



Sartorius PSC Optimization and Characterization Solution

Data Sheet Collection

SARTORIUS

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Ambr[®] 250 Modular



Technical Specification

Scope

System combines 2, 4, 6 or 8 "Easy-Connect" single-use bioreactors, automated platform, bioreactor controller and flexible system control software.

Recommended Working Space

System dimensions including monitor, excluding chiller and external system options.

Ambr[®] 250 Modular 2 vessel system

Width	Depth	Height
88.5 cm	45.5 cm	60 cm
35"	18"	24"

Ambr[®] 250 Modular 4 vessel system

Width	Depth	Height
127 cm	45.5 cm	60 cm
50"	18"	24"

Ambr® 250 Modular 6 vessel system

Width	Depth	Height
165.5 cm	45.5 cm	60 cm
65"	18"	24"

Ambr® 250 Modular 8 vessel system

Width	Depth	Height
204 cm	45.5 cm	60 cm
80"	18"	24"

System operating parameters

Agitation speed (standard)	150 - 4500 rpm
Agitation speed (wide range)	100 - 4500 rpm
Culture temperature	18 - 55°C ± 0.5°C
Post culture period chilling	6 - 8°C
Temperature shift rate	> 5°C per 30 mins
pH range	2.0 - 8.5
pH monitoring accuracy	± 0.02 pH units
DO (% air saturation) monitoring range	0 - 200%
DO monitoring accuracy	± 2% @ 100%
Maximum air or total gas flow	550 mL/min
Gas-flow monitoring accuracy	± 5% @ > 50 mL/min
Exhaust gas CO ₂ monitoring	0 - 20%
Exhaust gas CO ₂ monitoring accuracy	± 5% @ 5% CO ₂
Exhaust gas O ₂ monitoring range	0 - 50%
Exhaust gas O ₂ monitoring accuracy	± 2% @ 21% O ₂
Integrated pump design	Syringe pumps
Flow rates	0 - 20 mL/hr (viscosity dependent)
Pump dispense accuracy	± 5% @ >10 µL/hr
Integrated pumps per vessel	5
Peristaltic pumps per bioreactor	1
Number of 125 mL reservoirs per bioreactor	2
Number of 50 mL reservoirs per bioreactor	3

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

Maximum flow rate mL/min

Gases	Cell culture		Microbial	
	Sparge	Headspace	Gases	Sparge
Air N ₂	550	100	Air	550
O ₂	80	50	O ₂	120
CO ₂	75	50	N ₂	120

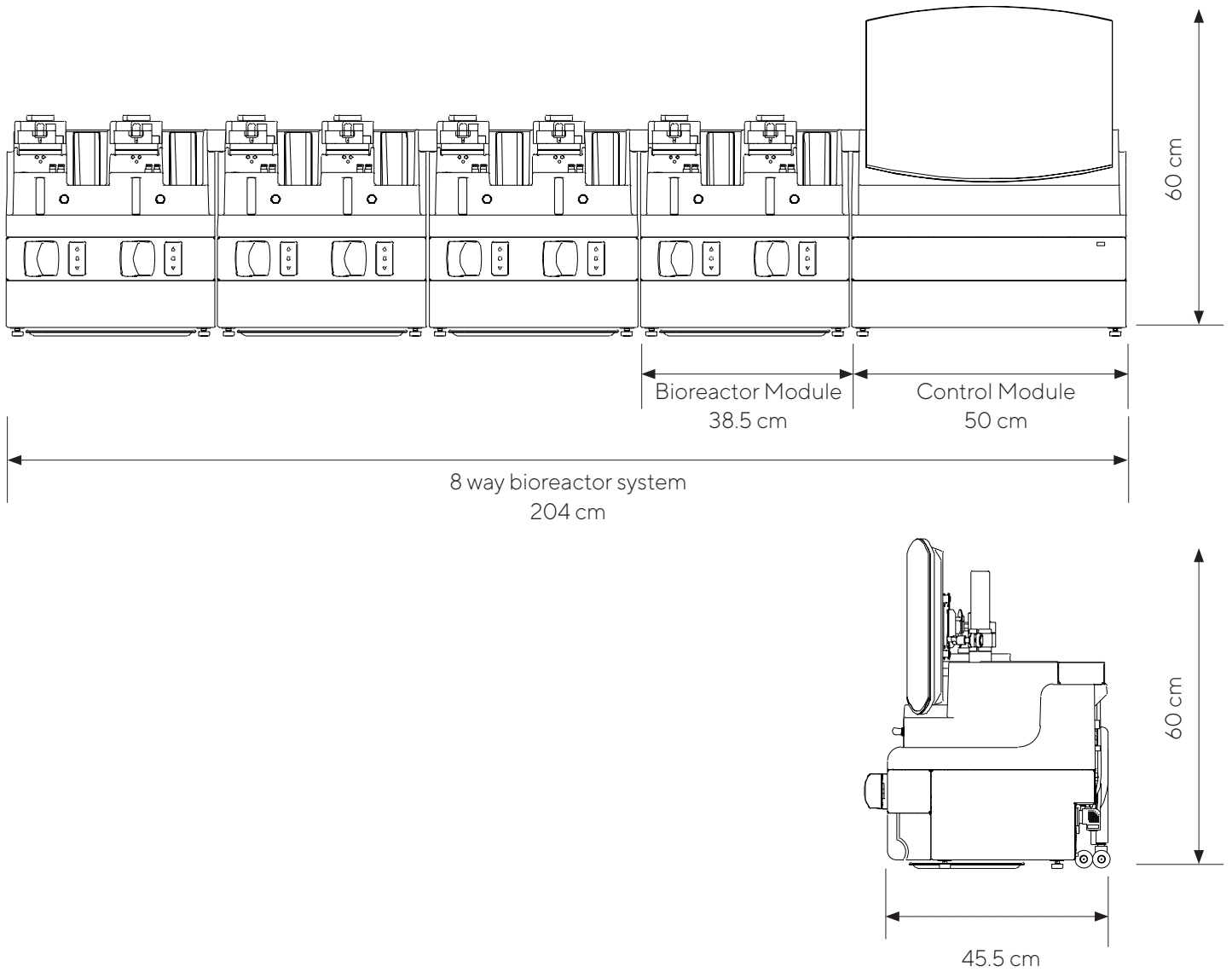
Bioreactor vessel general information

Construction material	Polycarbonate, polypropylene, polyethylene
Dimensions	Internal diameter 60 mm. Internal height 120 mm
Total volume	350 mL
Working volume	100 - 250 mL
pH monitoring technology	Single-use electrode
DO monitoring technology	Fluorescence based spot

Bioreactor vessel information

Bioreactor type	Cell culture	Cell culture	Microbial
Baffles	4	0	4
Number of impellers	2	1	2
Impeller type	Pitch blade	Elephant ear	Rushton turbine
Diameter	Ø26 mm	Ø30 mm	Ø20 mm
Power number	1.34	2.07	7.3
kLa	3.4/h @ 450 rpm, 200 mL water, 6 mL/min air	2.3/h @ 200 rpm, 200 mL water, 6 mL/min air	1780/h @ 4200 rpm, 250 mL water, 375 mL/min air
Maximum power input dependent on nature of culture	-	-	35.1 kW/m ³
Reynolds number	-	-	3.37 x 10 ⁴
Tip speed	-	-	4.71 m/s
Mixing time	-	-	0.642/s

Dimensions of Ambr[®] 250 Modular 8 vessel system



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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:

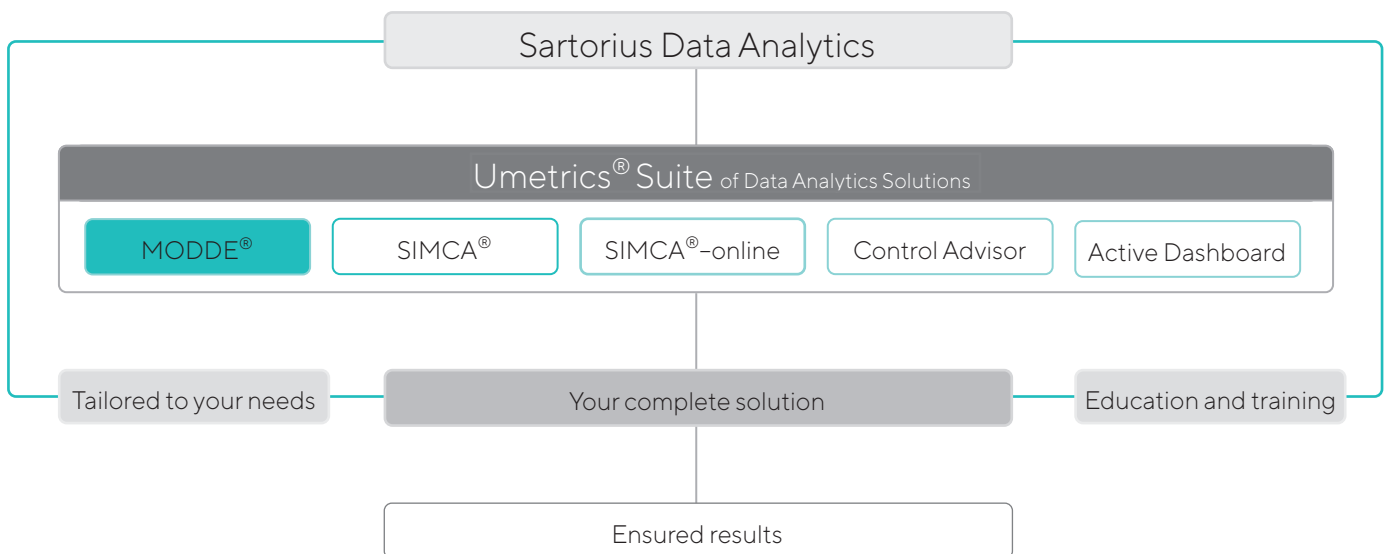
- In pharma and biopharma, there are a wide variety of aspects to consider when determining the correct tablet formulation. These include how the drug dissolves, its hardness and how it is administered, which can now be addressed with MODDE's advanced formulation DOE toolbox.
- In manufacturing there 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

The Umetrics Suite is a family of proven data analytics solutions that work seamlessly together. Other software solutions in the Umetrics Suite are:

- 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

These solutions give you control and confidence in your processes at every stage – from development to manufacturing.



Sartorius Data Analytics – Change a little. Grow a lot.

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.

Visit www.sartorius.com/umetrics for details or to download a free 30-day trial.

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E-mail: umetrics@sartorius-stedim.com

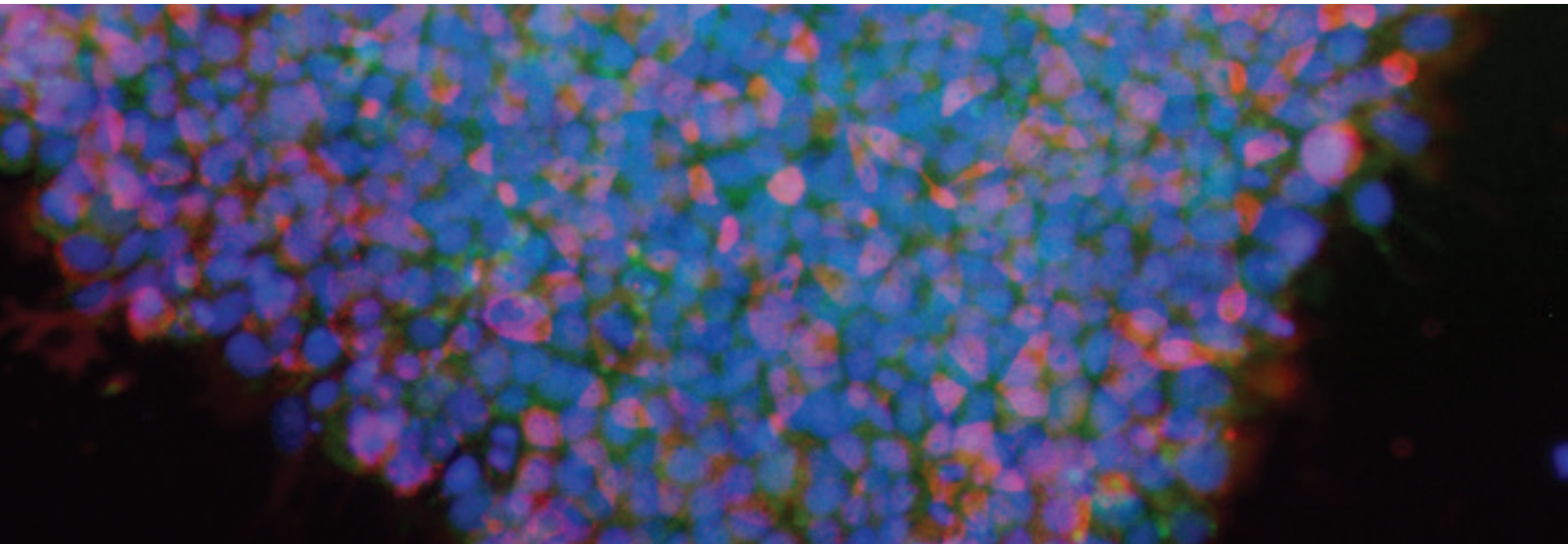


◀ www.sartorius.com/umetrics



NutriStem® hPSC XF Medium

A superior xeno-free, serum-free culture medium for hES and hiPS cells



- **Defined, serum-free, xeno-free**
- **Complete, ready-to-use**
- **Superior proliferation of undifferentiated hES and hiPS cells**
- **Stable pluripotency and genotype over long-term culture**
- **Extensively tested and widely referenced**
- **Flexible and compatible with multiple matrices (e.g. Matrigel and laminin)**

Expanding the culture of excellence

NutriStem® hPSC XF Medium is a defined, xeno-free, serum-free medium designed to support the growth and expansion of human induced pluripotent stem (hiPS) and human embryonic stem (hES) cells in a feeder-free environment. NutriStem® hPSC XF Medium offers the ability to culture human pluripotent cells without the need for high levels of bFGF and other stimulatory growth factors or cytokines. The low-protein formulation contains only the most essential components required for maintenance of hES and hiPS cells, providing a simplified medium and maintaining the cells' full differentiation potential.

The defined, xeno-free formulation of NutriStem® hPSC XF Medium provides consistent media performance and predictable cellular behavior, as well as increased reproducibility in long-term culture (over 50 passages). In addition, cells cultured in NutriStem® hPSC XF Medium show superior attachment and proliferation rates, making this medium ideal for high-throughput screening applications.

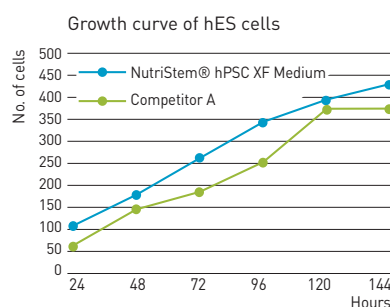


Figure 1: NutriStem® hPSC XF Medium enables excellent proliferation of undifferentiated hES and hiPS cells. Proliferation of H1 hES cells cultured in Matrigel-coated 96-well plates in NutriStem® hPSC XF Medium and the leading competing medium for feeder-free culture. Medium was changed and proliferation was assessed every 24 hours in culture.

Normal cell morphology and functional assesment of pluripotency

The formation of compact colonies of cells with a high nucleus-to-cytoplasm ratio, prominent nucleoli, and distinct colony borders are characteristic morphology traits of healthy undifferentiated hES and hiPS cells, and can be observed through a phase-contrast microscope (Figure 2). Human pluripotent stem cells hold the potential to differentiate into cell types of all three germ layers, i.e., endoderm, mesoderm, and ectoderm. This differentiation potential is assessed by the spontaneous differentiation within embryoid bodies cultured in vitro (Figure 3) and teratomas formed in vivo (Figure 4).

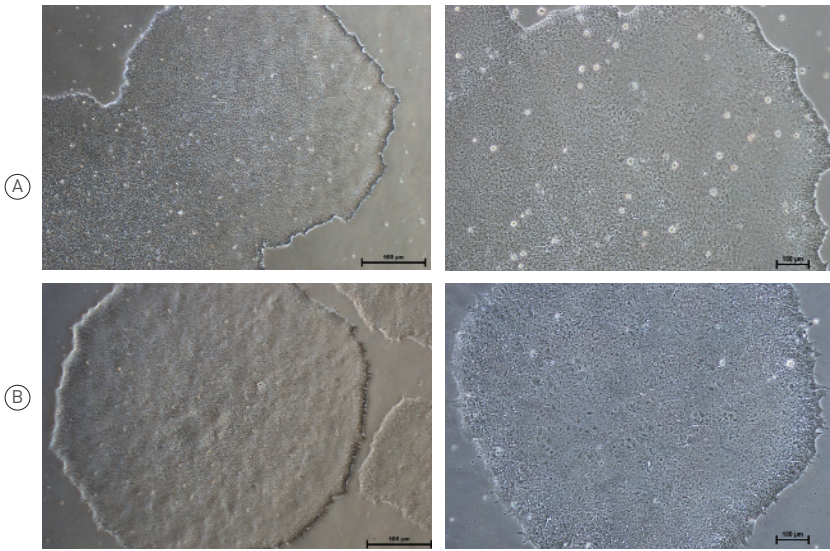


Figure 2: Normal Colony Morphology. H1 hES cells (panel A) and ACS-1014 hiPS cells (panel B) cultured in NutriStem® hPSC XF Medium on Matrigel-coated plates display colony morphologies typical of normal feeder-free hES and hiPS cell cultures, including a uniform colony of tightly compacted cells and distinct colony edges.

Ordering Information

Cat. #	Product	Qty
05-100-1A	NutriStem® hPSC XF Culture Medium	500 mL
05-100-1B	NutriStem® hPSC XF Culture Medium	100 mL
05-713-1A	NutriFreez™ D10 Cryopreservation Medium	500 mL
05-713-1B	NutriFreez™ D10 Cryopreservation Medium	100 mL
05-713-1C	NutriFreez™ D10 Cryopreservation Medium	20 mL
05-713-1D	NutriFreez™ D10 Cryopreservation Medium	10 mL
05-713-1E	NutriFreez™ D10 Cryopreservation Medium	50 mL
05-753-1F	LaminStem™ 521	1 mL
03-073-1B	Accutase Solution	100 mL
03-079-1B	Recombinant Trypsin-EDTA Solution	100 mL
03-079-1C	Recombinant Trypsin-EDTA Solution	20 mL

How to Order

Biological Industries | T. 972-4-996-0595 | F. 972-4-996-8896 | info@bioind.com

Biological Industries USA | T. 860.316.2702 | F. 860.269.0596 | orders@bioindusa.com

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Culture of Excellence

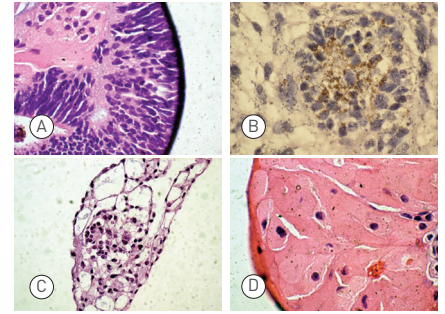


Figure 3: Embryoid Body Formation. Embryoid bodies (EBs) were generated from H9.2 hES cells cultured for 16 passages in NutriStem® hPSC XF Medium on Matrigel matrix as an evaluation of pluripotency. The pluripotent H9.2 cells were suspended in serum-supplemented medium, where they spontaneously formed EBs containing cells of embryonic germ layers. The following cell types were identified by examination of the histological sections of 14-day-old EBs stained with H&E: (A) neural rosette (ectoderm), (B) neural rosette stained with Tubulin, (C) primitive blood vessels (mesoderm), and (D) megakaryocytes (mesoderm).

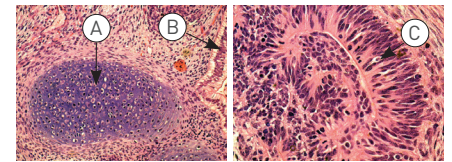


Figure 4: Teratoma Formation. H9.2 hES cells were cultured for 11 passages in NutriStem® hPSC XF Medium using a human foreskin fibroblast (HFF) feeder layer. The hES cells were subsequently injected into the hind leg muscle of SCID-beige mice for in vitro evaluation of pluripotency. The following tissues from all three germ layers were identified in H&E-stained histological sections of the teratoma 12 weeks post-injection: (A) cartilage (mesoderm), (B) epithelium (endoderm), and (C) neural rosette (ectoderm).

NutriStem® hPSC XF (GF-free) for Reprogramming

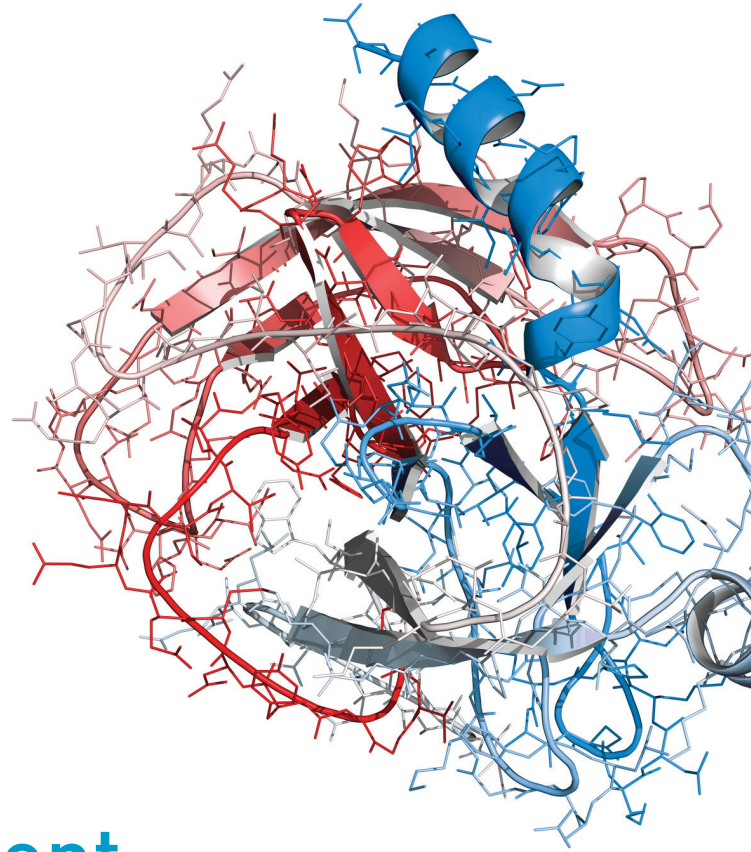
NutriStem® hPSC XF (growth factor free) culture medium (Cat. # 06-5100-01-1A) is an extremely rich complex medium. It contains the essential components required for the short-term maintenance of cells prior to manipulations such as the generation of induced pluripotent stem (iPS) cell colonies. iPSC lines can then be transferred to regular NutriStem® hPSC XF culture medium (Cat. # 05-100-1A) for expansion and long-term maintenance.



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Chemical structure of trypsin enzyme

All the way with animal component-free solutions

Animal Component-Free (ACF) Recombinant Trypsin Solutions

Alternative to porcine/bovine trypsin

- **Animal Component-Free (ACF)**

Eliminates the risk of viruses or other potential adventitious agents found in animal derived components.

- **High Purity**

- Pure enzyme solutions increase specificity and eliminate contaminating activities found in lower purity enzymes.
- Free of chymotrypsin, carboxypeptidase-A and other protease contaminants.
- Prevents the toxic effects induced by non-desirable proteases.

- **High Activity**

- Maximizes the yield of functionally viable cells.
- Recombinant Trypsin-EDTA Solution (Cat. No. 03-079-1) accelerates the dissociation phase.
- Results in efficient dissociation of adherent cell types (including primary and sensitive cells) from surfaces and tissues.
- Optimized for hMSCs, from a variety of sources, cultured in both serum-free and serum-containing systems.

- **Enzyme Inhibition**

Inactivation with Soybean Trypsin Inhibitor (SBTI, Cat. No. 03-048-1).

- **Ready-to-use**



Comparison of hMSC Dissociation with Various Trypsin Solutions

Recovery of hMSC- Adipose Tissue (AT) cultured in MSC NutriStem XF medium after dissociation with three different dissociation solutions

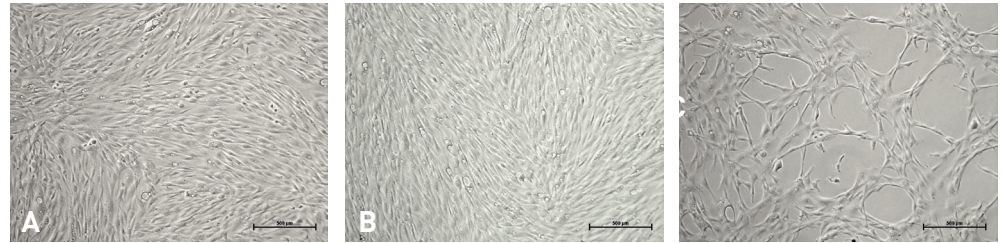


Figure 1.

hMSC-AT, 3 days post split I – Cells were equally seeded (5000cells/cm²) in MSC NutriStem® XF medium. The dissociation procedure was carried out at 37° using:
 A. Recombinant Trypsin Solution, without EDTA (BI's Cat. No. 03-078-1)
 B. Crystalline Trypsin (BI's Cat. No. 03-047-1) (high purity)
 C. Trypsin sol. C (BI's Cat. No. 03-053-1) (crude trypsin)

Rapid and Efficient Dislodging of hMSC with Recombinant Trypsin

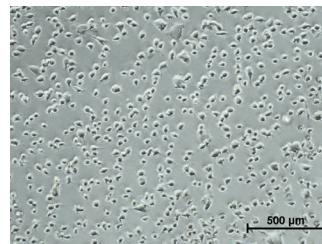
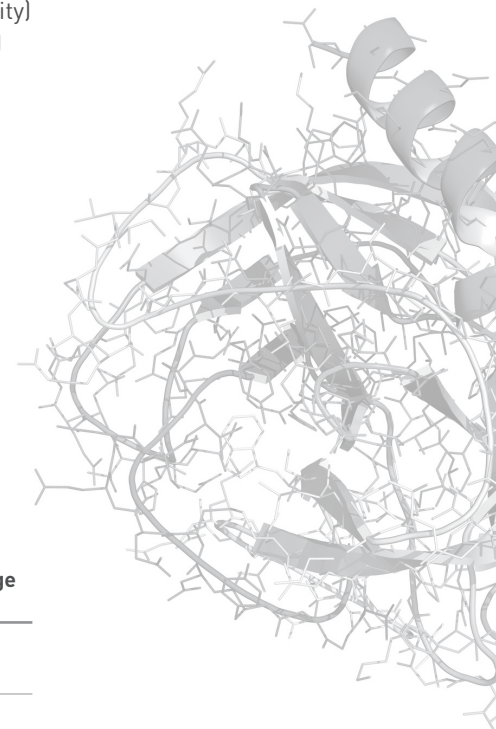


Figure 2.

hMSC-BM cultured in MSC NutriStem® XF medium, were incubated for 2-5 min at 37°. with Recombinant Trypsin Solution (Cat. No. 03-078-1)



Ordering Information

Product Name	Cat. No.	Unit Size	Storage Temp.
Recombinant Trypsin Solution	03-078-1B	100ml	RT
Recombinant Trypsin-EDTA Solution	03-079-1B	100ml	RT
Soybean Trypsin Inhibitor (SBTI) x50	03-048-1C	20ml	-20°C

Source of raw material:

The Recombinant Trypsin is produced by submerged fermentation of *Fusarium Oxysporum*.

It is derived from a production process which does not utilize any raw materials and/or processing aids of animal origin.

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.

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.

Protect Your Cells

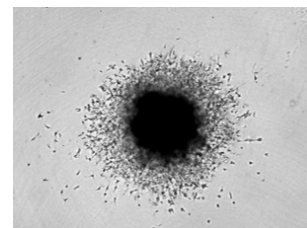
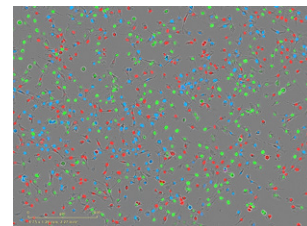
Patent-pending 3-color optical module includes a long wavelength, low phototoxicity Near IR channel and reagents designed for long term live-cell experiments.

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

Learn more at

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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

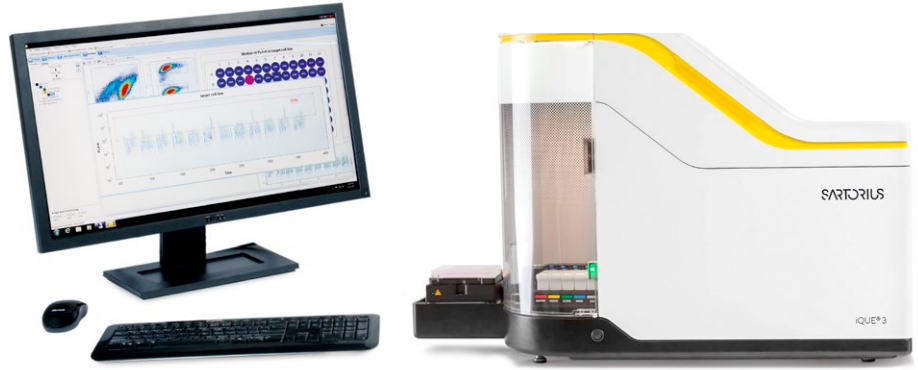
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iQue® 3

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	<ul style="list-style-type: none"> ▪ 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	<ul style="list-style-type: none"> ▪ Reduces evaporation ▪ Monitors fluid levels 			<ul style="list-style-type: none"> ▪ Automated QC bead vortexing 				
iQue Forecyt® Software	Features	<ul style="list-style-type: none"> ▪ Auto compensation ▪ Real-time whole-plate data analysis ▪ Dynamic linked gating ▪ Interactive heat maps, profile maps 			<ul style="list-style-type: none"> ▪ 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	<ul style="list-style-type: none"> ▪ CE labeled ▪ 21 CFR logging option compatible 			<ul style="list-style-type: none"> ▪ 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

Microsart® ATMP Mycoplasma

Rapid Real-time PCR
Mycoplasma Detection Kit
for testing ATMPs



Benefits

- 3 hours time-to-result
- Designed for ATMP testing
- Easy handling and highest level of security

Product Information

A standard DNA extraction followed by a TaqMan® probe real-time qPCR is used for the detection of Mycoplasma DNA. 200 µL sample volume can be used as starting material for DNA preparation. The isolated DNA is amplified in a qPCR cyclor and the evaluation can be performed with the standard cyclor software.

Introduction

Microsart® ATMP Mycoplasma utilizes quantitative, real-time PCR (qPCR) as the method of choice for sensitive and robust detection of Mycoplasma contaminations. The Microsart® ATMP Mycoplasma kit was validated according to EP 2.6.7 in combination with EP 2.6.21 with respect to detection limit for all listed Mycoplasma species, specificity and robustness for cell cultures and autologous cell transplants (e.g. chondrocytes).

Applications

The Microsart® ATMP Mycoplasma real-time PCR kit is especially designed for all hospitals, institutions and companies which are involved in testing Mycoplasma contamination according to EP 2.6.7 in cell-based therapeutics.

High Performance

The Microsart® ATMP Mycoplasma kit was developed for EP compliant Mycoplasma testing. A detection limit of less than 10 cfu/mL for all Mycoplasma species mentioned in the European Pharmacopoeia fulfills the requirements for sensitivity and specificity.

Fast Result

The Microsart® ATMP Mycoplasma kit is a fast and easy to use real-time PCR kit. The total procedure from DNA extraction to the PCR result takes only a few hours.

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

The Microsart® ATMP Mycoplasma kit is the perfect solution for all QC labs which perform Mycoplasma testing of cell-based therapeutics.

Technical Specifications

Each kit contains all required reagents for 25 reactions including polymerase as part of the Mycoplasma Mix. The expiry date of the unopened package is specified on the package label. The kit components are stored at +2 to +8°C. After opening and rehydration the kit 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.	SMB95-1003
Mycoplasma Mix	1 × lyophilized
Rehydration Buffer	1 × 1.0 mL
Positive Control	1 × lyophilized
Internal Control	1 × lyophilized
PCR grade Water	1 × 1.5 mL

Ordering Information

Mycoplasma Kits

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

Accessories

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

Related Products


Description	Quantity	Order No.
Microsart® AMP Mycoplasma	25	SMB95-1001
Microsart® Research Mycoplasma	25	SMB95-1005

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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 contaminants 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 cyclers 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

- Microsart® ATMP Sterile Release – contains all reagents for testing 10 patient samples for bacterial and fungal contamination including DNA extraction
- Microsart® ATMP Bacteria – contains all reagents for 100 qPCR reactions to test for bacterial contamination without DNA extraction
- Microsart® ATMP Fungi – contains all reagents for 100 qPCR reactions to test for fungal contamination without DNA extraction
- Microsart® Research Bacteria – contains all reagents for 25 | 100 qPCR reactions to test for bacterial contamination without need of DNA extraction
- 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	<i>Bacillus subtilis</i>
SMB95-2006	<i>Pseudomonas aeruginosa</i>
SMB95-2007	<i>Kocuria rhizophila</i>
SMB95-2008	<i>Clostridium sporogenes</i>
SMB95-2009	<i>Bacteroides vulgatus</i>
SMB95-2010	<i>Staphylococcus aureus</i>
SMB95-2011	<i>Mycoplasma arginini</i>
SMB95-2012	<i>Mycoplasma orale</i>
SMB95-2013	<i>Mycoplasma gallisepticum</i>
SMB95-2014	<i>Mycoplasma pneumoniae</i>
SMB95-2015	<i>Mycoplasma synoviae</i>
SMB95-2016	<i>Mycoplasma fermentans</i>
SMB95-2017	<i>Mycoplasma hyorhinis</i>
SMB95-2018	<i>Acholeplasma laidlawii</i>
SMB95-2019	<i>Spiroplasma citri</i>
SMB95-2020	<i>Mycoplasma salivarium</i>
SMB95-2037	<i>Candida albicans</i>
SMB95-2038	<i>Aspergillus brasiliensis</i>
SMB95-2039	<i>Aspergillus fumigatus</i>

Order No.	Description
SMB95-2040	<i>Penicillium chrysogenum</i>
SMB95-2041	<i>Candida glabrata</i>
SMB95-2042	<i>Candida krusei</i>
SMB95-2043	<i>Candida tropicalis</i>

Microsart® Calibration Reagent

1 vial, 10⁸ genomes/vial for all bacteria and 10⁶ genomes/vial for all fungi

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

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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NutriFreez[®] D10 Cryopreservation Medium

Powerful cryopreservation media optimized for various cells and tissues



NutriFreez[®] D10 Cryopreservation Medium is an optimized freezing solution designed and validated for the cryopreservation of various tissue and cell types, including but not limited to sensitive cell types such as hESCs, iPSCs, and MSCs. NutriFreez[®] D10 Medium maintains defined and animal component-free conditions during cryopreservation, essential to maintaining consistency when culturing cells in a xeno-free system. NutriFreez[®] D10 Medium is ready-to-use and pre-formulated with DMSO, providing a protective environment for cells during the freezing, storage, and thawing process. Cells preserved with NutriFreez[®] D10 Medium show excellent attachment (Figure 1) and maintain proper pluripotency marker expression after thawing, with superior results compared to both serum-containing freezing media, other serum-free solutions, and homebrew formulations¹.

- High recovery post thaw
- Ready-to-use solution
- Serum-free and protein-free
- Chemically-defined
- cGMP-manufactured

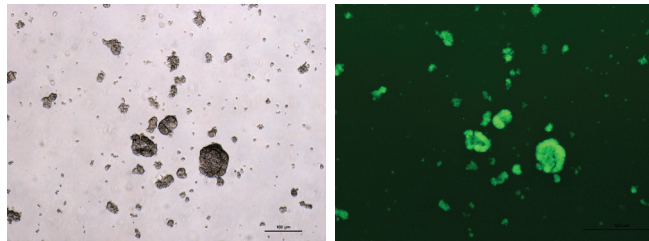


Figure 1: BG01V/hOG cells (an Oct4-GFP reporter hES cell line) frozen in NutriFreez[®] D10 Medium and thawed into NutriStem[®] hPSC Medium on Matrigel. Images taken just 1 hour post-thaw show excellent survival and attachment of the hES cells, with high expression of Oct4 (green).

Applicable Cell Types

- Human Embryonic Stem Cells
- Induced Pluripotent Stem Cells
- Human Mesenchymal Stem Cells
- Peripheral Blood Mononuclear Cells
- Human Endothelial Cells
- T cells, including Chimeric Antigen Receptor (CAR T) Cells and Tumor Infiltrating Lymphocytes (TILs)
- Neuron Cells
- Hybridomas
- CHO Cells
- Vero Cells
- Multiple mammalian cell lines: MRC-5, HEK-293, HepG2, HeLaBSC-1, BGM3T3, MA-10BHK-21

Ordering Information

Cat. #	Product	Qty
05-713-1A	NutriFreez [®] D10 Cryopreservation Medium	500 mL
05-713-1B		100 mL
05-713-1E		50 mL
05-713-1C		20 mL
05-713-1D		10 mL
05-714-1A	NutriFreez [®] D10 Cryopreservation Medium, w/o phenol red	500 mL
05-714-1B		100 mL

1. Nishishita N, et al. An effective freezing/thawing method for human pluripotent stem cells cultured in chemically-defined and feeder-free conditions. *AJSC* 2015;4(1):38-49.

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SIMCA[®]
Turn data into growth

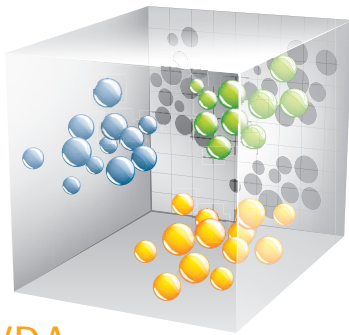
Simplifying Progress

SARTORIUS

SIMCA[®] helps you see what others don't

Every day your business creates a wide variety of data from many different sources. This data holds the key to better performance.

The challenge is to interpret this information in a meaningful way. But with so many parameters in play, it's hard to find a solution that's both powerful and smart enough. SIMCA gives you the ability to combine and analyze all these different data sources. It helps you to isolate, understand and act upon the hidden gems that hold the secret to greater business success.

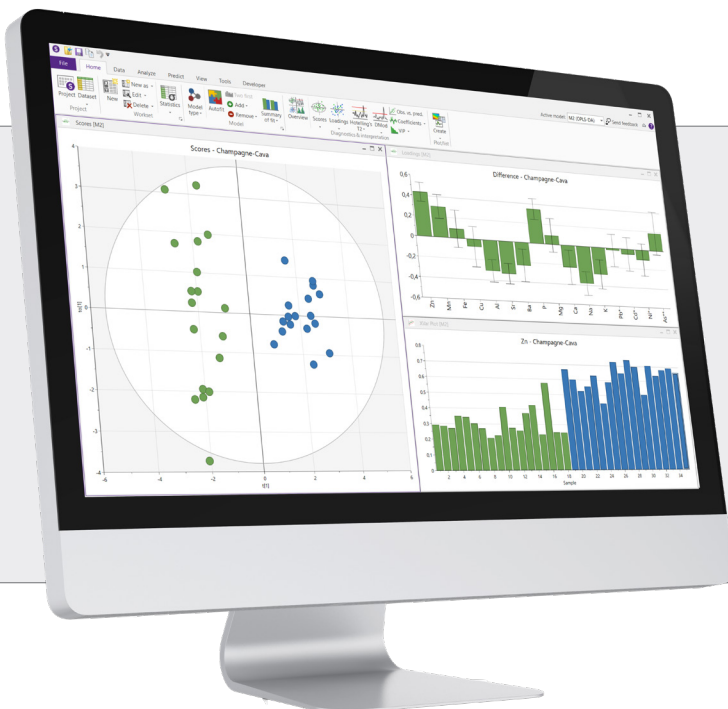


MVDA
Multivariate
Data Analysis

Who is using SIMCA?

Wherever you create data you can use SIMCA. That's why companies in many different industries have worked with us to help their business grow.

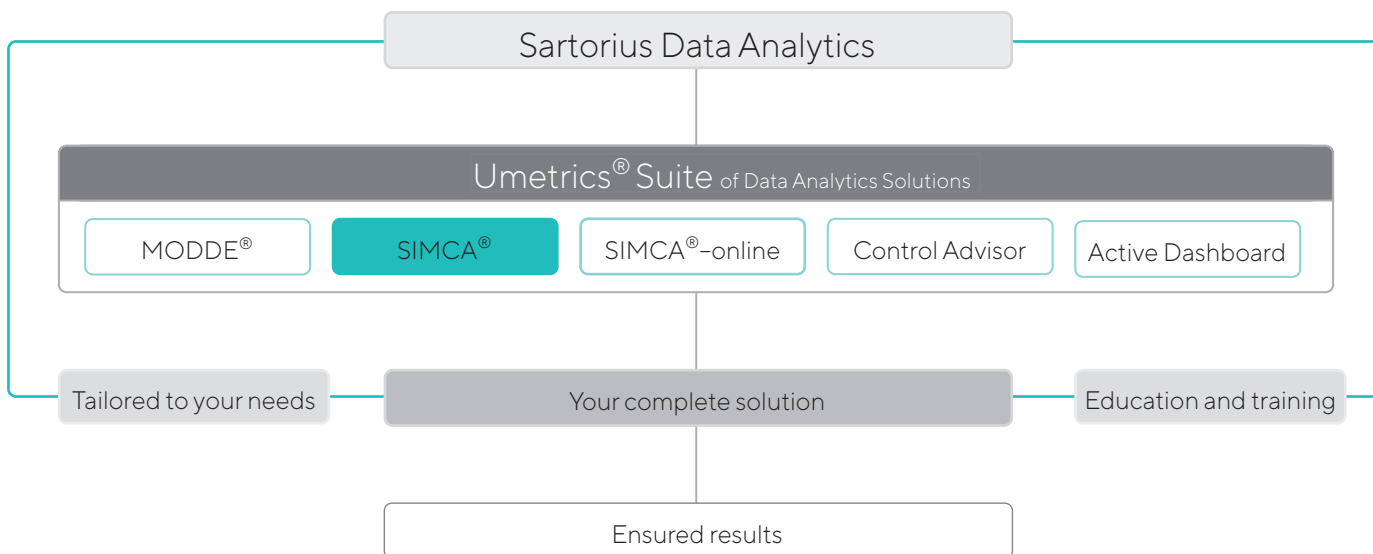
- A major bio-process company improved process yield by 75%, reduced cycle time by 40% and trebled plant output.
- An international food processing company resolved a logistics issue and saved USD 1 million per year in shipping costs.
- A wastewater treatment company used SIMCA to improve their processes for a cleaner, safer environment.



SIMCA at a glance:

- Interactive graphical interface
- Flexibility to handle complex data in many forms
- Powerful multivariate tool
- An easy way to script your workflow
- Seamless model update integration with SIMCA[®]-online

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.

A complete suite for business growth

The Umetrics Suite is a family of proven data analytics solutions that work seamlessly together. Other software solutions in the Umetrics Suite are:

- MODDE®
Design of Experiments to get it right from the start
- 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

These solutions give you control and confidence in your processes at every stage - from development to manufacturing.

“ Using SIMCA to solve problems has saved us millions of dollars over the years.

Timothy Michaelson, Senior Manufacturing Excellence Consultant at International Paper



Sartorius Data Analytics – Change a little. Grow a lot.

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.

Visit www.sartorius.com/umetrics for details or to download a free 30-day trial.

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