Millipore®

Expert Pharm/BioPharm
Products & CTDMO Services

Integritest® 5 Automatic Filter Test Instrument Services

A wide range of services to support every step of your journey

To help you navigate the highly regulated and complex biopharmaceutical industry, we offer a wide range of comprehensive services to meet your unique manufacturing requirements.

Our range of services can help you save time, lower costs, comply with regulation, and have peace of mind. All our services are performed by experienced personnel who have expertise and knowledge of our equipment.

Installation Services

- Installation Qualification/Operational Qualification (IQ/OQ)
- Performance Qualification Support (PQ)
- Network Qualification (NQ)
- Computerized System Qualification (CSQ)

Training

- Integritest® 5 operator training
- Filter integrity testing certification

Maintenance Services

- System service reliance plans
- Requalification
- Software update
- Spare parts

Benefits

- Ensure regulatory compliance
- Enable smooth and successful implementation and integration of system
- Receive direct access to replacement parts
- Ensure consistency and reliability with expert hands-on system training
- Offer optimal solutions for complex projects with tight deadlines

The Life Science business of Merck operates as MilliporeSigma in the U.S. and Canada.

Merck

Installation and Qualification

Our installation and qualification services help ensure your equipment is properly installed and functioning per your predefined requirements. All qualification tests are performed by our certified engineers and are based on 25 years of experience to ensure efficiency, safety, and consistency.

Installation Qualification/Operational Qualification (IQ/OQ)

Duration: 2 days per system

Description

Our IQ/OQ service ensures that the installation and operational qualification of your Integritest® 5 system is fully documented. During the IQ/OQ, the system will be tested to ensure that bubble point, diffusion and HydroCorr™ tests can be safely and accurately performed and reproduced.

Includes:

- IQ/OQ protocol
- Documentation verification
- Installation verification
- System configuration
- Calibration verification
- Filter integrity testing
- Error message check
- User access check
- Data management check
- Basic operator training (1 hour)

Filters (IQ/OQ)

A selection of our standard sterilizing-grade filters are used to complete the IQ/OQ testing:

- **Diffusion:** Durapore® 0.22 μm membrane hydrophilic 10" CVGL cartridge or KVGL capsule
- **Bubble point:** Durapore® 0.22 μm membrane hydrophilic 10" CVGL cartridge or KVGL capsule
- **HydroCorr™:** Aervent® 0.2 μm membrane hydrophilic 10" CTGR cartridge or KTGR capsule

Performance Qualification (PQ)

Duration: 0.3 day per filter application

Description

Our Performance Qualification service ensures that your Integritest® 5 system operates to your specific filter testing applications. The service includes one filter test application per service. Each application purchased will be triple-tested on site for accuracy and reproducibility and results will be documented.

Includes:

- PQ protocol writing and execution
- Filter test results

Network Qualification (NQ)

Prerequisites assistance from local IT administrator and configure network is needed

Duration: 1 day per system

Description

The Network Qualification service will document that the Integritest® 5 system functions properly when configured with network applications that are requested on site.

Includes:

- NQ protocol writing and execution
- System configuration and options
- Test report transfer
- Backup and Restore
- External printer set up
- Configuration management (settings, users and tests)

Site Acceptance Test (SAT)

Duration: 0.5 day per system

Description

Our SAT tests demonstrate that the system was not impacted by the transportation and installation of the system on site. We verify that the system has been correctly installed, configured and is performing as expected.

Includes:

- SAT protocol writing and execution
- Documentation verification
- Installation verification
- System configuration
- Calibration verification
- Final filter release test

Software Qualification Services

Computerized System Qualification (CSQ)

Duration: 2 days per system

Description

Our CSQ service ensures that software runs as intended and is reliable, accurate, and secure. Our experts will perform the industry-standard tests to support your CSQ requirements.

Includes:

- System software version identification
- Windows os configuration identification
- Electronic signature verification
- Electronically signed records
- Audit trail verification
- Back-up and recovery verification
- Reports verification/prints
- User management
- Privilege configuration
- Password policies

Integritest® 5: Installation and qualification services overview

	Installation Qualification (IQ/OQ)	Performance Qualification (PQ)*	Network Qualification (NQ)	Computerized System Qualification (CSQ)
Duration per system	2 days	0.3 day	1 day	2 days
Protocol ready to approve	X	X	X	X
Documentation verification	X			
Installation verification	X	X		
Operating conditions	X			
Unit settings	X			
Pressure sensor verification	X	X		
Diffusion test**	3 tests			
Bubble point test**	3 tests			
HydroCorr™ test**	3 tests			
Filter test from process range*		3 tests***		
Alarm management	X			
User management	X			
Data management	X			
Basic operator training (1 hour) ****	X			
IT review and configuration			X	
Network communication			X	
System configuration and options			X	
Test report transfer			X	
Backup and Restore			X	
External printer set up			X	
Domain or Cluster mode			X	
System identification				X
Security controls				X
Audit trail				X
Electronic record and signatures				X
Print out contents				X
Backup and Restore				X
File export & backup	X	X	X	

* Per filter application

** With Durapore® 0.22 µm hydrophilic 10" filter (Diffusion and Bubble Point) and Aervent® 0.2 µm hydrophobic 10" filter (HydroCorr™)

*** Per filter

**** No certificate

Training

Operator Training on Filter Integrity Tester

Description

Training is recommended after new equipment installation at customer site (IQOQ), to certify operator for the operations of the new equipment.

Includes:

- ½ day course, for 5 attendees
- Overview of Integritest® 5 instrument
- Installation and setup
- Operating the instrument
- Troubleshooting
- Service and maintenance
- Practical Session: Install equipment, perform filter test, review and sign test report

Filter Integrity Testing Certification

Description

Our training is designed for operators and engineers who are responsible for automatic integrity testing of sterilizing filters in the pharmaceutical and biopharmaceutical industries. Using a combination of theory and hands-on instruction, users will learn the key procedures of filter integrity testing, how to read printouts from automatic filter integrity testers and troubleshoot filter-integrity test processes. All current filter integrity tests that apply to all liquid and gas membrane filtration applications, including bubble point, diffusive flow and water intrusion, will be covered.

2 days course:

Standard course duration including hands-on applications and Certification of Achievement.

Includes:

- Introduction to sterilizing filtration
- Bubble point and diffusion theory and manual test methods
- Practical session - diffusion and bubble point
- Automatic integrity testing method
- Practical session - automatic integrity testing
- Hydrophobic filter integrity testing method
- Practical session - hydrophobic filter integrity testing
- Certification test
- Establishing and troubleshooting filter integrity testing processes

1 day course:

Shortened course without practical sessions (only a demo part), Certification of Attendance only.

Includes:

- Introduction to sterilizing filtration
- Bubble point and diffusion theory and manual test methods
- Automatic integrity testing method
- Hydrophobic filter integrity testing method
- Establishing and troubleshooting filter integrity testing processes

Support, Maintenance and Requalification Services

Our support services provide everything you need to keep your equipment running smoothly and efficiently. These services cover critical and cGMP required areas such as maintenance, re-qualification, software update and repair.

System Service Reliance Plans

To support you in ensuring optimum equipment uptime and regulatory compliance while mitigating risks, we have developed System Service Reliance Plans, a complete range of services for your equipment. These comprehensive service and support packages allow you to select the coverage level that best fits your needs.

- **Essential Reliance Plan:** includes a selection of preventive maintenance and troubleshooting services

- **Advanced Reliance Plan:** provides higher coverage, with faster response time and priority access to remote and on-site support

- **Total Reliance Plan:** guarantees the highest level of protection for your equipment and our fastest reaction time

Requalification (ReQ)

Duration: 0.5 days per system

Description

While the maintenance or repair service verifies that your Integritest® 5 system is operational, our requalification service will demonstrate that the system has remained in the qualified state and is compliant with regulations. The requalification within defined time intervals will ensure that your system is qualified throughout its entire lifecycle.

Should be executed together with the yearly preventive maintenance visit covered by the System Service Reliance Plan, or after system repair.

Includes:

- ReQ protocol
- Diffusion test
- Bubble point test
- HydroCorr™ tests
- System check
- File management

Integritest® 5 Instrument Maintenance and Requalification Services Overview

	Service Reliance Plans (yearly preventive maintenance visit)	Software Update (SU)	Re-qualification (ReQ)	Workshop repair workshop labor and PM
Duration per system	0.5 day	0.5 day	0.5 day	Assessment is needed
Protocol ready to approve	X	X	X	X
Initial status & software records	X			X
Visual inspection	X			X
Date & time verification & setting	X			X
Leak test	X			X
Pressure sensor verification	X			X
Calibration & maintenance date set	X			X
Diffusion test			X	
Bubble point test			X	
Hydrocorr™ test			X	
System check as found		X		
Software update		X		
System check as left	X	X		X
Filter test release		X		
Spare parts	Purchased separately			Purchased separately
Repair labor				X
Travel	X			

For additional details, please refer to the System Service Reliance Plans Data Sheet (**DS7881EN**) available at **SigmaAldrich.com/services-plans.**

Installation Services	
Integritest® 5 – SAT execution including protocol in English and travel	**SSVSATIT5**
Integritest® 5 – IQOQ execution including protocol in English and travel	**SSVQUAIT5**
Integritest® 5 – Add-on to IQ/OQ: Filter PQ - qualify customer process filter	**SSVQFIIT5**
Integritest® 5 – Add-on to IQOQ: Qualify network applications (Standalone, Master or Slave mode)	**SSVQNEIT5**
Integritest® 5 – Add-on to IQOQ: Computerized system qualification	**SSVCSVIT5**
Training	
Integritest® 5 – Operator training on filter integrity tester (1/2 day)	**PTROPEIT5**
Integritest® 5 – Certification to automatic filter integrity testing - 2 days at M Lab™ collaboration center	**TRAUOPCER**
Integritest® 5 – Certification to automatic filter integrity testing - 2 days at customer site	**TRCSAUOPCER**
Integritest® 5 – Certification to automatic filter integrity testing - 1 day at M Lab™ collaboration center	**TRINTEST**
Integritest® 5 – Certification to automatic filter integrity testing – 1 day at customer site	**TRCSINTEST**
Maintenance, support and requalification Services	
Integritest® 5 – Essential Reliance Plan	**SSVESPIT5**
Integritest® 5 – Advanced Reliance Plan	**SSVESPIT5 + SSVADCIT5**
Integritest® 5 – Total Reliance Plan	**SSVESPIT5 + SSVTOCIT5**
Integritest® 5 – Preventive Maintenance – additional to service plan	**SSVPRMIT5**
Integritest® 5 – Add-on to Preventive Maintenance: Software update	**SSVSWUIT**
Integritest® 5 – Add-on to Preventive Maintenance or repair: Re-qualification execution	**SSVRQUIT5**
Repair and spare parts	
Please refer to spare parts list available at **SigmaAldrich.com/integrity-testers**	

We have built a unique collection of life science brands with unrivalled experience in supporting your scientific advancements.

Millipore. **Sigma-Aldrich.** **Supelco.** **Milli-Q.** **SAFC.** **BioReliance.**