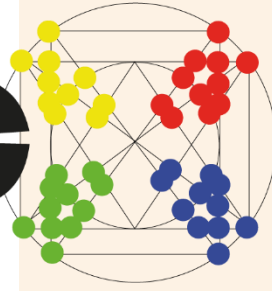


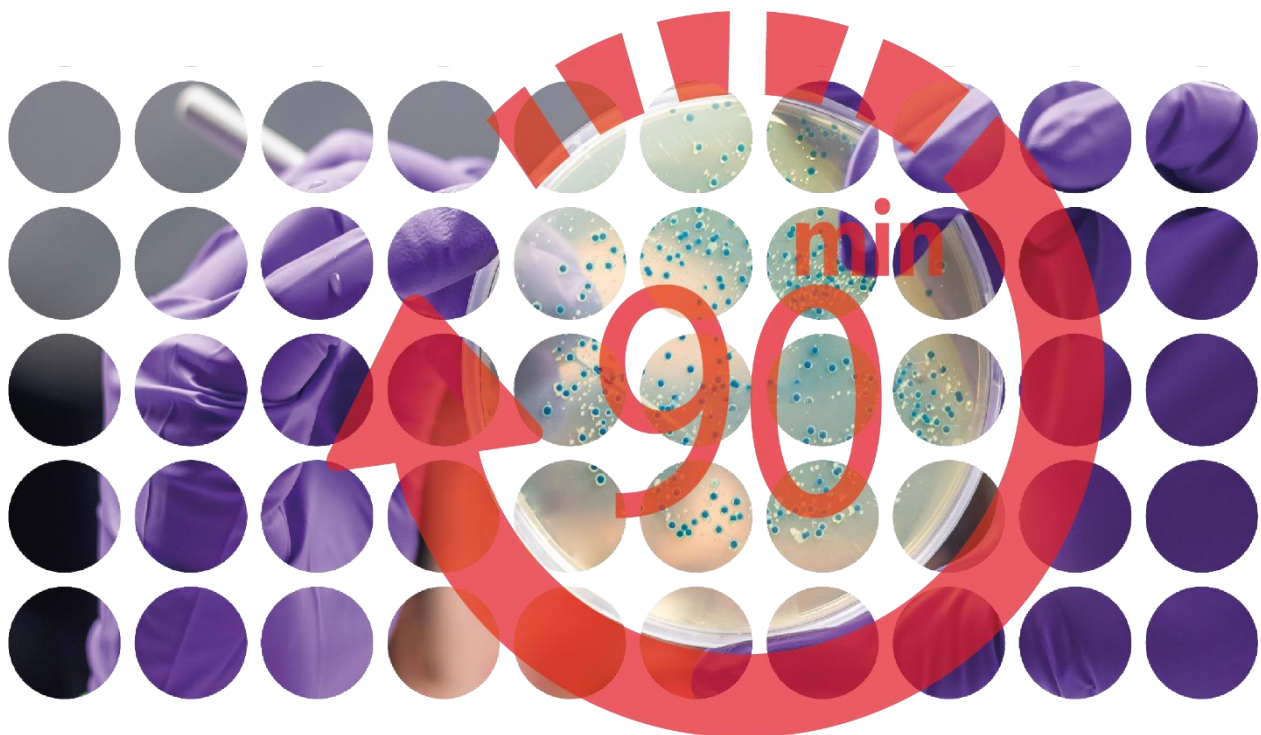
# mibio



## GramRay MK3 | Detect & ID In One Run



# Ultra-Rapid Results



## Microbiology at the Speed of Light

**Stop waiting for results to ensure safety.** The **GramRay MK3** revolutionizes microbiological quality control. Instead of waiting days for traditional incubation, you get sterility verification and precise microbial identification within minutes to hours. For your facility, this means Same Day Release, eliminating costly quarantine periods, and having absolute confidence in your product's quality.

## Precision Meets AI

**Complex analysis at the push of a button.** Our system harnesses the power of Raman spectroscopy combined with our intelligent DeepMorph AI. The AI automatically and accurately scans your sample to pinpoint potentially viable cells before the spectroscopic analysis even begins. This allows you to determine not only the exact taxonomic classification (bacteria,

yeasts, fungi) down to the single-cell level, but also their vitality status (LIVE / VBNC / DEAD) — rapidly, reliably, and fully cGMP-compliant.

**Environmental, IPC, Water, Bioburden Monitoring with unprecedented time2result:**

- 10 min Root Cause
- 90 min Release & Bioburden
- 90 min AMR testing
- 8 Samples one run

# Ultimate Flexibility

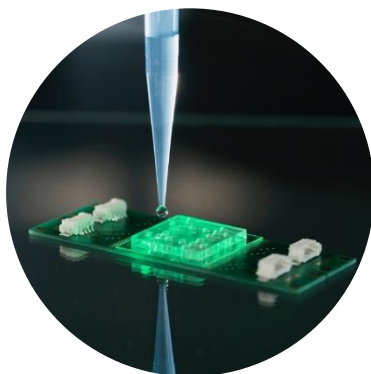
## Sample Preparation

Whether you need to detect single microbes or immediately identify isolates, the **GramRay MK3** easily adapts to your scope of analysis. Alongside proven methods like **Direct Filtration** (for the highest recovery rates) and **Direct Spotting** (for rapid isolate testing), the system now seamlessly integrates with cutting-edge approaches:

- **Microfluidics & Well Plates:** Perfect for automated, liquid-based, high-throughput analysis.
- **In-Situ & AMR Measurements:** Monitor microbial behavior and test Antimicrobial Resistance (AMR) in real time, directly within the culture.



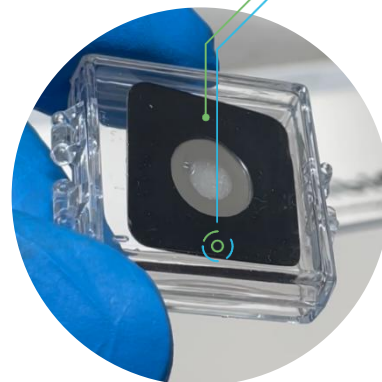
With volume from 0.1 to 500 mL, you can prepare a sample for analysis with a flow rate of 4-16 mL/minute. mibiC's reusable, easy-to-use, and easy-to-clean & autoclave filtration system ensures the highest recovery rates.



With the **GramRay MK3** filter membrane, you are guaranteed the highest quality and ease of use. The membranes have a 0.45  $\mu\text{m}$  pore size and are metal-coated. That makes them perfect for epifluorescence and background-free Raman signals.

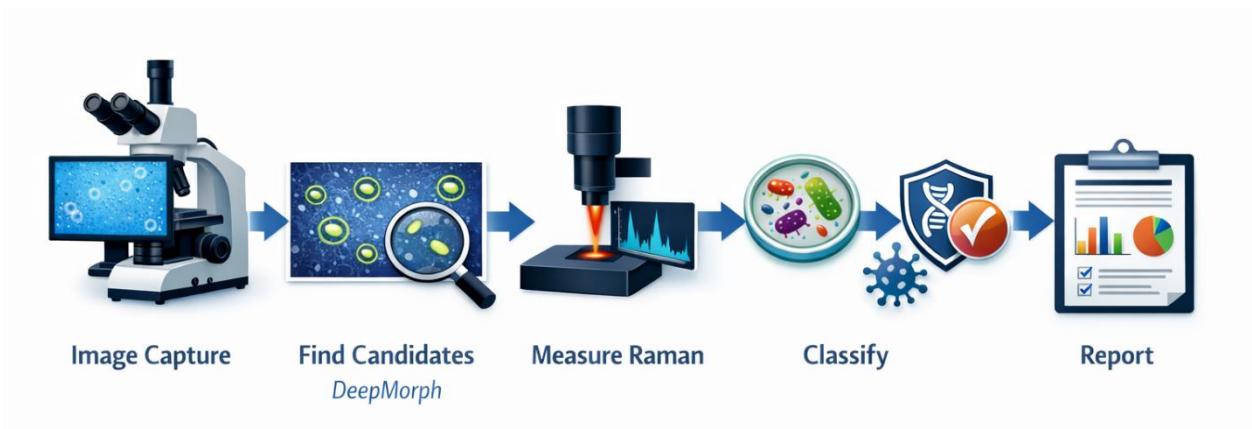
HIGHEST RECOVERY RATES AND LOWEST LOD

DIRECT FILTRATION



Apply a 10  $\mu\text{L}$  drop of your sample suspension (either taken directly from a colony or from an unfilterable matrix) onto the sample substrate. On a 40 °C plate, the droplet dries within just 5 minutes, creating the perfect sample for immediate isolate identification or database updates.

# Smart Software



## ID Microbes in Minutes

With **GramRay MK3**, you can quantify & ID viable microbial cells in as little as **90 minutes**, including phenotypic characterization and **species-level classification**.

## Leverage Single-Cell Insight

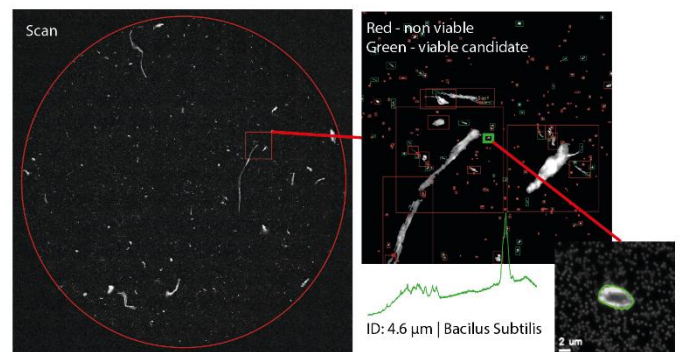
By combining **counting** and **detecting single cells**, GramRay MK3 delivers true phenotypic information at cellular resolution.

## Intuitive, Compliant Workflow

The user interface is designed for simplicity and reliability.

**CFR Part 11-compliant user management** and full **data integrity** are built in, generating **cGMP-compliant pass/fail results**.

## DeepMorph AI – Smarter Detection



mibiC's **DeepMorph AI** identifies potential viable cells before Raman analysis.

Trained on our proprietary dataset created from mibiC's own optical setups and filter membranes, it increases the likelihood of detecting viable microbes **by up to tenfold**.

## Open Microbiological Concept

Build and expand your own **machine-learning microbial library** — unique to your product and facility.

With **RamanMetrix™**, any microbial species can be trained using only **300 single-cell spectra in about two hours**.

Differentiate between lab isolates and biofilm-derived product isolates in just **10 seconds per microbe**, supported by the **Biophotonics Diagnostics curated Raman Microbes Database**.

Accuracy: **0.93** Balanced accuracy: **0.917** Cohen's kappa: **0.923**

Confusion table for training data



True \ Predicted	[1]	[2]	[3]	[4]	[5]	[6]	[7]	[8]	[9]	[10]	[11]	[12]	[13]	[14]	[15]	[16]	sens	spec
Alicyclobacillus Aciditerrestris	[1] 62	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0.954	0.996
Bacillus Coagulans	[2] 0	33	0	0	3	0	0	0	2	3	1	0	0	0	0	0	0.786	0.997
Bacillus Licheniformis	[3] 0	0	56	0	5	0	0	0	0	3	0	0	0	0	0	0	0.875	0.988
Bacillus Megaterium	[4] 0	0	2	43	1	1	0	1	2	4	0	0	0	0	0	0	0.796	1
Bacillus Subtilis	[5] 0	0	3	0	55	0	0	0	0	0	0	0	0	0	0	0	0.948	0.993
Candida Tropicalis	[6] 0	0	0	0	0	31	0	0	0	0	0	0	0	4	0	0	0.886	0.999
Hanseniaspora Valbyensis	[7] 4	0	0	0	0	0	163	0	0	0	1	0	0	0	1	8	0.921	0.998
Lactobacillus brevis	[8] 0	0	0	0	0	0	53	0	1	0	0	0	0	0	0	0	0.981	0.999
Lactobacillus Fermentum	[9] 0	0	0	0	0	0	1	0	20	0	0	0	0	0	0	0	0.952	0.989
Lactobacillus Plantarum	[10] 0	0	0	0	0	0	0	1	2	77	0	0	0	0	0	1	0.951	0.988
Paenibacillus Polymyxa	[11] 0	0	7	0	0	0	0	8	0	234	0	0	0	0	0	0	0.94	0.998
Pediococcus Acidilactici	[12] 0	4	1	0	0	0	0	1	5	0	125	0	0	0	0	0	0.919	0.999
Pediococcus Pentosaceus	[13] 0	0	0	0	0	0	0	1	0	0	1	37	0	0	0	0	0.949	1
Saccharomyces Cerevisiae	[14] 0	0	0	0	0	0	0	0	0	0	0	0	0	191	0	0	1	0.997
Zygosaccharomyces Parabailii	[15] 0	0	0	0	0	0	2	0	0	0	0	0	0	0	42	3	0.894	0.993
Zygosaccharomyces Rouxii	[16] 1	0	0	0	0	0	0	0	0	0	0	0	0	0	8	105	0.921	0.991

# Versions

## The GramRay MK3 Portfolio: Tailored to Your Lab

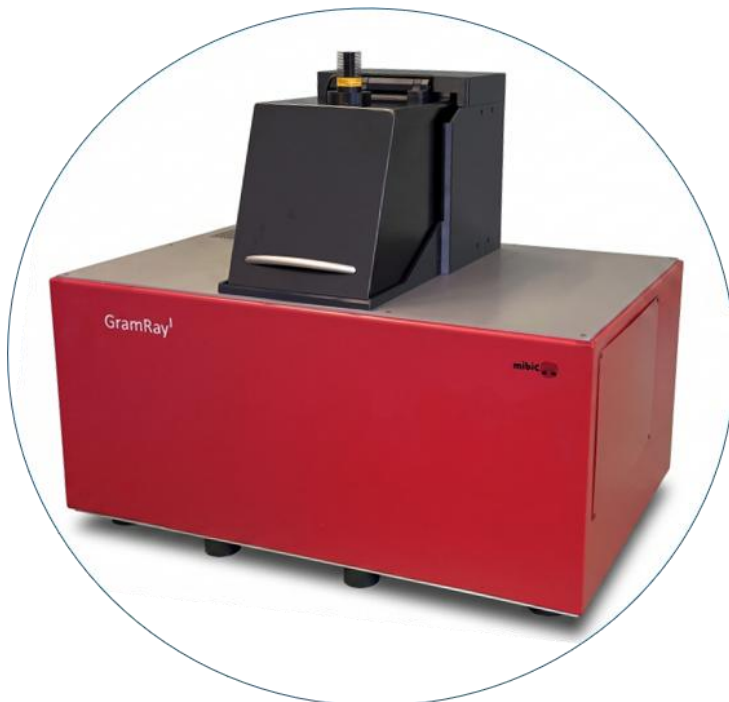
**Hardware designed with your applications in mind.** To perfectly support your specific requirements, we offer two distinct system configurations:

- **The Inverted Model:** Compact, robust, and ideal for routine operations. With its bottom-up optical path, it is the perfect choice for working with *well plates* and *microfluidic chips*, allowing samples to be analyzed directly in their medium without interference.
- **The Upright Model:** The versatile all-rounder, featuring an ultrafast laser-based autofocus system designed for a wide variety of filter membranes and solid sample types.



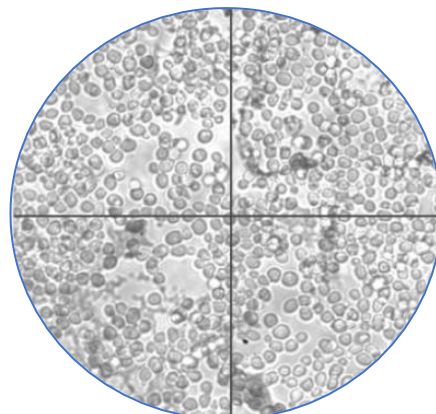
### GramRay<sup>u</sup> MK3 Upright

magnifications. Its versatile design accommodates a wide range of sample types, from a variety of filters to DEP-chips, ensuring flexibility for diverse applications.



### GramRay<sup>i</sup> MK3 Inverted

The inverted model is compact and robust, ideal for routine applications or in-situ measurements. It is also the platform used for ultra-fast AMR testing.



# Specifications

## cGMP Control & push button operation

- Simple measurements recipe creation
- CE marked & 21 CFR Part 11 compliant | User hierarchy-levels, audit trail, data integrity

## Identification and artificial intelligence - RAMANMETRIX™

- Software package for easy training of new microorganisms' species for ID
- Integrated automated spectra comparison and result
- Curated microbe database available

## Microbial counting

- Measuring interval for image recognition of individual microbes: 0.5  $\mu\text{m}$  - 50  $\mu\text{m}$
- Identification for Gram +/- bacteria, yeasts, fungi
- Image Analysis for Dark-Field Illumination / Fluorescence
- Morphology and/or **DeepMorph-AI** multi-modal directed Raman spectroscopy

## Spectroscopy

- Raman engine ( $\leq 25$  mW @ 532 nm or  $\leq 55$  mW 633 nm optimized for single cell identification)
- Faster and Superfast Raman engine options available reduce ID time 2-3 fold
- ID time per microbe: 1-20 s
- Laser power - selectable from 5% to 100%
- Spectral Resolution – 4-12  $\text{cm}^{-1}$
- Wavelength range 100-4.000  $\text{cm}^{-1}$
- Laser safety - Class 1
- Lens - 100x, 0.9 NA, 1.0 mm WD.
- ID & verify up to 400 microbes/hour

## Documentation and results

- Original and binarized image data, Raman spectrum, database match
- Number of viable and non-viable microbes

## Image analysis and sample unit

- 2 MP camera scanning and targeting
- Closed-loop motorized x,y,z stage with a restart accuracy of < 100 nm
- Illumination - dark field, fluorescence, and transmitted
- Magnification - 100x | 1000x

## Calibration and self-tests

- Autocalibration before each run
- Automatic self-tests for optical and analytical stability
- Includes positive & negative controls for verification

## Environmental parameters

- Mains voltage + power - 110-230 V, 500 W
- Temperature range 17-25  $^{\circ}\text{C}$ ,
- Humidity range 10-75 % non-condensing

## Space Requirements

- [I] Dimension - 55x60x35 cm , 52 kg
- [U] Dimension - 80x60x80 cm, 75 kg
- Vibration Isolation recommended

## System Components

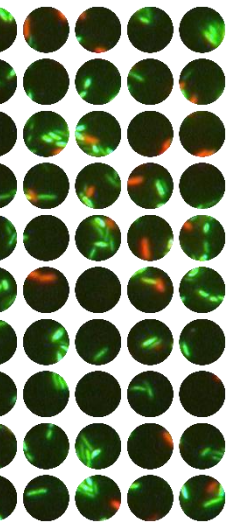
- Spectrometer & **GramRay MK3**
- PC with **GramRay MK3** Software
- Illumination from 405 to 750 nm flexible, see Illumination<sup>+</sup>

# GramRay MK3 Illumination<sup>+</sup>



## Applications

- **Autofluorescence Unit Identification**  
– Identify Bio-Fluorescent Particle Counters data by means of automated Raman spectroscopy. Illuminate with 365 nm UV light and classify detected particles as biofluorescent particles (BFP; i.e., biologic) or inert (i.e., nonbiologic).
- **Detect microbes in challenging matrices** – evade auto-fluorescing background with near IR illumination at 785 nm.
- **Live/dead staining for Stable Isotope Raman, SIRA studies** - Use multiple fluorescing dyes.



## Benefits

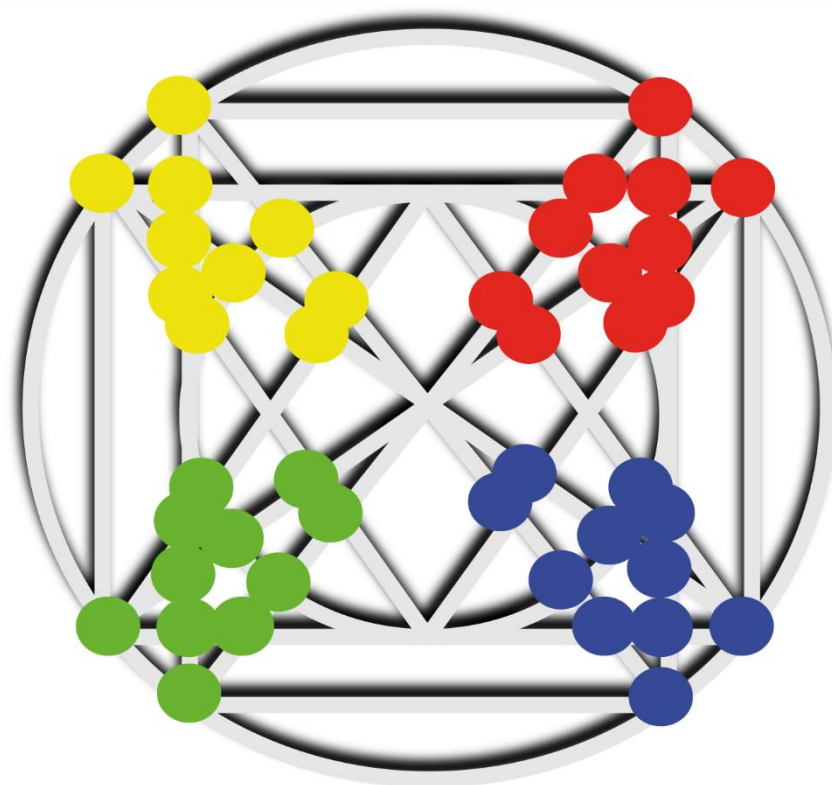
- Use DeepMorph with multiple modalities e.g. **autofluorescence-guided** Raman spectroscopy to streamline classification
- **Enhance GramRay MK3's** Limit of Detection, **LOD**, and avoid matrix Interferences
- **Ultra-Flexible selection of fluorescence** excitation for multiple studies
- **Maximizes selectivity** for time-saving Raman viability and Identification.
- **Push-button operated** and fully integrated and automated to **generate cGMP-compliant results**
- Much higher intensity light source than standard results in **faster scanning time**

## Features

- **Multiwavelength labelling with multiple chromophores**
- 6 different light sources
- **Single-Band Filter Sets** Ultraviolet 350/380 nm | Violet (380-410 nm) | Blue (420-450 nm) | Cyan (460-490 nm) | Teal (500-520 nm) | Green (525-570 nm) | Yellow (570-600 nm) | Red (620-660 nm) | nIR (710-750 nm)
- Detection of Fluorophores commonly used for fluorescence in situ, **FISH hybridization enabled**
- Broadest spectral coverage, including near infrared (nIR)
- Excitation of DAPI, GFP/FITC, YFP, Cy3, mCherry, Cy5, and spectrally similar fluorophores as Cy7 and ICG, and for other applications that benefit from the enhanced tissue penetration of nIR light.
- **Mercury-free**

## Technology

- Fully integrated into **GramRay MK3's** software
- Liquid Light guide connected
- Solid state **365 nm Ultraviolet** source
- Solid state **735 nm Near-IR** source



## **microbiology @ the speed of light**

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+49 (0) 30 53041750 ||| || **microbiology @ the speed of light** || | mibi-c.com |||||  
same day release || single microbe viability detection & ID || yeast | bacteria | fungi | VBNC