

Rapid & Automated Mycoplasma Detection

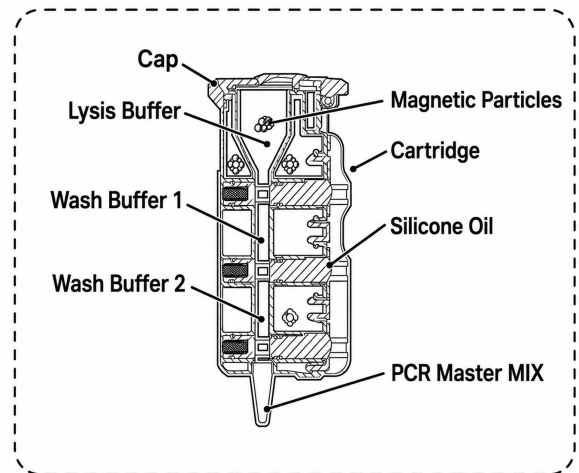
Advanced QC Solutions: Digitization, Automation and Real-time Release



Applied Cells Mycoplasma Detection System (Hubble™)

Hubble™ transforms RMM (rapid microbiological method) into a streamlined, fast, fully automated, and easily portable laboratory system.

- **Integrates nucleic acid extraction and real-time PCR assay, allowing a turn-around time of 2.5 hours from sample to result.**
- **Requires less than 5 minutes of hands-on time and does not require specific DNA extraction and PCR expertise to operate.**



FAST. SIMPLE. ACCURATE.
ON-TIME MYCOPLASMA DETECTION FOR ANYONE, ANYWHERE

Easy On-time Testing

- Complete automation from sample to result
- Hands-on time < 5 mins.

High Sensitivity & Efficiency

- LOD ≤ 10 CFU/ml
- Four independent assays in a single run

High Specificity

- No cross-reactivity with different bacteria or cell lines
- No sample matrix interference

Data Reliability

- Fully validated workflow
- Effective internal control across every stage
- 21 CFR Part 11 compliance

Comprehensive coverage

- Able to detect over 180 species of Mycoplasma, Spiroplasma and Acholeplasma

Accessible Anywhere and to Anyone

- No PCR lab or skills required
- Seamless integration from extraction to amplification without manual intervention

SHENTEK Mycoplasma DetectInnova Cassette



A closed, disposable system that contains all necessary reagents for nucleic acid extraction, purification, amplification and detection --- enabling an efficient, all-in-one workflow from sample preparation to result analysis.

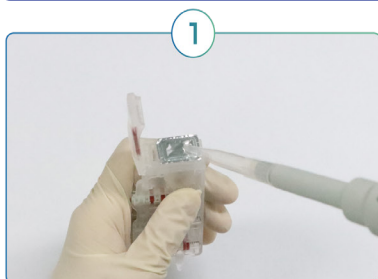
It uses magnetic particle separation technology and real-time fluorescence PCR technology.

After sampling or simplified preparation, the user pipettes magnetic particles and sample combined with IC into the cassette, inserts the cassette into an DetectInnova System, and starts a test.

The entire test takes approximately 3 hours.

Designed for use with the DetectInnova System.

INTEGRATED CASSETTE COVERS AN AUTOMATED NUCLEIC EXTRACTION AND ANALYSIS SYSTEM



By utilizing single-use cassettes, the system significantly minimizes hands-on time, offering a streamlined solution for on-time testing across various biotherapeutic products to anyone and anywhere.

Specifications

Description	Details
LOD	10 CFU/mL
Limit of Blank	NCS (FAM): no amplification curves or Ct≥40
	Internal control, ROX: Ct<40
Specificity	No interference was showed with 4 types of sample matrix (DMEM (20% FBS + 10% DMSO), DMEM (10% FBS), ExpiCHO™, ExpiCHO™ (10%DMSO))
	Negative results were obtained from testing 18 genomic DNAs (engineered cells and bacteria)
Strain Specificity	Bioinformatics analysis shows the system can detect nearly 200 species genomic DNA
	Positive results was showed using eleven control strains (Mycoplasma orale, Mycoplasma pneumoniae, Mycoplasma hominis, Acholeplasma laidlawii, Mycoplasma salivarium, Mycoplasma fermentans, Spiroplasma citri, Mycoplasma hyorhinitis, Mycoplasma arginine, Mycoplasma synoviae, and Mycoplasma gallisepticum)
Robustness	Detect 10 CFU/mL of Mycoplasma species (orale, hyorhinitis, pneumoniae, fermentans) in high-density CHO-S cell substrate (10 ⁷ cells/mL) with >95% detection rates
	Sample volume: 0.2ml-1ml
Repeatability	Sample Detection Repeatability (CV/Ct ≤ 10%)