

## Milliflex® Quantum – Rapid Detection System

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

- 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

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.



MilliporeSigma offers 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

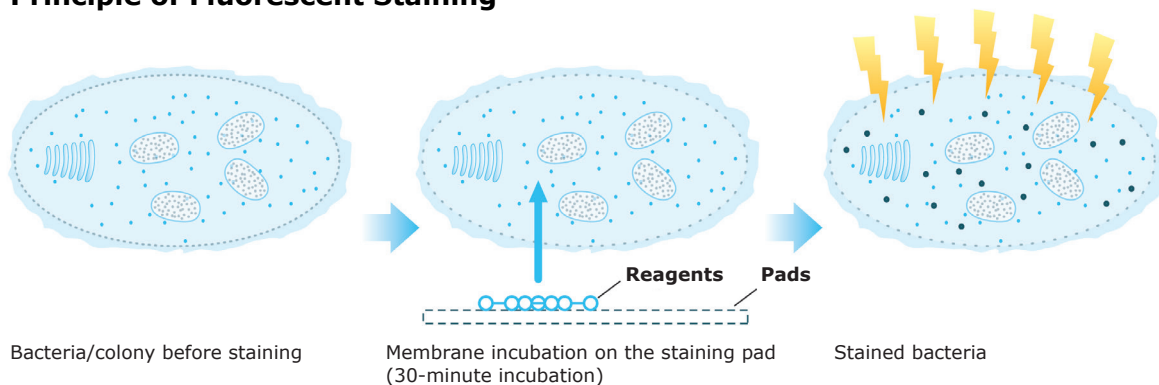
The Milliflex® Quantum system is based on two proven technologies: membrane filtration and fluorescent staining.

The Milliflex® Quantum method utilizes proven Milliflex® membrane filtration devices for sample preparation, which ensures consistent, reliable results. Large sample volumes can be processed through the Milliflex® 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.

## Principle of Fluorescent Staining



**Figure 1.**

## 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.).

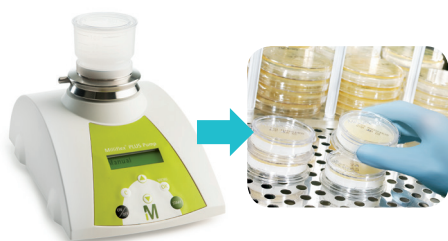
## Results in 3 Easy Steps

The Milliflex® Quantum system consists of a reader, camera and fluorescent reagents used in combination with our Milliflex® PLUS pump, Milliflex® filtration devices and media cassettes. 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 through presterilized, disposable Milliflex® filter units. Place membrane filter base onto a prefilled agar cassette and incubate.



Filtration

Incubation

### 2. Fluorescent Staining

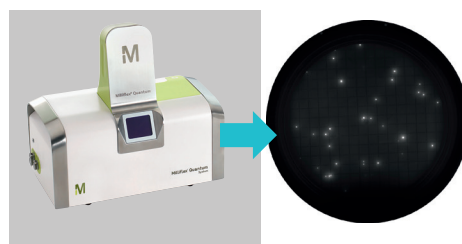
Transfer membrane to a pad pre-wetted with fluorescent reagent and incubate for 30 minutes.



Staining

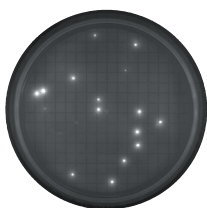
### 3. Counting CFUs

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

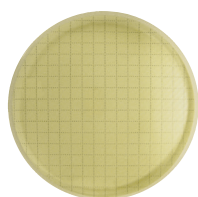


Counting

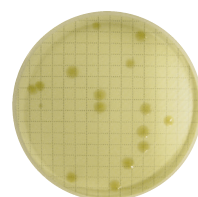
## Reincubate for Microorganism Identification



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 prefilled 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.

## Comprehensive Support and Services

Save your QC resources for other critical projects. Our highly experienced applications professionals will help you streamline your method implementation and validation work. We can determine the proper testing conditions and develop methods specific to your product, provide test protocols, data, reports and recommendations. Our experts are available to assist you with your complete testing needs.

## 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

The Milliflex® Quantum platform is simple and economical, enabling the user to focus resources on the validation method. MilliporeSigma also offers 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.



## 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 the MilliporeSigma 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

|                                                                                                                      |                                                           |
|----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|
| <b>Detection Area</b>                                                                                                | Within the area of the 55 mm diameter Milliflex® membrane |
| <b>System Limit of Detection (LOD)</b>                                                                               | 1 colony-forming unit (CFU)/sample                        |
| <b>Dimensions</b>                                                                                                    |                                                           |
| <b>Milliflex® Quantum Reader</b>                                                                                     |                                                           |
| 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.)                                         |
| <b>Materials of Construction</b>                                                                                     |                                                           |
| <b>Milliflex® Quantum Reader</b>                                                                                     |                                                           |
| 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                                      |
| <b>Camera</b>                                                                                                        |                                                           |
| Front plate                                                                                                          | 304L stainless steel                                      |
| Housing                                                                                                              | Aluminum with epoxy coating                               |
| Window                                                                                                               | Glass                                                     |
| <b>Membrane Transfer Tool</b>                                                                                        |                                                           |
| Housing (black parts)                                                                                                | Polyoxymethylene (POM)                                    |
| Body and lever                                                                                                       | 1.4462 stainless steel                                    |
| Seal                                                                                                                 | Silicone                                                  |
| Removal Rack                                                                                                         | Polyphenylsulfone (PPSU)                                  |
| <b>Power Supply</b>                                                                                                  |                                                           |
| <b>Milliflex® Quantum Reader</b>                                                                                     |                                                           |
| Input                                                                                                                | 100 – 200 VAC, 50 – 60 Hz                                 |
| Output                                                                                                               | 24 VAC, Direct Current                                    |
| <b>Milliflex® Quantum Camera</b>                                                                                     |                                                           |
| Input                                                                                                                | Powered by the computer used                              |
| Output                                                                                                               | Powered by the computer used                              |
| <b>Operating Requirements</b>                                                                                        |                                                           |
| <b>Milliflex® Quantum Reader (with or without camera)</b>                                                            |                                                           |
| 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.                                      |                                                           |
| <b>Regulatory Compliance</b>                                                                                         |                                                           |
| The Milliflex® Quantum reader is compliant with Electromagnetic Compatibility Directive 89/336/EEC and is CE-marked. |                                                           |

## Ordering Information

| Description                                                                                                                               | Qty./Pk  | Cat. No.                          |
|-------------------------------------------------------------------------------------------------------------------------------------------|----------|-----------------------------------|
| <b>Milliflex® Quantum System Kits</b>                                                                                                     |          |                                   |
| Milliflex® Quantum standard kit includes 1 reader, 1 reader stand, 1 membrane transfer tool, 1 removal rack, 1 camera and installation CD | 1        | <b>MXQUANK01</b>                  |
| <b>Milliflex® Quantum Hardware and Accessories</b>                                                                                        |          |                                   |
| Milliflex® Quantum reader                                                                                                                 | 1        | <b>MXQREAD01</b>                  |
| Milliflex® Quantum reader stand                                                                                                           | 1        | <b>MXQSUP001</b>                  |
| Milliflex® Quantum membrane transfer tool                                                                                                 | 1        | <b>MXQTRT001</b>                  |
| Milliflex® Quantum camera                                                                                                                 | 1        | <b>MXQCAM001</b>                  |
| Milliflex® Quantum adapters                                                                                                               | 5        | <b>MXQADAP05</b>                  |
| Removal rack                                                                                                                              | 1        | <b>REMRACK01</b>                  |
| <b>Milliflex® Quantum Consumables Kits</b>                                                                                                |          |                                   |
| <b>Universal kits</b>                                                                                                                     |          |                                   |
| 48 Milliflex® HA 100 mL funnel units (0.45 µm cellulose esters membrane), fluorescent reagents                                            | 48 tests | <b>MXQTV0KT1</b>                  |
| 48 Milliflex® HA 250 mL funnel units (0.45 µm cellulose esters membrane), fluorescent reagents                                            | 48 tests | <b>MXQTV0KT2</b>                  |
| 48 Milliflex® GS 100 mL funnel units (0.22 µm cellulose esters membrane), fluorescent reagents                                            | 48 tests | <b>MXQTV0KT3</b>                  |
| Milliflex® Quantum funnel labels                                                                                                          | 1,000    | <b>MXQLAB001</b>                  |
| Milliflex® liquid cassettes                                                                                                               | 120      | <b>MXLMC0120</b>                  |
| <b>Milliflex® Quantum</b>                                                                                                                 |          |                                   |
| Feasibility Study                                                                                                                         |          | <b>QSMDEV01</b>                   |
| Method Development                                                                                                                        |          | <b>Contact<br/>MilliporeSigma</b> |
| Installation and Training                                                                                                                 |          | <b>QSINSTL11</b>                  |
| Validation Protocol (A4)                                                                                                                  |          | <b>MXQUA4VP1</b>                  |
| Validation Protocol (Letter)                                                                                                              |          | <b>MXQULTVP1</b>                  |
| On-Site Validation Services                                                                                                               |          | <b>Contact<br/>MilliporeSigma</b> |
| Initial Maintenance Contract (services performed at MilliporeSigma)*                                                                      |          | <b>QSPMQUA00</b>                  |
| Standard Maintenance Contract (services performed at MilliporeSigma)*                                                                     |          | <b>QSPMQUA01</b>                  |
| Premium Maintenance Contract (services performed at MilliporeSigma)*                                                                      |          | <b>QSPMQUA02</b>                  |
| Milliflex® Quantum System Rental (1 month)                                                                                                |          | <b>RENTALQUA</b>                  |
| <b>Milliflex® PLUS Pumps</b>                                                                                                              |          |                                   |
| Milliflex® PLUS pump, single head kit                                                                                                     | 1        | <b>MXPP LUS 01</b>                |
| Milliflex® PLUS pump, double head kit                                                                                                     | 1        | <b>MXPP LUS 02</b>                |
| Milliflex® PLUS pump, triple head kit                                                                                                     | 1        | <b>MXPP LUS 03</b>                |
| <b>Milliflex® PLUS Pump Accessories</b>                                                                                                   |          |                                   |
| Additional Milliflex® head                                                                                                                | 1        | <b>MXPH EAD 01</b>                |
| Milliflex® PLUS pump                                                                                                                      | 1        | <b>MXPP UMP 01</b>                |
| Milliflex® PLUS printer                                                                                                                   | 1        | <b>MXPR INT 01</b>                |
| Manifold tray for 2 pumps                                                                                                                 | 1        | <b>MXPP TRY 02</b>                |
| Manifold tray for 3 pumps                                                                                                                 | 1        | <b>MXPP TRY 03</b>                |

\* Contact MilliporeSigma for information about additional maintenance contract levels.

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