

MERCK

SECURE YOUR PHARMA ANALYSIS & QC

Click to start



Let's provide trust. Together.

Trust our analytical products in every stage of your biologics, biosimilars, and pharmaceuticals drugs development.

Millipore®

Preparation, Separation,
Filtration & Monitoring Products

Supelco.

Analytical Products

BioReliance®

Pharma & Biopharma
Manufacturing &
Testing Services

Milli-Q®

Lab Water Solutions

Sigma-Aldrich®

Lab & Production Materials



**Ask our
experts
NOW!**

The life science business of Merck operates as
MilliporeSigma in the U.S. and Canada.

SigmaAldrich.com/pharmaQC



Merck has brought together the world's leading Life Science brands, so whatever your life science problem, you can benefit from our expert products and services.

Supelco®

Analytical Products

The Supelco® portfolio of analytical solutions of Merck is developed by analytical chemists for analytical chemists to ensure your results are accurate, precise and reproducible. Every product is meticulously quality-controlled to maintain the integrity of your testing protocols and, with our dedicated scientists, the expertise you need is always on hand.

Sigma-Aldrich®

Lab & Production Materials

The Sigma-Aldrich® portfolio of Merck offers a strong and ever-expanding offering of lab and production materials. Through our technical support and scientific partnerships, we help connect our customers with a whole world of progress.

Milli-Q®

Lab Water Solutions

The Milli-Q® portfolio of lab water solutions of Merck takes care of all your water quality and purity needs. Our solutions are backed by consistent quality and full compliance and work seamlessly together to let you focus on your vital work.

Millipore®

Preparation, Separation, Filtration & Monitoring Products

The Millipore® portfolio of Merck offers an ecosystem of industry-leading products and services, spanning preparation, separation, filtration and monitoring – all of which are deeply rooted in quality, reliability and timetested processes. Our proven products, regulatory and application expertise are a strong foundation you can rely on to consistently perform at the highest level.

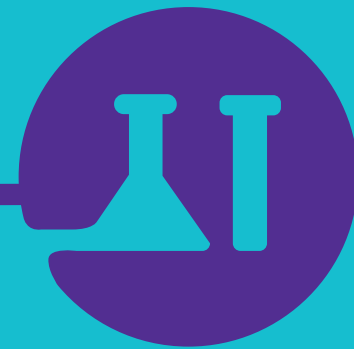
BioReliance®

Pharma & Biopharma Manufacturing & Testing Services

The BioReliance® portfolio of Merck encompasses biopharmaceutical characterization, safety testing and process development, as well as clinical and commercial biomanufacturing. Our experienced teams and operational expertise make us the partner who supports you all the way and always has your vital goal in mind.

Workflow: Small Molecules & Biologics Drug Analysis

Click on each to discover more



Discovery



Product Characterization
& Method Development



Analytical QC



Microbial QC



MultiScreen® Filter Plates



Life Science Research Tools



Small Molecule Discovery



ADME/Tox



SPE Products and Formats



Milli-Q® Pure and Ultrapure Water

Key to Icons



Home Page



Respective Page



More Information



Close



External weblink



MultiScreen® Filter Plates

The MultiScreen® Filter Plates portfolio enables researchers to perform a variety of applications in drug discovery including cell-based assays, ADME compound profiling, biochemical assays, and sample preparation



- Plates with 96- and 384-well format.
- 96% or more reduction in radioactive waste over traditional cell harvesting methods.
- Reduced sample-to-sample variability.
- Enhanced assay reproducibility.
- Sidewalls for barcode placement and robust handling.
- Customization available for:
 - Membrane type and pore size
 - Plate housing material
 - Plate/receiver assembly combinations
 - Plate lot reserve





Life Science Research Tools

Our Life Sciences Portfolio delivers products and services for life science research in academic and pharmaceutical environments performing basic research, drug discovery, and diagnostics.



- Antibodies
- Cell Culture
- Functional Genomics & Gene Search
- Drug Discovery
- Western Blotting
- Labware
- Roche products and biochemical reagents
- Antibiotics
- Tissue Diagnostics





Small Molecule Discovery



Aldrich Market Select

- With 14 million in stock products, 8 million unique structures, our customizable service creates a pain-free solution for your unique small molecule library design needs..

SYNTHIA™ Retrosynthesis Software

- Easily analyze custom pathways for known and novel molecules against your search criteria—and quickly go from imagining what's possible to testing what's probable.

Chemical Synthesis

- Empowering synthetic chemists to make molecules in new or more efficient ways with a broad portfolio of organic and inorganic chemicals and solvents.

Chemical Biology

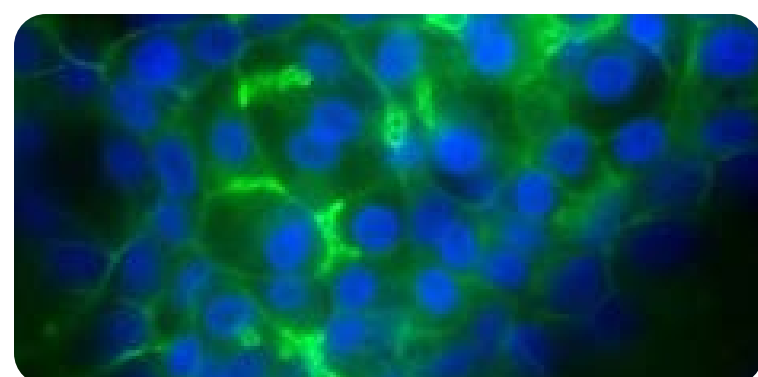
- Tools to accelerate your research of “undruggable” targets include our off-the-shelf DNA-encoded library for lead discovery and protein degrader building blocks for synthesis of degrader libraries containing your target warhead.





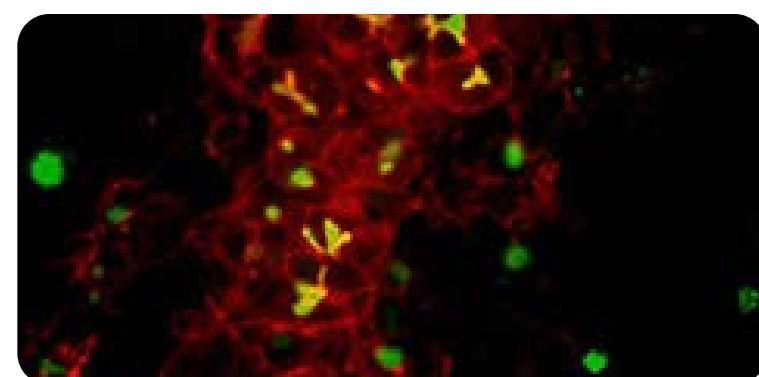
In Vitro Safety Systems - ADME, DMPK, Tox

For ADME/Tox & DMPK scientists, performing Tier1/Tier2 safety testing assays, we provide more predictive *in vitro* model systems for intestine, liver, and kidney with primary, wild type and engineered cell lines, addressing transporters and nuclear receptors related to cyp induction, listed in the FDA and EMA preclinical guidance documents.



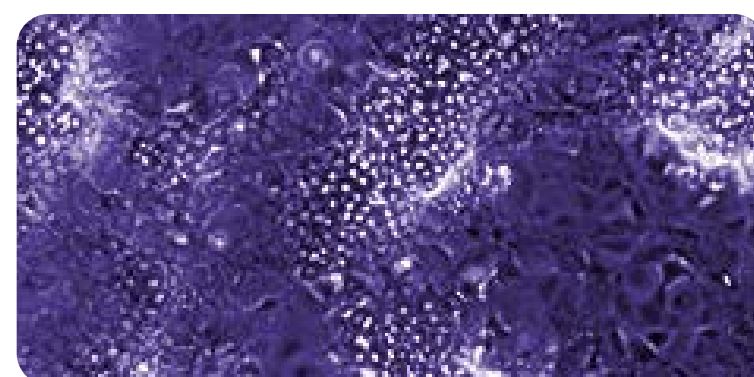
Permeability & Transporter Assays

- Caco-2 cell line models.
- HepaRG™ transporter KO cell line models
- Kidney transporter KO cell line models
- Transwell plates
- MDCKII



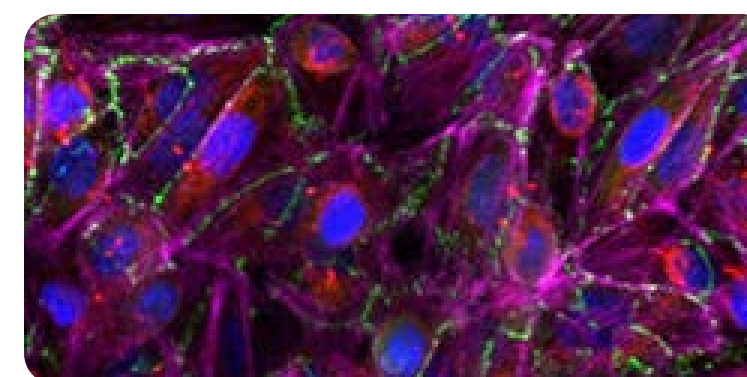
Metabolism Assays

- HepaRG™ 5F cell line and metabolism KO models
- Liver preparations and fractions
- CYP450 microsomes and purified proteins.
- idMOC plates
- Substrates and inhibitors.
- CYPExpress P450 enzymes
- Glutathione S-Transferases (GST)



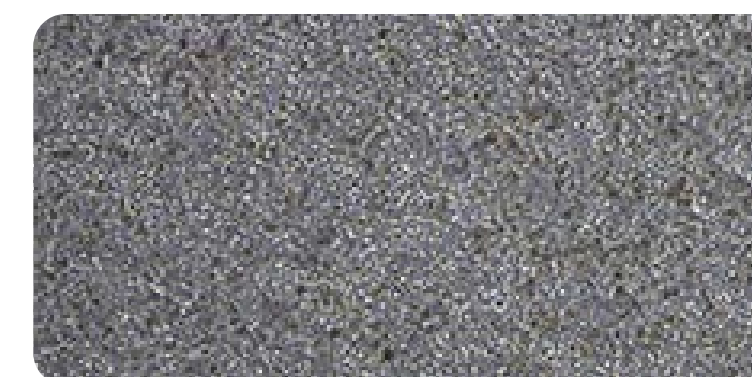
Toxicology Assays

- Kidney SA7K cell line model
- Cytotoxicity, Proliferation and Viability Reagents
- iPSC-derived neural cell line models.
- idMOC plates



3D Cell Culture Innovation

- AIM Biotech 3D Organ-On-A-Chip
- Mimetas 3D Nephrotoxicity Model



Liver Cell Culture Tools

- View Current Primary Human Hepatocyte Lots For Reservation



SOLVO Biotechnology

- SOLVO® Membrane Vesicle Transporter Assays





Solid Phase Extraction (SPE) Products & Formats



SPE Cartridges and 96-well plates

- HybridSPE® products for complete protein and phospholipid removal from biological matrices.
- Discovery SPE cartridges and 96-well plates are quality controlled for pharmaceutical and clinical applications.
- Supel® Swift HLB general-use SPE cartridges for the extraction of a broad range of compounds from aqueous samples



Online SPE Cartridges

- Supel™ Genie Online SPE cartridges enable a seamless hands-free workflow that eliminates human error.



HybridSPE DPX Tips

- HybridSPE DPX Tips enable a completely automated sample preparation workflow for extraction in seconds.
- Amenable to low sample volumes.
- Unique chemistry for excellent recovery of both hydrophobic and hydrophilic analytes.





Milli-Q® Lab Water Solutions for All Your Water Purity Needs

Our Milli-Q® Lab Water Solutions portfolio offers a broad range of pure and ultrapure water purification systems and services designed for scientists working in pharmaceutical laboratories.



Milli-Q® IQ 7003/05/10/15 pure and ultrapure water system

Convenient access to pure and ultrapure water

- This compact and ergonomic system delivers both types of water directly from a tap water source.
- Easy-to-use dispensers give convenient access to purified water, even on distant benches.





Milli-Q® Lab Water Solutions for All Your Water Purity Needs



Milli-Q® IQ 7003/05/10/15 pure and ultrapure water system



Workflow: Small Molecules & Biologics Drug Analysis

Click on each to discover more










 **Discovery**






 **Product Characterization & Method Development**

 **Analytical QC**

 **Microbial QC**

-  **U/HPLC, & LC-MS Columns, Solvents, and Reagents**
-  **Biologics, Peptides, and Small Molecule Mass Spec & QC Standards**
-  **Milli-Q® Pure and Ultrapure Water**
-  **Filtration Tools**
-  **Proteomics Grade Enzymes & Digestion Kits**
-  **Microextraction Devices for Limited Sample Size**
-  **Reveal the True Identity of your Molecule**

Key to Icons

-  Home Page
-  Respective Page
-  More Information
-  Close
-  External weblink

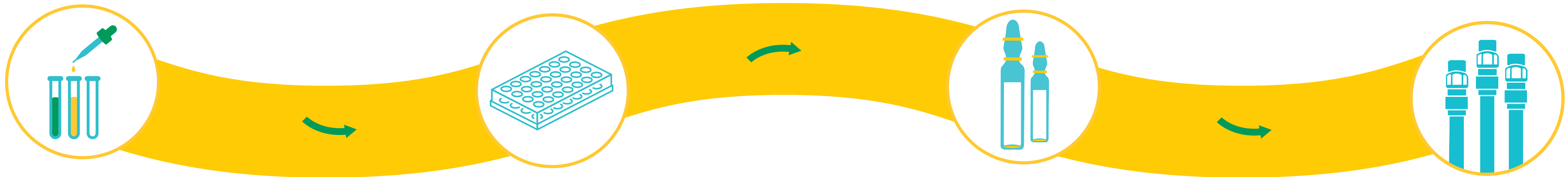
Product Characterization & Method Development



U/HPLC, & LC-MS Columns, Solvents, and Reagents for every application

We provide a premier selection of proven analytical tools and consumables that meet the requirements of scientists who primarily use the LC-MS technique for separation and analysis of drugs and biomolecules or for analytical assays.

LC-MS Workflow



Sample Collection

- Full Labware Portfolio
- Pipettes, Pipettors and Tips
- Multiwell Plates
- Microcentrifuge Tubes
- Vials

Sample Preparation

- SPE Cartridges and 96-well Plates
- SPME (BioSPME) 96-well Tips and Needle Probes
- QuEChERS dSPE
- 96-tip (dispersive) dSPE
- SLE Cartridges
- Online SPE Cartridges
- Millex® Filters
- Smplicity® Filtration System

Standardization & Calibration

- Certified Reference Materials
- Standards Search
- Analytical Standards

Chromatographic & Separation Analysis

- U/HPLC-MS Columns
- U/HPLC-MS Solvents
- LC-MS Reagents
- TLC-MS
- Reference Materials
- Accessories



Millipore[®]
Preparation, Separation,
Filtration & Monitoring Products

Supelco[®]
Analytical Products

Sigma-Aldrich[®]
Lab & Production Materials

Product Characterization & Method Development



Biologics, Peptides, and Small Molecule Mass Spec & QC Standards

Mass spectrometry reagents

The expanding field of proteomics requires high-quality mass spectrometry reagents. We offer a variety of products including:

- ProteoMass MALDI Calibration Kits.
- MALDI Mass Spectrometry calibrants.
- MALDI matrices.
- Protease Profiler.
- Guanidination kits.
- Trypsin products.

Reference Materials

From the qualification of APIs to identification of elemental impurities, to the determination of the sterility of end products, we offer a vast portfolio of reference materials:

- Primary Standards: USP, EP, BP.
- Secondary Standards.
- Snap & Shoot Standards.
- Impurity Standards & Impurity Mixture Solutions.
- Extractables and Leachables.
- Elemental Impurity Standards.
- Microbiological Standards.
- Physical Properties.
- Phytochemicals.



Supelco[®]
Analytical Products

Sigma-Aldrich[®]
Lab & Production Materials

Product Characterization & Method Development



Milli-Q® Lab Water Solutions for All Your Water Purity Needs

Our Milli-Q® Lab Water Solutions portfolio offers a broad range of pure and ultrapure water purification systems and services designed for scientists working in pharmaceutical laboratories.



Milli-Q® IQ 7003/05/10/15 pure and ultrapure water system

Convenient access to pure and ultrapure water

- This compact and ergonomic system delivers both types of water directly from a tap water source.
- Easy-to-use dispensers give convenient access to purified water, even on distant benches.



Product Characterization & Method Development



Milli-Q® Lab Water Solutions for All Your Water Purity Needs



Milli-Q® IQ 7003/05/10/15 pure and ultrapure water system



Product Characterization & Method Development



Filtration Tools

We provide a range of membranes and filter holders to support filtration needs across multiple solvent and sample types.



Membranes Filters, Filter Holders and Accessories

Membrane filters

- Durapore® polyvinylidene fluoride (PVDF).
- Millipore Express® polyethersulfone (PES).
- MF-Millipore™ mixed cellulose esters (MCE).
- Fluoropore™ and Omnipore™ polytetrafluoroethylene (PTFE).
- Isopore™ polycarbonate.
- Strat-M® membrane for transdermal diffusion studies.

Filter Holders and Accessories

- Millicup™-FLEX disposable vacuum filtration units.
- Glass and stainless steel vacuum filter holders.
- Pressure vessels.

Nonsterile Millex® Syringe Filters

Prepare samples using low-extractable Millex® syringe filters to ensure clean baselines and protect instrument performance for dissolution testing, LC-MS, HPLC, ion chromatography, and more.



Product Characterization & Method Development



Proteomics Grade Enzymes & Digestion Kits

The expanding field of proteomics requires high-quality mass spectrometry reagents.

We offer a variety of products including:

- SOLu-Trypsin, Advanced Proteomics Grade
- Trypsin Spin Columns, Proteomics Grade
- Trypsin, Proteomics Grade
- Trypsin Profile IGD Kit
- SOLu-Trypsin Rapid Digestion Kit
- ProteoMass MALDI Calibration Kits
- MALDI Mass Spectrometry calibrants
- MALDI matrices
- Protease Profiler
- Guanidination kits



Product Characterization & Method Development



Microextraction Devices for Limited Sample Size

Solid Phase Microextraction (SPME) is an innovative, solvent-free sample preparation technology that is fast, economical, and versatile. We have developed an Application Reference Guide listing over 3000 applications that have been published on the use of SPME.



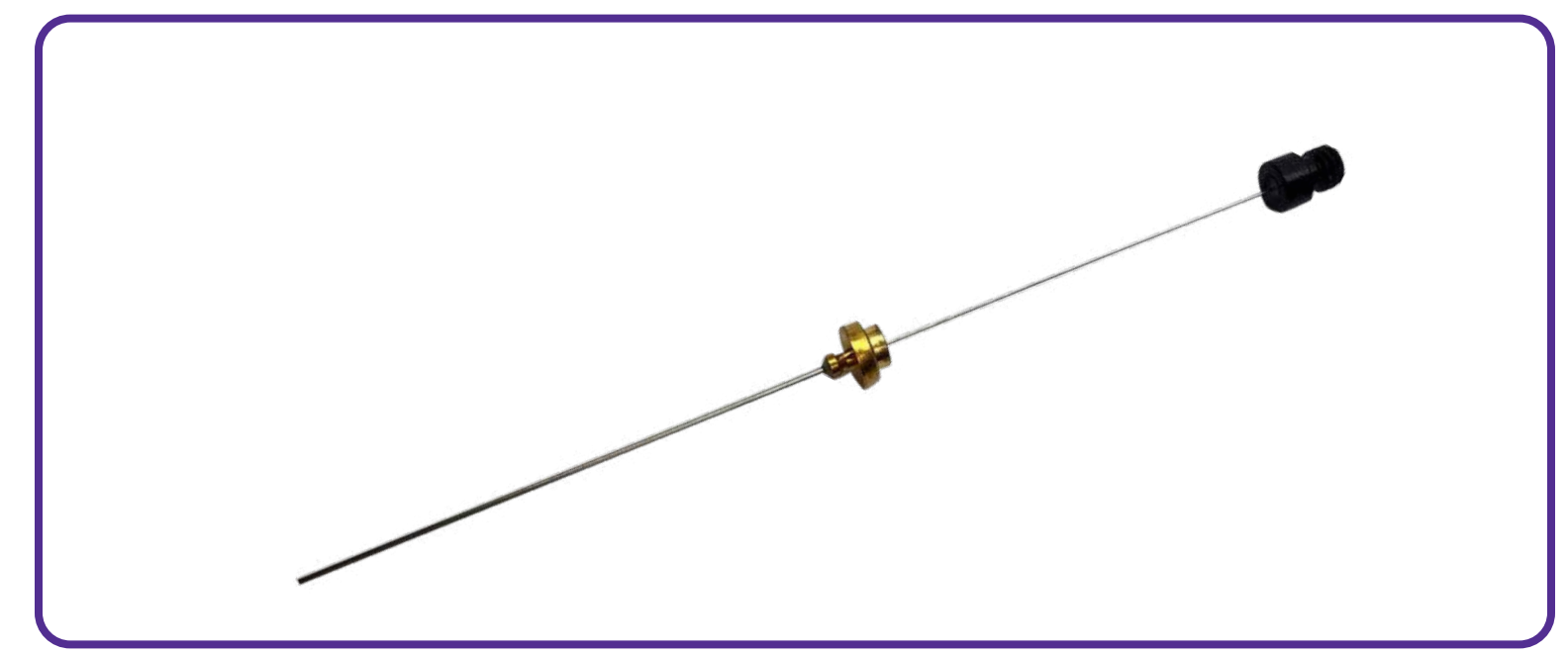
Smart SPME Fibers

- Can be used with the PAL autosampler system.
- Equipped with a unique smart chip, they enable traceability, ease of use and increased productivity through automation.



SPME for LC Analysis

- Selective extraction of a broad range of analytes from biological samples.
- While repelling unwanted macromolecules and matrix.



Nitinol-core SPME Fibers

- Enhanced fiber reproducibility.
- Greater fiber durability.
- Maintained selectivity for method consistency.
- Core inertness to ensure analyte stability.



Product Characterization & Method Development



Reveal the True Identity of Your Molecule

We ensure the security of supply for critical raw materials that you depend on for business continuity. From discovery, through clinical phases, up to and including commercial supply, we can help you through every stage of the molecule life cycle.

Services for Bioprocessing

- Cell Sciences & Development
- Process Development Services & Support
- imMEDIATE ADVANTAGE™: Small Volume Custom Media
- Trace Element Testing

Biopharmaceutical Expression Systems

- CHOZN® Platform
- Cell Line Engineering and Development
- CHOZN® Cell Lines
- CHOZN® Media and Feed System
- CompoZr® Zinc Finger Nucleases

Bioprocessing products

- Cell Culture Media (Catalog and Classical Medias)
- Dry Powder Media (Clinical and Commercial Capabilities)
- Raw Materials for Bioprocessing
 - Upstream Components and Supplements
 - Process Chemicals for Purification
 - Clean-In-Place

Bulk Packaging

- Liquid Packaging
- Powder Transfer Bags



BioReliance®

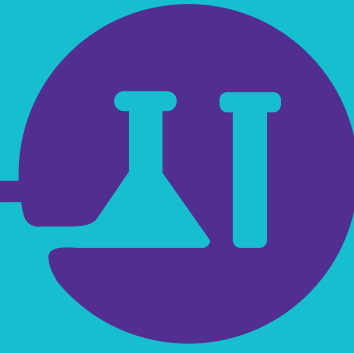
Pharma & Biopharma
Manufacturing &
Testing Services

Workflow: Small Molecules & Biologics Drug Analysis

Click on each to discover more



 **Discovery**













 **Product Characterization
& Method Development**








 **Analytical QC**



 **Microbial QC**

-  **HPLC Columns that meet USP, EP, and ICH Guidelines**
-  **HPLC Grade Solvents & Reagents**
-  **Solvents, Inorganics, Safety & Essentials**
-  **Karl Fischer & Titration Products**
-  **USP, EP and BP Primary Reference Materials & Secondary (Working) Standards**
-  **Gas Chromatography**
-  **Thin Layer Chromatography**
-  **ICH Q3D Elemental Impurity Testing**
-  **Filtration Products for Dissolution Testing**
-  **Milli-Q® Pure and Ultrapure Water**

Key to Icons


-  Home Page
-  Respective Page
-  More Information
-  Close
-  External weblink



HPLC Columns that meet USP, EP, and ICH Guidelines

A wide selection of high-performance HPLC Columns, Buffers, Reagents, Standards, and Accessories.



- HPLC & UHPLC Columns 
- HPLC Buffers & Reagents
- HPLC Accessories (a selection of products to maximize the performance of your HPLC system)
- Derivatization Reagents
- Analytical Standards and Reference Materials



Analytical Quality Control



HPLC & UHPLC Columns



We offer a wide selection of HPLC, UHPLC, and LC-MS columns for small and large molecule analysis. Our portfolio includes those employing fully porous particles (FPP), superficially porous particles (SPP), monolithic columns. A wide range of chiral columns, size exclusion chromatography and ion exchange modes are also available.



Fast Results with Maximum Resolution on any U/HPLC System Superficially Porous Particles (SPP)

- Ascentis® Express fused-core U/HPLC columns with superior column efficiency.
- BIOshell™ fused-core U/HPLC columns for biomolecule separations.



U/HPLC Columns for robust monograph methods Fully Porous Particles (FPP)

- Purospher™ STAR U/HPLC columns for peak symmetry and extended pH stability.
- Discovery® and Ascentis® columns for a broad range of selectivities.
- SeQuant® ZIC-HILIC for separation of polar compounds.
- Titan™ monodisperse UHPLC columns.



Rapid and Cost-Efficient Analysis of Matrix-Rich Samples Monolithic Silica U/HPLC columns

- Chromolith® monolithic silica U/HPLC columns for extended column lifetime at very low backpressure.
- Chromolith® WP 300 monolithic silica U/HPLC columns for biomolecule separations.



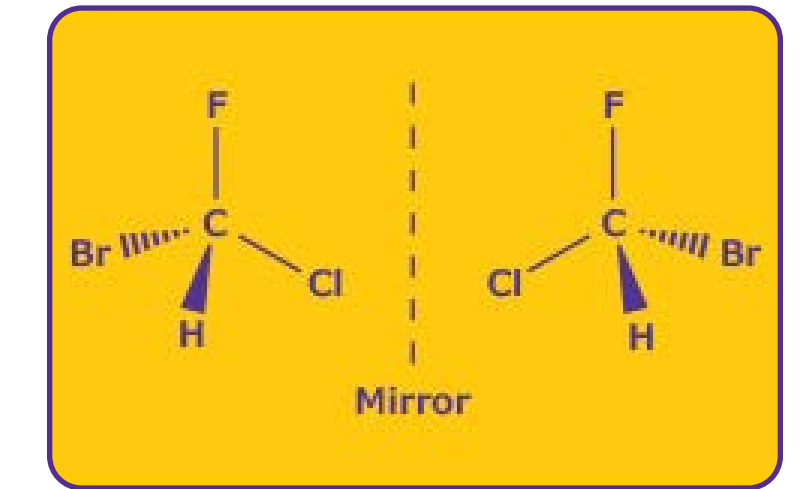
U/HPLC Columns for supercritical fluid chromatography (SFC)

- GreenSep™ SFC Columns.



SEC, Ion-Exchange and HIC Biomolecule separation (available just in Europe and in the US)

- Tosoh
- Sepax
- GE



U/HPLC Columns for superior chiral separations

- Astec CHIROBIOTIC®



Analytical Quality Control



Discover the Solvent Center

Discover our solvent center created to aid all visitors in their exploration of the right solvent by providing a concise summary of solvents by purity, grade, application, product lines or market, as well as packaging options, literature listings and special offers.



Solvents for Classical Analysis

- EMSURE® Premium Grade products.
- EMPARTA® Standard Grade Products.
- EMPLURA® Basic Grade Products.



Solvents for Instrumental Analysis

- HPLC
- LC-MS
- UHPLC-MS
- HPLC Blends
- GC Headspace
- GC-ECD/GC-FID
- GC-MS
- Spectrophotometric Solvents
- NMR



Analytical Quality Control



Solvents, Inorganics, Safety & Essentials

Our EMSURE® products come with the new smart label and in unique packaging with suitable safety equipment. They offer highest quality and compliance to international norms. They enable easy data access, safe and convenient use as well as reliable results, less number of analysis and compliance.



Smart Products

EMSURE® Premium Grade solvents and inorganics for demanding or regulated Analytical applications.



Smart Labels

Better data handling with our new 2D smart labels, embedding a 2D data matrix barcode which allows for processing directly in your LIMS or ERP system.



Smart Handling

- Withdrawal systems for solvents.
- Withdrawal systems for inorganics.
- Acids in Safebreak bottles.
- Packaging and Safe Handling.
- Safety Accessories.



Analytical Quality Control



2D Smart Labels



No typos, no manual writing and no outdated safety data

Smart labels incorporate a 2D data matrix barcode which contains the product data encoded using Global Standard One (GS1) specifications allowing direct processing in your LIMS or ERP system. This barcode provides seamless access to essential product information (item code, batch number, shelf life, etc.) and product documentation (CoA, SDS, etc.).



- Easy, quick and convenient access to product data
- Seamless access to safety data
- Mobile access via App or via website with a hand-held scanner
- Direct processing in LIMS or ERP



Analytical Quality Control



Karl Fischer and Titration Products For Reliable Analytical Results

Titripur® Volumetric solution, Certipur® volumetric standards and all Aquastar® Karl Fischer reagents and standards offer a complete portfolio for accurate, fast and precise titration results. Our new titration products with RFID technology make your titration process faster and more secure.



Titripur® Volumetric Solutions

Ready-to-use volumetric solutions compliant with the European/US Pharmacopeia and certified according to ISO 17025.



Aquastar® Karl Fischer Reagents

A whole range of Karl Fischer reagents for volumetric and coulometric water content determination in gaseous, liquid and solid samples.



Titripac® Volumetric Solutions

A hermetically sealed packaging available in 4L and 10L volume, can be directly connected to the titrator and keeps the solution stable from the first to the last drop during use.



Aquastar® Karl Fischer Water Standards

Certified Reference Materials (CRMs), produced under the double accreditation of ISO/IEC 17025 and ISO 17034.



Certipur® Volumetric Standards & pH Buffer CRMs

Volumetric standards for titer determination and buffer solutions for calibration of electrodes, both under the double accreditation of ISO/IEC 17025 and ISO 17034.



Titrisol® Volumetric Concentrates

Volumetric concentrates in ampoules offer flexibility for preparation of different concentrations of volumetric solutions.



Titration Goes Digital

Products to transfer data seamlessly from an embedded RFID on the bottles to the titrator.





Analytical Standards for the Pharma Industry

From the qualification of Active Pharmaceutical Ingredients (APIs), to identification of elemental impurities, to the determination of the sterility of end products, reference materials are a critical component of pharmaceutical manufacturing.



We are your partner to help you meet regulatory demands and keep drug materials safe.

- Primary Standards: USP, EP, BP
- Fully Certified Secondary Standards with traceability to Primary Standards
- Snap & Shoot Standards
- Impurity Standards & Impurity Mixture Solutions
- Extractables and Leachables
- Inorganic elemental impurity mixes according to ICH Q3D guidelines
- Microbiological Standards
- Physical Properties Standards (ex. pH Value, conductivity, color and viscosity)
- Phytochemical Standards



Analytical Quality Control

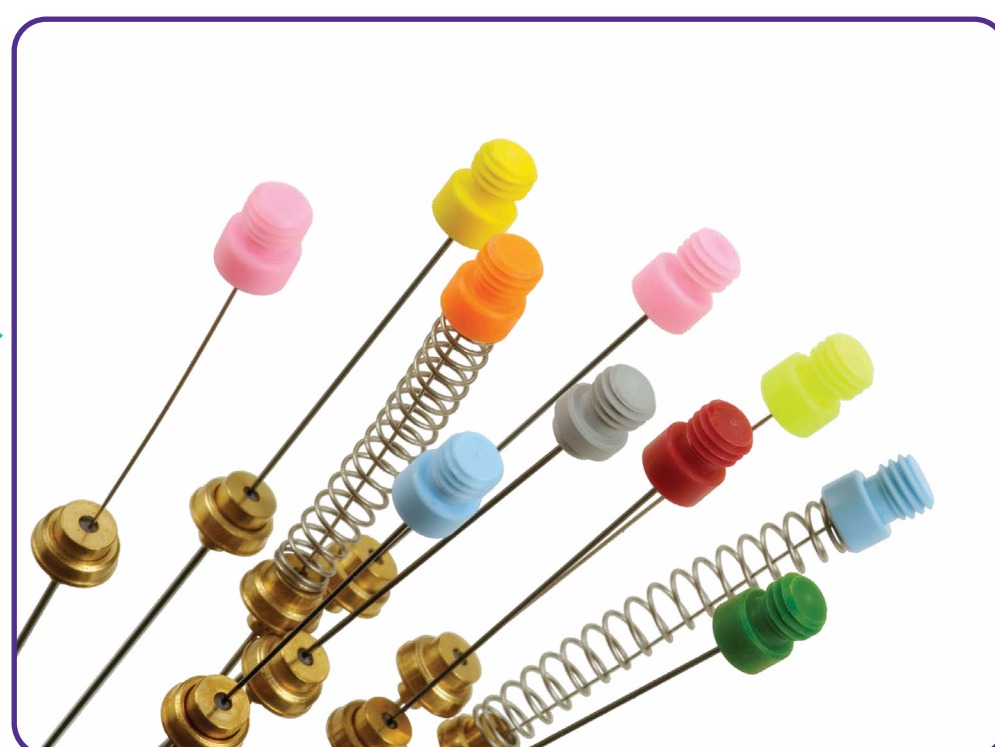


Gas Chromatography

Our full-line of capillary gas chromatography (GC and GC/MS) columns includes ionic liquid, MS-grade, Fast GC, GCxGC, chiral, and PLOT columns. Check out our comprehensive line of GC accessories, calibration standards, extraction solvents, and gas purification/management products.

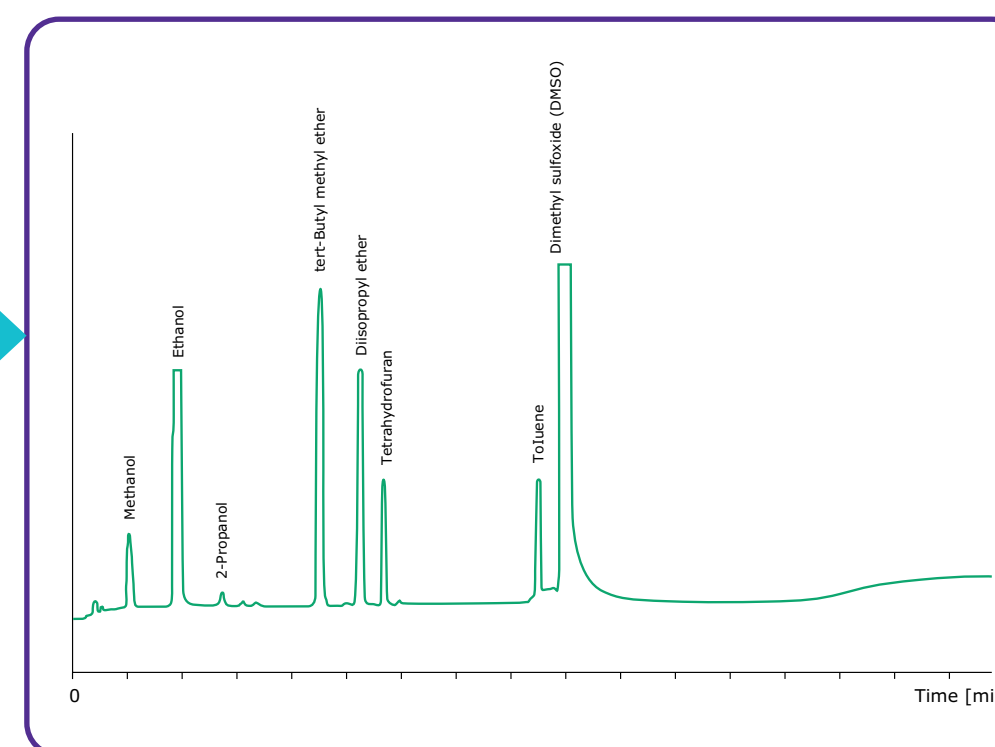


Proficiency Testing



Sample Preparation & Collection

- Solvents
- SPME & SPE
- Purge & Traps
- Derivatization Reagents
- Air Monitoring



GC analysis

- Capillary GC Columns
- Packed GC Columns
- GC Accessories
- Gas Management
- GC Adsorbents
- GC Reference Materials



Detection & Calibration

A comprehensive portfolio of certified reference materials and reference standards available neat, in solution or in a matrix.





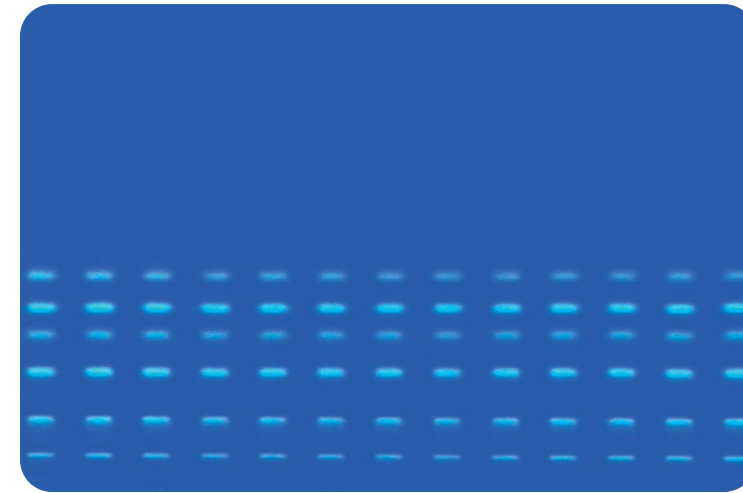
Thin-Layer Chromatography

As the leading supplier of Thin-Layer Chromatography (TLC) consumables, we offer an extensive portfolio for TLC, preparative TLC, and high performance TLC (HPTLC) including plates, reagents and accessories. Our special MS-grade TLC and HPTLC plates are designed specifically for coupling with MS.



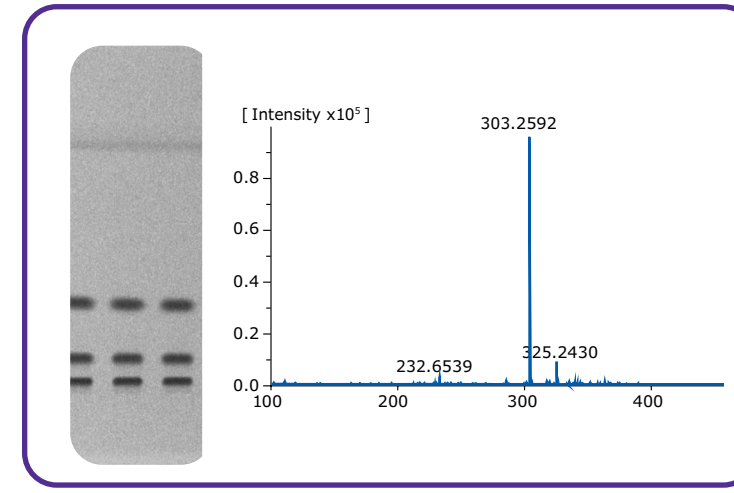
TLC Plates (Thin-Layer Chromatography)

- Silica Gel 60 Plates.
- Modified Silica.
- Aluminum Oxide.
- Cellulose.
- Kieselguhr and Mixed Layer.
- TLC and HPTLC Plates with Concentrating Zone.
- GLP-Plates.
- Multiformat.



HPTLC Plates (High- Performance Thin-Layer Chromatography)

- Silica.
- Modified silica.
- Cellulose.
- LiChrospher® (optimized for High-Throughput Separations).
- Premium purity.
- ProteoChrom®.
- TLC and HPTLC Plates with Concentrating Zone.
- GLP-Plates.
- Multiformat.



MS-grade TLC and HPTLC plates for Mass Spectrometry

MS-grade plates for TLC-MS and HPTLC-MS allow the coupling to MS for fast trace analysis with extremely low detection limits.



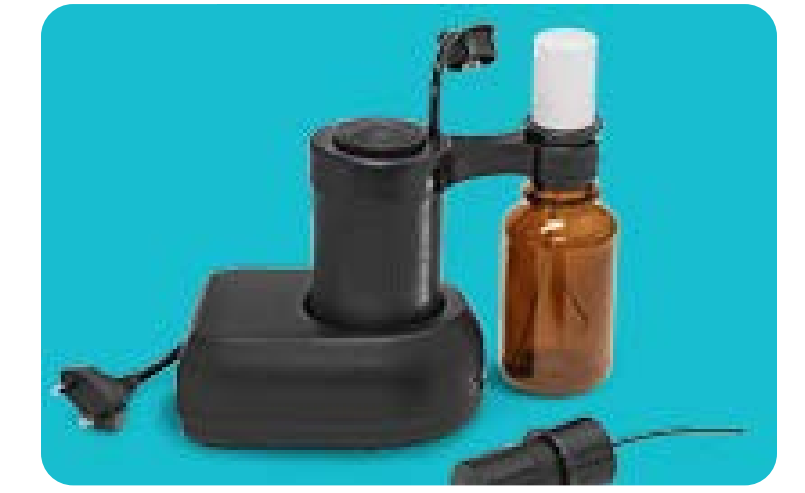
PLC (Preparative Layer) Plates

Preparative layer (PLC) plates for separation and purification of samples varying in quantity.



TLC Adsorbents

Adsorbents for TLC and preparative TLC.



Accessories

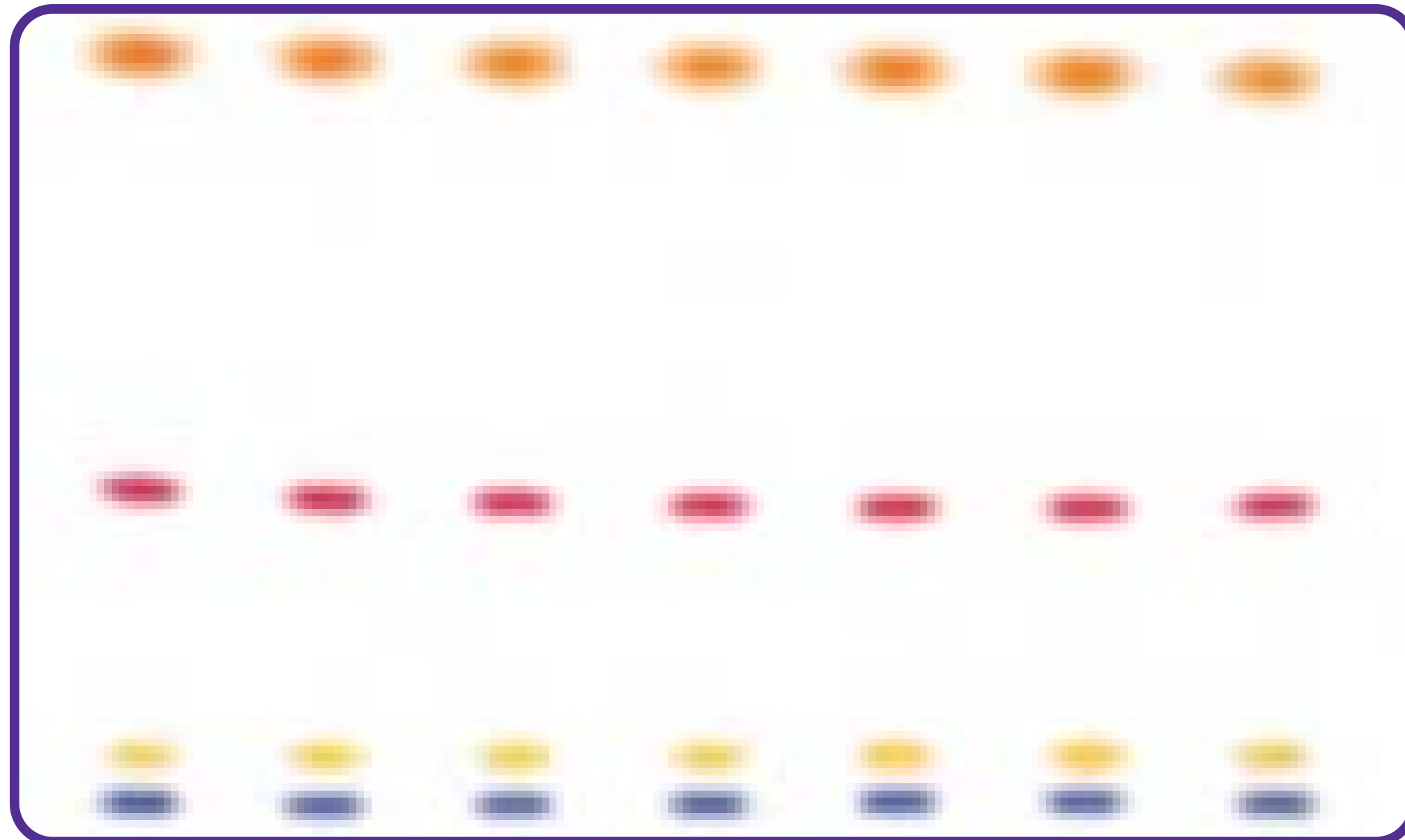
Other products, such as products for plate spotting and development, visualization, sample recovery and storage.



TLC Silica Gel 60 G Plates - Fully compliant with international pharmacopoeia



For QA/QC labs using older Ph. Eur. monograph methods which require plates with gypsum binder, our TLC silica gel 60 G plates are recommended and fulfill the performance test requirements of Ph. Eur. for G plates with gypsum.



CoA includes the performance test result for TLC plates according to Ph. Eur.

The chromatogram shows four clear separated spots according to Ph. Eur. test conditions and fulfills Ph. Eur. requirements.

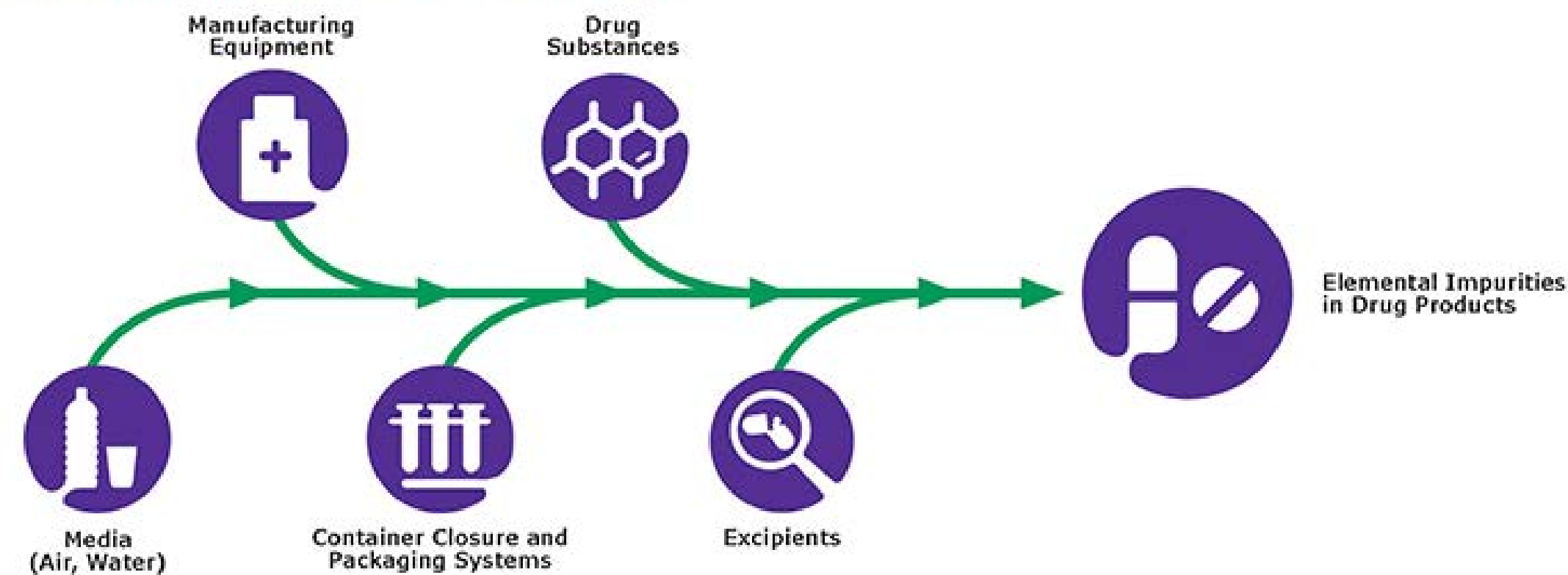




ICH Q3D Elemental Impurity Testing

Metallic contamination may arise from several sources along the whole process of drug manufacturing. Our ICH Q3D elemental impurity mixes with element ratios corresponding to the oral, parenteral and inhalation concentrations of the ICH Q3D guideline, ensure the safety of your medicinal products. These *TraceCERT*[®] elemental impurity certified reference material mixes are in accordance with ICH Q3D guidelines for USP 232, and Ph. Eur. 5.20.

Potential Sources of Elemental Impurities



- Unique level of accuracy and lot-specific value.
- Produced according to ISO Guide 17034 and analyzed in our ISO/IEC 17025 accredited lab.
- Comprehensive documentation according to ISO Guide 31 including proper uncertainty calculation, expiry date and storage information.
- Packaged in special FEP bottles and opaque, gas-tight aluminum foil bags for extended stability.
- Convenient 100 mL package size.





Why is Filtration Important in Dissolution Testing?

Samples pulled from dissolution baths during testing contain both dissolved and undissolved Active Pharmaceutical Ingredients (API). Microporous membranes, such as those used in Millex[®] syringe filters, separate undissolved from dissolved API, stopping the dissolution process. In addition to capturing API release and stability at the given time point, filtration removes particulates to prepare the sample for downstream testing methods, including HPLC.



Filtration products

- 13 mm Millex[®] syringe filters for 1–10 mL samples.
- 33 mm Millex[®] syringe filters for 10–100 mL samples.
- Automation-compatible Millex[®] syringe filters for 10–100 mL samples.
- Millex[®] syringe filters for Samplicity[®] G2 system.
- Samplicity[®] G2 filtration system and accessories.

Reagents

- Highly consistent quality.
- Save time by avoiding weighing and preparation steps.
- Available for 6, 10 and 25 L target volume.



Analytical Quality Control



Milli-Q® Lab Water Solutions for All Your Water Purity Needs

Our Milli-Q® Lab Water Solutions portfolio offers a broad range of pure and ultrapure water purification systems and services designed for scientists working in pharmaceutical laboratories.



Milli-Q® IQ 7003/05/10/15 pure and ultrapure water system

Convenient access to pure and ultrapure water

- This compact and ergonomic system delivers both types of water directly from a tap water source.

Match your water quality to your analyses:

- Each POD dispenser can be fitted with a specific **Application Pak** that provides final purification tailored to your applications' needs.
- The **Milli-Q® IQ Element purification unit** delivers water suitable for trace elemental analyses



Analytical Quality Control



Milli-Q® Lab Water Solutions for All Your Water Purity Needs



Milli-Q® IQ 7003/05/10/15 pure and ultrapure water system



Workflow: Small Molecules & Biologics Drug Analysis

Click on each to discover more



 **Discovery**












 **Product Characterization
& Method Development**








 **Analytical QC**



 **Microbial QC**

-  **Bioburden Testing**
-  **Sterility Testing**
-  **Pyrogen Testing**
-  **Microorganism Reference Materials**
-  **Mycoplasma and Viral Testing Options**
-  **Environmental Monitoring**
-  **Media Fill Testing**
-  **Milli-Q® Pure and Ultrapure Water**
-  **Service and Method Development Support**

Key to Icons

-  Home Page
-  Respective Page
-  More Information
-  Close
-  External weblink

Microbial Quality Control



Bioburden Testing

False results can waste valuable time. To help you streamline your entire microbial limit test workflow, we offer traditional and rapid bioburden testing filtration and detection equipment, along with a full range of long life solid media and quantitative detection solutions.



Filtration

- Milliflex Oasis® system.
- Microfil® filtration system.
- MicropreSure® On-line filtration system.



Culture Media

- Culture media for compendial methods.
- Reference microorganisms for culture media testing.



Detection

- Milliflex® Quantum rapid detection system.



Microbial Quality Control



Milliflex Oasis® System for Bioburden and Pharmaceutical Water Testing



We have taken time to closely observe your complete laboratory workflow to improvement areas identify and developed, hand-in-hand with users, a solution that simplifies and secures your microbial testing process.



With our new Milliflex Oasis® system, we raised comfort in bioburden testing to new levels:

- Productivity
- Result reliability
- Regulatory compliance

The system comes with color-coded media plates and crystal clear funnels, providing traceability from A to Z.



Microbial Quality Control



Long-life Culture Media for Compendial Methods



We provide a wide range of pharmacopoeia-compliant dehydrated and ready-to-use culture media, and substances required for:



- Sample preparation
- Microbial enumeration tests
- Tests for specified microorganisms

Certified reference microorganisms

Our Vitroids™ and LENTICULE® discs contain viable microorganisms in a certified quantity (ISO 17025), produced under reproducible conditions (ISO Guide 17034) with strains obtained from CECT®, NCTC and other collections.

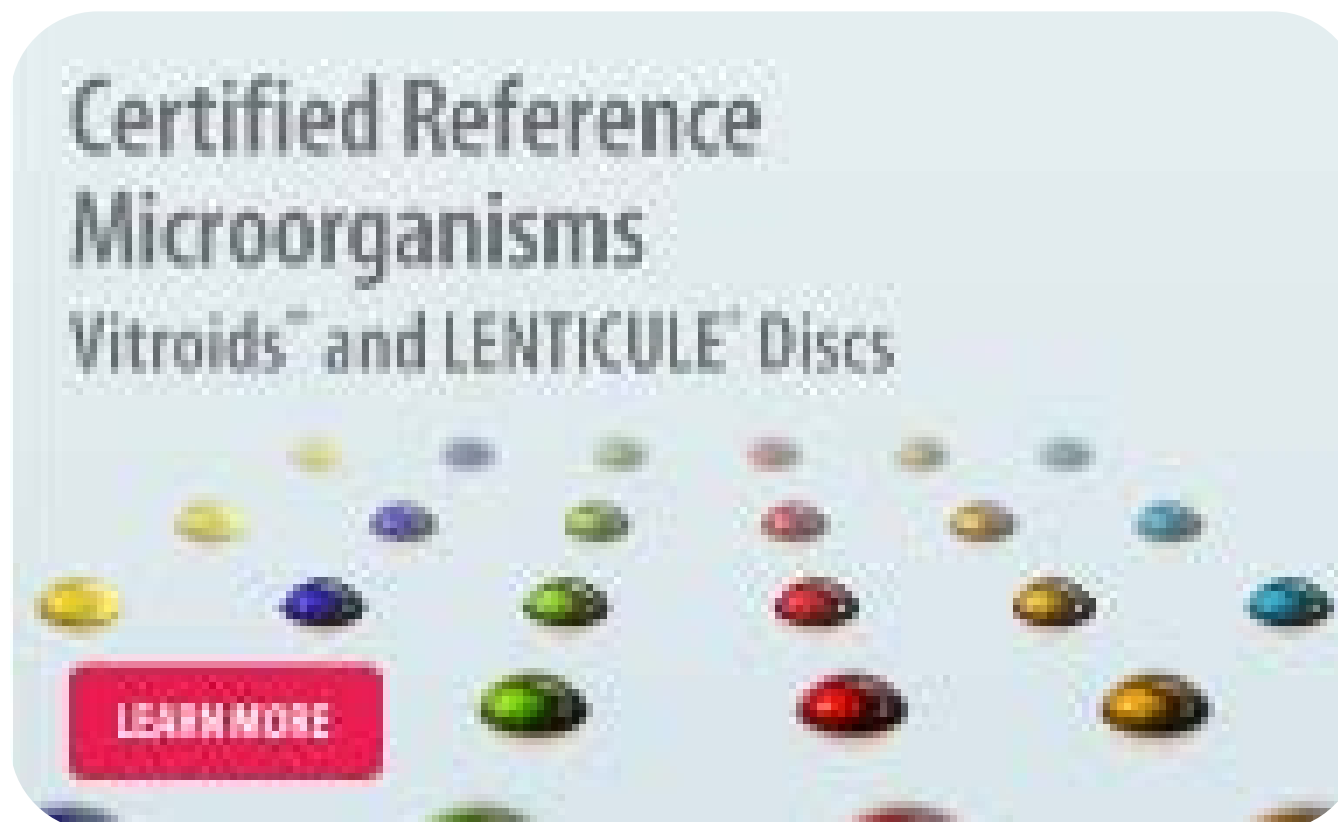




Microorganism Reference Materials



Vitroids™ and LENTICULE® discs contain viable microorganisms in a certified quantity (ISO 17025), produced under reproducible conditions (ISO Guide 17034) with strains obtained from CECT®, NCTC and other collections. The discs consist of bacteria or fungi in a solid water soluble matrix. Microorganisms in this form are stable for at least one year and are in a viable stage (no lag phase or recovery time).



Bacteria

- *Staphylococcus aureus* WDCM 00032.
- *Pseudomonas aeruginosa* WDCM 00026.
- *Bacillus subtilis* WDCM 00003.
- *Salmonella enterica* serovar *Typhimurium* WDCM 00031.
- *Salmonella enterica* serovar *Abony* WDCM 00029.
- *Escherichia coli* WDCM 00012.
- *Clostridium sporogenes* WDCM 00008.

Yeast

Candida albicans WDCM 00054 Vitroids™.

Mold

Aspergillus brasiliensis WDCM 00053 Vitroids™.

Control

Vitroids™ Blank 0 CFU

Find Microbiology Standards by standard, agency or method





Milliflex® Quantum Rapid Detection System



Rapid detection methods can speed up your microbiology quality control workflow and therefore allow faster product release. The Milliflex® Quantum system uses fluorescent-based technology for fast quantitative detection of microorganisms over a broad range of filterable matrices.



- Non-destructive method
- Easy to use system, requiring minimal training
- Compact hardware fits on any lab bench
- Validation services available



Microbial Quality Control



Sterility Testing - USP, EU and JP Pharmacopoeias Compliant

Our large variety of sterility testing membrane filtration devices and pumps, along with sterile culture media and rinsing fluids can help you to stay compliant with Pharmacopoeias (USP <71>, EU Pharm. <2.6.1> and JP Pharm. <4.06>, whether you use membrane filtration or direct inoculation methods.



Sterility Testing by Membrane Filtration

- Steritest™ NEO devices for membrane filtrations.
- Filtration devices with short needle.



Culture Media, Rinsing Fluids and Solvent

- Culture Media (TSB, FTM, clear FTM).
- Rinsing fluid (Fluid A, Fluid D and Fluid K).
- Solvent (Sterile Isopropyl Myristate).



Hardware & Accessories

- Steritest™ Symbio peristaltic pump.
- Accessories to improve your workflow steps.



Sterility Testing by Direct Inoculation

- Sterility testing media for non-filterable samples.





Steritest™ NEO devices for Sterility Tests by Membrane Filtration



Our Steritest™ NEO devices simplify every aspect of sterility testing, from handling to traceability, all within a closed system. The Steritest™ sterility test system offers an optimized and fully regulatory compliant testing process (USP <71>, EU Pharmacopoeia < 2.6.1> and JP Pharmacopoeia <4.06>).



- New protective caps uncovering either a short 35-mm or a long 60-mm needle.
- New designed needle guard and needle protector.
- A brand new short needle (20-mm) for small sample containers.
- Colored clamps.
- Tube placement mark.



Microbial Quality Control



Steritest™ Culture Media and Rinsing Fluids



Our sterility media and rinsing fluids are a critical component of your Steritest™ solution. They provide the highest level of quality and testing confidence. They have been formulated and tested to meet the requirements of the USP <71>, EU Pharmacopoeia < 2.6.1> and JP Pharmacopoeia <4.06>.



- Optimal cap design to reduce the risk of cross contamination and growth inhibition.
- High standards manufacturing process (ISO® 9001 controlled environments).
- Multiple configuration and volumes.
- Improved traceability through barcodes on each bottle.
- Validated to fulfill all your sterility and bioburden needs.



Microbial Quality Control



Steritest™ Symbio Pump



Our sterility testing Steritest™ Symbio pumps accompanied by our smart accessories are designed for ideal integration into any testing environment (cleanroom, isolator, or laminar flow hood).



- Designed to fit all your testing environments.
- Language option for an easier reading and execution of the working steps (10 languages).
- Automatic head closure to ease and secure tubing installation with no risk of pinching gloves.
- Pressure control to minimize risk of false results and test interruptions due to high pressure in the canisters.
- Services and Trainings - Reduction of time needed to perform preventive maintenance.





PyroMAT® *In Vitro* Test Kits for Pyrogen and Endotoxin Testing

No more animal-based pyrogen tests.

Detect both endotoxin and non-endotoxin pyrogens in one *in vitro* assay. The PyroMAT® system gives an *in vitro* alternative to conventional animal testing in accordance with regulatory guidelines.



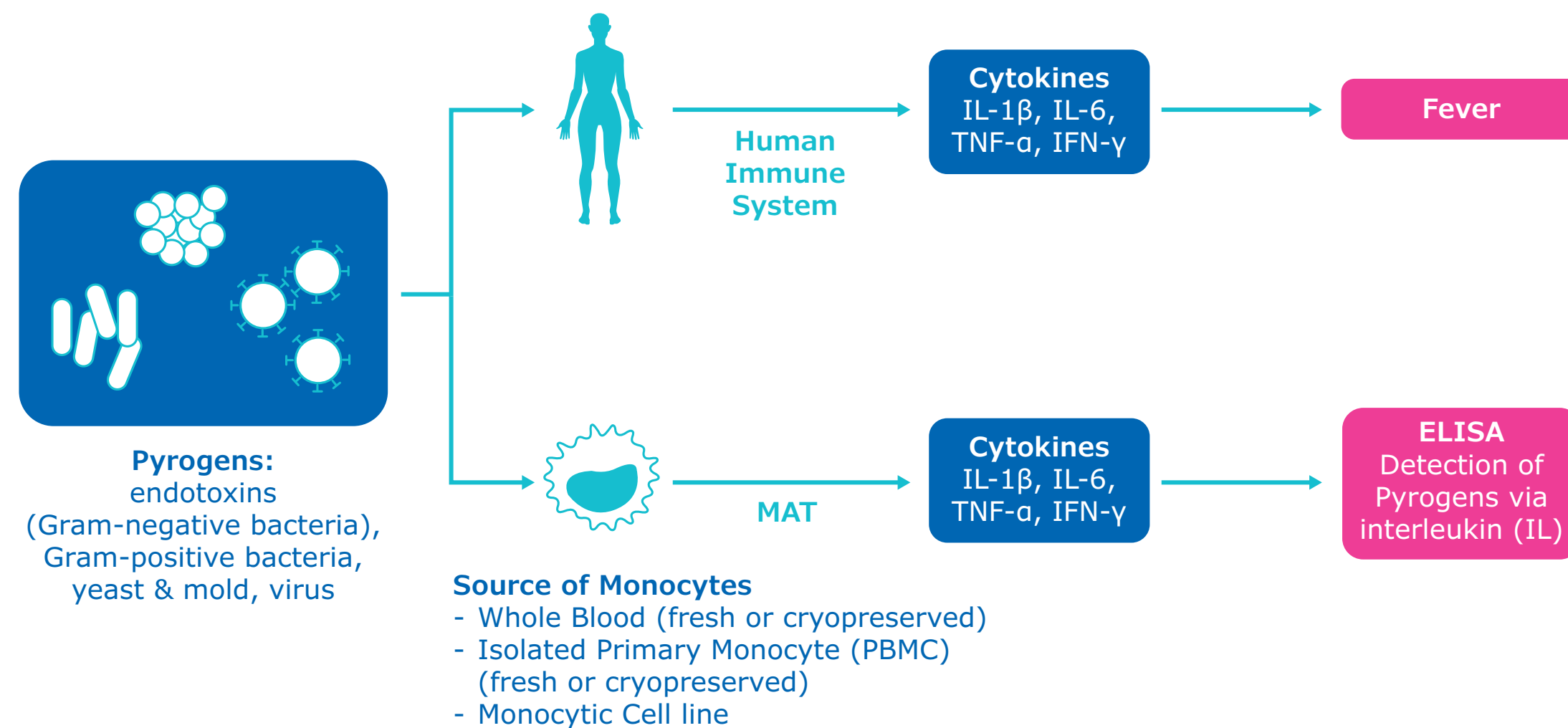
How does the PyroMAT®
system work ? 



Microbial Quality Control



How Does the PyroMAT[®] System Work ?



- Detection of a broad range of pyrogens.
- *In Vitro* assay that mimics the human immune reaction.
- Compliance with international regulations and guidelines.
- Standardized reactivity and high sensitivity (LOD 0.05 EU/mL).
- Qualified cells: Mono-Mac-6.





Mycoplasma and Viral Testing Options

Testing for mycoplasma is required for biologicals produced for clinical investigation and as licensed biologicals including Recombinant Proteins, Monoclonal Antibodies, Viral Vaccines (live and inactivated), Novel Therapies. Our mycoplasma detection assays are offered to cGMP, are validated to the current ICH guidelines, and meet or exceed the United States Pharmacopeia, European Pharmacopoeia, Japanese Pharmacio.

Regulatory-compliant methods

- Agar and semi-solid broth methods
- Detection of both cell dependent and cell associated mycoplasma
- Indicator cell lines
- Quantitative PCR
- ELISA

Assays for detection of mycoplasma use optimal

- Mycoplasma growth conditions
- Growth media
- Incubation conditions
- Sub-culture schedule
- Indicator cells for non-cultivable mycoplasma



Microbial Quality Control



Environmental Monitoring

Beside a comprehensive portfolio of microbial air, surface and personnel monitoring solutions for all levels of safety, from less critical environments to highly critical cleanrooms and isolators, our services include IQ/OQ, maintenance, calibration, product validation, application notes and support.



Isolator Solutions

- Microbial Air Samplers for Isolators.
- IsoBag®



Active Microbial Air Monitoring

- Portable Microbial Air Samplers.
- Gamma Irradiated Settle Plates.
- Non-irradiated Settle Plates.



Passive Microbial Air Monitoring

- Gamma Irradiated Settle Plates.
- Non-irradiated Settle Plates.



Surface & Personnel Monitoring

- Gamma Irradiated Contact Plates.
- Non-irradiated Contact Plates.
- Gamma Irradiated Swabs.
- Contact Slides.





Microbial Air Samplers for Isolators



MAS-100[®] ISO recommended for Pharmaceutical manufacturing facilities is designed for simple and reliable microbial monitoring of ambient air and compressed gas. Based on the Anderson impaction principle, air is aspirated through a perforated lid. The MAS-100[®] instruments have a flow rate of 100 liters/min.



- Precise, reproducible measurements and outstanding user flexibility.
- Excellent collection efficiency.
- Fully automatic calibration.
- Validation documents in accordance with ISO 14698 part 1 and part 2.

MAS-100 instruments manufactured by MBV AG,
Switzerland,
www.mbv.ch.
MBV. Air. Nothing else.





Environmental Monitoring in Isolators



IsoBag® ease the environmental monitoring workflow in aseptic production isolators by containing readily gamma-irradiated contact or settle plates. These unique transportation and packaging bags are simply mounted to the alpha port of the isolator. This keeps the plates available for use at any time.



- Mount readily gamma-irradiated contact or settle plates directly to your isolator without prior decontamination.
- Contains readily gamma-irradiated contact or settle plates.



Microbial Quality Control



MAS-100 NT[®] Microbial Air Sampler with Air Outlet Particle Filter for Ultra-sensitive Areas and Cleanrooms



Air sampler for environmental monitoring in GMP environments

- Eliminate the risk of cleanroom cross-contamination.
- Viable air samplers are used for quantitative determination of airborne contamination in cleanrooms and isolators. To maintain the cleanliness of the environment, the air flow should neither disturb the unidirectional air flow nor pose a contamination risk to the environment.
- As portable air samplers are sometimes moved and used in various environments with different levels of microbial contamination, there might be a risk of cross-contamination from higher to low contaminated environments.

MAS-100 instruments manufactured by MBV AG,
Switzerland,
www.mbv.ch;
MBV. Air. Nothing else.



Microbial Quality Control



Settle Plates for Active and Passive Air Monitoring



Our settle plates meet all relevant international standards and regulations, including EU cGMP, FDA Aseptic Guidance and USP <1116>.

The new TSA (Tryptic soy agar) media including the four neutralizers lecithin (L), Tween 80 (T), Histidine (H) and sodium Thiosulfate (Thio) provides additional unique features:



NEW - TSA LTHThio ICR/ICR+

- 12 months shelf-life.
- Decrease the frequencies of incoming controls.
- Cost reduction.

Add-ons to the certificate of analyses:

- Verification of anaerobic growth for lockable plates.
- Functionality check of individual 2 D matrix code.
- Disinfectant test part of the release testing.



Microbial Quality Control



Settle Plates for Active and Passive Air Monitoring



Our range of non-irradiated settle plates are designed for use in non-controlled and less critical controlled cleanrooms. They can be used for passive and active air monitoring as well as glove prints. Ten plates each are single bagged.



**Non-irradiated settle plates
(LI settle plates)**

- Single-bagged settle plates.
- Ideal for monitoring less critical cleanroom areas, such as grade C ,D and E, or non-specified environments.
- Their high-filling volume 30 mL in 90 mm settle plates reduces the percentage of water loss during the air monitoring procedures.
- 2D Data matrix barcode on each plate: paperless and secure identification of individual plates.
- Long shelf life (6-9 months) : fewer incoming goods controls.



Microbial Quality Control



Contact Plates for Personnel and Surface Monitoring



Our ready-to-use contact plates can be used for environmental monitoring of surfaces in critical clean rooms and isolators (ICR series). The ICRplus/RTplus versions are lockable and can be safely transported for incubation under aerobic, microaerophilic or anaerobic conditions.



NEW - TSA LTHThio contact ICR/ICR+

The new TSA (Tryptic soy agar) media including the four neutralizers lecithin (L), Tween 80 (T), Histidine (H) and sodium Thiosulfate (Thio) provides additional unique features:

- 12 months shelf-life.
- Decrease the frequencies of incoming controls.
- Cost reduction.

Add-ons to the certificate of analyses:

- verification of anaerobic growth for lockable plates.
- functionality check of individual 2-D matrix code.
- disinfectant test part of the release testing.





Non-irradiated Contact Plates for Personnel and Surface Monitoring



Our RT and RT plus ready-to-use contact plates are designed for microbial monitoring of dry surfaces such as floors, walls, textiles and working garments of personnel in controlled areas.

Non-irradiated contact plates - RT and RT plus plates for monitoring in controlled areas:

- 2D Data matrix barcode on each plate: Safe and paperless identification of individual plates.
- Room temperature stability: Storable at site of use.

Lid in CLOSED Position

- Safe transportation from sampling area to the lab
- Recommended for prolonged aerobic incubation period

Lid in VENT Position

- Mandatory for incubation under microaerophilic or anaerobic conditions
- Suitable also for short-term incubation under aerobic conditions



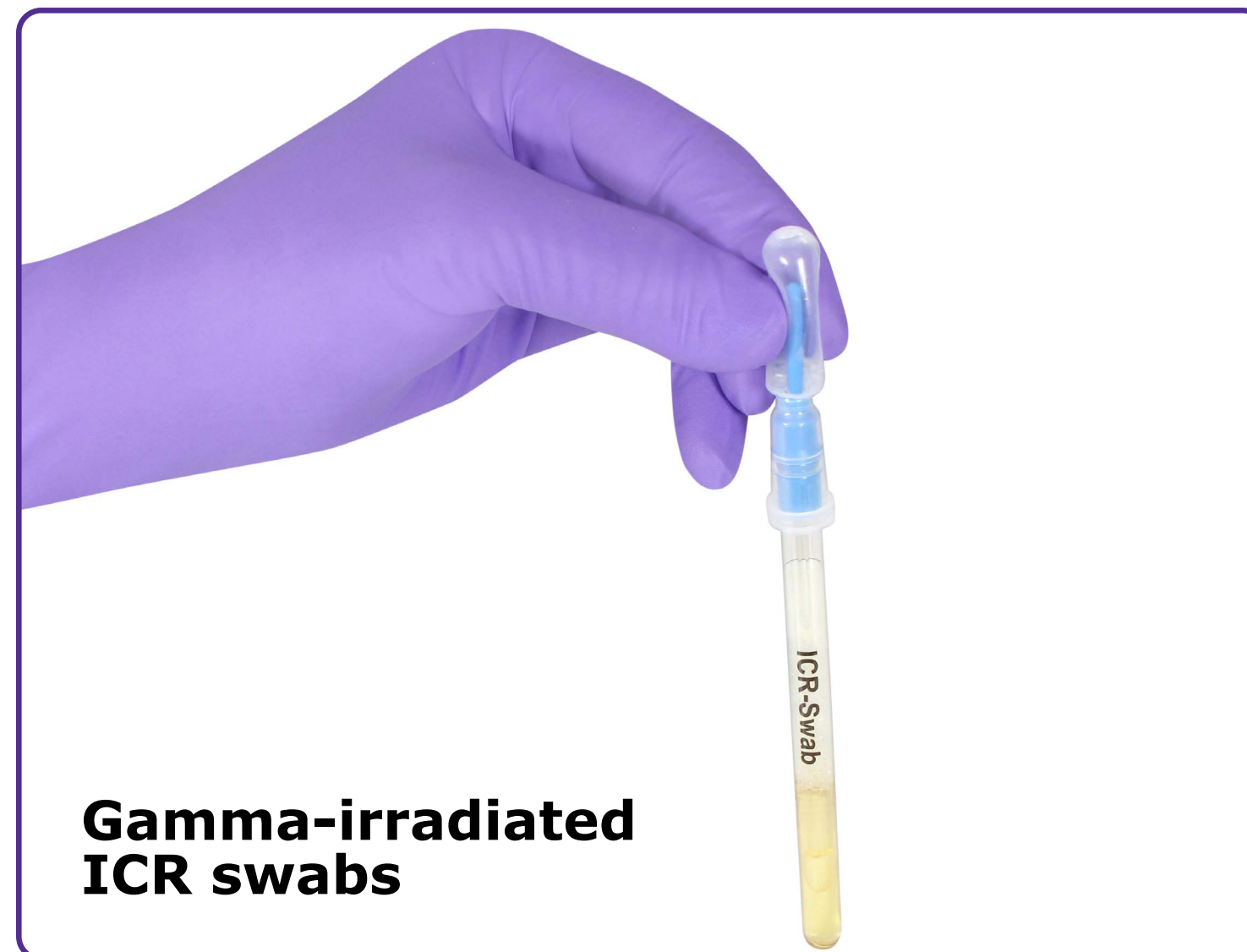
Microbial Quality Control



Gamma-irradiated Swabs for Surface and Personnel Monitoring in Isolators and Cleanrooms



The ICR-Swab is a unique swab system for environmental monitoring of dry surfaces, such as filling needles, equipment recesses, uneven surfaces and tubing in clean rooms and isolators. It is designed for qualitative presence/absence tests for microbiological contamination.



- The swab requires opening only once for sampling, addition of broth, incubation.
- Triple bagged and gamma-sterilized to minimize contamination risks in clean-rooms.
- Detection of turbidity, are performed within the closed system, minimizing the risk of potential contamination from handling.
- 2D Data matrix barcode on each plate for secure identification of individual swabs.
- Storage up to room temperature: storable at site of use.



Microbial Quality Control



Superior Quality Culture Media for Reliable Media Fill Testing

Have peace of mind with our irradiated granulated and ready-to-use sterile liquid culture media. We ensure that all these media are cold filterable. All our culture media are supplied for the ultimate security of your aseptic process.



Granulated and irradiated media for media fill testing

- Minimal dust.
- Excellent solubility.
- Optimized cold filtration properties.
- maximum security and performance.



Ready-to-use liquid media for media fill testing

- Tryptic Soy Broth (TSB) prepared according to European and US pharmacopeias.
- 80 cm long tube with an MPC connector for direct connection to the filling line.



Microbial Quality Control



Ready-To-Use (RTU) Liquid Media for Media Fill Testing



Pre-filtered and ready to go Gas-impermeable bags for greater safety and convenience.



Connection of bag with (from left to right):

- Inlet tubing.
- Outlet tubing.
- Injection port.



Handle at top of bag for convenient use.



10 L bag containing TSB, triple-bagged in transport box.



Microbial Quality Control



Milli-Q® Lab Water Solutions for All Your Water Purity Needs

Our Milli-Q® Lab Water Solutions portfolio offers a broad range of pure and ultrapure water purification systems and services designed for scientists working in pharmaceutical laboratories.



Milli-Q® IQ 7003/05/10/15 pure and ultrapure water system

Convenient access to pure and ultrapure water

- This compact and ergonomic system delivers both types of water directly from a tap water source.
- Easy-to-use dispensers give convenient access to purified water, even on distant benches.



Microbial Quality Control



Milli-Q® Lab Water Solutions for All Your Water Purity Needs



Milli-Q® IQ 7003/05/10/15 pure and ultrapure water system



Microbial Quality Control



Service and Method Development Support

With our long history of serving the pharmaceutical industry, we have pioneered and refined ground-breaking solutions, demonstrating the regulatory and technological expertise to make compliance as simple as possible, and help save your valuable resources.



Bioburden Services

- Feasibility Study.
- Method Development & Consultancy.
- Customer Validation Protocols.
- IQ/OQ and Requalification Services.
- PQ Consultancy and Execution Services.



Sterility Services

- Method Development & Consultancy.
- Validation Protocols: IQ/OQ/PQ & Requalification.
- Steritest™ Service Plans.
- Steritest™ Training Services.



Environmental Monitoring Services

- Customer Validation Protocols.
- IQ/OQ Service.
- PQ Consultancy.



Pyrogen Services

- Feasibility Study.
- Method Development & Consultancy.
- PSV Validation Consultancy and Execution Services.
- Data Analysis for PSV and Routine Testing.



Instrument Services

- Calibration.
- Preventive Maintenance.
- Service Plans.
- Repairs.
- End of Life Verification.



HELLO EXPERT!



Tell us how we can help you and an expert will be in contact with you soon.

SigmaAldrich.com/pharmaQC-ContactUs

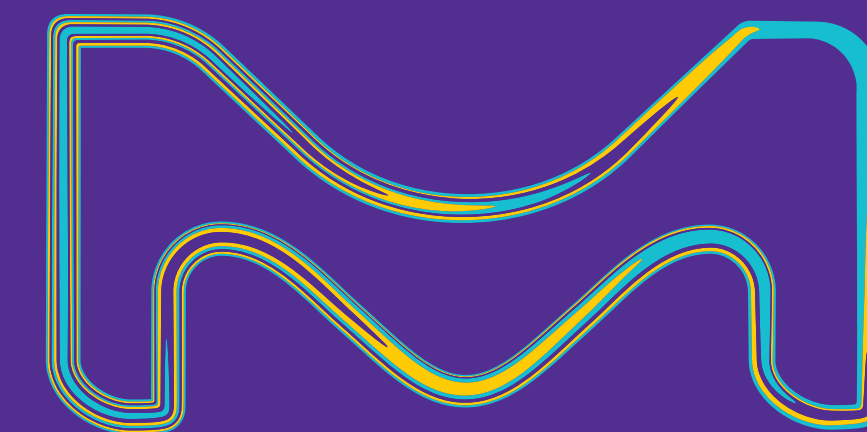


Stay in touch:

Subscribe to the Analytix Reporter journal 

Update your profile 





Back to start

© 2020 Merck KGaA, Darmstadt, Germany and/or its affiliates. All Rights Reserved. Merck and the vibrant M are trademarks of Merck KGaA, Darmstadt, Germany or its affiliates. All other trademarks are the property of their respective owners. Detailed information on trademarks is available via publicly accessible resources.

Lit. No. MK_FB5519EN Ver. 1.0 30724 11/2020