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FINAL REPORT

NEEDLE FREE IV CONNECTOR SYSTEMS FLUID DISPLACEMENT TEST

PROTOCOL NO. 200409004-05

LABORATORY NO. 315124

PREPARED FOR:

JIM KAISER
RYMED TECHNOLOGIES, INC.

SUBMITTED BY:

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06 Jan 2006

Jim Kaiser
Rymed Technologies, Inc.
6613 Alberta Cove
Austin, TX 78739

Dear Jim:

This letter regards the sample identification of the Needle Free IV Connector Systems Fluid Displacement Test performed for Rymed Technologies, Inc. under Nelson Laboratory number 315124. In an effort to remain independent and provide unbiased test results we have coded the sample identification of the comparison samples you submitted. For your reference, I have included the coding below:

Original ID	**Coded ID**
ICU Medical MicroClave	Comparison Sample A

If you have any questions or concerns with this information or its presentation, please let me know. Thank you for testing with Nelson Laboratories, Inc.

Sincerely,

Marissa E. Edgmand
Report Specialist

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NEEDLE FREE IV CONNECTOR SYSTEMS FLUID DISPLACEMENT TEST

LABORATORY NUMBER:	315124
PROTOCOL NUMBER:	200409004-05
SAMPLE SOURCE:	RyMed Technologies, Inc.
SAMPLE IDENTIFICATION:	Comparison Sample A P.O. #7356
DEVIATIONS:	None
DATA ARCHIVE LOCATION:	Sequentially by lab number
PROTOCOL APPROVAL DATE:	13 Dec 2005
SAMPLE RECEIVED DATE:	23 Dec 2005
LAB PHASE START DATE:	30 Dec 2005
LAB PHASE COMPLETION DATE:	30 Dec 2005
REPORT ISSUE DATE:	06 Jan 2006

INTRODUCTION:

This test was performed to determine the positive and negative movement of fluid through a catheter upon connection and disconnection of each test sample from an I.V. line.

ACCEPTANCE CRITERIA:

This was a functionality test.

PROCEDURE:

Test Set Up: A 250 mL bag of normal saline was hung above the I.V. line and test sample. Red coloring was injected at 2 mL per bag of saline. The I.V. line was attached to the bag of saline. The drip chamber on the I.V. line was squeezed to fill the chamber half full of red saline fluid. The roller clamp was opened to completely prime the I.V. set. The I.V. connector sample was attached to the microbore tubing. The I.V. set was connected to the sample. The roller clamp was opened to prime the I.V. connector sample and microbore tubing. The roller clamp was left opened as the I.V. line was disconnected from the connector sample. This action fully primed the microbore tubing to the distal end.

I.V. Line Connector Attachment: After the tubing was primed, the I.V. line was connected to the test sample. The amount of fluid movement was measured with a balance, ruler, or micrometer. The line was re-primed for the next sample. The I.V. line connector attachment phase was performed in triplicate.

I.V. Line Connector Detachment: With the I.V. line attached to the test sample, the microbore tubing was primed to the distal end. The I.V. line was detached from the test sample. The amount of fluid movement was measured with a balance, ruler, or micrometer. The line was re-primed for the next sample. The I.V. line connector attachment phase was performed in triplicate.

Statistical Analysis of Results: The percent relative standard deviation (%RSD) was calculated for each set of replicates from each sample. Then the %RSD was calculated for the attachment and detachment results.

RESULTS:

The results are presented in Table 1.

Michelle Lee, B.S. RM(NRM)
Biocompatibility Section Leader

Audrey P. Turley, B.S. RM(NRM)
Study Director

Study Completion Date

APT/mlb

TABLE 1. Comparison Sample A

Sample	DETACHMENT (-)					ATTACHMENT (+)				
	Replicate #1	Replicate #2	Replicate #3	Mean (mL)	%RSD	Replicate #1	Replicate #2	Replicate #3	Mean (mL)	%RSD
1	0.027	0.032	0.029	0.0291	7.0	0.009	0.016	0.013	0.0127	22.6
2	0.019	0.026	0.032	0.0257	19.5	0.016	0.012	0.012	0.0133	14.1
3	0.026	0.029	0.032	0.0293	8.0	0.011	0.009	0.010	0.0100	8.2
OVERALL				0.0280	11.5304	OVERALL			0.0120	14.9816

(-) Negative fluid movement.
(+) Positive fluid movement.