

AdvSHENTEK

Mycoplasma DetectInnova System



The AdvSHENTEK Mycoplasma DetectInnova System transformed RMM (Rapid Microbiological Method) into a fast and easily portable laboratory system. It integrates nucleic acid extraction with real-time PCR into a streamlined and fully automated procedure, enabling four independent assays to be completed in 3.5 hours from sample preparation to final results. Importantly, the system requires less than 5 minutes of hands-on time, without specific DNA extraction and PCR expertise to operate.

PN#1613106

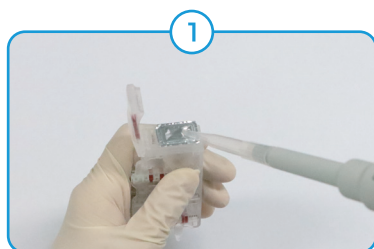
PN#16031010405

TECHNICAL SPECIFICATIONS

Method	Automated nucleic acid extraction + real-time PCR
Detection Limit	≤10 cfu/mL or 100 cp/mL
Format	Single-use cassette
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
Software/compliance	21 CFR PART 11 / USP / EP / JP

Rapid, Simple, Accurate
Easy and fast Mycoplasma Detection to Anyone & Anywhere

Rapid 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 DetectInnova 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 DetectInnova LOD at 10 CFU/mL in Different Matrices

Sample Matrix		Strain					
		Mycoplasma orale		Mycoplasma hyorhinis		Mycoplasma pneumoniae	
		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. hyorhins</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 µL-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 - 5x10 ⁷				24/24
	Fresh CAR-T	10 ⁵ - 10 ⁶	100 µL			24/24

DetectInnova System for Automated & On-time Mycoplasma Detection



Fast setup with Pre-filled cassette



Wide Coverage (>200 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



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- ✓ Operate with Ease, Anytime
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