



Performance Characteristics	Test Method	Acceptance Criteria	Results	
			Composition A	Composition B
Fluid Resistance Performance (mmHg)	ASTM F1862-07 – Standard Test Method for Resistance of Surgical Mask to Penetration by Synthetic Blood See Attachment 3.1	Low Barrier: 80	80mmHg Low Barrier	80mmHg Low Barrier
		Moderate Barrier: 120		
		High Barrier: 160		
Particulate Filtration Efficiency Performance (%)	ASTM F2299 – Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres See Attachment 3.2	Low Barrier: Not Required	98.8% High Barrier	98.6% High Barrier
		Moderate Barrier: >=98		
		High Barrier: >=98		
Bacterial Filtration Efficiency Performance (%)	ASTM F2101 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Surgical masks using a Biological Aerosol of Staphylococcus Aureus See Attachment 3.3	Low Barrier: >=95	99.2% High Barrier	99.1% High Barrier
		Moderate Barrier: >=98		
		High Barrier: >=98		
Differential Pressure (Delta-P)(mm H ₂ O/cm ²)	Differential Pressure (Delta-P) Test – MIL-M-36945C 4.4.1.1.1 Method 1 Military Specifications: Surgical Mask, disposable (June 12, 1975) See Attachment 3.3	Low Barrier: <4.0	2.9 High Barrier	2.9 High Barrier
		Moderate Barrier: <5.0		
		High Barrier: <5.0		
Flammability class Class I	Flammability Test Method: Standard for Flammability of Clothing Textiles See Attachment 3.4	Class I: Flame Spread ≥ 3.5 seconds	7.1 Class I High Barrier	8.5 Class I High Barrier

Table 6: Performance characteristics, test methods and acceptance criteria and/or results of bench testing procedures



FINAL REPORT

SYNTHETIC BLOOD PENETRATION RESISTANCE

PROCEDURE NO. STP0012 REV 03
PROTOCOL DETAIL SHEET NO. 200903491 REV 01

LABORATORY NO. 507286

PREPARED FOR:
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TO
TOT

Lab Number: 507296

Form No.	PDS Approval Form	Revision	200903491
Revision	1	Effective Date	
PREPARED FOR SPONSOR		LABORATORY/CONTRACTOR	
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WWW: www.mochigase.com		WWW: www.nelsonlab.com	
TEST METHOD AND/OR TEST SPECIFICATIONS			
PARENTAL DOCUMENT: Synthetic Blood Penetration Resistance, STP012.0			
SECTION: Microbiology			
ISSUE DATE: 26-Nov-2009		EXPIRATION DATE: 25-Nov-2011	
REVISION:			
No changes to the Standard Testing Protocol.			
METHOD DESCRIPTION:			
Test according to Standard Test Protocol.			
<input type="checkbox"/> Additional pages attached for product specifications. <input type="checkbox"/> No additional pages needed.			

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SIGNATURE: <i>Toshihisa Tsushima</i>	SIGNATURE: <i>Adam Fontana</i>
DATE: <i>Nov 27, 2009</i>	DATE: <i>21 Dec 2009</i>
PRINT NAME: Toshihisa Tsushima	PRINT NAME: Adam Fontana
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LAB NUMBER: 507296	FORM: <input type="checkbox"/> FOR-GLP <input type="checkbox"/> FOR-GLP



Mochigase Co., Ltd.
Lab Number 507296

Synthetic Blood Penetration Resistance

TABLE 1. Synthetic Blood Penetration Resistance
Sample Identification: 0475 / MPEA04
Test Pressure: 80 mm Hg

SAMPLE NUMBER	SYNTHETIC BLOOD PENETRATION	SAMPLE NUMBER	SYNTHETIC BLOOD PENETRATION
1	None Seen	17	None Seen
2	None Seen	18	None Seen
3	None Seen	19	None Seen
4	None Seen	20	None Seen
5	None Seen	21	None Seen
6	None Seen	22	None Seen
7	None Seen	23	None Seen
8	None Seen	24	None Seen
9	None Seen	25	None Seen
10	None Seen	26	None Seen
11	None Seen	27	None Seen
12	None Seen	28	None Seen
13	None Seen	29	None Seen
14	None Seen	30	None Seen
15	None Seen	31	None Seen
16	None Seen	32	None Seen



Mochigase Co., Ltd.
Lab Number 507296

Synthetic Blood Penetration Resistance

TABLE 2. Synthetic Blood Penetration Resistance
Sample Identification: 0475 / PS0020--EL70
Test Pressure: 80 mm Hg

SAMPLE NUMBER	SYNTHETIC BLOOD PENETRATION	SAMPLE NUMBER	SYNTHETIC BLOOD PENETRATION
1	None Seen	17	None Seen
2	None Seen	18	None Seen
3	None Seen	19	None Seen
4	None Seen	20	None Seen
5	None Seen	21	None Seen
6	None Seen	22	None Seen
7	None Seen	23	None Seen
8	None Seen	24	None Seen
9	None Seen	25	None Seen
10	None Seen	26	None Seen
11	None Seen	27	None Seen
12	None Seen	28	None Seen
13	None Seen	29	None Seen
14	None Seen	30	None Seen
15	None Seen	31	None Seen
16	None Seen	32	None Seen



FINAL REPORT

LATEX PARTICLE CHALLENGE

PROCEDURE NO. STP0005 REV 03
PROTOCOL DETAIL SHEET NO. 200903447 REV 01

LABORATORY NO. 501236

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Lab Number: 501236

		TITLE: PDS Approval Form NUMBER: 200903447 REVISION: 1
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PROTOCOL SPECIFICATIONS PARENTAL DOCUMENT: Latex Particle Challenge, STP0005, 3 SECTION: Aerobiology PDS INITIATION DATE: 20-Nov-2009 EXPIRATION DATE: 20-Nov-2011 REVISION: No changes to the Standard Testing Protocol. METHOD DESCRIPTION: Test according to Standard Test Protocol.		
<input type="checkbox"/> Additional pages attached to protocol specifications <input checked="" type="checkbox"/> No additional pages needed		

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FOR OFFICE USE ONLY LAB NUMBER: <i>501236</i> <input checked="" type="checkbox"/> PDA QLP <input type="checkbox"/> NON-QLP			



Mochigase Co., Ltd.
Lab Number 501236

Latex Particle Challenge

PFE (%) > 98%

TABLE 1. Results
Sample Identification: 0475 / PS0020--EL70

SAMPLE NUMBER	AVERAGE SAMPLE COUNTS	AVERAGE CONTROL COUNTS	FILTRATION EFFICIENCY (%)
1	148	10431	98.6
2	143	10541	98.6
3	117	10583	98.9
4	112	11648	99.04
5	174	12760	98.6

SAMPLE AREA TESTED: 91.5 cm²

PARTICLE SIZE: 0.1 µm (0.097 ± 0.003 µm)

AVERAGE FILTRATION EFFICIENCY: 98.8%

STANDARD DEVIATION: 0.20

Comply with requirements defined in:
U.S. ASTM F 2299 Standard: 98%
Chinese Standard Technical Requirements for Protective Face Mask for Medical Use YY 0469: 30%



FINAL REPORT
 BACTERIAL FILTRATION EFFICIENCY
 AND DIFFERENTIAL PRESSURE
 PROCEDURE NO. STP0004 REV 02
 PROTOCOL DETAIL SHEET NO. 200903324 REV 01
 LABORATORY NO. 501244

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Lab Number: 501237

FORM NO. 200903324		REVISION: 1
NELSON LABORATORIES PDS Approval Form		
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EMAIL: toshihisa@mol.mochigase.jp	PHONE: 011-81-850-872711	
FAX: 011-81-850-873888		
PROTOCOL SPECIFICATIONS		
PARENTAL DOCUMENT: BFE and Delta P Tests, STP004.2	SECTION: Aerobiology	
PDS IN EFFECT DATE: 12-Nov-2009	EXPIRATION DATE: 12-Nov-2011	
SOP/FORMS: No changes to the Standard Testing Protocol.		
METHODS/INSTRUMENTS: Test according to Standard Test Protocol.		
Additional pages attached for protocol specifications. No additional pages needed.		
The sponsor is responsible for bacteriostatic efficacy characterization. This includes, but is not limited to, sterility, strength, purity, and stability. "PLEASE SIGN, DATE, & RETURN TO NELSON LABORATORIES"		
SPONSOR APPROVAL:		NELSON LABS STUDY DIRECTOR APPROVAL:
SIGNATURE: <i>Toshihisa Mochigase</i>	DATE: <i>Mar 12 2010</i>	SIGNATURE: <i>Steve Galt</i>
DATE: <i>Mar 12 2010</i>	PRINT NAME: <i>Toshihisa Mochigase</i>	DATE: <i>Mar 12 2010</i>
PRINT NAME: <i>Toshihisa Mochigase</i>	PRINT NAME: <i>Steve Galt</i>	
FOR SERVICE USE ONLY		
LAB NUMBER: 501237	TEST TYPE: <input checked="" type="checkbox"/> PDA-GLP	<input type="checkbox"/> NON-GLP
SAMPLE ID: 0475	SAMPLE ID: PS0020-EL70	



Mochigase Co., Ltd.
 Lab Number 501237

Bacterial Filtration Efficiency
 and Differential Pressure

BFE(%) ≥ 99%

TABLE 1. Results
 Sample Identification: 0475 / PS0020-EL70

UNIT NUMBER	ΔP (mm H ₂ O/cm ²)	PERCENT BFE
1	2.6	99.1%
2	2.7	99.2%
3	2.9	99.5%
4	2.7	99.7%
5	2.8	99.7%

CONTROL AVERAGE: 2348 CFU

MEAN PARTICLE SIZE: 3.1 μm

Comply with requirements defined in:
 U.S. ASTM F 2299 Standard
 European Standard EN 14683 ≥ 98%
 Chinese Standard Technical Requirements for Protective Face Mask for Medical Use YY 0469 ≥ 95%



FINAL REPORT
FLAMMABILITY OF CLOTHING TEXTILES
PROCEDURE NO. STP0073 REV 03
PROTOCOL DETAIL SHEET NO. 200903287 REV 01
LABORATORY NO. 501241

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Mochigase Co., Ltd.
Lab Number 501241

Flammability of Clothing Textiles

TABLE 1. Results
Sample Identification: 0475 / MPEA04
Flammability: Type A, Class 1 – Average sample flame spread is $\geq 3 \frac{1}{2}$ seconds.

REPLICATE NUMBER	TIME OF FLAME SPREAD (in seconds)
1	6.7
2	7.5
3	7.3
4	8.1
5	6.1
Average	7.1

Qualified:
U.S. 16 CFR Part 1610 Standard for the Flammability of Clothing: Class I



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Lab Number 501237

Bacterial Filtration Efficiency
and Differential Pressure

TABLE 1. Results
Sample Identification: 0475 / PS0020-EL70

UNIT NUMBER	ΔP (mm H ₂ O/cm ²)	PERCENT BFE
1	2.6	99.1%
2	2.7	99.2%
3	2.9	99.5%
4	2.7	99.7%
5	2.8	99.7%

CONTROL AVERAGE: 2348 CFU
MEAN PARTICLE SIZE: 3.1 μ m

Qualified:
U.S. Standard 4.4.1.2 of MIL-M-36954C (8.0LPM)
European Standard EN14683 < 49 Pa/cm² Highest Level
China Standard Technical Requirements for Protective Face Mask for Medical Use
YY 0469 < 49 Pa/cm²