

# Rapid Microbial Methods Overview

## Different Possible Method Applications

### Qualitative Methods

Numerical result indicating total number of microbes present in the sample

### Quantitative Methods

Presence or absence result indicates microbial contamination

### Identification Methods

Provides species or genus name for containment in a sample

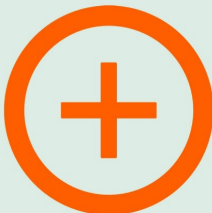
## Rapid Methods used in the Industrial microbiological market

- Nucleic-acid-based detection (uses DNA/RNA targets)
- Antibody-based detection
- Biochemical detection
- Enzymatic detection (ATP)
- Independence methods
- Flow-cytometry based methods



## Rapid Methods Advantages

- Ease of use
- High throughput capabilities
- Minimal training requirements
- Compliance with process-analytical technology initiatives (PAT for USA and EMA for EU)
- High specificity & sensitivity
- Ability to interface with laboratory information management systems
- Data trending ability



## Rapid methods disadvantages

- Not one Rmm has been able to replace traditional methods in total
- Rapid methods require high upfront capital investments
- Costa per test is high compared with culture tests



## Potential applications for Rmm's

- Raw material testing
- In-process testing
- Microbial limit testing
- Bio burden assessment
- Process water testing
- Environmental monitoring
- Sterility testing

