



检验检测报告

项目名称: 十万级净化车间洁净性能综合检测
委托单位: 安徽美润康包装有限公司
受检单位: 安徽美润康包装有限公司
检测类别: 委托检测

安徽省德通检测技术有限公司

AnHui De Tong Testing Technology Co., Ltd





检验检测报告

报告编号：AHDT-2025-049

检测项目	十万级净化车间洁净性能综合检测	
检测类型	委托检测	
检测参数	换气次数、静压差、悬浮粒子数、噪声、照度、温度、相对湿度、沉降菌、浮游菌	
委托单位	安徽美润康包装有限公司	
委托单位地址	安庆市迎江区经开区老峰镇皖江高科孵化园一期 B9 栋	
受检单位	安徽美润康包装有限公司	
检测地址	安庆市迎江区经开区老峰镇皖江高科孵化园一期 B9 栋	
检测单位	安徽省德通检测技术有限公司	
检测方式	☒ 现场检测 ☐ 送样检测	
受检区域（净化级别）	10 间洁净室【均 D 级（即十万级）】	
检测状态	静态	
检测日期	2025.06.13~2025.06.15	
检验依据	《洁净室施工及验收规范》（GB 50591-2010）	
评价依据	《医药工业洁净厂房设计规范》（GB 50457-2019） 《洁净厂房设计规范》（GB 50073-2013） 《无菌医疗器械生产管理规范》（YY/T 0033-2000）	
主要检测设备	尘埃粒子计数器（AHDT-YQ-047）	校准有效日期:2026.02.04
	压差计（AHDT-YQ-017）	校准有效日期:2026.02.04
	风量仪（AHDT-YQ-008）	校准有效日期:2026.02.10
	声级计（AHDT-YQ-042）	校准有效日期:2025.10.29
	温湿度测试仪（AHDT-YQ-040）	校准有效日期:2025.09.25
	照度计（AHDT-YQ-024）	校准有效日期:2026.02.04
	浮游菌采样器（AHDT-YQ-009）	校准有效日期:2026.02.04
检验检测结论	经检测，所检参数均符合评价依据要求。	
备注	/	
编制	肖文博	肖文博
审核	徐光宏	徐光宏
批准	张允新	张允新
		签发日期：2025 年 06 月 20 日



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换气次数（次/h）

检测区域	技术要求	检测结果	单项判定
男一更（8.1m ² ）	≥10	15.9	合格
女一更（14.1m ² ）		11.2	合格
男二更（6.9m ² ）		18.8	合格
女二更（16.2m ² ）		10.2	合格
洗手消毒（10.9m ² ）		11.8	合格
器具间（4.8m ² ）		27.6	合格
洁具间（4.1m ² ）		32.7	合格
实验室（7.7m ² ）		21.6	合格
十万级净化车间（156.3m ² ）		10.2	合格
十万级净化车间（436.5m ² ）		10.5	合格
备注	/		

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静压差 (Pa)

检测区域	技术要求		检测结果	单项判定
男一更（8.1m ² ）	→非洁净区	≥5	5	合格
女一更（14.1m ² ）	→非洁净区		5	合格
实验室（7.7m ² ）	→非洁净区		9	合格
十万级净化车间（156.3m ² ）	→非洁净区		29	合格
十万级净化车间（436.5m ² ）	→非洁净区		24	合格
备注	/			

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悬浮粒子数 (粒/m³)

检测区域	技术要求		检测结果		单项判定
男一更 (8.1m ²)	≥0.5μm	≤3520000	Amax	1436713	合格
			UCL	1753906	
	≥5.0μm	≤29000	Amax	1366	
			UCL	1991	
女一更 (14.1m ²)	≥0.5μm	≤3520000	Amax	593451	合格
			UCL	763196	
	≥5.0μm	≤29000	Amax	4534	
			UCL	6755	
男二更 (6.9m ²)	≥0.5μm	≤3520000	Amax	876525	合格
			UCL	1891335	
	≥5.0μm	≤29000	Amax	4393	
			UCL	13431	
女二更 (16.2m ²)	≥0.5μm	≤3520000	Amax	2142885	合格
			UCL	2797816	
	≥5.0μm	≤29000	Amax	7491	
			UCL	12088	
洗手消毒 (10.9m ²)	≥0.5μm	≤3520000	Amax	1753851	合格
			UCL	2757592	
	≥5.0μm	≤29000	Amax	4087	
			UCL	9340	
器具间 (4.8m ²)	≥0.5μm	≤3520000	Amax	489293	合格
			UCL	1312093	
	≥5.0μm	≤29000	Amax	2661	
			UCL	8885	
洁具间 (4.1m ²)	≥0.5μm	≤3520000	Amax	1423121	合格
			UCL	2309341	
	≥5.0μm	≤29000	Amax	7620	
			UCL	25946	
实验室 (7.7m ²)	≥0.5μm	≤3520000	Amax	547043	合格
			UCL	1562729	
	≥5.0μm	≤29000	Amax	1048	
			UCL	2768	
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悬浮粒子数（粒/m³）

检测区域	技术要求		检测结果		单项判定
十万级净化车间 (156.3m ²)	≥0.5μm	≤3520000	Amax	89623	合格
			UCL	101556	
	≥5.0μm	≤29000	Amax	153	
			UCL	187	
十万级净化车间 (436.5m ²)	≥0.5μm	≤3520000	59021		合格
	≥5.0μm	≤29000	327		
备注	/				

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照度 (lx)

检测区域	技术要求		检测结果		单项判定
	平均照度	照度均匀度	平均照度	照度均匀度	
男一更（8.1m ² ）	≥200	≥0.7	545	0.8	合格
女一更（14.1m ² ）			766	0.9	合格
男二更（6.9m ² ）			525	0.8	合格
女二更（16.2m ² ）			695	0.8	合格
洗手消毒（10.9m ² ）			450	0.8	合格
器具间（4.8m ² ）			583	0.8	合格
洁具间（4.1m ² ）			651	0.8	合格
实验室（7.7m ² ）			426	0.8	合格
十万级净化车间（156.3m ² ）	≥300		951	0.8	合格
十万级净化车间（436.5m ² ）			621	0.8	合格
备 注	/				

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噪声 dB (A)			
检测区域	技术要求	检测结果	单项判定
男一更 (8.1m²)	≤60	57.8	合格
女一更 (14.1m²)		59.5	合格
男二更 (6.9m²)		58.3	合格
女二更 (16.2m²)		58.8	合格
洗手消毒 (10.9m²)		59.2	合格
器具间 (4.8m²)		59.3	合格
洁具间 (4.1m²)		59.2	合格
实验室 (7.7m²)		58.9	合格
十万级净化车间 (156.3m²)		58.6	合格
十万级净化车间 (436.5m²)		59.3	合格
备 注	/		

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温度 (℃)、相对湿度 (%)

检测区域	技术要求		检测结果		单项判定	
	温度	相对湿度	温度	相对湿度	温度	相对湿度
男一更（8.1m ² ）	18~26	45~65	23.0	58	合格	合格
女一更（14.1m ² ）			22.5	57	合格	合格
男二更（6.9m ² ）			23.1	58	合格	合格
女二更（16.2m ² ）			22.5	58	合格	合格
洗手消毒（10.9m ² ）			22.5	59	合格	合格
器具间（4.8m ² ）			22.6	57	合格	合格
洁具间（4.1m ² ）			22.9	59	合格	合格
实验室（7.7m ² ）			22.4	58	合格	合格
十万级净化车间（156.3m ² ）			22.8	56	合格	合格
十万级净化车间（436.5m ² ）			22.3	57	合格	合格
备 注	/					

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沉降菌（CFU/皿·0.5h）

检测区域	技术要求	检测结果	单项判定
男一更（8.1m²）	≤10	0.5	合格
女一更（14.1m²）		1	合格
男二更（6.9m²）		0	合格
女二更（16.2m²）		0.5	合格
洗手消毒（10.9m²）		0	合格
器具间（4.8m²）		0	合格
洁具间（4.1m²）		1	合格
实验室（7.7m²）		0.5	合格
十万级净化车间（156.3m²）		0.3	合格
十万级净化车间（436.5m²）		0.8	合格
备注	/		

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浮游菌（CFU/m ³ ）			
检测区域	技术要求	检测结果	单项判定
男一更（8.1m ² ）	≤500	5	合格
女一更（14.1m ² ）		2.5	合格
男二更（6.9m ² ）		7.5	合格
女二更（16.2m ² ）		2.5	合格
洗手消毒（10.9m ² ）		0	合格
器具间（4.8m ² ）		2.5	合格
洁具间（4.1m ² ）		2.5	合格
实验室（7.7m ² ）		0	合格
十万级净化车间（156.3m ² ）		3.3	合格
十万级净化车间（436.5m ² ）		1.9	合格

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检验检测报告说明

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安徽省德通检测技术有限公司

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Anhui Detong Testing Technology Co., Ltd.
Anhuisheng Detong Testing Technology Co.,Ltd

Report No.:AHDT-2025-049



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Inspection and Testing Report

Project Name:Comprehensive Cleanliness Performance Testing of a
Class 100,000 Cleanroom

client: Anhui Meirunkang Packaging Co., Ltd.

Inspected Entity: Anhui Meirunkang Packaging Co., Ltd.

Detection Category: Delegation of Testing

Anhui Detong Testing Technology Co., Ltd.

AnHui De Tong Testing Technology Co.,Ltd





Inspection and Testing Report

Report No.: AHDT-2025-049

Surveillance project	Comprehensive Cleanliness Performance Testing for Class 100,000 Cleanrooms	
Detection Type	Entrusted Testing	
Detection Parameters	Air change rate, static pressure differential, suspended particle count, noise level, illuminance, temperature, relative humidity, settling bacteria, airborne bacteria	
Client	Anhui Meirunkang Packaging Co., Ltd.	
Address of the commissioning entity	Building B9, Phase I, Wanjiang High-Tech Incubation Park, Laofeng Town, Yingjiang District, Anqing City	
Inspected Entity	Anhui Meirunkang Packaging Co., Ltd.	
Detection address	Building B9, Phase I, Wanjiang High-Tech Incubation Park, Laofeng Town, Yingjiang District, Anqing City	
Testing Agency	Anhui Detong Testing Technology Co., Ltd.	
Detection mode	☒ on-site test ☐ Sample Testing	
Inspection area (cleanliness level)	10 cleanrooms [all classified as Class D (i.e., Class 100,000)]	
Detection Status	Static state	
Inspection Date	2025. 06. 13~2025. 06. 15	
Inspection standard	"Code for Construction and Acceptance of Cleanrooms"(GB50591-2010)	
Evaluation Basis	"Design Code for Cleanrooms in the Pharmaceutical Industry"(GB50457-2019) "Code for Design of Cleanrooms"(GB50073-2013) "Production Management Specification for Sterile Medical Devices"(YY/T0033-2000)	
Primary Testing Equipment	Dust Particle Counter (AHDT-YQ-047)	Calibration validity date: 2026-02-04
	Differential pressure gauge (AHDT-YQ-017)	Calibration validity date: 2026-02-04
	Air Flow Meter (AHDT-YQ-008)	Calibration validity date: 2026-02-10
	Sound Level Meter (AHDT-YQ-042)	Calibration expiration date: October 29,2025
	Temperature and Humidity Tester (AHDT-YQ-040)	Calibration validity date: 2025-09-25
	Illuminance Meter (AHDT-YQ-024)	Calibration validity date: 2026-02-04
	Aerophilic Microorganism Sampler (AHDT-YQ-009)	Calibration validity date: 2026-02-04
Inspection and Testing Conclusions	Testing has confirmed that all measured parameters comply with the requirements of the evaluation criteria.	
Remarks	/	
Prepared by	<u>Xiao Wenbo</u>	肖文博
Examine and verify	<u>Xu Guanghong</u>	徐光宏
Ratify	<u>Zhang Yunxin</u>	张云新
(Special Seal for Inspection and Testing) Date of Issue: June 20, 2025 检验检测专用章		

Inspection and Testing Report

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Air Change Rate (times/h)

Surveyed area	Technical requirement	Detection result	Single-item assessment
Male subject 1 (8.1 m ²)	≥ 10	15.9	Qualified
Female Lead Actress (14.1 m ²)		11.2	Qualified
Second male lead (6.9 m ²)		18.8	Qualified
Female second character (16.2 m ²)		10.2	Qualified
Hand washing and disinfection (10.9 m ²)		11.8	Qualified
Equipment room (4.8 m ²)		27.6	Qualified
Sanitary ware room (4.1 m ²)		32.7	Qualified
Laboratory (7.7 m ²)		21.6	Qualified
Class 100,000 cleanroom (156.3 m ²)		10.2	Qualified
Class 100,000 cleanroom (436.5 m ²)		10.5	Qualified
Remarks	/		

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static pressure difference(Pa)

Surveyed area	Technical requirement		Detection result	Single-item assessment
Male subject 1 (8.1 m ²)	→ Non-clean area	≥5	5	Qualified
Female Lead Actress (14.1 m ²)	→ Non-clean area		5	Qualified
Laboratory (7.7 m ²)	→ Non-clean area		9	Qualified
Class 100,000 cleanroom (156.3 m ²)	→ Non-clean area		29	Qualified
Class 100,000 cleanroom (436.5 m ²)	→ Non-clean area		24	Qualified
Remarks	1			

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Number of Suspended Particles (particles/M³)

Surveyed area	Technical requirement		Detection result		Single-item assessment
Male subject 1 (8.1 m ²)	≥0.5 μm	≤3520000	Amax	1436713	Qualified
			UCL	1753906	
	≥5.0 μm	≤29000	Amax	1366	
			UCL	1991	
Female Lead Actress (14.1 m ²)	≥0.5 μm	≤3520000	Amax	593451	Qualified
			UCL	763196	
	≥5.0 μm	≤29000	Amax	4534	
			UCL	6755	
Second male lead (6.9 m ²)	≥0.5 μm	≤3520000	Amax	876525	Qualified
			UCL	1891335	
	≥5.0 μm	≤29000	Amax	4393	
			UCL	13431	
Female second character (16.2 m ²)	≥0.5 μm	≤3520000	Amax	2142885	Qualified
			UCL	2797816	
	≥5.0 μm	≤29000	Amax	7491	
			UCL	12088	
Hand washing and disinfection (10.9 m ²)	≥0.5 μm	≤3520000	Amax	1753851	Qualified
			UCL	2757592	
	≥5.0 μm	≤29000	Amax	4087	
			UCL	9340	
Equipment room (4.8 m ²)	≥0.5 μm	≤3520000	Amax	489293	Qualified
			UCL	1312093	
	≥5.0 μm	≤29000	Amax	2661	
			UCL	8885	
Sanitary ware room (4.1 m ²)	≥0.5 μm	≤3520000	Amax	1423121	Qualified
			UCL	2309341	
	≥5.0 μm	≤29000	Amax	7620	
			UCL	25946	
Laboratory (7.7 m ²)	≥0.5 μm	≤3520000	Amax	547043	Qualified
			UCL	1562729	
	≥5.0 μm	≤29000	Amax	1048	
			UCL	2768	
Remarks	/				

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2025-049 Number of suspended particles (particles/m³)

Surveyed area	Technical requirement		Detection result		Single-item assessment
Class 100,000 cleanroom (156. 3m²)	≥0. 5 μ m	≤3520000	Amax	89623	Qualified
			UCL	101556	
	≥5. 0 μ m	≤29000	Amax	153	
			UCL	187	
Class 100,000 cleanroom (436. 5m²)	≥0. 5 μ m	≤3520000	59021		Qualified
	≥5. 0 μ m	≤29000	327		
Remarks	/				

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Illuminance(lx)

Surveyed area	Technical requirement		Detection result		Single-item assessment
	Average illuminance	Uniformity of illuminance	Average illuminance	Uniformity of illuminance	
Male subject 1 (8.1 m ²)	≥200	≥0.7	545	0.8	Qualified
Female Lead Actress (14.1 m ²)			766	0.9	Qualified
Second male lead (6.9 m ²)			525	0.8	Qualified
Female second character (16.2 m ²)			695	0.8	Qualified
Hand washing and disinfection (10.9 m ²)			450	0.8	Qualified
Equipment room (4.8 m ²)			583	0.8	Qualified
Sanitary ware room (4.1 m ²)			651	0.8	Qualified
Laboratory (7.7 m ²)			426	0.8	Qualified
Class 100,000 cleanroom (156.3 m ²)			≥300		951
Class 100,000 cleanroom (436.5 m ²)	621	0.8			Qualified
Remarks	/				

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Inspection and Testing Report

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Noise DB(A)

Surveyed area	Technical requirement	Detection result	Single-item assessment
Male subject 1 (8.1 m ²)	≤60	57.8	Qualified
Female Lead Actress (14.1 m ²)		59.5	Qualified
Second male lead (6.9 m ²)		58.3	Qualified
Female second character (16.2 m ²)		58.8	Qualified
Hand washing and disinfection (10.9 m ²)		59.2	Qualified
Equipment room (4.8 m ²)		59.3	Qualified
Sanitary ware room (4.1 m ²)		59.2	Qualified
Laboratory (7.7 m ²)		58.9	Qualified
Class 100,000 cleanroom (156.3 m ²)		58.6	Qualified
Class 100,000 cleanroom (436.5 m ²)		59.3	Qualified
Remarks	/		

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Temperature (°C), Relative Humidity (%)

Surveyed area	Technical requirement		Detection result		Single-item assessment	
	Temperature	Relative humidity	Temperature	Relative humidity	Temperature	Relative humidity
Male subject 1 (8.1 m ²)	18~26	45~65	23.0	58	Qualified	Qualified
Female Lead Actress (14.1 m ²)			22.5	57	Qualified	Qualified
Second male lead (6.9 m ²)			23.1	58	Qualified	Qualified
Female second character (16.2 m ²)			22.5	58	Qualified	Qualified
Hand washing and disinfection (10.9 m ²)			22.5	59	Qualified	Qualified
Equipment room (4.8 m ²)			22.6	57	Qualified	Qualified
Sanitary ware room (4.1 m ²)			22.9	59	Qualified	Qualified
Laboratory (7.7 m ²)			22.4	58	Qualified	Qualified
Class 100,000 cleanroom (156.3 m ²)			22.8	56	Qualified	Qualified
Class 100,000 cleanroom (436.5 m ²)			22.3	57	Qualified	Qualified
Remarks	/					

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Inspection and Testing Report

Report No.:AHDT-2025-049

Settling bacteria (CFU/plate · 0.5H)

Surveyed area	Technical requirement	Detection result	Single-item assessment
Male subject 1 (8.1 m ²)	≤10	0.5	Qualified
Female Lead Actress (14.1 m ²)		1	Qualified
Second male lead (6.9 m ²)		0	Qualified
Female second character (16.2 m ²)		0.5	Qualified
Hand washing and disinfection (10.9 m ²)		0	Qualified
Equipment room (4.8 m ²)		0	Qualified
Sanitary ware room (4.1 m ²)		1	Qualified
Laboratory (7.7 m ²)		0.5	Qualified
Class 100,000 cleanroom (156.3 m ²)		0.3	Qualified
Class 100,000 cleanroom (436.5 m ²)		0.8	Qualified
Remarks	/		

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Inspection and Testing Report

Report No.: AHDT-2025-049

Free-Floating Bacteria(CFU/m³)

Surveyed area	Technical requirement	Detection result	Single-item assessment
Male subject 1 (8.1 m ²)	≤500	5	Qualified
Female Lead Actress (14.1 m ²)		2.5	Qualified
Second male lead (6.9 m ²)		7.5	Qualified
Female second character (16.2 m ²)		2.5	Qualified
Hand washing and disinfection (10.9 m ²)		0	Qualified
Equipment room (4.8 m ²)		2.5	Qualified
Sanitary ware room (4.1 m ²)		2.5	Qualified
Laboratory (7.7 m ²)		0	Qualified
Class 100,000 cleanroom (156.3 m ²)		3.3	Qualified
Class 100,000 cleanroom (436.5 m ²)		1.9	Qualified

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Report Finalized

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