

INTRODUCTION OF THE NOVEL TECHNOLOGY PLATFORM



Isolation | Staining | Stable Isotope | Epi-Fluorescence | Raman | Viability
& ID by AI



GENERAL WORKFLOW:

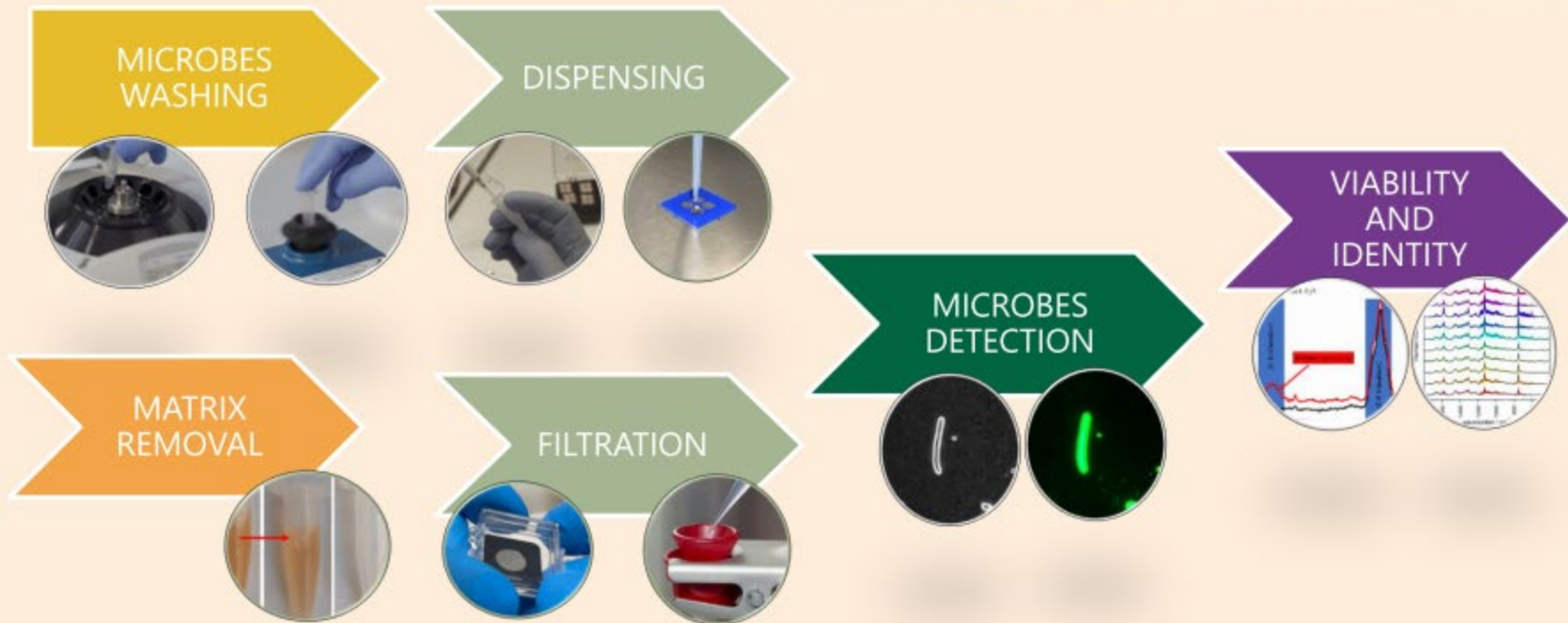


Image analysis + Raman

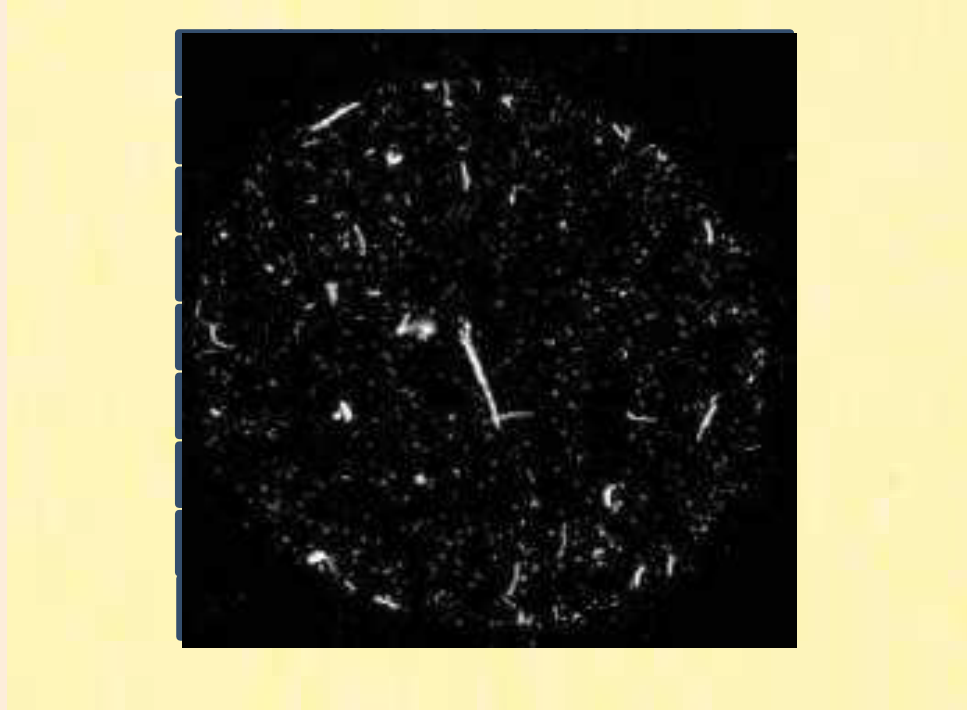
Viability + species ID

Number microbes



Automated Enumeration

- Metal foil with 0.4 μm pores RAMAN inactive



Measurement: Image analysis + Fluorescence Targeting + Raman

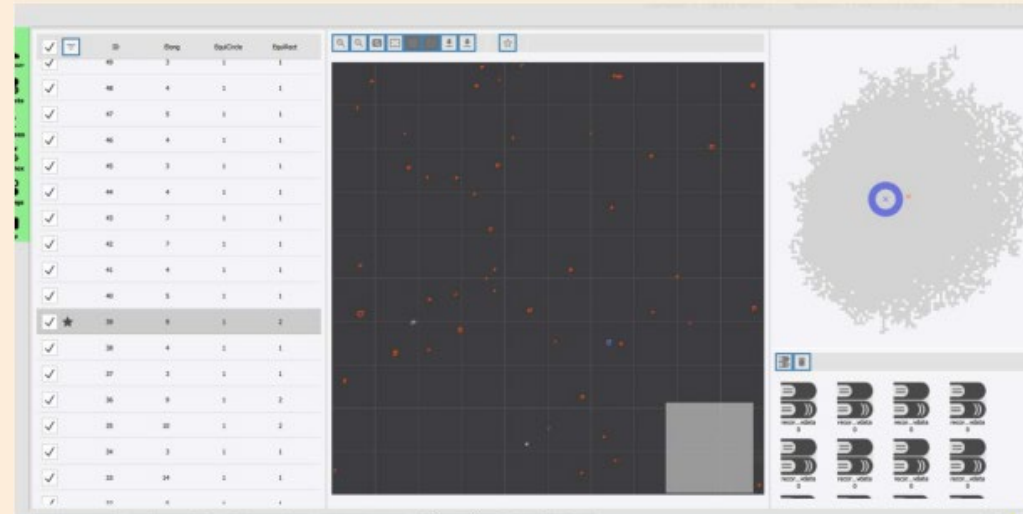
1. Scan filter with dark-field
100-5000 Images

2. Scan filter with Fluorescence mode
(if necessary, in case of large amount of debris) or as viability marker

3. Selection of potential microbes for Raman Spectroscopy

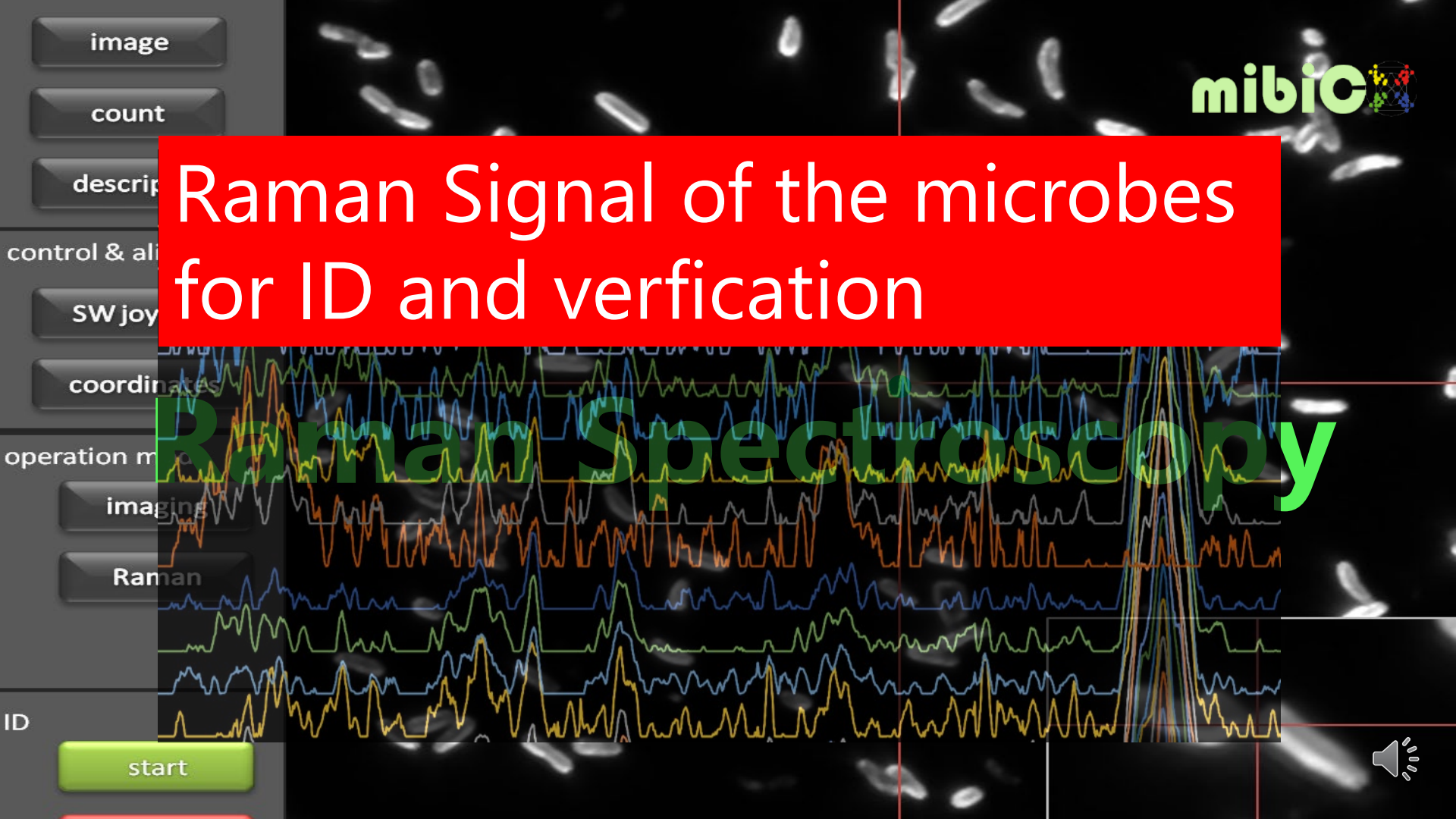
4. Verification of potential microbes by Raman Spectroscopy

5. Single cell technique, no amplification necessary, may be helpful

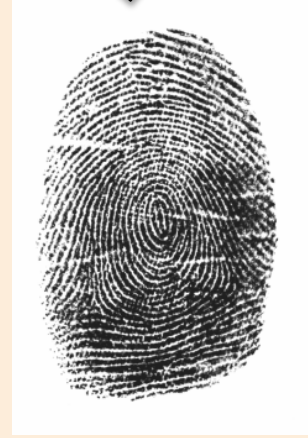
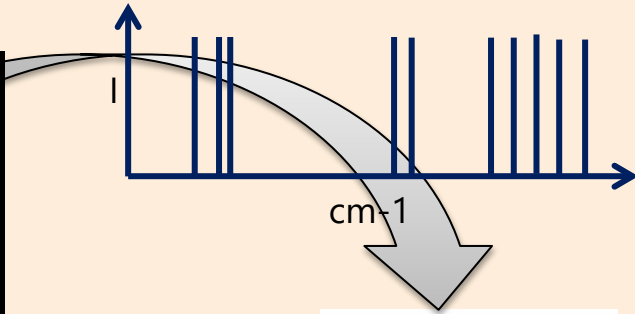
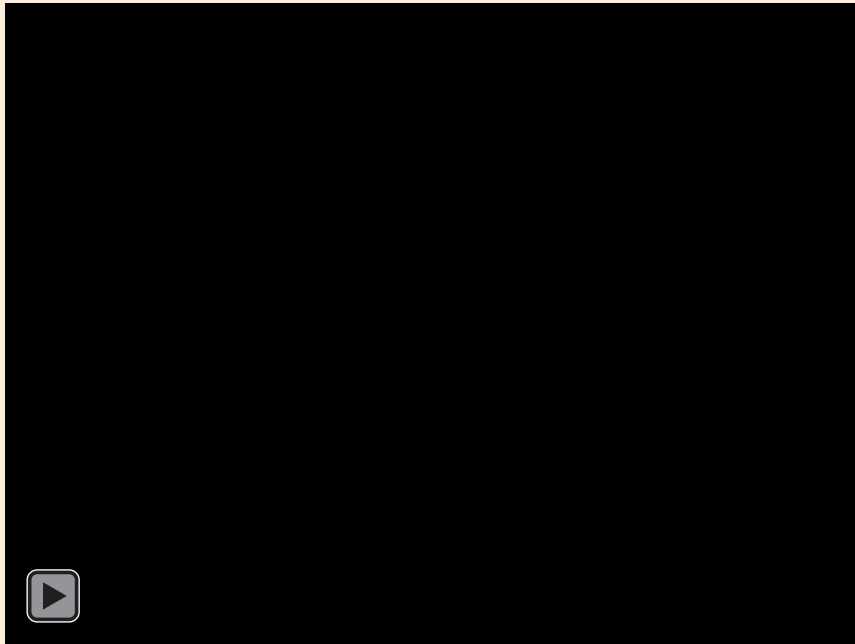


Raman Signal of the microbes for ID and verification

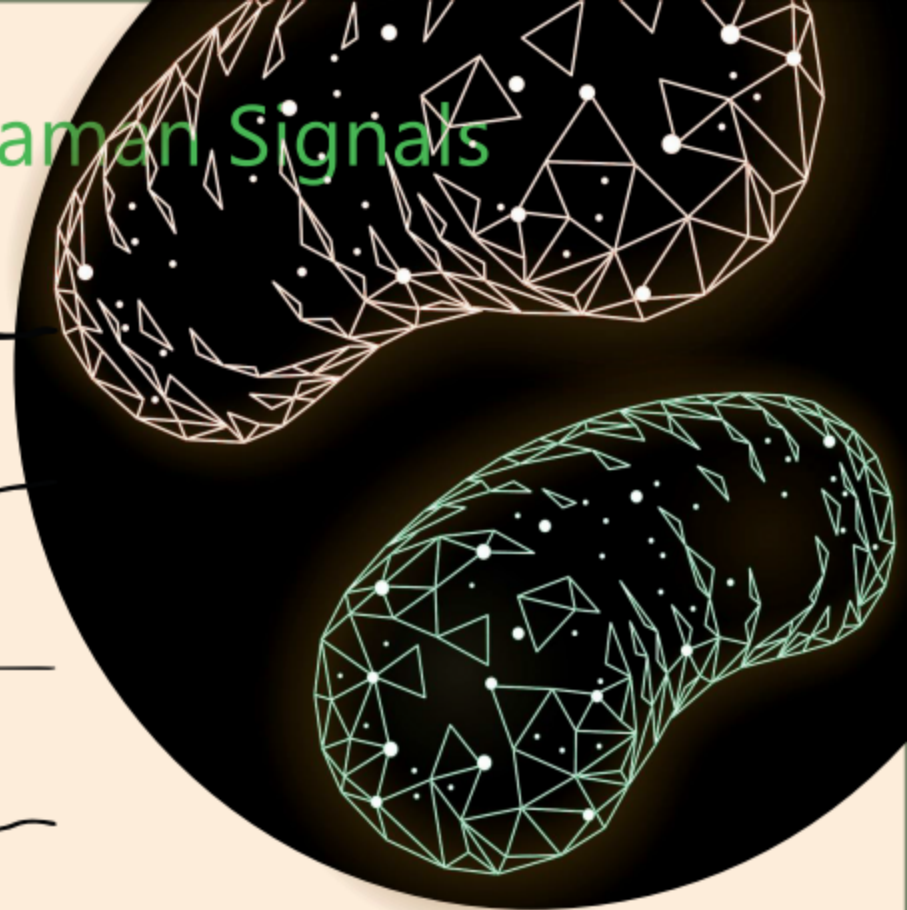
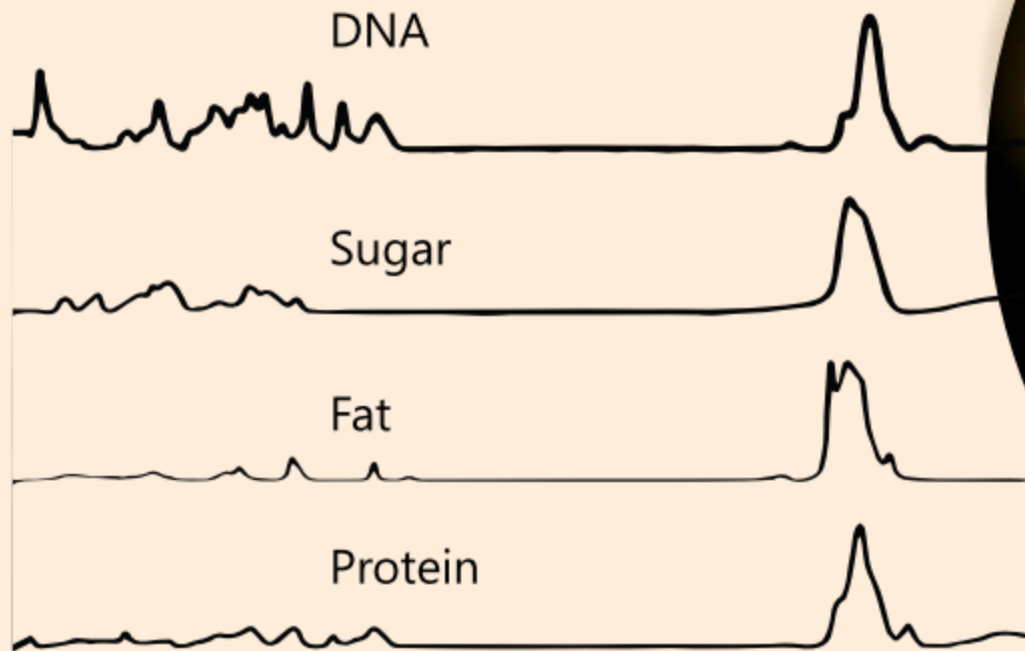
Raman Spectroscopy



Molecular Spectroscopy



Microbe Components Raman Signals



Slide 8

DETECT VIABLE MICROBES AND MEASURE
THEIR VITALITY LEVEL: LIVE|VBNC|DEAD

STABLE ISOTOPE

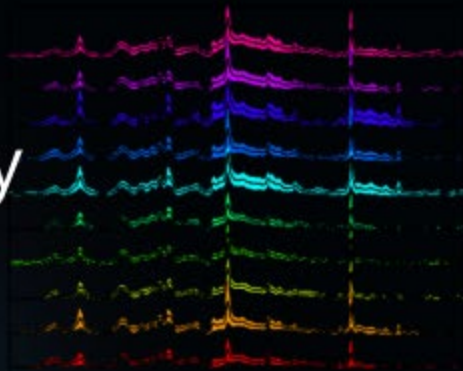
AI determines viability & identity

IDENTIFY AND DIFFERENTIATE IMMEDIATE
MICROBES SPECIES AND GENUS

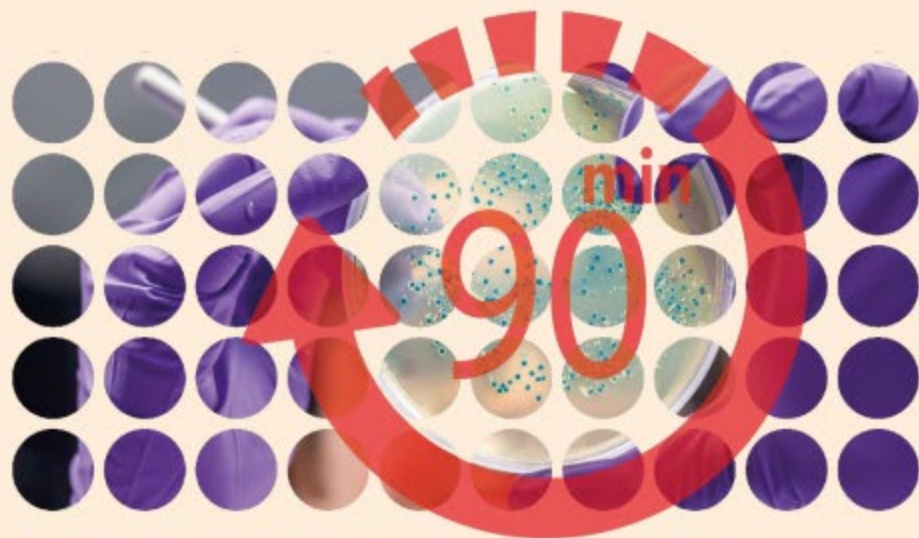
SUB-SPECIES ID



STABLE ISOTOPE



- Viability:
 - dead/live/VBNC
- IDentity:
 - Yeast | Fungi | Bacteria
 - Genus
 - Species
 - Sub-Species
 - Origin



LOD | Accuracy | Automation & Data Integrity | Time2Result

POSSIBILITIES, HURDLES & POTENTIAL BENEFITS

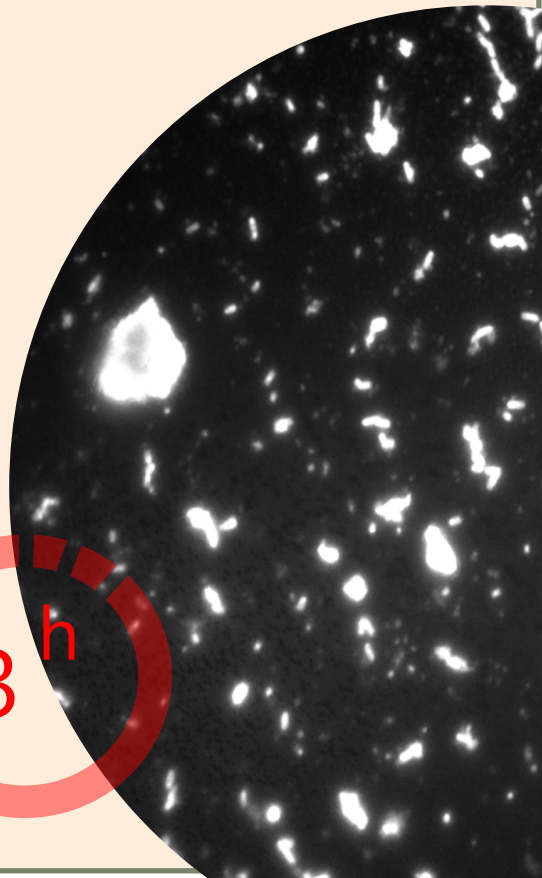
Detection & ID @ LOD 1000 in Cell Based Therapeutic [1 mL 2 E6 Cells]



- USP <1071>
- EP 2.6.27 **Result before Administration**
 - LOD <100 CFU
 - Sample Volume 0.1-10 ml
 - Wide Range of Microorganisms with low false neg. and positive
 - Easy, Aseptic, Validation possible

Challenges | Solutions | Outlook

- Lysis of the Mamalian Cells creates a lot of debris
 - Cell Concentration dependand!
- Enzymes are used to digest debris
- Debris is in the similar size as microbes
- Efficient cleaning up and selective staining is neccesary
- LOD of <1000 was established
- TTR: 3 h





Quick result less than 24 hours



Cost-effective for large number of samples



Additional Information by ID



More safe product

GRAM^{RAY} benefits & advantages

