

Hubble

QUALITY CONTROL
MADE EASY ✦

Mycoplasma DetectInnova System



PN#1613106



PN#16031010405

The Hubble™ System transformed RMM (rapid microbiological method) into a streamlined, fast, fully automated laboratory system. It combines nucleic acid extraction and real-time PCR into a fully integrated workflow, delivering results for four independent assays within 3.5 hours from sample to result. Importantly it only requires less than 5 minutes of hands-on time, without specific DNA extraction and PCR expertise to operate.



Closed, Fully Automated System

- Integrated from extraction to detection
- No contamination with closed cassette



Flexible & Training Light

- Up to 4 independent cartridges per run
- No PCR specialized skills required



Regulation Compliant

- Built-in controls
- Validated workflow
- 21 CFR Part 11, USP/EP/JP



High Performance

- LOD ≤ 10 CFU/mL with high specificity
- No cross-reactivity or matrix interference



Fast & Easy

- < 5 min hands-on time
- ~3 hours to result (walk-away)



High Sample Capacity & Large Species Library

- Up to 1.0 mL sample input
- 180+ species of *Mycoplasma*, *Spiroplasma*, *Acholeplasma*



Rapid, Simple, Accurate
On-time Mycoplasma Detection to Anyone & Anywhere

On-time Testing in 3 Easy Steps to Anywhere & Anyone



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

Table 1 Detection Level at 10 & 100 CFU/mL For Different Mycoplasma Species

Strains	Detection Concentration	
	10 CFU/mL	100 CFU/mL
<i>Mycoplasma synoviae</i>	24/24	24/24
<i>Mycoplasma arginini</i>	24/24	24/24
<i>Mycoplasma gallisepticum</i>	24/24	24/24
<i>Spiroplasma citri</i>	24/24	24/24
* <i>Mycoplasma orale</i>	24/24	24/24
<i>Mycoplasma hyorhinis</i>	24/24	24/24
* <i>Acholeplasma laidlawii</i>	24/24	24/24
* <i>Mycoplasma fermentans</i>	24/24	24/24
* <i>Mycoplasma hominis</i>	24/24	24/24
* <i>Mycoplasma pneumoniae</i>	24/24	24/24
* <i>Mycoplasma salivarium</i>	24/24	24/24

*Strains sourced from TTR of ATCC

Note: 24/24=24 out of 24 test results positive

Table 2 LOD Results at 5 CFU/mL

Strains	Test Conc. (CFU/mL)	Detection rate (%)	Acceptance Criteria	Conclusion
<i>Mycoplasma gallisepticum</i>	5	100	Detection rate at least above 95%	Pass
<i>Mycoplasma arginini</i>	5	100		Pass
<i>Mycoplasma synoviae</i>	5	100		Pass

Table 3 LOD at 10 CFU/mL in Different Matrices

Sample Matrices		Strains					
		<i>Mycoplasma orale</i>		<i>Mycoplasma hyorhinis</i>		<i>Mycoplasma pneumoniae</i>	
		10 CFU	100 CFU	10 CFU	100 CFU	10 CFU	100 CFU
5% human albumin		24/24	24/24	24/24	24/24	24/24	24/24
CHO-S	10 ⁶ cells/mL	24/24	24/24	24/24	24/24	24/24	24/24
	10 ⁷ cells/mL	24/24	24/24	24/24	24/24	24/24	24/24

Note: 24/24=24 out of 24 test results positive

Table 4 Sensitivity Assessment in Media/Buffers

Sample Types	Sample Details	Sample Volume	Organism	Concentration (CFU/mL)	Detection Rate
Media or buffer solution	DMEM	1 mL	<i>M. orale</i> / <i>M. hyorhinis</i> / <i>M. pneumoniae</i>	10 CFU/mL	24/24
	DMEM (10% FBS)				24/24
	DMEM (20% FBS+10% DMSO)				24/24
	Cryostor CS10				24/24
	PBS				24/24
	ExpiCHO Expression Medium				24/24

Table 5 Sensitivity Assessment in 1 mL In-process Control

Sample Types	Cell Density	Sample Volume	Organism	Concentration (CFU/mL)	Detection Rate
UPB (Unprocessed Bulk)	CHO 10 ⁷⁻⁸ cells/mL	1 mL	<i>M. orale</i>	10	8/8
			<i>M. salivarium</i>	10	8/8
			<i>M. hominis</i>	10	8/8
			<i>A. laidlawii</i>	10	8/8
			<i>M. fermentans</i>	10	8/8
			<i>M. pneumoniae</i>	10	8/8
			<i>M. hyorhinis</i>	10	8/8
			<i>M. orale</i>	5	2/2
			<i>M. salivarium</i>	5	2/2
			<i>M. fermentans</i>	5	2/2
			<i>M. pneumoniae</i>	5	2/2

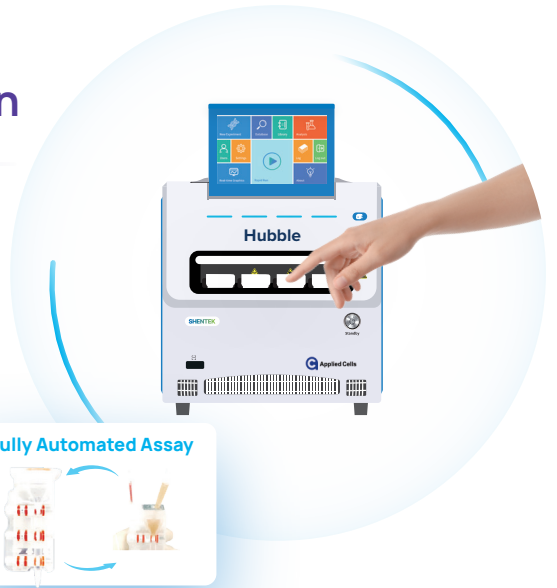
Table 6 Sensitivity Assessment in Different Cell Samples

Sample Types	Sample Details	Cell Density (per mL)	Sample Volume	Organism	Concentration (CFU/mL)	Detection Rate
Cell therapy products	Jurkat Cell line	$10^6 - 10^7$	1 mL	<i>M. orale</i> / <i>M. hyorhinis</i> / <i>M. pneumoniae</i>	10 CFU/mL	24/24
	Jurkat Cell line (5% DMSO+5% HBS)	10^8				24/24
	TILs	$10^6 - 10^7$				24/24
	CD19 CAR-T-A	2.0×10^6	200 μ L-1 mL			24/24
	CD19 CAR-T-R	2.0×10^6				24/24
	CD19 CAR-T-C	2.0×10^6				24/24
	BCMA CAR-T-Z	10^7				24/24
	BCMA CAR-T -C	10^7				24/24
	BCMA CAR-T-F	10^7				24/24
	IIT CAR-T	$10^6 - 5 \times 10^7$	100 μ L			24/24
	Fresh CAR-T	$10^5 - 10^6$				24/24

Hubble™ System for Automated & On-time Mycoplasma Detection



-  **Fast setup with Pre-filled cassette**
-  **Wide Coverage (>180 species)**
-  **Seamless workflow from extraction to result**
-  **LOD (10 cfu/mL) in different sample matrices**
-  **On-demand testing for bioprocessing**
-  **21 CFR Part 11 GMP Compliance**



Visit Our Website to Schedule Your Demo

- ✓ Quick Start Guide Available
- ✓ Operate with Ease, Anytime
- ✓ Need Help? Reach Out to Us!

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