



FINAL REPORT

NEEDLE FREE IV CONNECTOR SYSTEMS FLUID DISPLACEMENT TEST

PROTOCOL NO. 200409004-04

LABORATORY NO. 301988

PREPARED FOR:

JIM KAISER
RYMED TECHNOLOGIES, INC.

SUBMITTED BY:

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NELSON LABORATORIES, INC.

STUDY DIRECTOR GLP CERTIFICATION

USFDA (21 CFR PART 58)

USEPA (40 CFR PART 160)

NEEDLE FREE IV CONNECTOR SYSTEMS FLUID DISPLACEMENT TEST

I CERTIFY THAT THE TEST WAS CONDUCTED IN ACCORDANCE
WITH THE USFDA OR USEPA REGULATIONS AS NOTED ABOVE.

LABORATORY NO. 301988

STUDY DIRECTOR: Audrey Gurley DATE: 16 Sep 2005



NELSON LABORATORIES, INC.

QAU AUDIT STATEMENT

[X] USFDA (21 CFR PART 58)

[] USEPA (40 CFR PART 160)

NEEDLE FREE IV CONNECTOR SYSTEMS FLUID DISPLACEMENT TEST

Study Director:

Final Report Dated:

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

16 Sep 2005

1. The test was conducted in accordance with the USFDA or USEPA Regulations as noted above. All laboratory results pertaining to this study are recorded in Nelson Laboratories' Data File Number 301988.
2. In accordance with the Good Laboratory Practice Regulations, the IV Line Connector Attachment phase(s) of this study was inspected by the Quality Assurance Unit on: 08 Sep 2005. The findings of the inspection(s) were reported to Management and to the Study Director on: 16 Sep 2005.
3. The Quality Assurance Unit has reviewed this report and has determined that the methods and standard operating procedures are accurately described, and that the reported results accurately reflect the raw data.
4. The name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel, involved in the study:

Michelle Lee
Audrey Turley

Dr. Jerry Nelson
Jeff Hills

QUALITY ASSURANCE: *Jessica D. Anderson* DATE: 16 Sep 2005



NEEDLE FREE IV CONNECTOR SYSTEMS FLUID DISPLACEMENT TEST

LABORATORY NUMBER:	301988
PROTOCOL NUMBER:	200409004-04
SAMPLE SOURCE:	RyMed Technologies, Inc.
SAMPLE IDENTIFICATION:	Needle Free I.V. Connector Fluid Displacement - InVision-Plus RYM - 3000 Lot #311 P.O. #7304
DEVIATIONS:	None
DATA ARCHIVE LOCATION:	Sequentially by lab number
PROTOCOL APPROVAL DATE:	07 Sep 2005
SAMPLE RECEIVED DATE:	26 Aug 2005
LAB PHASE START DATE:	07 Sep 2005
LAB PHASE COMPLETION DATE:	09 Sep 2005
REPORT ISSUE DATE:	16 Sep 2005
TOTAL NUMBER OF PAGES:	9

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. The sponsor will compare this data to historical data.

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 into the bag of saline at 2 mL red coloring 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. All bubbles were removed from the Y-Site then the roller clamp was closed. 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 on 11 different samples at five replicates per sample.

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 on 11 different samples at five replicates per sample.

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:

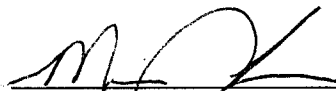
The results are presented in Tables 1 and 2. The results are summarized in Table 3.

CONCLUSION:

Interpretation of the data is the responsibility of the sponsor and no conclusion can be made by Nelson Laboratories, Inc.

STATEMENT OF UNCERTAINTY:

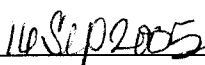
If applicable, the statement of uncertainty is available to sponsors upon request.



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



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



Study Completion Date

TABLE 1. I.V. Line Detachment for RyMed Sample

Sample	Replicate #1	Replicate #2	Replicate #3	Replicate #4	Replicate #5	Mean (mL)	%RSD*
1	0.003 mL	0.003 mL	0.002 mL	0.001 mL	0.000 mL	0.0019	70.7
2	0.001 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0001	200.0
3	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0000	ERR
4	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0000	ERR
5	0.000 mL	0.001 mL	0.000 mL	0.000 mL	0.000 mL	0.0002	200.0
6	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0000	ERR
7	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0000	ERR
8	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0000	ERR
9	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0000	ERR
10	0.000 mL	0.000 mL	0.000 mL	0.002 mL	0.000 mL	0.0003	200.0
11	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0000	ERR
OVERALL						0.0002	ERR

* Percent RSD values are high due to the small numbers in the data used to perform the calculation.

TABLE 2. I.V. Line Attachment for RyMed Sample

Sample	Replicate #1	Replicate #2	Replicate #3	Replicate #4	Replicate #5	Mean (mL)	%RSD*
1	0.006 mL	0.000 mL	0.001 mL	0.000 mL	0.000 mL	0.0014	166.6
2	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0000	ERR
3	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0000	ERR
4	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0000	ERR
5	0.011 mL	0.010 mL	0.000 mL	0.003 mL	0.000 mL	0.0048	99.8
6	0.000 mL	0.007 mL	0.003 mL	0.000 mL	0.022 mL	0.0064	128.3
7	0.011 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0022	200.0
8	0.000 mL	0.000 mL	0.000 mL	0.006 mL	0.013 mL	0.0038	135.6
9	0.006 mL	0.009 mL	0.000 mL	0.010 mL	0.002 mL	0.0054	71.8
10	0.000 mL	0.000 mL	0.000 mL	0.003 mL	0.000 mL	0.0006	200.0
11	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0000	ERR
OVERALL						0.0022	ERR

* Percent RSD values are high due to the small numbers in the data used to perform the calculation.

TABLE 3. Summary of Results

SAMPLE	ATTACHMENT (AVG.)	DETACHMENT (AVG.)
InVision-Plus	0.0022 mL (+)	0.0002 mL (-)

(-) Negative fluid movement

(+) Positive fluid movement



RyMed Technologies, inc.
Lab Number 301988

Needle Free IV Connector Systems Fluid Displacement Test
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