

Hubble[®]

AUTOMATED MYCOPLASMA
DETECTION FOR CELL THERAPY
MANUFACTURING WORKFLOWS



Closed, automated workflow

- Integrated from extraction to detection
- Reduced contamination risk with closed cassette workflow



Flexible and training-light

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



Compliance-ready

- 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 h result (walk-away workflow)



High sample capacity and broad species coverage

- 0.1–1.0 mL sample input
- 180+ species of *Mycoplasma*,
Spiroplasma, *Acholeplasma*



Rapid, Simple, Accurate

On-time mycoplasma detection for simplified near-line operation.

TECHNICAL SPECIFICATIONS

FEATURE	HUBBLE® FAST QC
Method	Automated nucleic acid extraction + real-time PCR
Format	Single-use cassette
Target	Mycoplasma detection
Time to result	~3 hours
Hands-on time	<5 min for simple samples
Sample input	0.1–1.0 mL
Throughput	Up to 4 independent assays per run
Detection coverage	180+ species of Mycoplasma, Spiroplasma, Acholeplasma
Controls	Built-in internal controls
Software/compliance	21 CFR Part 11 support; USP/EP/JP alignment

Detection level at 10 and 100 CFU/mL for representative 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

LOD at 10 CFU/mL across tested 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
	10 ⁷ cells/mL	24/24	24/24	24/24	24/24	24/24

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

Sample-to-result mycoplasma QC in three steps

The single-use cassette workflow is designed to reduce hands-on time and simplify near-line mycoplasma QC for cell therapy manufacturing and in-process testing workflows. Hubble® detects representative Mycoplasma, Spiroplasma, and Acholeplasma strains at low CFU/mL levels across buffer, media, in-process, and cell therapy sample matrices.



Sensitivity assessment in media/buffers - 100% detection across all samples

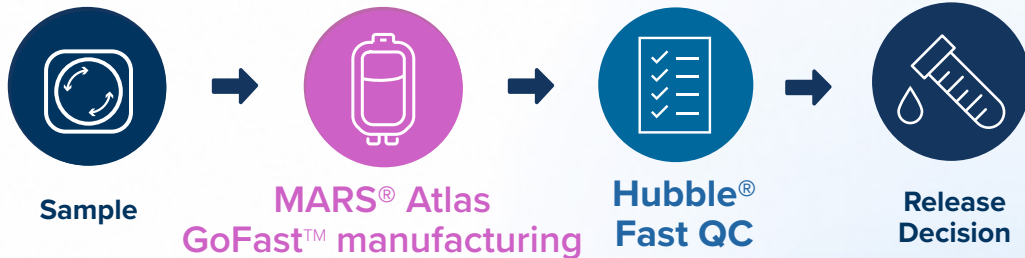
SAMPLE TYPES	SAMPLE DETAILS	SAMPLE VOLUME	ORGANISM	CONCENTRATION (CFU/ML)	DETECTION RATE
Media or buffer solution	DMEM	1 mL	<i>M. orale</i> / <i>M. hyorhinis</i> / <i>M. pneumoniae</i>	10 CFU/mL	24/24
	DMEM (10% FBS)				24/24
	DMEM (20% FBS+10% DMSO)				24/24
	Cryostor CS10				24/24
	PBS				24/24
	ExpiCHO Expression Medium				24/24

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			

Fast QC for GoFast™ cell therapy development

GoFast™ rapid cell therapy manufacturing is reducing production timelines from weeks to days. As manufacturing accelerates, QC testing must also become faster, more automated, and easier to run near the process. Hubble® supports fast mycoplasma QC by integrating nucleic acid extraction and real-time PCR into a closed, cartridge-based workflow.



Designed to support regulated QC workflows

21 CFR Part 11 support
USP <63> and USP <77>
EP <2.6.7> and EP <2.6.21>
ISO 13485
IQ/OQ/PQ

In collaboration with
SHENTEK
QC Solutions

**DISCUSS IMPLEMENTATION FOR YOUR
CELL THERAPY WORKFLOW**
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ISO 13485:2016



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