

RAPID, ENUMERATED BIOIDENTIFICATION SYSTEM



INTEGRATED BIODETECTION AND BIOIDENTIFICATION IN MINUTES*

Battelle's Rapid, Enumerated Bioidentification System (REBS™) provides a rapid and flexible next-generation microbial detection, identification and enumeration capability. REBS non-destructively detects and identifies microbial contamination in the air, raw materials, in-process fluids or finished products within minutes from a single test sample. REBS increases manufacturing productivity, reduces inventory expenses, and generates working capital.

REBS rapidly and accurately detects, identifies and enumerates particulates and microbiological contaminants without the need for expensive reagents and other consumables. REBS permits secondary identification confirmation using the original test sample due to the fact that it is non-destructive.

REBS can be configured to identify environmental or liquid samples, providing a highly flexible contaminant microbial detection and identification platform. REBS has demonstrated identification performance with contaminants such as bacteria, fungus, molds, yeasts and endotoxins. REBS offers an integrated Quality Assurance solution for your operations.

REBS CAPABILITIES:

- Perform rapid detection, identification and enumeration without the need to culture
- Detect single microbiological contaminants with spectroscopic identification
- Phenotypically identify contaminants by analyzing molecular bonding within materials
- Provide compatibility with many viability stain protocols

- Provide non-destructive results, enabling secondary identification confirmation
- Deliver automated detection, identification and enumeration results reporting
- Mean time between failures ~ 10,000 hours

ADVANTAGES:

- Select particulate identity at biological, genus, species and, in some cases, strain levels
- Microbial identification library is easily upgraded for emerging contaminants
- Identify contaminants within minutes and initiate mitigation within hours
- Identify stressed or stained cells, including viable but non-culturable
- Reduce product losses
- Increase product surety without increasing labor costs
- Low total-cost-of-ownership because consumables such as reagents are not required
- Non-destructive detection allows secondary confirmation



*Demonstrated in laboratory tests with the top 10 microbes that caused product recalls over the last 10 years (L. Jimenez, "Microbial Diversity in Pharmaceutical Product Recalls and Environments," PDA Journal of Pharmaceutical Science and Technology, Vol. 61, Issue 5, pp. 383-399 (2007).)

Rapid, Enumerated Bioidentification System (REBS)

Increased Productivity | Reduced Inventory Expenses | Increased Working Capital

HARDWARE

Detects, identifies, and enumerates in minutes

- Yeasts, fungi, gram-positive and gram-negative cells, spores, molds
- Determine objectionable limits within minutes, including chemical additives, composition and concentration

Single cell sensitivity

Non-destructive detection method permits secondary confirmation

Minimal sample preparation

- Staining for viability only
- No amplification or lysing

Sample traceability

- Open Database Connectivity (ODBC) and Laboratory Information Management System (LIMS) compatibility

Size

- Detection and identification engine: 46 cm × 46 cm × 61 cm (1.5' × 1.5' × 2')
- Detection and identification engine weight: < 45 Kg (100 lbs.)

SOFTWARE

Modular system with easily upgradable library for emerging contaminants

- Software validation
- Periodic library updates
- Facility-specific library expansion services
- Compliant to the requirements of 21 CFR Part 11

EXTENDED SUPPORT

Technology validation services

Extended maintenance warranty and service contract

Leasing options available

Facility contamination tracking service

Facility risk assessment modeling

Complementary analytical methods development

In-line near real-time contamination control

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