

Milliflex® Quantum Rapid Detection System

An easy-to-use, non-destructive,
fluorescent staining-based system for
faster microbial detection

To monitor product quality effectively, it's critical to test for microbial contamination throughout the manufacturing process. However, traditional microbiological methods are slow and require several days to obtain test results. In order to keep pace with today's increasing production demands, you need to reduce the time to result. By doing so, your company will be able to address contamination events sooner, avoid line shutdowns, release product to the market faster, and reduce warehousing costs. The ability to obtain microbiology test results earlier also enables you to gain better control and understanding of your manufacturing process.

- Non-destructive method enables reliable identification using any ID technology
- Easy-to-use system with simple workflow requires minimal training
- Results comparable to compendial method, enabling faster validation so that you can benefit from rapid detection sooner
- Economical, robust system
- Compact hardware fits on any laboratory bench



We offer the solution you need with the Milliflex® Quantum system: a rapid fluorescent-based technology designed for fast quantitative detection of microorganisms over a broad range of filterable matrices. This easy-to-use and simple system uses industry-standard membrane filtration techniques to detect viable and culturable microorganisms down to 1 CFU per sample. Test results are also comparable to your current microbial test results, which facilitates validation of this rapid system in any laboratory. The non-destructiveness of this method also allows you to identify any microorganisms detected during the initial fluorescent count, using your current ID methodology.



Applications

- Raw material (media, buffers, pharmaceutical ingredients and water)
- In-process samples (bioburden prior to sterilization, CIP/SIP samples, cell culture/fermentation samples, media for fermentation, buffers for manufacturing, and intermediate process samples)
- Final product
- Environmental samples

Based on Proven Technologies

The Milliflex® Quantum system is based on two proven technologies: membrane filtration and fluorescent staining.

The Milliflex® Quantum method utilizes proven

Milliflex Oasis® membrane filtration devices for sample preparation, which ensures consistent, reliable results. Large sample volumes can be processed through the Milliflex Oasis® funnel. The unique design ensures all substances that could inhibit microbial growth are rinsed away. After filtration and incubation, reagent is applied to the membrane, staining any retained viable and culturable microorganisms with a fluorescent marker. The reaction requires active microbial metabolism for enzymatic cleavage of a non-fluorescent substrate. Once cleaved inside the cell, the substrate liberates free fluorochrome into the microorganism cytoplasm (see Figure 1).

As fluorochrome accumulates inside the cells, the signal is naturally amplified. The cells are then exposed to the excitation wavelength of the fluorescent dye in the Milliflex® Quantum reader so that they can be visually counted.

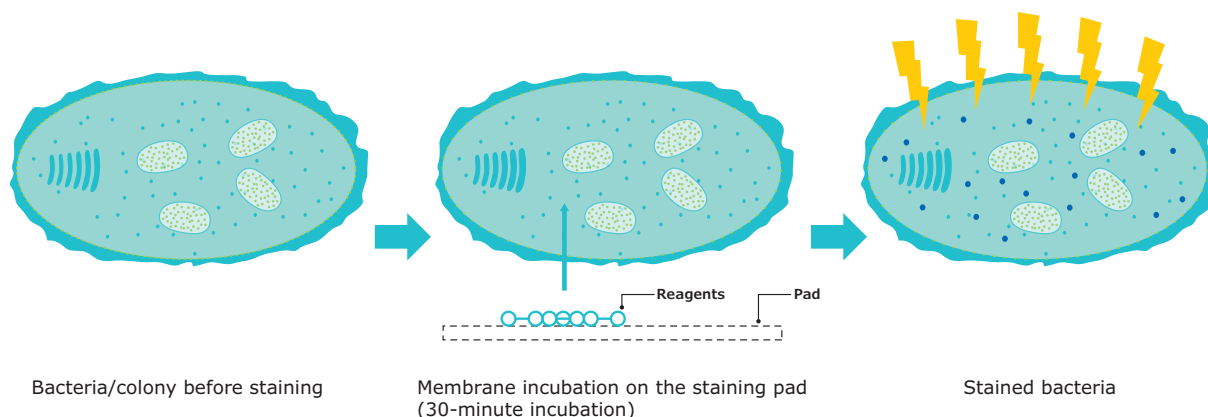


Figure 1. Principle of Fluorescent Staining

Detection with Optional Subsequent Identification

The non-destructive Milliflex® Quantum system not only delivers rapid test results, it also enables you to continue to grow the microorganisms in order to identify them using any standard ID technology. The majority of rapid test systems are destructive in nature and offer only limited capabilities for investigation and identification of microorganism in case of a contamination event. This can cause serious problems

during your investigation and add to the complexity of implementing an appropriate root cause analysis and corrective/preventive action (CAPA) plan.

With the Milliflex® Quantum system, your QC personnel can recover any microorganism detected after reincubation. Microorganisms can then be collected for further identification using existing ID methodologies (biochemical, morphological, nucleic acid analytics, etc.).

Results in 3 Easy Steps

The Milliflex® Quantum system consists of a reader, camera and fluorescent reagents used in combination with our Milliflex Oasis® pump, Milliflex Oasis® filtration devices and media plates. The Milliflex®

Quantum Universal kit is used for the detection of microorganisms in all sample matrices. The simple, 3-step, non-destructive method ensures consistent and accurate microbiological results, while reducing overall time to result. If contamination is detected, simply reincubate your membrane for later identification.

Rapid Bioburden Testing in 3 Easy Steps

1. Sample Preparation

Filter the desired sample volume Milliflex Oasis® presterilized, disposable Milliflex® filter units. Place membrane filter base onto a pre-filled agar cassette and incubate

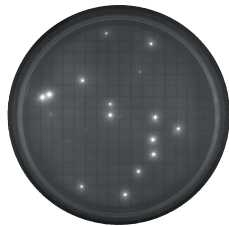
2. Fluorescent Staining

Transfer membrane to a pad pre-wetted with fluorescent reagent and incubate for 30 minutes.

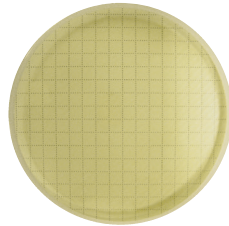
3. Counting CFUs

Count fluorescent colonies through the window of the Milliflex® Quantum reader or use the camera to view the colonies on your computer screen.

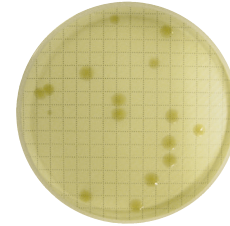
Reincubate for Microorganism Identification



Visualize plate after staining. View of membrane in the reader.



CFUs are not visible outside the reader.



After reincubation, CFUs are visible to the eye.

Reincubation Step

Place membrane on a pre-filled agar media cassette and reincubate. Collect and isolate the microorganisms and identify using any existing ID methodology.

Example: Tested sample of in-process, non-sterile water using the Milliflex® Quantum system. After detection, membrane was reincubated for full growth and identification.

Streamlined Validation

The validation process of an alternative method can be long and intensive, which makes changing from a traditional to rapid microbiological technology a common challenge for many companies. This is primarily due to the need to compare rapid and traditional microbiology test results — a process that can be quite complex. In addition, hardware complexity can also increase the difficulty of the validation process.

The Milliflex® Quantum system overcomes these challenges by offering a solution based on minimal change to the compendial tests. Sample preparation and incubation conditions remain identical to traditional microbiology. Results are still based on industry-standard membrane filtration and therefore comparable to your current test results.

The Milliflex® Quantum platform is simple and economical, enabling the user to focus resources on the validation method. We also offer a comprehensive range of services to support the implementation, including IQ, OQ, and PQ guidelines. If you're looking for peace of mind, the Milliflex® Quantum system is the ideal choice when adopting a rapid technology.

- Protocol based on current compendial test methods simplifies the comparison of rapid results with existing microbiological data.
- Simple hardware facilitates the validation process.
- Easy-to-use equipment reduces operator training time.

Feasibility Study with Your Sample

- Assessment of product compatibility with Milliflex® Quantum fluorescent technology
- Basic test method setup

On-Site System Evaluation

On-site system trials, including:

- Equipment installation
- Operator training
- Evaluation protocol definition
- Data analysis support

Method Development for Samples Requiring Customized SOPs

- Determine the most efficient filtration and rinsing procedure
- Determine optimal incubation time
- Recovery assessment with all test microorganisms
- Test method confirmation with additional microorganisms
- Complete report with optimized test method



Milliflex® Quantum On-Site Validation Services

Our scientists offer expert assistance with the implementation of our Validation Protocol within your laboratory. They can help you ensure that all test criteria lead to a completely qualified and accurate test method, including hardware, expendables and product-testing method (S.O.P.).

Our validation services include:

- On-site support for implementation of qualification tests
- Operator technical training
- Execution of the test methods
- Consultancy (validation strategy & PQ)
- On-site data analysis support and report generation
- Phone and email support during validation

Milliflex® Quantum Validation Protocol

We provide complete descriptions of all the activities necessary for proving the suitability of the test methodology. Validation Protocols consist of the following test methods:

- **Master Plan**
 - Define structure, and identify role responsibilities for qualification
 - SOP lists
- **Installation Qualification (IQ)**
 - Verification and identification of our product
 - Verification of product's utilities and operating environment requirements
 - Equipment and personnel preparation
- **Operational Qualification (OQ)**
 - Verification of product's functionality (hardware, software, devices)
- **Performance Qualification (PQ)**
 - Test method suitability verification (microbiology validation procedures)

Milliflex® Quantum Preventive Maintenance Contract

Proactive preventive maintenance and system verification are crucial for the efficient operation of critical testing equipment. We recommend checking the system on an annual basis to ensure that its performance remains compliant with the specifications. Our maintenance technicians comply with GMP/GLP procedures.

Our full-coverage initial contract protects your system from date of delivery. It includes system servicing, recalibration and delivery of a new certificate of conformity before the end of the warranty.



Specifications

Detection Area	Within the area of the 55 mm diameter Milliflex® membrane
System Limit of Detection (LOD)	1 colony-forming unit (CFU)/sample
Dimensions	
Milliflex® Quantum Reader	
Width	14.2 cm (5.6 in.)
Depth	24.9 cm (9.8 in.)
Height	12.5 cm (4.9 in.)
Weight	4.4 kg (9.7 lbs.)
Materials of Construction	
Milliflex® Quantum Reader	
Housing	Aluminum sheet 1050, polyester
Optical chamber	304L stainless steel
Handle	304L stainless steel
Optical filter	OG550 glass filter
LED protector	Transparent polycarbonate
Foot	Polyvinyl chloride (PVC)
Milliflex® Quantum Reader Stand	304L stainless steel
Camera	
Front plate	304L stainless steel
Housing	Aluminum with epoxy coating
Window	Glass
Membrane transfer tool & removal rack	
Housing	304L stainless steel
Body and lever	1.4462 stainless steel
Seal	Silicone
Removal Rack	Polyphenylsulfone (PPSU)
Power Supply	
Milliflex® Quantum Reader	
Input	100 – 200 VAC, 50 – 60 Hz
Output	24 VAC, Direct Current
Milliflex® Quantum Camera	
Input	Powered by the computer used
Output	Powered by the computer used
Operating Requirements	
Milliflex® Quantum Reader (with or without camera)	
Ambient temperature	15 – 40°C (59°F to 104°F)
Relative humidity	< 90%
Altitude	< 3,000 m (9,842 ft.)
The Milliflex® Quantum reader and camera can be used under a laminar flow hood.	
Regulatory Compliance	
The Milliflex® Quantum reader is compliant with Electromagnetic Compatibility Directive 89/336/EEC and is CE-marked.	

Ordering Information

Cat. No.	Description	Qty./Pk
Milliflex® Quantum System Kits		
MMQUANK01	Milliflex® Quantum standard kit includes 1 reader, 1 reader stand, 1 membrane transfer tool, 1 removal rack, 1 camera and installation files on USB key	1
Milliflex® Quantum Hardware and Accessories		
MXQREAD01	Milliflex® Quantum reader	1
MXQSUP001	Milliflex® Quantum reader stand	1
MMHEADQU1	Milliflex® Quantum membrane transfer tool for Milliflex Oasis® system	1
MXQCAM001	Milliflex® Quantum camera	1
MXQADAP05	Milliflex® Quantum adapters	5
REMRACKMM	Removal rack	1
Milliflex® Quantum Consumables Kits		
Universal kits		
MMQTV0KT1	48 Milliflex Oasis® HA 100 mL funnel units (0.45 µm cellulose esters membrane), fluorescent reagents	48 tests
MMQTV0KT2	48 Milliflex Oasis® HA 250 mL funnel units (0.45 µm cellulose esters membrane), fluorescent reagents	48 tests
MMQTV0KT3	48 Milliflex Oasis® GS 100 mL funnel units (0.22 µm cellulose esters membrane), fluorescent reagents	48 tests
MMQTV0KT4	48 Milliflex Oasis® 100 mL funnel units (0.45µm black cellulose ester membrane), fluorescent reagents	48 tests
MXLMC0120	Milliflex® liquid cassettes	120
Milliflex® Quantum Services		
QSMDEV01	Feasibility Study	
MXQUA4VP2	Validation Protocol (A4)	
MXQULTVP2	Validation Protocol (Letter)	
QSPMQUA00	Initial Maintenance Contract (services performed at Merck)*	
QSPMQUA01	Standard Maintenance Contract (services performed at Merck)*	
QSPMQUA02	Premium Maintenance Contract (services performed at Merck)*	
RENTALQUA	Milliflex® Quantum System Rental (1 month)	
Milliflex Oasis® filtration pump		
MMSYSTEMM1	Milliflex Oasis® filtration pump, one system with two filtration heads and no power supply	1
MMPWRSPAU	Milliflex Oasis® power supply for one two three filtration power pumps - Australia	1
MMPWRSPBR	Milliflex Oasis® power supply for one two three filtration power pumps - Brazil	1
MMPWRSPCN	Milliflex Oasis® power supply for one two three filtration power pumps - China	1
MMPWRSPDK	Milliflex Oasis® power supply for one two three filtration power pumps - Denmark	1
MMPWRSP EU	Milliflex Oasis® power supply for one two three filtration power pumps - Europe	1
MMPWRSPIN	Milliflex Oasis® power supply for one two three filtration power pumps - India	1
MMPWRSPJP	Milliflex Oasis® power supply for one two three filtration power pumps - Japan	1
MMPWRSPSZ	Milliflex Oasis® power supply for one two three filtration power pumps - Switzerland	1
MMPWRSPUK	Milliflex Oasis® power supply for one two three filtration power pumps - United Kingdom	1
MMPWRSPUS	Milliflex Oasis® power supply for one two three filtration power pumps - United States	1
MMPWRSPZA	Milliflex Oasis® power supply for one two three filtration power pumps - South Africa	1
MMHEADMM1	Milliflex Oasis® filtration head	1
Milliflex Oasis® filtration head**		
MMGASKTSK	Milliflex Oasis® internal flow sanitization gasket kit	5
MMSANSYFU	Milliflex Oasis® consumables for internal flow sanitization kit	24

*Contact us for installation, training and additional maintenance contract levels

**Note: refer to the Milliflex Oasis® datasheet for a complete list of accessories

To place an order or receive technical assistance

Order/Customer Service: SigmaAldrich.com/order

Technical Service: SigmaAldrich.com/techservice

Safety-related Information: SigmaAldrich.com/safetycenter

SigmaAldrich.com/Quantum

Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt, Germany

