcomes.

(B) PBMCs were separated from peripheral blood of a lymphoma patient. Tested mediums were supplemented with 50 ng/ml OKT3 and 300 IU/ml IL2. At day 2 post seeding, 2 – 3M cells for the G-Rex24 were transduced with a CD19-CAR lentiviral vector in 6w/p pre-coated with RTN. Post transduction the cells were collected and reseeded. At day 4, 4 ml fresh medium +IL2 were added and at day 6, 50% medium was replaced with fresh medium + IL2. At day 9 transduction efficiency was evaluated and at day 10 Fold expansion was measured.

4Cell® Nutri-T Cell Medium: Sartorius is Your Reliable Supply Partner

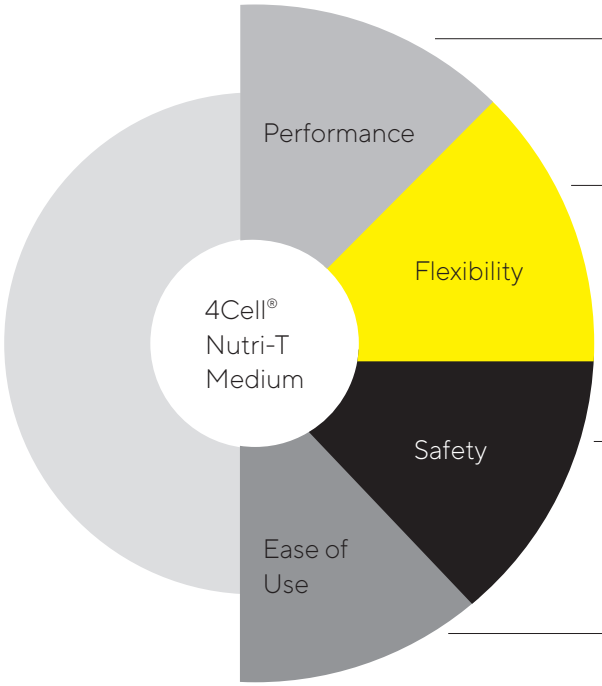
When working with a patient's cells, the materials used and the time from cell isolation to patient administration with the final product are critical. You cannot afford to waste time as a result of production or shipment delays.

Sartorius is your trusted partner. With multiple distribution sites and a robust supply chain, we can guarantee your media is on time, lot-to-lot consistent, and of the highest quality.

Ordering Information

Product Description	Size & Package	Storage	Cat. No.
4Cell® Nutri-T medium	1L Bottle (Liquid)	2 – 8 °C	05-11F2001-1K

Your Benefits at a Glance



- Superior fold expansion
- Excellent % viability and % of CD8+ expression
- High transduction efficiency % for CAR-T applications

- Superior performance for healthy PBMC, TIL, and CAR-T applications
- Superior performance with cancer patient-derived cells
- Excellent performance with low initial seeding concentrations

- No serum means elimination of serum-associated risk
- Manufactured in accordance with ISO 13408 guidelines
- Robust release testing

- No need to source, store, or purchase serum
- Low lead-time as Nutri-T is on-shelf at global Sartorius sites
- Sartorius technical support and complementary products

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DIR: 2637243-000-00
Status: 12 | 21 | 2020

SARTORIUS

Product Datasheet

Microsart® Research Mycoplasma

Mycoplasma Detection Kit for qPCR

Benefits

- Easy to use
- Highest flexibility
- Maximum reliability

Product Information

Microsart® Research Mycoplasma enables a fast and robust detection of Mycoplasma DNA in cell culture supernatants most applicable in research and development. Carefully selected primer | probe combinations are highly specific for a region within the 16 S rRNA gene of at least 110 Mycoplasma species.

Working Principle

2 µL of sample material, e.g. cell culture supernatant, can be added directly to the PCR reaction tube. For the detection of Mycoplasma DNA a TaqMan® real-time qPCR is used. Depending on the sample matrix the Sartorius spin-column based DNA preparation can be performed prior to PCR analysis to increase sensitivity or prevent inhibition. 200 µL sample volume can be used as starting material for DNA preparation if using the Microsart® AMP Extraction kit.
2 µL of isolated DNA extract are amplified in a qPCR cycler and the evaluation can be performed with the standard cycler software.

Applications

The Microsart® Research Mycoplasma real-time PCR protocol is especially designed for fast and reliable screening of cell culture supernatants most applicable in research and development, e. g. biotech and bio-pharmaceutical research and development, university and governmental research groups. It is used for direct detection of *Mollicutes (Mycoplasma, Acholeplasma, Spiroplasma)* in cell culture, cell culture media components and derived biologicals.

Fast Result

Microsart® Research Mycoplasma utilizes real-time PCR (qPCR). The kit can be performed with any type of real-time PCR cycler able to detect the fluorescence dyes FAM™ and ROX™. The detection procedure can be performed within 3 hours.

Easy Handling

The kit contains all essential components in a ready-to-use master mix.

- Screening with a small sample volume
- Cost saving (in case there is no EP 2.6.7 compliance required)

TaqMan® Probes

The application of TaqMan® probes adds specificity to the PCR detection system. Highly specific results are already generated during the cycling process – no subsequent melting curve analysis is needed.

Contamination Prevention

The kit contains dUTP instead of dTTP, so the option is available to degrade amplicons from previous analyses by using uracil-DNA glycosylase (UNG). Thus, the occurrence of false-positive results can be minimized. UNG is not included in the kit.

Summary

For scientists and lab technicians who need to screen cell culture supernatnants for Mycoplasma DNA, Sartorius offers the Microsart® RESEARCH Mycoplasma Detection Kit.

Technical Specifications

Each kit contains reagents for 25 reactions. The expiry date of the unopened package is specified on the package label. The kit compontents are stored at +2 to +8°C. After opening and rehydration the components need to be stored below -18°C. The LOT specific Certificate of Analysis can be downloaded from the manufacturer's website (www.minerva-biolabs.com).

Kit Component	25 Reactions
Order No.	SMB95-1005
Mycoplasma Mix	1 × lyophilized
Rehydration Buffer	1 × 1.0 mL
Positive Control	1 × lyophilized
PCR grade Water	1 × 1.0 mL

Ordering Information

Mycoplasma Kits

Description	Quantity	Order No.
Microsart® Research Mycoplasma	25	SMB95-1005

Accessories

Description	Quantity	Order No.
Microsart® AMP Extraction	50 extractions	SMB95-2003

Related Products

Description	Quantity	Order No.
Microsart® AMP Mycoplasma	25	SMB95-1001
Microsart® ATMP Mycoplasma	25	SMB95-1003

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Status: 10 | 2021

SARTORIUS

Product Datasheet

Microsart® ATMP Bacteria | Fungi | Sterile Release Microsart® Research Bacteria | Fungi

Rapid Detection of Total Fungi in ATMPs Prior Treatment

Benefits

- All critical bacterial and fungal contaminents detected in one test
- 3h-result: prior to treatment
- Specific TaqMan® probes reduce false-positives
- Non-infectious validation standards
- Less pipetting: controls already included

Product Information

Microsart® ATMP: Contaminated ATMPs pose life-threatening risks for immunocompromised patients. Microbial release test results prior to treatment are critical to patient safety. Microsart® ATMP Bacteria and Fungi or combined Microsart® ATMP Sterile Release that is ready prepared for single samples, enable the detection of bacterial and fungal contamination within 3 hours validated according to EP 5.1.6 and EP 2.6.27. During kit validation sensitivity (5 to 99 CFU/ml) was proven for 19 bacterial and 7 fungal species including 6 standard USP and EP strains. Comparability to the compendial method was demonstrated. The kit is not suitable to replace sterility testing according EP 2.6.1 or USP <71> yet. The Microsart® ATMP kits should be used as precheck test to get rapid QC results for ATMPs.

Microsart® Research Bacteria and Fungi are used for fast and reliable direct detection of microbial contamination in cell cultures, cell culture supernatants and cell media components in research and development or whenever there is no need for regulation conform testing (i.e. according to EP/USP/JP).

Kit Components and Storage

Each kit contains all required reagents for the qPCR reaction. Due to lyophilization they are less temperature sensitive and ensure highest performance stability. Color-coded tubes with master mix, buffers, positive control and negative control, make the handling as simple as possible. For details, see kit components table on page 2.

The expiry date and the storage conditions of the unopened package are noted on the package label. The kit components are stored until use at +2° C to +8° C and must be stored after rehydration or opening at < -18° C. Please note: The master mix, also called Bacteria | Fungi Mix, should be protected from light all the time.

Test Principle

Microsart® ATMP | Research utilizes real-time PCR. The detection procedure can be performed within 3 hours, including less than 1 hour hands-on time. In contrast to the detection by cell cultivation method, samples do not need to contain vital bacteria.

The assay can be performed with any type of real-time PCR cycler able to detect the fluorescence dyes FAM™ and ROX™.

Bacteria or fungi are specifically detected by amplifying a highly conserved 16S|18S rRNA coding region in the bacterial | fungal genome. The amplification is detected at 520 nm (FAM™ channel). The kit includes primer and FAM™ labeled TaqMan® probes which allow the specific detection of more than 95% of all known bacterial and fungal species so far described as contaminants of cell cultures and media components. Eukaryotic DNA is not amplified by this primer | probe system.

False negative results due to PCR inhibitors or improper DNA extraction are detected by the internal amplification control which is part of the PCR master mix. The amplification of the internal amplification control is detected at 610 nm (ROX™ channel).

Product Versions

a. Microsart® ATMP Sterile Release – contains all reagents for testing 10 patient samples for bacterial and fungal contamination including DNA extraction
b. Microsart® ATMP Bacteria – contains all reagents for 100 qPCR reactions to test for bacterial contamination without DNA extraction
c. Microsart® ATMP Fungi – contains all reagents for 100 qPCR reactions to test for fungal contamination without DNA extraction
d. Microsart® Research Bacteria – contains all reagents for 25 | 100 qPCR reactions to test for bacterial contamination without need of DNA extraction
e. Microsart® Research Fungi – contains all reagents for 25 | 100 qPCR reactions to test for fungal contamination without need of DNA extraction

The lot specific Certificate of Analysis can be downloaded from the manufacturer's website (www.minerva-biolabs.com).

Kit Components

Order No.	Cap color	Microsart® ATMP Sterile Release SMB95-1007 (10 patient samples)	Microsart® ATMP Bacteria SMB95-1008 (100 rxn)	Microsart® ATMP Fungi SMB95-1012 (100 rxn)	Microsart® Research Bacteria (25|100) SMB95-1009 (25 rxn) SMB95-1010 (100 rxn)	Microsart® Research Fungi (25|100) SMB95-1014 (25 rxn) SMB95-1013 (100 rxn)
ATMP Bacteria Mix	red	10 × lyophilized	4 × lyophilized	–	4 × lyophilized	–
ATMP Fungi Mix	orange	10 × lyophilized	–	4 × lyophilized	–	4 × lyophilized
Rehydration Buffer	blue	10 × 0.3 ml	4 × 0.5 ml	4 × 0.5 ml	4 × 0.5 ml	4 × 0.5 ml
Positive Control DNA	green	10 × lyophilized	1 × lyophilized	1 × lyophilized	1 × lyophilized	1 × lyophilized
Internal Control DNA	yellow	10 × lyophilized	4 × lyophilized	4 × lyophilized	4 × lyophilized	4 × lyophilized
PCR grade Water	white	20 × 0.3 ml	5 × 1.5 ml	5 × 1.5 ml	5 × 1.5 ml	5 × 1.5 ml
Lysis Buffer	transparent	10 × 1.8 ml	–	–	–	–
Suspension Buffer	violet	10 × 0.4 ml	–	–	–	–
Processing Tubes	–	10 × 3	-	-	-	-

Related Products

DNA Extraction Kit		
Order No.	**Description**	**Quantity**
SMB95-2001	Microsart® ATMP Extraction	Reagents for 50 extractions
SMB95-2003	Microsart® AMP Extraction (only for Mycoplasma qPCR)	Reagents for 50 extractions

Mycoplasma Detection Kits for qPCR		
Order No.	**Description**	**Quantity**
SMB95-1001|1002	Microsart® AMP Mycoplasma	25 | 100 reactions
SMB95-1003|1004	Microsart® ATMP Mycoplasma	25 | 100 reactions
SMB95-1005|1006	Microsart® Research Mycoplasma	25 | 100 reactions

Microsart® Validation Standard according to EP 2.6.7 and USP <63> for Mycoplasma species and EP 2.6.1, EP 2.6.27 and USP <71> for other bacteria and fungi

3 vials with 10 CFU/vial for Mycoplasma species and 6 vials with 99 CFU/vial for other bacteria and all fungi

Order No.	Description
SMB95-2005	*Bacillus subtilis*
SMB95-2006	*Pseudomonas aeruginosa*
SMB95-2007	*Kocuria rhizophila*
SMB95-2008	*Clostridium sporogenes*
SMB95-2009	*Bacteroides vulgatus*
SMB95-2010	*Staphylococcus aureus*
SMB95-2011	*Mycoplasma arginini*
SMB95-2012	*Mycoplasma orale*
SMB95-2013	*Mycoplasma gallisepticum*
SMB95-2014	*Mycoplasma pneumoniae*
SMB95-2015	*Mycoplasma synoviae*
SMB95-2016	*Mycoplasma fermentans*
SMB95-2017	*Mycoplasma hyorhinis*
SMB95-2018	*Acholeplasma laidlawii*
SMB95-2019	*Spiroplasma citri*
SMB95-2020	*Mycoplasma salivarium*
SMB95-2037	*Candida albicans*
SMB95-2038	*Aspergillus brasiliensis*
SMB95-2039	*Aspergillus fumigatus*
SMB95-2040	*Penicillium chrysogenum*
SMB95-2041	*Candida glabrata*
SMB95-2042	*Candida krusei*
SMB95-2043	*Candida tropicalis*

Microsart® Calibration Reagent

1 vial, 10^8 genomes/vial for all bacteria and 10^6 genomes/vial for all fungi

Order No.	Description
SMB95-2021	*Mycoplasma arginini*
SMB95-2022	*Mycoplasma orale*
SMB95-2023	*Mycoplasma gallisepticum*
SMB95-2024	*Mycoplasma pneumoniae*
SMB95-2025	*Mycoplasma synoviae*
SMB95-2026	*Mycoplasma fermentans*
SMB95-2027	*Mycoplasma hyorhinis*
SMB95-2028	*Acholeplasma laidlawii*
SMB95-2029	*Spiroplasma citri*
SMB95-2030	*Bacillus subtilis*
SMB95-2031	*Pseudomonas aeruginosa*
SMB95-2032	*Kocuria rhizophila*
SMB95-2033	*Clostridium sporogenes*
SMB95-2034	*Bacteroides vulgatus*
SMB95-2035	*Staphylococcus aureus*
SMB95-2036	*Mycoplasma salivarium*
SMB95-2044	*Candida albicans*
SMB95-2045	*Aspergillus brasiliensis*
SMB95-2046	*Aspergillus fumigatus*
SMB95-2047	*Penicillium chrysogenum*
SMB95-2048	*Candida glabrata*
SMB95-2049	*Candida krusei*
SMB95-2050	*Candida tropicalis*

User-Supplied Equipment and Material

- For DNA extraction we recommend the DNA-free Microsart® ATMP Extraction kit, Order No. SMB95-2001
- DNA-free PCR reaction tubes for the specific qPCR device
- Microcentrifuge for 1.5 ml reaction tubes, i.e. Centrisart A-14, Order No. A-14-1EU
- Pipettes with DNA-free filter tips (10, 100 and 1000 µl)
- qPCR device with filter sets for the detection of the fluorescence dyes FAM™ and ROX™ and suitable for 25 µl reaction volume

For PCR support and recommendation please contact **PCR@Sartorius.com**.

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