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Submitted By
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LATEX PARTICLE CHALLENGE – FINAL REPORT

Laboratory Number:	470531
Procedure Number:	STP0005 REV 02
Sample Source:	SiHong Tengda Nonwovens Co. Ltd.
Sample Identification:	Refer to Table 1
Deviations:	None
Statement of Uncertainty:	If applicable, available upon request
Sample Received Date:	08 Apr 2009
Lab Phase Start Date:	21 Apr 2009
Lab Phase Completion Date:	22 Apr 2009
Report Issue Date:	23 Apr 2009

Procedure: The Latex Particle Challenge procedure is performed to determine the particle filtration efficiency of various materials and filtration devices using a challenge of monodispersed polystyrene (latex) microspheres obtained from Duke Scientific, Palo Alto, CA.

The procedure employed the basic test method described in ASTM F2299, but incorporates a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. The flow rate through the test system was maintained at 1 CFM \pm 5%. The control particle concentration passed through the sample was maintained at 10,000-15,000 particles per cubic foot. Filtration efficiencies are calculated by comparison to control values.

Results: A reference control was included to verify the test system was within acceptable control limits. The results are summarized in Table 1.


Adrienne Sandall, B.S.
Study Director


27 Apr 2009
Study Completion Date

JZW

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TABLE 1. Results
Sample Identification: TD-P25

SAMPLE NUMBER	AVERAGE SAMPLE COUNTS	AVERAGE CONTROL COUNTS	FILTRATION EFFICIENCY
1	7	10972	99.936%
2	8	10634	99.928%
3	7	10470	99.930%
4	7	11410	99.942%
5	7	12877	99.948%

SAMPLE AREA TESTED: 91.5 cm²

PARTICLE SIZE: 0.1 μ m (0.097 \pm 0.003 μ m)

PARTICLE BACKGROUND: <1 particles/min

AVERAGE FILTRATION EFFICIENCY: 99.937%

STANDARD DEVIATION: 0.0084

検査会社: ネルソンラボラトリー社
 米国ユタ州ソルトレイク市

ラテックス微粒子濾過効率 — 最終レポート

実験番号	470531
手順番号	STP0005 REV 02
試料元	
試料内容	図 1 参照
試料受け取り日	2009年4月8日
実験開始日	2009年4月21日
実験終了日	2009年4月22日
レポート発行日	2009年4月23日

手順: ラテックスの微粒子測定方法は、カリフォルニア州のデュークサイエンティフィック社から購入した単分散ポリスチレン(ラテックス)の微粒子を使って、各種材料や濾過器具の微粒子濾過効率を調べます。

この手順はASTM F2299にある基本的なテスト方法を応用したが、微粒子は電荷をもっているのでこの捕集はより自然な状態を表しています。非中性されたエアロゾルもサージカルマスクに関するFDAの指導書に明記されています。テストシステムに対する流量割合は、1CFM ± 5% に保たれています。試料を通過する微粒子の濃度は1キュービックフィートあたり10,000から15,000 粒子になっています。濾過効率は捕集値との比較によって計算されます。

結果: テストシステムは受容範囲であることが照明された。その概要は図1を参照してください。

図 1 結果
 試料内容: TD-P25

試料数	試料計測 平均	捕集計測 平均	濾過効率
1	7	10972	99.936%
2	8	10634	99.928%
3	7	10470	99.930%
4	7	11410	99.942%
5	7	12877	99.948%

テストした試料の範囲 91.5 cm²
 微粒子のサイズ: 0.1µ m (0.097 ± 0.003 µ m)
 微粒子の背景: <1微粒子/分
 濾過効率平均: 99.937%
 標準誤差: 0.0084


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**BACTERIAL FILTRATION EFFICIENCY
AND DIFFERENTIAL PRESSURE - FINAL REPORT**

Laboratory Number:	391205
Procedure Number:	STP0004 REV 02
Sample Source:	TengDa Nonwovens Co., Ltd.
Sample Identification:	Refer to Table 1
Deviations:	None
Statement of Uncertainty:	If applicable, available upon request
Andersen Sampler Flow Rate:	28.3 L/min. (1 CFM)
BFE Conditioning:	4 hours minimum at 21 ± 5°C and 85 ± 5% relative humidity
Sample Received Date:	23 Aug 2007
Lab Phase Start Date:	27 Aug 2007
Lab Phase Completion Date:	05 Sep 2007
Report Issue Date:	06 Sep 2007
Results:	Refer to Table 1

The Bacterial Filtration Efficiency (BFE) procedure is performed to determine the filtration efficiency of various materials and filtration devices using a challenge organism of *Staphylococcus aureus*. This procedure complies with ASTM F2101. The Differential Pressure (Delta P or ΔP) test is performed to determine the air exchange differential (breathability) of porous materials.



Technical Reviewer



Stacey Cushing, B.S.
Study Director

06 Sep 2007

Study Completion Date



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TABLE 1. Results

SAMPLE IDENTIFICATION	ΔP (mm H ₂ O/cm ²)	PERCENT BFE
PZZ02602XB - 1	1.8	99.9%
PZZ02602XB - 2	1.9	>99.9%*
PZZ02602XB - 3	1.8	99.9%
PZZ02602XB - 4	1.9	>99.9%*
PZZ02602XB - 5	1.8	99.7%

CONTROL AVERAGE: 2358 CFU

MEAN PARTICLE SIZE (MPS): 3.1 μ m

* There were no detected colonies on any of the Andersen sampler plates for this sample.

検査会社: ネルソンラボラトリー社
 米国ユタ州ソルトレイク市

バクテリア濾過効率と圧力差 — 最終レポート

実験番号	391205
手順番号	STP0004 REV 02
試料元	
試料内容	図 1 参照
アンダーセンサンプラー流量割合	28.3 L / 分 (1 CFM)
BFEの条件	温度 21±5°C、湿度 85±5% で最低4時間
試料受け取り日	2007年8月23日
実験開始日	2007年8月27日
実験終了日	2007年9月5日
レポート発行日	2007年9月6日
結果	図 1 参照

バクテリア濾過効率 (BFE) の検査は黄色ブドウ球菌の免疫体を使って、種々の材料や濾過装置の濾過効率を調べます。この手順は ASTM F2101 に従っています。圧力差 (デルタP 又は ΔP) テストは浸透性の材料の空気透過性 (呼吸可能度) を調べるために行います。

図 1 結果

試料内容	ΔP (mm H ₂ O/cm ²)	BFE パーセント
PZZ02602XB-1	1.8	99.9%
PZZ02602XB-2	1.9	>99.9%
PZZ02602XB-3	1.8	99.9%
PZZ02602XB-4	1.9	>99.9%
PZZ02602XB-5	1.8	99.7%

コントロール平均: 2358 CFU
 微細粒子のサイズ(MPS) 3.1μ m

* この試料のアンダーセンサンプラーの盤上にはコロニー(細菌群体)は検知されなかった。