Sartorius T-Cell Optimization and Characterization Solution

Data Sheet Collection

SARTORIUS

Table of Contents

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

	Cell culture		Microbial	
Gases	**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

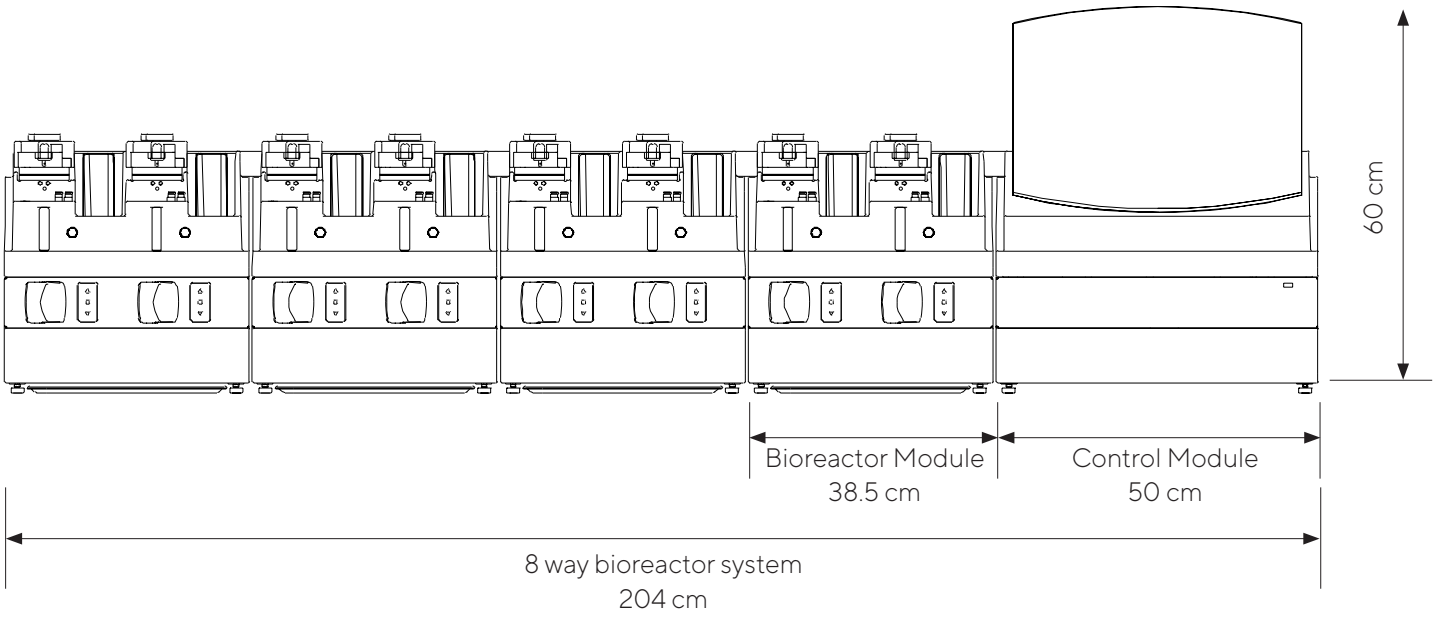
Bioreactor vessel general information

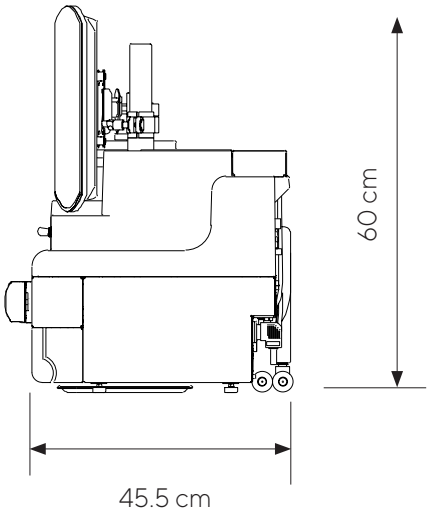
Construction material	Polycarbonate, polypropylene, polyethylene
Dimensions	Internal diameter 60 mm. Internal height 120 mm
Total volume	350 mL
Working volume	100 - 250 mL
pH monitoring technology	Single-use electrode
DO monitoring technology	Fluorescence based spot

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	-	-	3.37×10^4
Tip speed	-	-	4.71 m/s
Mixing time	-	-	0.642/s

Dimensions of Ambr® 250 Modular 8 vessel system





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MODDE®

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Simplifying Progress

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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?

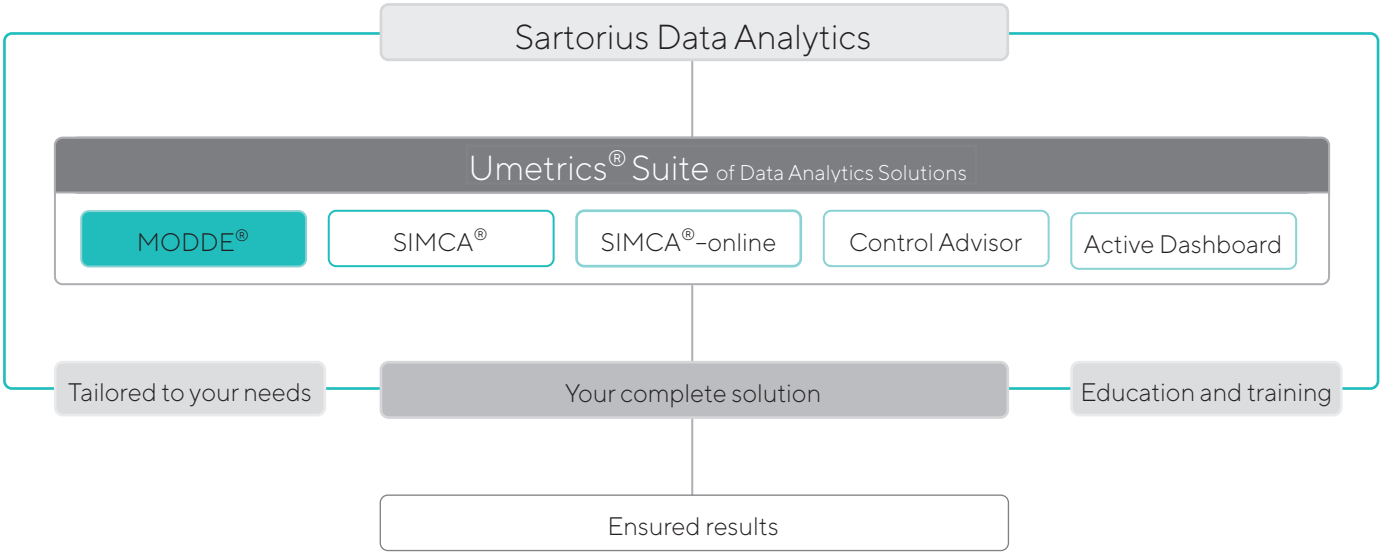
MODDE is helping companies in many different industries to design more effective experiments and create more effective strategies for tackling process problems. For instance:

- 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.

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

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- SIMCA®
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- 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.

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

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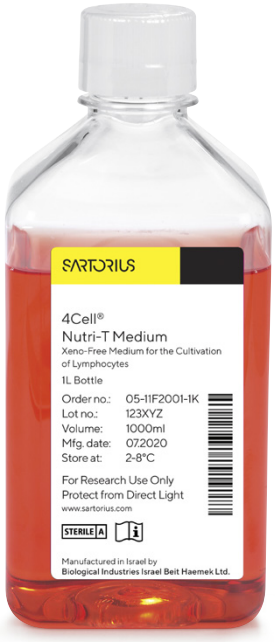
Product Datasheet

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.

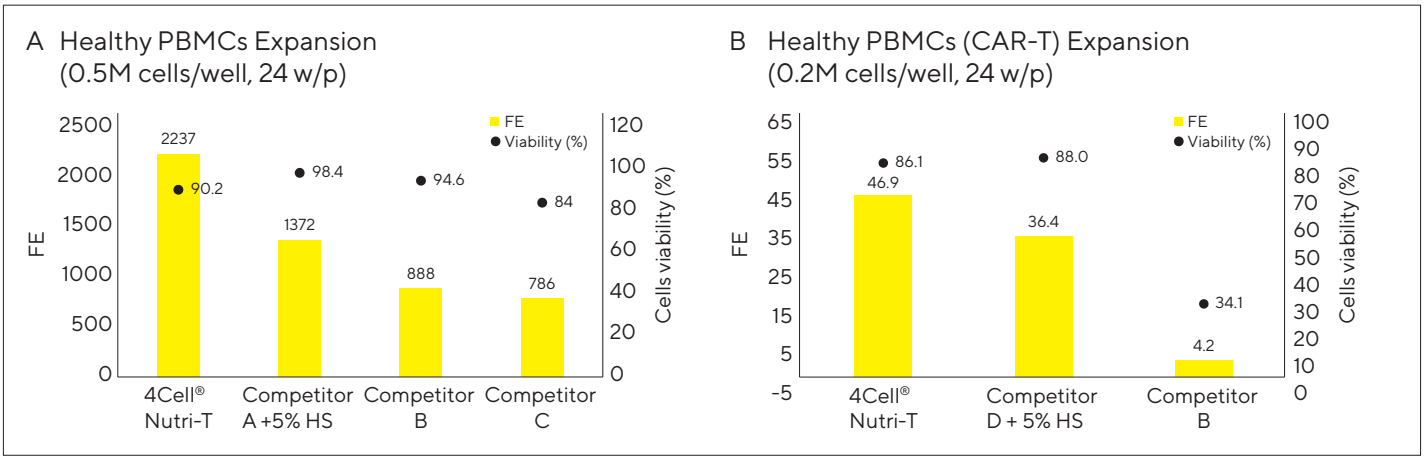
Product Snapshot

- 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



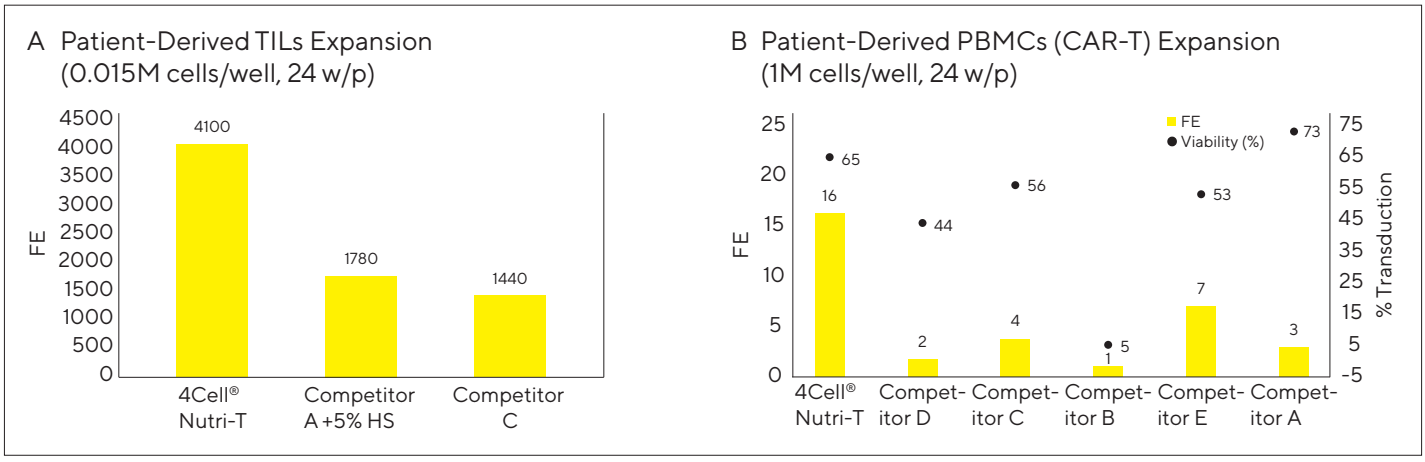
(A) 0.5M healthy donor PBMCs were seeded in 24w plates (2 ml media/well). Cells were activated with TransAct 1:100 and 600 IU/ml IL-2. Cells were split and media renewed every 2 – 3 days. Fold expansion (FE) and cell viability were measured at Day 11.

(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

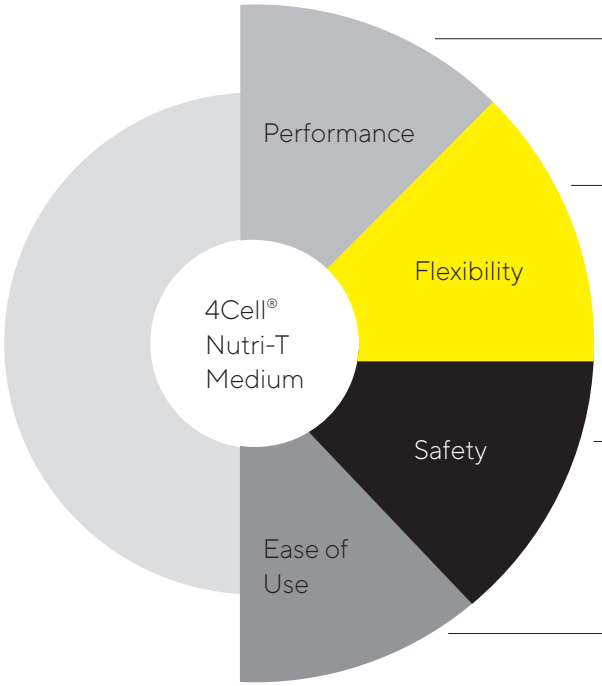
When working with a patient's cells, the materials used and the time from cell isolation to patient administration with the final product are critical. You cannot afford to waste time as a result of production or shipment delays.

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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Product Datasheet

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 cycler and the evaluation can be performed with the standard cycler 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 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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Status: 09 | 2021

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

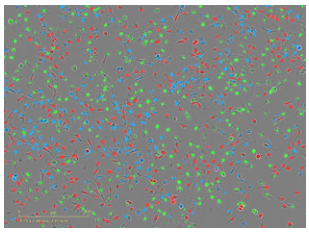
Go Where Your Research Takes You

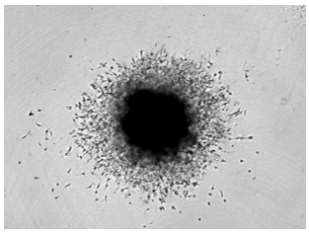
Study complex immune-tumor cell interactions, synaptic activity in neuronal co-cultures, metabolism in cancer cells, and much more—with a single platform.

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

Learn more at
www.sartorius.com/incucyte

E-Mail orders.US07@sartorius.com

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APAC: +81 3 5826 4795

See how the Incucyte is driving research forward at **www.essenbio.com/publications**

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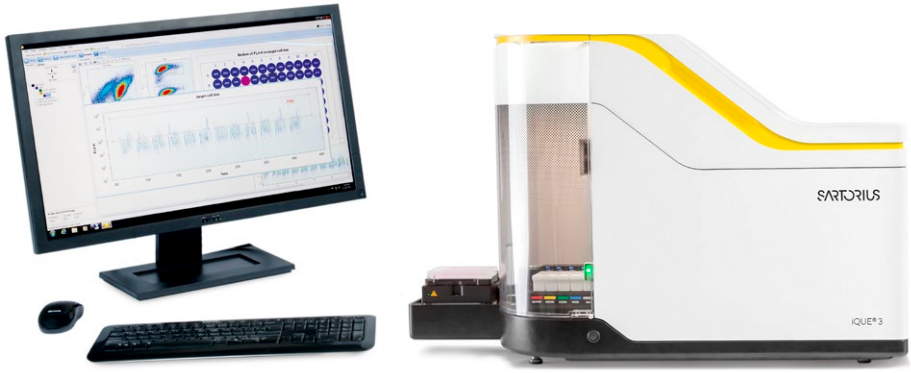
Technical Specifications

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**

SIMCA®

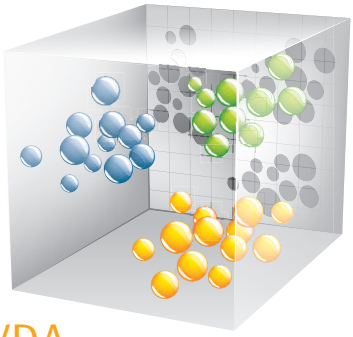
Turn data into growth

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?

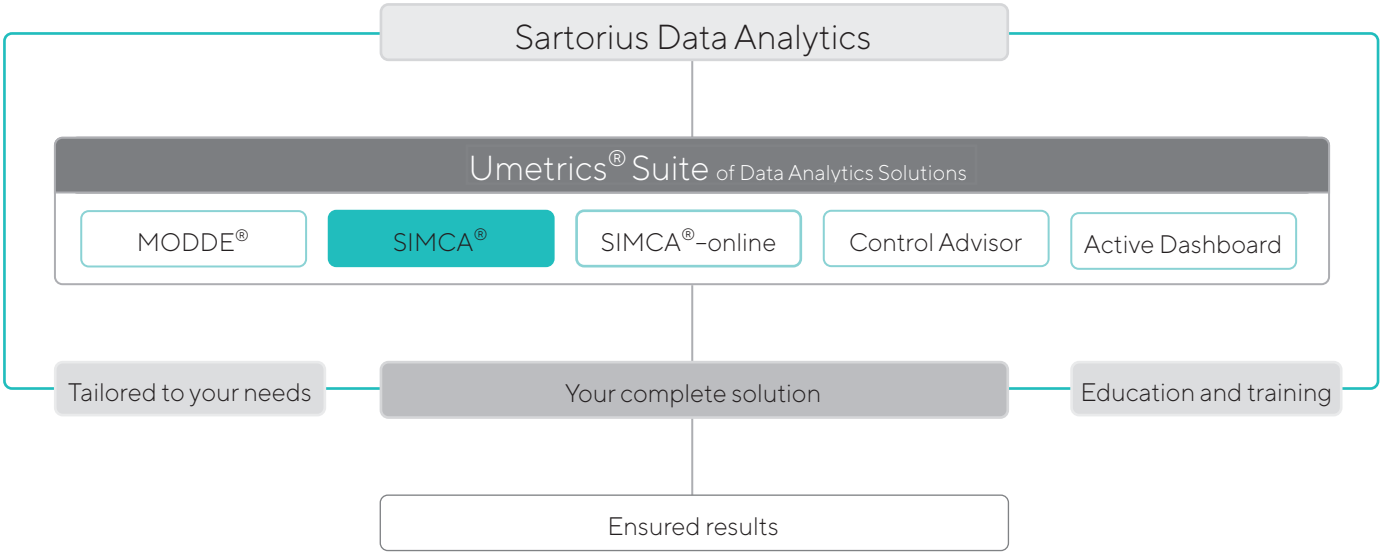
Wherever you create data you can use SIMCA. That's why companies in many different industries have worked with us to help their business grow.

- 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



> "Using SIMCA to solve problems has saved us millions of dollars over the years.
>
> Timothy Michaelson, Senior Manufacturing Excellence Consultant at International Paper

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.

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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