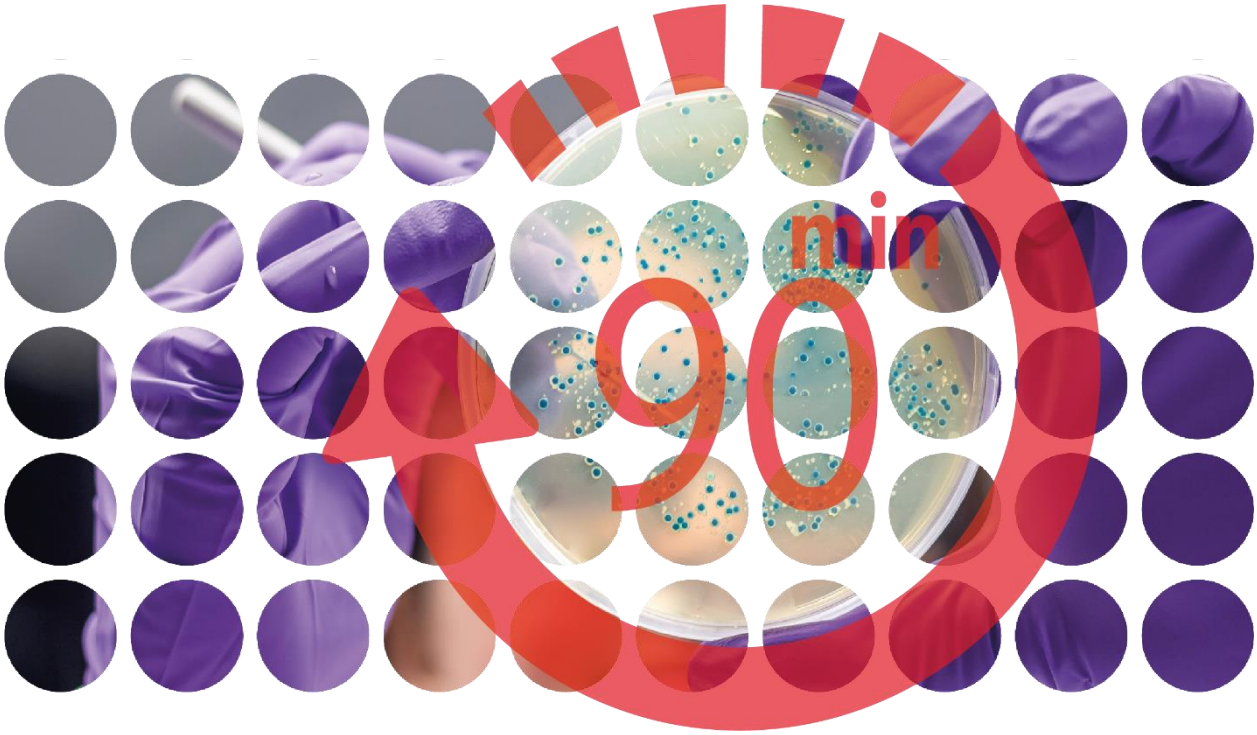
mibiC

GRAM^{RAY} Ensuring Microbiological Quality

microbiology @ the *speed* of light

Ultra-Rapid Control



Detect & ID within minutes

instead of days. No need to quarantine product prior to release. Save time and storage costs. Accurate determination of microorganisms assures the long-term security that you need to guarantee the safest, highest quality product always.

Same Day Release

becomes possible at last with detection and ID in one step and with one unit. **GRAM^{RAY}** has been designed to provide fast, cost-effective and reliable information on all microorganisms Use **GRAM^{RAY}** as a first responder warning system. Get from any sample the number and species of all living microbes before problems can arise. Make your release decisions within the same day instead of after a 2–7-day incubation period.

Maximize Product Quality & Compliance

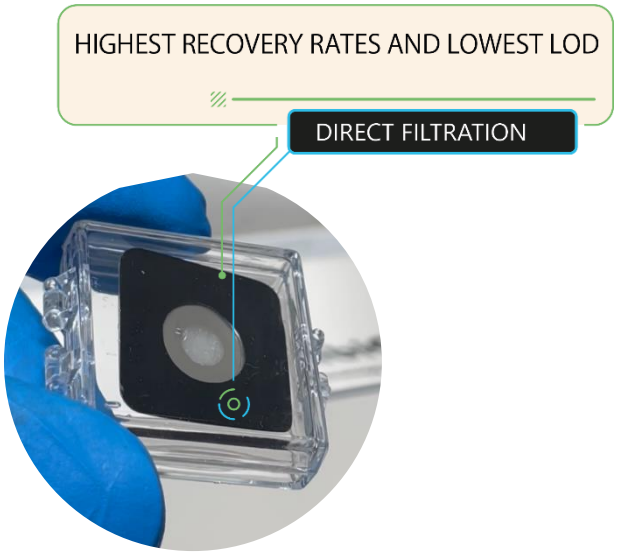
with GRAM^{RAY} integrated into the company's HACCP system. Detect and identify microbial contamination of raw ingredients, in-process media, and finished goods. **GRAM^{RAY}** provides results more quickly with less hands-on labor than with conventional microbiology methods.

- Environmental, IPC, Water, Bioburden Monitoring
- 90 min Root Cause
- Real time Release

Push-button Results

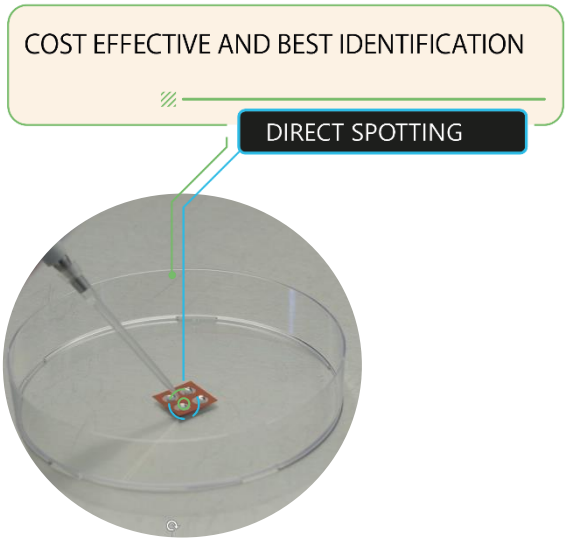
Tailored to the task

Whether you would like to detect a single microbe in your sample or like to have an immediate ID from your isolates you can select from basically **2 different** sample preparation paths:



With **GRAM**[RAY] filter membrane you are guaranteed highest quality and ease of use. The membranes have a 0.45 µm pore size and are metal coated. That makes them perfect for epifluorescence and background-free Raman signals.

With volume of up to 5 ml you can prepare a sample for analysis in just 5 minutes. mibiC´s reusable easy to use and easy to clean filtration system ensures the highest recovery rates.



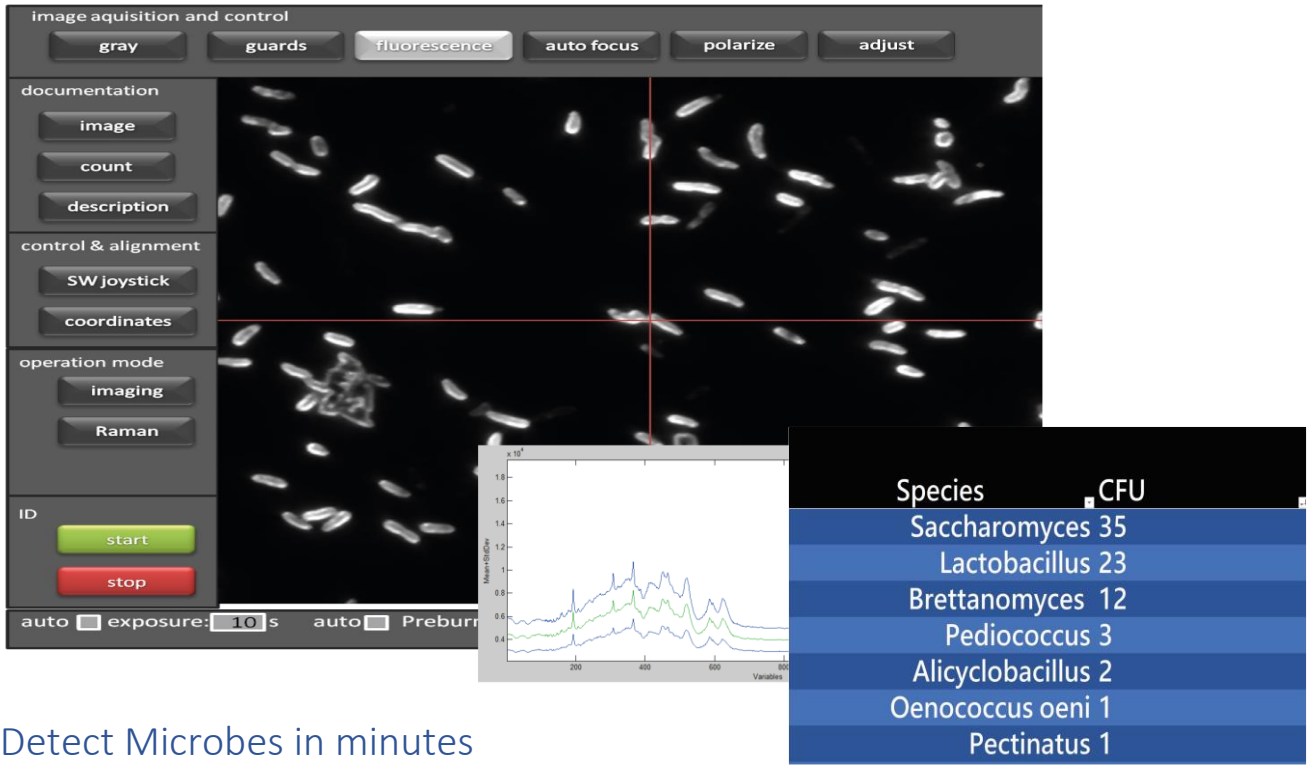
Simply put a 10µL drop of your sample suspension either from a colony from your plate or isolated from your unfilterable matrix onto the sample substrate. On a 40°C plate it dries up in just 5 min. Makes this the perfect sample for immediate isolate ID or database updates.

Low-cost sample substrates

With the 1X, 4X up to 24 X high-quality sample carriers' cost-effective way to automatically measure multiple spots. The smooth metal surface guarantees optimal spectral quality.

mibiC´s substrates are manufactured to the highest standards in-house at mibiC and certified for quality.

Dedicated Magic



Detect Microbes in minutes

with **GRAM**[RAY.] you can quantify the number of viable microbial cells in just 20 minutes. Including their phenotypic characterization with species-level classification.

Leverage the power of single cell phenotypic information

with the combination of counting and detecting single cells. Automated analysis assures compliance. **GRAM**[RAY] offers the fastest analysis and highest throughput using Raman Spectral analysis.

Measure every microbe's metabolism

Unlike classical methods, the **GRAM**[RAY] technique doesn't require extended incubation of samples. This allows you to classify microbes as dead, living, and viable but not culturable (**VBNC**) in just 2 hours with mibiC´s "stable isotope" technique.

With the easy-to-use intuitive user interface

you generate cGMP compliant pass/fail-results showing the number of viable cells and their species.

Open microbiological concept

Build a machine learning library of microbes unique to your product and facility.

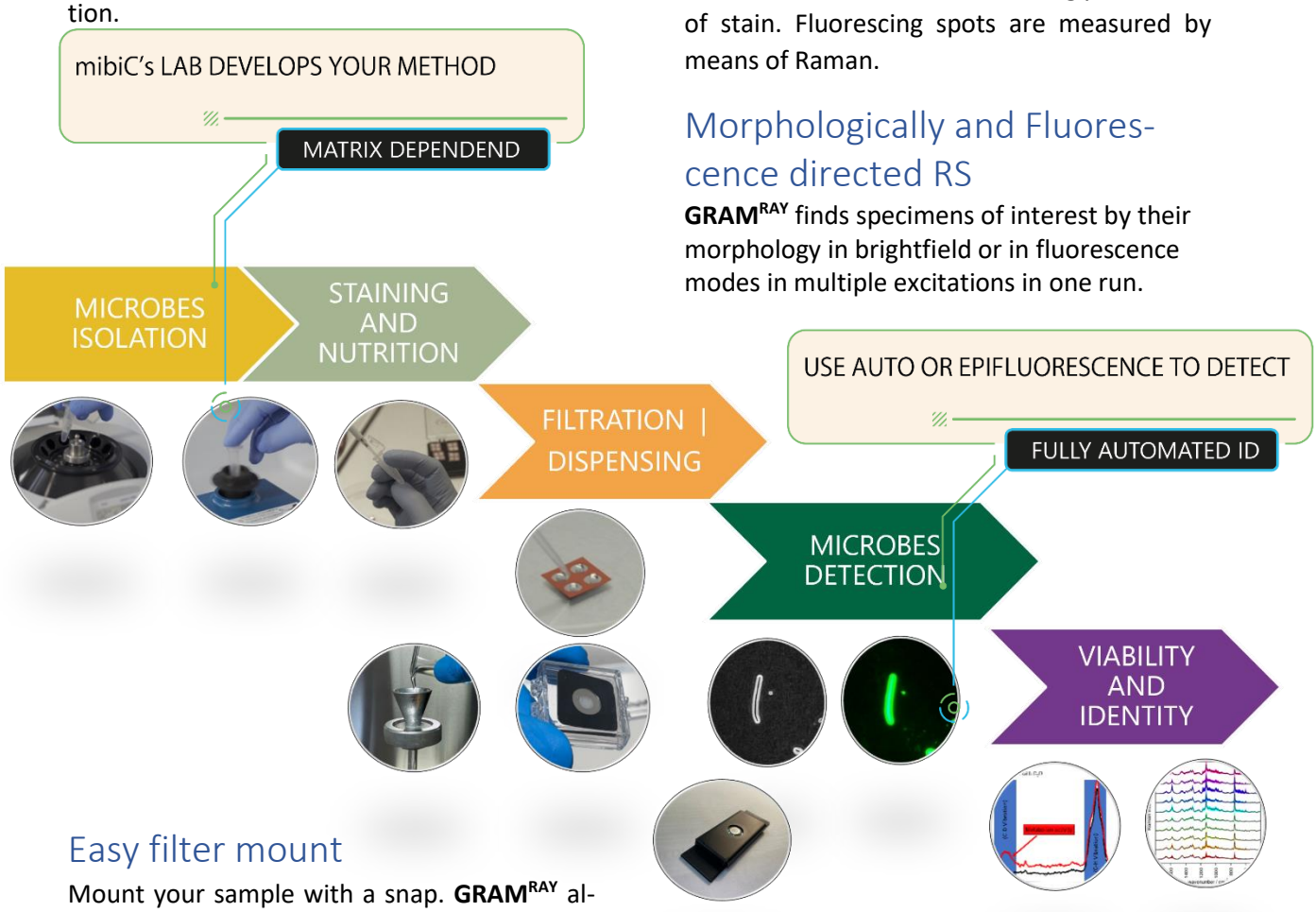
With **RAMANMETRIX**[TM] any species can be measured and learned with the required 300 single microbe spectra in just 2 hours. With your house germs and their origin, you differentiate lab isolates from bio film bred product isolates in just 15 s/microbe.

Rely on the biophotonics diagnostics curated Raman microbes database. Send your spectra in for confirmation or update of the library.

Dedicated Magic

Immediate Isolate ID

Resuspend your isolate´s from the CFU and spot it directly onto the sample carrier. You pick the right method and measure up to 400 microbes / hour for ID and database generation.



Easy filter mount

Mount your sample with a snap. **GRAM**[RAY] already knows the samples' location and measures it after the push of a button.

Run multiple samples at once

with the dedicated sample holders. Load either a single filter membrane or up to 24 filtered samples at once.

With the spotted samples you can mount and run up to 24 samples and walk away.

Auto Focus & Auto Scan

Integrated autofocus and scanning procedures are prestored in your method. The entire filtered sample is measured in minutes. Chose the illumination and filter matching your choice of stain. Fluorescing spots are measured by means of Raman.

Morphologically and Fluorescence directed RS

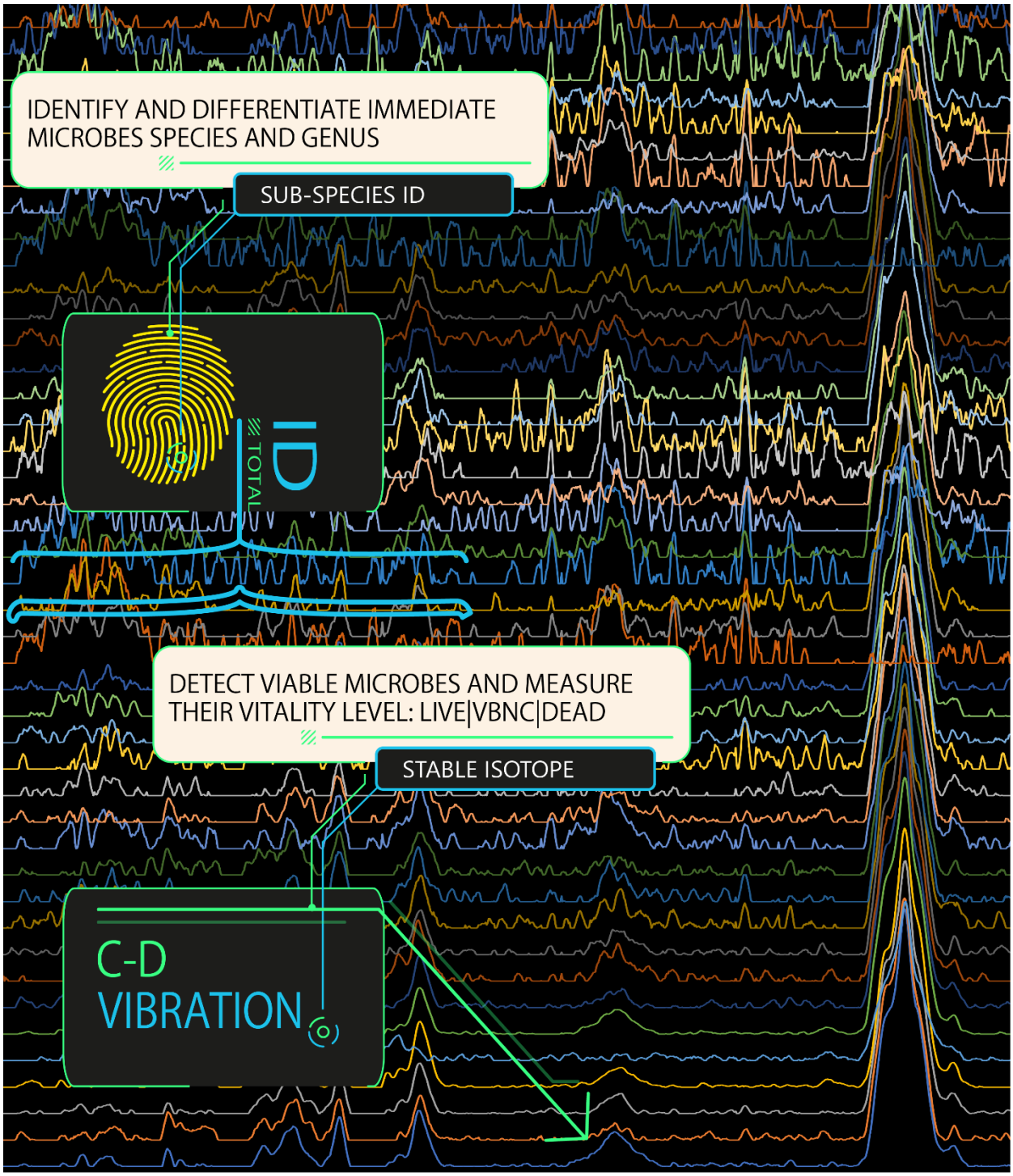
GRAM[RAY] finds specimens of interest by their morphology in brightfield or in fluorescence modes in multiple excitations in one run.

Highest Throughput Raman

The **GRAM**[RAY] is designed specifically for microbe detection and identification. Using the Raman technique **GRAM**[RAY] shows the highest quantum efficiency of any instrument on the market today. Read what scientists are saying in more than 150 Peer reviewed publications based on the Raman platform technology.

Artificial Intelligence

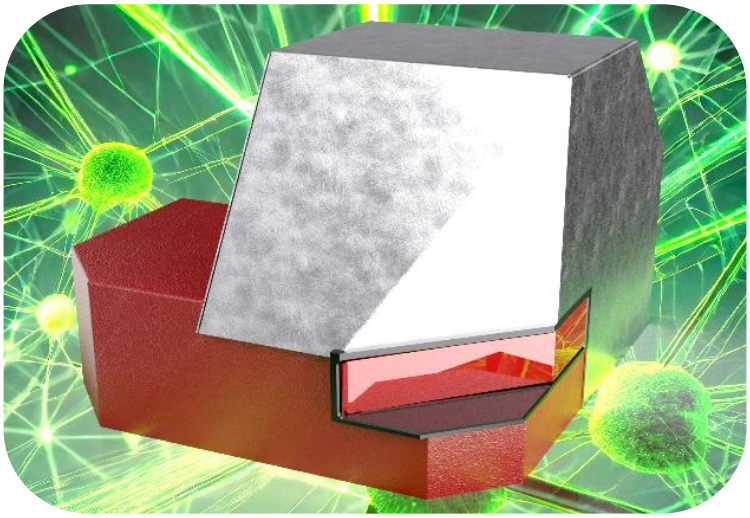
- **GRAM**[RAY] offers the most powerful Artificial Intelligence for microbe identification in **RAMANMETRIX**[TM] software.
- After automated selection for spectroscopy all potential microbes are Raman probed.
- Individual Raman spectra are automatically compared with the constructed data model.
- The quality of the spectrum and the correspondence with the data model is evaluated.
- Viability is measured by means of Stable Isotope Raman [SIRA]
- Identity by AI match with previously learned microbes [Gram +/- bacteria, yeasts, fungi]



GramRay^{U} & GramRay^{I}

Introducing the GramRay MKIII Series: Inverted and Upright Versions

Experience cutting-edge microbial detection with the GramRay MKIII, available in both upright and inverted models. Utilizing advanced Raman spectroscopy, these systems deliver ultra-fast microbial detection with unparalleled precision.



The upright model features a laser-based, ultra-fast autofocus system, capable of up to six magnifications. Its versatile design accommodates a wide range of sample types, from a variety of filters to DEP-chips, ensuring flexibility for diverse applications.

The inverted model is compact and robust, ideal for routine applications.

Feature Description	GramRay^{i} MKIII Inverted	GramRay^{u} MKIII Upright
Laser-based Autofocus (AF)		✓
Linear Motors	✓	✓
Turret with Up to 5 Lenses		✓
Enhanced Software with Machine Learning	✓	✓
Minimized Thermal Drift	✓	✓
Epi-fluorescence and Auto-fluorescence (Optional)	✓	✓
Scanning Speed with 50x Lens / 25x Lens and jump to high N.A. lense for Raman		✓
Normal and Fast Raman Detectors	✓	✓
Weight and Dimensions	50 kg, 50x60x50 cm	75 kg, 60x60x70 cm

GRAM^{RAY} Features & Spec.

cGMP Control & push button operation

- Simple measurements recipe creation
- CE marked & 21 CFR Part 11 compliant | User hierarchy-levels, audit trail, data integrity
- Highest accuracy and speed in fluorescence directed Raman spectroscopy through automated exposure, illumination modes, autofocus and binarization control

Identification and artificial intelligence - RAMANMETRIX™

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

Microbial counting and detection

- Measuring interval for image recognition of individual microbes: 0.5 µm - 50 µm
- Identification for Gram +/- bacteria, yeasts, fungi
- Image Analysis for Dark Field Illumination / Fluorescence
- Morphology and Fluorescence directed Raman spectroscopy

Spectroscopy

- Raman engine (≤ 23 mW @ 532 nm or 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 cm^{-1}
- Wavelength range 100-4.000 cm^{-1}
- Laser safety - Class 1
- Lens - 100x, 0.9 NA, 1.0 mm WD.
- ID & verify up to 300 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 for target evaluation and documentation
- 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 and self-tests

Environmental parameters

- Mains voltage + power - 110-230 V, 500 W
- Temperature range 17-25 °C,
- Humidity range 10-75 % non-condensing

Space Requirements

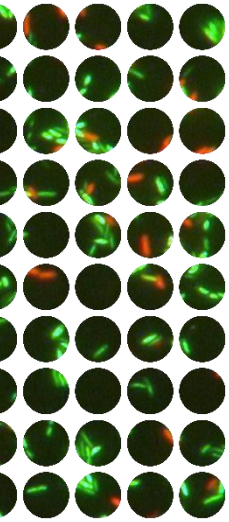
- Dimensions - 55x60x35 cm
- Weight - 52 kg
- Vibration Isolation recommended

System Components

- Spectrometer & **GRAM^{RAY}**
- PC with **GRAM^{RAY}** Software
- Illumination
    - Flexible Illumination fully integrated Epi-Fluorescence with multiwavelength labeling with up to 4 different filters

GRAM^{RAY} Illumination^{+}

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 - e.g. dead live staining CYTO9 and PI for classical viability and VBNC studies with stable isotopes as metabolic markers.

Benefits

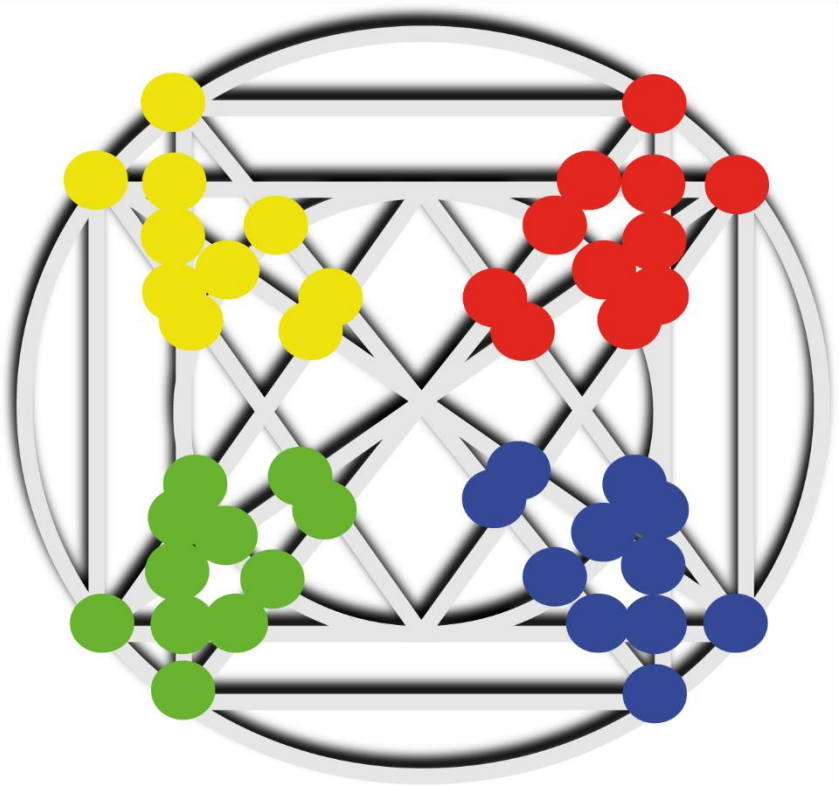
- Use **autofluorescence guided** Raman spectroscopy to streamline classification
- **Enhance GRAM^{RAY}**'s Limit of Detection, **LOD** and avoid matrix Interferences
- **Ultra-Flexible selection of fluorescence e**xcitation for multiple studies
- **Maximizes selectivity** for time saving Raman viability 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 labeling with multiple chromophores**
- 6 different light sources
- **Single-Band Filter Set**s 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 **GRAM^{RAY}**'s software
- Liquid Light guide connected
- Solid state **365 nm Ultraviolet** source
- Solid state **735 nm Near-IR** source



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mibiC GmbH & Co. KG ||||| Ostendstrasse 25| Haus 6 |||| ||12459 Berlin | |||| Phone: +49 (0) 30 53041750 ||| || **microbiology @ the speed of light** || | mibi-c.com ||||| same day release || single microbe viability detection & ID || yeast | bacteria | fungi | VBNC