



January 21<sup>th</sup> 2008

To: XX

From: I. Vande Velde

Reference: 2007-021

Cc: XX

**Re: IH monitoring during surrogate testing of dispensing isolator Walker Barrier Systems (S/N 33583-1) in the Pharmacy (V2, room 112), November 2<sup>nd</sup>, 21<sup>st</sup> and 30<sup>th</sup> (background) and December 21<sup>st</sup> (test) 2007**

Executive summary

*June 5<sup>th</sup> 2007, the factory acceptance test of the dispensing isolator was done in New Lisbon (see report 2007-010). In the mean time, the dispensing isolator is installed on site in Vacaville. On December 21<sup>st</sup> 2007, a surrogate test (Mannitol) was performed.*

*The results of this surrogate test confirm the good results that were obtained during the factory acceptance test.*

*Mannitol was only detected in some of the wipe samples.*

*Actions:*

- *Additional sampling will be performed during the cleaning validation, where the actives instead of a surrogate will be used (done).*
- *Because some product was detected in some of the wipe samples:*
  - *Operators need to wipe the surface of the beta-containers after undocking;*
  - *Special attention is needed to make sure the inside border of the Boyer door is cleaned well;*
  - *A fixed connection to the drain must be considered to avoid splashes of water contaminated with the actives.*

1. Aim of the monitoring

June 5<sup>th</sup> 2007, the factory acceptance test of the dispensing isolator was done in New Lisbon (see report 2007-010).

In the mean time, the dispensing isolator is installed on site in Vacaville.

On December 21<sup>st</sup> 2007, a surrogate test (Mannitol) was performed. The protocol described in note N07-004 was used as a guideline for this test.

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## 2. Equipment

### 2.1. *Sampling pumps*

See attachment 1. for the detailed calibration information of the pumps.

Filters: Glass fiber filter (IOM 2)  
Sampling device: IOM, SKC Ltd.

### 2.2. *Wipe samples*

Filters: 7 cm glass fiber filters (November 21<sup>st</sup> and 30<sup>th</sup>) or TX714 large alpha swabs (December 21<sup>st</sup>).

Solvent: deionized water.

## 3. Process description, sampling approach and analysis

See some pictures in attachment 3.

### 3.1. *Process description, sampling approach and analysis*

To make sure the room was free of contamination with Mannitol before start of the test, background air samples were collected in room 112.

Additionally, some wipe samples were taken of the beta-container after the closed bags with Mannitol were transferred into this beta-container.

Because the results of these wipe samples were not as good as expected, the beta-container was cleaned another time very thoroughly before wipes were taken again.

The operators simulated a dispensing activity with the Mannitol (scoop Mannitol from one bag into another inside the isolator). The different transfer ports were used to challenge the containment of the isolator as much as possible. Afterwards, the operators soiled the isolator to prepare the isolator for a cleaning test.

The isolator was cleaned, first with the spray balls, followed by a manual spray, squeegee, drying with compressed air, drying with tissues and final cleaning with IPA wipes.

Personal air samples were collected for both operators during these tasks.

Additionally, some area samples were taken at critical locations near the isolator as described in note N07-004.

The sampling was stopped just before the isolator was opened. A new personal sample was started for both operators to check the exposure once the isolator was opened after the cleaning.

Because the activities were performed with a non-active compound, operators were wearing the standard GMP gowning.

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### 3.2. Analysis

The samples were analysed by Bureau Veritas.  
A high pressure liquid chromatography method was used (NAT-2001-00441).

## 4. Results background sampling

### 4.1. Air samples 11.02.2007 (all area samples)

<i>Nr.</i>	<i>Location</i>	<i>Pump</i>	<i>Dur. (min)</i>	<i>Conc. (<math>\mu\text{g}/\text{m}^3</math>)</i>
27075006	Within 6 inches of the alpha port at the bottom right side of the isolator - right back corner	X1007	188	< 0.0026
27075012	Within 6 inches of the alpha port at the bottom left side of the isolator - left back corner	X1004	195	< 0.0025
27075030	In middle of room on ground	SN 00714 (VV5)	183	< 0.0027
27075018	Right side isolator (+/- 80 cm height)	X1003	190	< 0.0026
27075015	Left wall room - middle - +/- 80 cm height	X1006	188	< 0.0026
27075029	Back wall room - right side from emergency door - +/- 80 cm height	SN 00787 (VV3)	181	< 0.0027
27075009	Next to eye wash station - +/- 80 cm height	X1005	189	< 0.0026

### 4.2. Wipe samples (11.21.07 and 11.30.07)

<i>Nr.</i>	<i>Location</i>	<i>Concentration (<math>\mu\text{g}/\text{swab}</math>)</i>	<i>Concentration (<math>\mu\text{g}/100 \text{ cm}^2</math>)*</i>
<b>11.21.07</b>			
1	Blank	< 0.1	-
2	Top beta-canister 350 mm (= 961 cm <sup>2</sup> )	5.9	0.61
3	Side 1 (300 cm <sup>2</sup> )	0.57	0.19
4	Side 2 (300 cm <sup>2</sup> )	0.2	0.07
5	Handles (100 cm <sup>2</sup> )	0.9	0.9
<b>11.30.07 (retest after thoroughly cleaning)</b>			
27228466	Blank	< 0.1	-
27228471	Top beta-canister 350 mm (= 961 cm <sup>2</sup> )	0.25	0.026
27223341	Side 1 (300 cm <sup>2</sup> )	< 0.1	< 0.033
27228465	Side 2 (300 cm <sup>2</sup> )	< 0.1	< 0.033
27228472	Handles (100 cm <sup>2</sup> )	< 0.1	< 0.1

\* Limits wipe samples are expressed as  $\mu\text{g}/100 \text{ cm}^2$ .

## 5. Results test

### 5.1. Air samples (12.21.2007)

<i>Nr.</i>	<i>Activity</i>	<i>Pump</i>	<i>Dur. (min)</i>	<i>Conc. (<math>\mu\text{g}/\text{m}^3</math>)</i>
<i>Area samples</i>				
27079546	Within 6 inches of the alpha port at the bottom left side of the isolator - left back corner	SN 00791 (VV1)	174	< 0.0029
27079535	Within 6 inches of the alpha port at the bottom left	SN 00787 (VV3)	194	< 0.0026

	side of the isolator - right side			
27079537	Within 6 inches of the alpha port at the bottom right side of the isolator - left side	SN 00714 (VV5)	193	< 0.0026
27079533	Within 6 inches of the alpha port at the bottom right side of the isolator - right back corner	624200	190	< 0.0026
27079551	Within 6 inches of the alpha port on the left side of the isolator - above	X1005	190	< 0.0026
27085127	Within 6 inches of the alpha port on the left side of the isolator - underneath	X1003	190	< 0.0026
27085130	Within 6 inches of the Boyer door on the right side of the isolator - above	SN 00782 (VV2)	190	< 0.0026
27079543	Within 6 inches of the Boyer door on the right side of the isolator - underneath	X1004	190	< 0.0027
27079538	Next to the exhaust discharge	624214	217	< 0.0023
27079541	Within 6 inches of the isolator sphincter port	SN 00695 (VV4)	190	< 0.0026
27079534	Left of 2 <sup>nd</sup> glove from right side	624280	185	< 0.0028
27079552	Right of 2 <sup>nd</sup> glove from left side: ackground - stopped when activities with Mannitol started	624277	95	< 0.0053
27079547	Right of 2 <sup>nd</sup> glove from left side: started when activities with Mannitol started	624277	125	< 0.004
27085084	Near drain	624210	108	< 0.0046
27085102	Blank	-		< 0.001 on filter
<b>Personal samples</b>				
27079539	Personal - operator 1 - activities with closed isolator	X1007	88	< 0.0038
27085106	Personal - operator 1 - started when isolator opened after cleaning	X1007	23	< 0.021
27075027	Personal - operator 2 - activities with closed isolator	X1006	89	< 0.0038
27079550	Personal - operator 2 - started when isolator opened after cleaning	X1006	24	< 0.021

### 5.2. Wipe samples

<b>Nr.</b>	<b>Location</b>	<b>Concentration (µg/swab)</b>	<b>Concentration (µg/100 cm<sup>2</sup>)</b>
27223343	Next to drain	8.2	8.2
27223344	Blank	< 0.1	< 0.1
27228468	Interior beta-canister used to transfer cleaning materials after opening to refill with cleaning materials	< 0.1	< 0.1
27223347	Around glove right side isolator	< 0.1	< 0.1
27228467	Inside border Boyer door (after cleaning)	0.46	0.46
27228469	Top beta-canister 350 mm (= 961 cm <sup>2</sup> )	96	9.9

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## 6. Discussion

In none of the air samples Mannitol was detected.

Based on the statistical analysis on the 2 personal samples with the isolator in closed condition, no respiratory protection is needed while working with actives in the isolator (with more than 95 % confidence) (see details in attachment 4.).

In some of the wipes Mannitol was detected.

## 7. Conclusion

The results of this surrogate test confirm the good results that were obtained during the factory acceptance test (see report 2007-010).

Mannitol was only detected in some of the wipe samples.

### *Actions:*

- Additional sampling will be performed during the cleaning validation, where the actives instead of a surrogate will be used (done).
- Because some product was detected in some of the wipe samples:
  - Operators need to wipe the surface of the beta-containers after undocking;
  - Special attention is needed to make sure the inside border of the Boyer door is cleaned well;
  - A fixed connection to the drain must be considered to avoid splashes of water contaminated with the actives.

Kind regards,

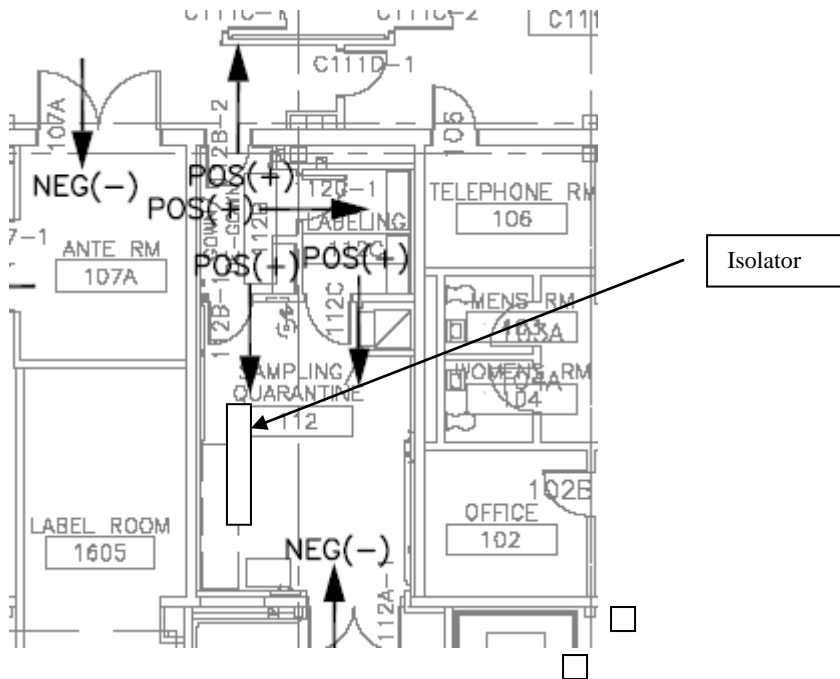


Ingrid Vande Velde

- + attachment 1: Layout Pharmacy
- + attachment 2: Calibration data of the pumps
- + attachment 3: Pictures
- + attachment 4: Statistics
- + attachment 5: Analytical laboratory reports Bureau Veritas:  
508642 - 511452 - 511453 - 506993
- + attachment 6: Industrial hygiene field data sheets (in original report only)
- + attachment 7: Note N07-004 (in original report only)

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## Attachment 1: Layout room 112



## Attachment 2: Calibration data of the pumps

Type	Number	Flow before (l/min)	Date	Flow after (l/min)	Date	Average flow (l/min)
<b>Background 11.02.07</b>						
Gilair 5	20070901007	2.029	1102.07	2.065	11.02.07	2.047
Gilair 5	20070901004	2.062	1102.07	2.100	1102.07	2.081
SKC Aircheck 2000	SN 00714 (VV5)	1.981	1102.07	2.017	1102.07	1.999
Gilair 5	20070901003	2.023	1102.07	2.100	1102.07	2.062
Gilair 5	20070901006	2.039	1102.07	2.090	1102.07	2.065
SKC Aircheck 2000	SN 00787 (VV3)	2.032	1102.07	2.048	1102.07	2.040
Gilair 5	20070901005	2.047	1102.07	2.070	1102.07	2.058
<b>Test 12.21.07</b>						
SKC Aircheck 2000	SN 00791 (VV1)	1.973	12.20.07	2.024	12.21.07	1.999
SKC Aircheck 2000	SN 00787 (VV3)	2.000	12.20.07	1.999	12.21.07	2.000
SKC Aircheck 2000	SN 00714 (VV5)	1.994	12.20.07	2.020	12.20.07	2.007
SKC Aircheck 52	624200	1.999	12.20.07	2.000	12.21.07	2.000
Gilair 5	20070901005	2.027	12.20.07	2.068	12.20.07	2.048
Gilair 5	20070901003	2.014	12.20.07	2.035	12.21.07	2.025
SKC Aircheck 2000	SN 00782 (VV2)	2.014	12.20.07	2.044	12.20.07	2.029
Gilair 5	20070901004	1.977	12.20.07	1.993	12.20.07	1.985
SKC Aircheck 52	624214	2.006	12.20.07	1.999	12.21.07	2.003
SKC Aircheck 2000	SN 00695 (VV4)	1.978	12.20.07	2.014	12.21.07	1.996
SKC Aircheck 52	624280	1.969	12.20.07	1.932	12.21.07	1.951
SKC Aircheck 52	624277	2.011	12.20.07	1.957	12.21.07	1.984
SKC Aircheck 52	624210	2.007	12.20.07	1.993	12.21.07	2.000
Gilair 5	20070901007	2.048	12.20.07	2.068	12.21.07	2.058
Gilair 5	20070901006	1.986	12.20.07	2.054	12.21.07	2.020

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Attachment 3: Pictures



Background air sampling in room



Cleaning bin before 2<sup>nd</sup> cycle wipe samples



Sample locations during test



Soiling of isolator with Mannitol



Cleaning isolator

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## Attachment 4: Statistics on personal samples closed isolator

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Version: IHDataAnalyst V1.0  
Date: 1/23/2008 4:32:14 PM  
File: H:\Vacaville\Reports IH\Reports IH 2007\Statistics\2007-021.xls

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### FACILITY INFORMATION

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Facility: Vacaville (Alza - GPSG)  
Department: Pharmacy  
Building: V2, room 112  
Process: Dispensing  
Task: Dispensing Mannitol in isolator and cleaning (surrogate test) - closed isolator

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### SUBSTANCE INFORMATION

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Substance: Mannitol  
OEL: 0.05 ug/m<sup>3</sup>

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### COMMENTS

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DEL of 0.05 ug/m<sup>3</sup> was used as OEL

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### EXPOSURE ASSESSMENT SUMMARY

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Final Rating:  
Certainty Level:  
Start Date:

Final APF:  
Certainty Level:  
Start Date:

Final Rating w/ PPE:  
Certainty Level:

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### CENSORED DATA INFORMATION

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Total n =	2	
(Num. >= LOD) =	0	0 % uncensored
(Num. < LOD) =	2	100 % censored
(Num. unique LODs) =	1	
(Max LOD) =	0.0038	

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### GOODNESS-OF-FIT TEST

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Note: Dataset is censored. GOF test may be misleading.  
Subjective Analysis:  
Do the data appear to be (reasonably) lognormal?  
Comments:

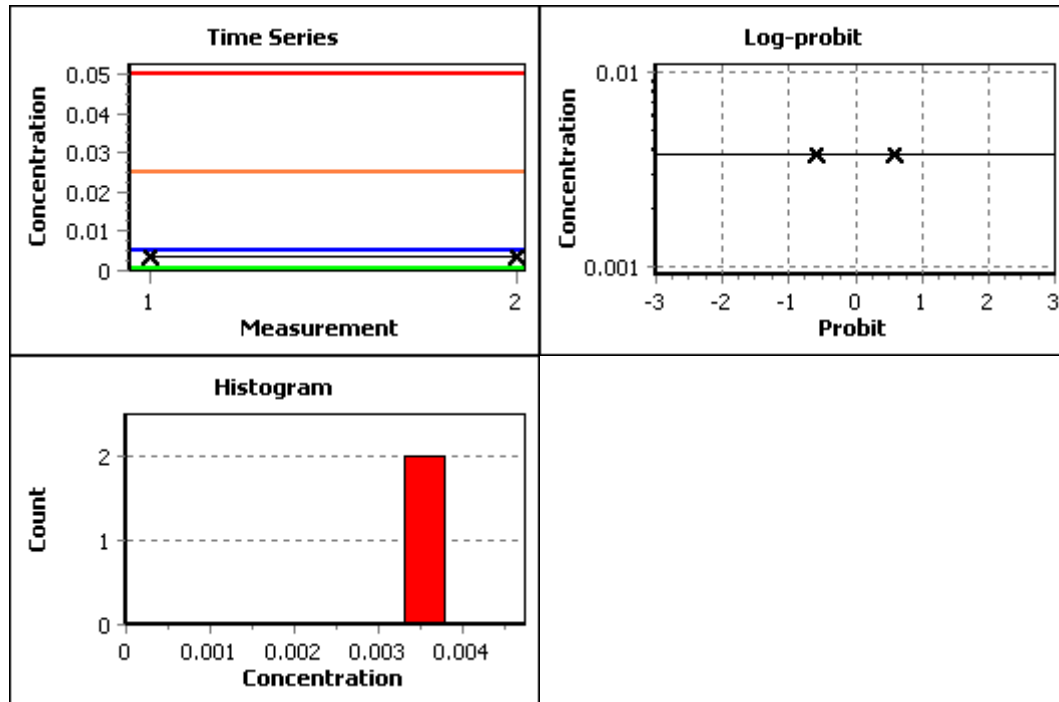
Objective Analysis:  
Note: n<3, cannot do GOF test  
Comments:

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Goodness-of-fit Charts:



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ORDER STATISTICS

n = 2  
min = 0.0038  
max = 0.0038  
median = 0.0038

---

CDA METHOD SELECTION

CDA method: MLE (Maximum Likelihood Estimation)

Note: The dataset is 100% censored. Statistical analysis is not possible using LPR- or MLE-based methods.

Note: All parametric confidence intervals were calculated using the full sample size.

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DESCRIPTIVE STATISTICS

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COMPLIANCE STATISTICS

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NON-PARAMETRIC COMPLIANCE STATISTICS

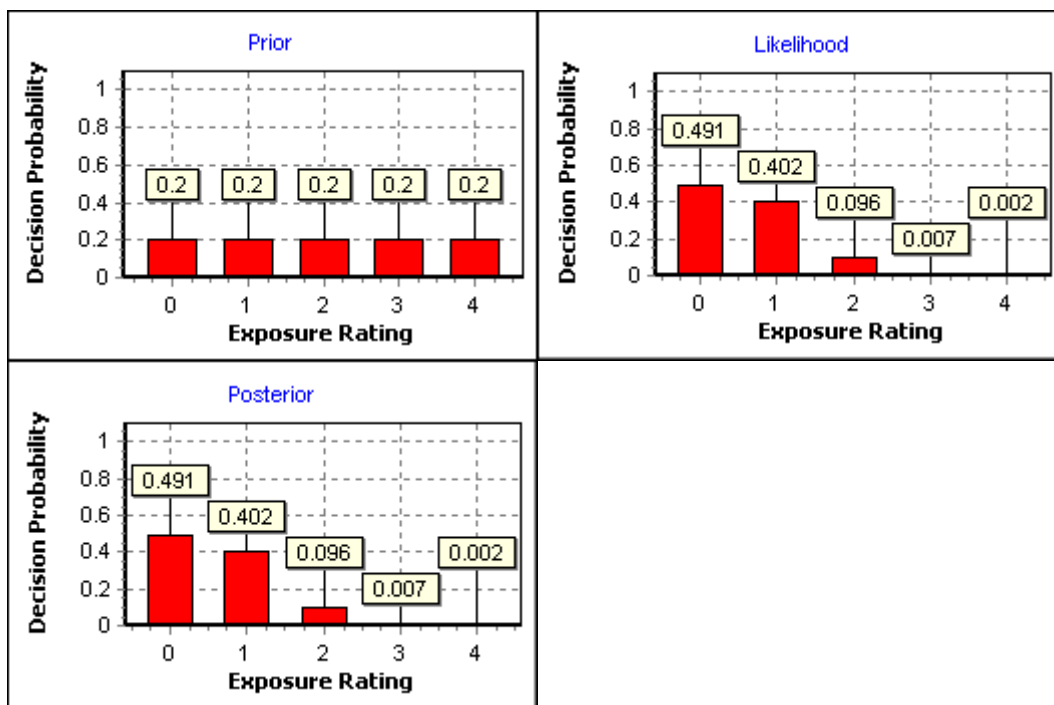
---

BAYESIAN DECISION ANALYSIS

Note: Decision Charts were calculated with adjustment for censored data.

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Exposure Rating:	0-T	1-HC	2-WC	3-C	4-PC
Cutoff (ug/m <sup>3</sup> )	0.0005	0.005	0.025	0.05	>0.05
Cutoff (%OEL)	1	10	50	100	>100
Prior	0.2	0.2	0.2	0.2	0.2
Likelihood	0.491	0.402	0.096	0.007	0.002
Posterior	0.491	0.402	0.096	0.007	0.002
Cum Likelihood	0.491	0.894	0.990	0.998	
Cum Posterior	0.491	0.894	0.990	0.998	



Parameter space: Gmin = 1.02E-5 Gmax = 0.25  
Dmin = 1.05 Dmax = 4

### PPE SELECTION

Note: PPE Selection Charts were calculated with adjustment for censored data.

Respirator APF:	1	10	50	1000	>1000
Prior	0.2	0.2	0.2	0.2	0.2
Likelihood	0.951	0.049	0.000	0.000	0.000





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Health, Safety & Environmental Services

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Toll Free (888) 576-7522

**TO:**

INGRID VANDE VELDE  
ALZA  
700 EUBANKS DR.  
VACAVILLE, CA 95688  
USA

REPORT DATE NOV 07, 2007  
SAMPLES REC'D NOV 05, 2007  
REQUEST NUMBER 508642  
PAGE NUMBER 1 OF 4

SAMPLE	AIR VOLUME / ANALYSIS REQUESTED	MEDIA TYPE	/ RESULTS	ANALYZED DATE
27075006	384.8 Liters MANNITOL	25mm Glass Fiber Filter Micrograms < 0.001	Micrograms/Cubic Meter < 0.0026	NOV 07, 2007
27075012	405.8 Liters MANNITOL	25mm Glass Fiber Filter Micrograms < 0.001	Micrograms/Cubic Meter < 0.0025	NOV 07, 2007
27075030	365.8 Liters MANNITOL	25mm Glass Fiber Filter Micrograms < 0.001	Micrograms/Cubic Meter < 0.0027	NOV 07, 2007
27075018	391.7 Liters MANNITOL	25mm Glass Fiber Filter Micrograms < 0.001	Micrograms/Cubic Meter < 0.0026	NOV 07, 2007
27075015	388.1 Liters MANNITOL	25mm Glass Fiber Filter Micrograms < 0.001	Micrograms/Cubic Meter < 0.0026	NOV 07, 2007

**COMMENTS:**

IF PRESENT, DE MEANS DESORPTION EFFICIENCY

Respectfully submitted,

William M. Walsh, CIH, ROH  
Vice President, Laboratory Services

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**TO:**

INGRID VANDE VELDE  
ALZA  
700 EUBANKS DR.  
VACAVILLE, CA 95688  
USA

REPORT DATE NOV 07, 2007  
SAMPLES REC'D NOV 05, 2007  
REQUEST NUMBER 508642  
PAGE NUMBER 2 OF 4

SAMPLE	AIR VOLUME / ANALYSIS REQUESTED	MEDIA TYPE	/ RESULTS	ANALYZED DATE
27075029	369.2 Liters MANNITOL	25mm Glass Fiber Filter Micrograms < 0.001	Micrograms/Cubic Meter < 0.0027	NOV 07, 2007
27075009	389.1 Liters MANNITOL	25mm Glass Fiber Filter Micrograms < 0.001	Micrograms/Cubic Meter < 0.0026	NOV 07, 2007
27075024	MANNITOL (BLANK)	25mm Glass Fiber Filter Micrograms < 0.001  NONE DETECTED		NOV 07, 2007

**COMMENTS:**

IF PRESENT, DE MEANS DESORPTION EFFICIENCY

Respectfully submitted,

William M. Walsh, CIH, ROH  
Vice President, Laboratory Services

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VACAVILLE, CA 95688  
USA

REPORT DATE NOV 07, 2007  
SAMPLES REC'D NOV 05, 2007  
REQUEST NUMBER 508642  
PAGE NUMBER 3 OF 4

REPORTING LIMIT	ANALYSIS REQUESTED	METHODOLOGY	CAS #
.001 Micrograms	MANNITOL IOM2	NAT-2001-00441 HIGH PRESSURE LIQUID CHROMATOGRAPHY	69-65-8

**COMMENTS:**

- \* CONCENTRATION CALCULATED USING AIR VOLUMES SUPPLIED BY CLIENT
- \* UNLESS OTHERWISE NOTED, SAMPLES RECEIVED IN GOOD CONDITION
- \* MODIFICATIONS MAY BE MADE TO ABOVE METHODS TO OPTIMIZE RESULTS (AVAILABLE UPON REQUEST)
- \* RESULTS ARE STRICTLY LIMITED TO SAMPLES ANALYZED

**Respectfully submitted,**

William M. Walsh, CIH, ROH  
Vice President, Laboratory Services

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USA

REPORT DATE NOV 07, 2007  
SAMPLES REC'D NOV 05, 2007  
REQUEST NUMBER 508642  
PAGE NUMBER 4 OF 4

REQUEST CLIENT COMMENTS:

REQUEST LAB COMMENTS:

REF: PO #991960905.

UNLESS OTHERWISE NOTED, ALL QC CRITERIA WERE MET.

Respectfully submitted,

William M. Walsh, CIH, ROH  
Vice President, Laboratory Services

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USA

REPORT DATE NOV 28, 2007  
SAMPLES REC'D NOV 26, 2007  
REQUEST NUMBER 511452  
PAGE NUMBER 1 OF 3

SAMPLE	AIR VOLUME / ANALYSIS REQUESTED	MEDIA TYPE / RESULTS	ANALYZED DATE
1	MANNITOL	7cm Glass Fiber Filter Micrograms < 0.1	NOV 28, 2007
2	MANNITOL	7cm Glass Fiber Filter Micrograms 5.9	NOV 28, 2007
3	MANNITOL	7cm Glass Fiber Filter Micrograms 0.57	NOV 28, 2007
4	MANNITOL	7cm Glass Fiber Filter Micrograms 0.2	NOV 28, 2007
5	MANNITOL	7cm Glass Fiber Filter Micrograms 0.9	NOV 28, 2007

**COMMENTS:**

IF PRESENT, DE MEANS DESORPTION EFFICIENCY

Respectfully submitted,

William M. Walsh, CIH, ROH  
Vice President, Laboratory Services

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USA

REPORT DATE NOV 28, 2007  
SAMPLES REC'D NOV 26, 2007  
REQUEST NUMBER 511452  
PAGE NUMBER 2 OF 3

REPORTING LIMIT	ANALYSIS REQUESTED	METHODOLOGY	CAS #
.1 Micrograms	MANNITOL SW2	NAT-2001-00441 HIGH PRESSURE LIQUID CHROMATOGRAPHY	69-65-8

**COMMENTS:**

- \* CONCENTRATION CALCULATED USING AIR VOLUMES SUPPLIED BY CLIENT
- \* UNLESS OTHERWISE NOTED, SAMPLES RECEIVED IN GOOD CONDITION
- \* MODIFICATIONS MAY BE MADE TO ABOVE METHODS TO OPTIMIZE RESULTS (AVAILABLE UPON REQUEST)
- \* RESULTS ARE STRICTLY LIMITED TO SAMPLES ANALYZED

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REPORT DATE NOV 28, 2007  
SAMPLES REC'D NOV 26, 2007  
REQUEST NUMBER 511452  
PAGE NUMBER 3 OF 3

REQUEST CLIENT COMMENTS:

REQUEST LAB COMMENTS:

REF : P.O.# 991960905. ASAP.

UNLESS OTHERWISE NOTED, ALL QC CRITERIA WERE MET.

Respectfully submitted,

William M. Walsh, CIH, ROH  
Vice President, Laboratory Services

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REPORT DATE DEC 14, 2007  
SAMPLES REC'D DEC 05, 2007  
REQUEST NUMBER 511453  
PAGE NUMBER 1 OF 5

SAMPLE	AIR VOLUME / ANALYSIS REQUESTED	MEDIA TYPE	/ RESULTS	ANALYZED DATE
27079545	330.21 Liters FENTANYL	25mm Glass Fiber Filter Micrograms 91	Micrograms/Cubic Meter 270	DEC 14, 2007
27075021	345.41 Liters FENTANYL	25mm Glass Fiber Filter Micrograms 12	Micrograms/Cubic Meter 36	DEC 14, 2007
27079540	277 Liters FENTANYL	25mm Glass Fiber Filter Micrograms 0.0033	Micrograms/Cubic Meter 0.012	DEC 14, 2007
27079548	44.15 Liters FENTANYL	25mm Glass Fiber Filter Micrograms 0.012	Micrograms/Cubic Meter 0.27	DEC 14, 2007
27079549	69.41 Liters FENTANYL	25mm Glass Fiber Filter Micrograms 0.17	Micrograms/Cubic Meter 2.4	DEC 14, 2007

**COMMENTS:**

IF PRESENT, DE MEANS DESORPTION EFFICIENCY

Respectfully submitted,

William M. Walsh, CIH, ROH  
Vice President, Laboratory Services

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Health, Safety & Environmental Services

## Industrial Hygiene Laboratory

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**TO:**

INGRID VANDE VELDE  
ALZA  
700 EUBANKS DR.  
VACAVILLE, CA 95688  
USA

REPORT DATE DEC 14, 2007  
SAMPLES REC'D DEC 05, 2007  
REQUEST NUMBER 511453  
PAGE NUMBER 2 OF 5

SAMPLE	AIR VOLUME / ANALYSIS REQUESTED	MEDIA TYPE	/ RESULTS	ANALYZED DATE
27079542	68.41 Liters FENTANYL	25mm Glass Fiber Filter Micrograms 2.6	Micrograms/Cubic Meter 37	DEC 14, 2007
27079544	FENTANYL (BLANK)	25mm Glass Fiber Filter Micrograms 0.036 DETECTED		DEC 14, 2007

**COMMENTS:**

IF PRESENT, DE MEANS DESORPTION EFFICIENCY

Respectfully submitted,

William M. Walsh, CIH, ROH  
Vice President, Laboratory Services

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USA

REPORT DATE DEC 14, 2007  
SAMPLES REC'D DEC 05, 2007  
REQUEST NUMBER 511650  
PAGE NUMBER 3 OF 5

SAMPLE	AIR VOLUME / ANALYSIS REQUESTED	MEDIA TYPE / RESULTS	ANALYZED DATE
27228466	MANNITOL	7cm Glass Fiber Filter Micrograms < 0.1	DEC 14, 2007
27228471	MANNITOL	7cm Glass Fiber Filter Micrograms 0.25	DEC 14, 2007
27223341	MANNITOL	7cm Glass Fiber Filter Micrograms < 0.1	DEC 14, 2007
27228465	MANNITOL	7cm Glass Fiber Filter Micrograms < 0.1	DEC 14, 2007
27228472	MANNITOL	7cm Glass Fiber Filter Micrograms < 0.1	DEC 14, 2007

**COMMENTS:**

IF PRESENT, DE MEANS DESORPTION EFFICIENCY

Respectfully submitted,

William M. Walsh, CIH, ROH  
Vice President, Laboratory Services

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USA

REPORT DATE DEC 14, 2007  
SAMPLES REC'D DEC 05, 2007  
REQUEST NUMBER 511453  
PAGE NUMBER 4 OF 5

REPORTING LIMIT	ANALYSIS REQUESTED	METHODOLOGY	CAS #
.001 Micrograms	FENTANYL IOM2	NAT-2003-05515 LC/MS	118357-29-2
.1 Micrograms	MANNITOL SW2	NAT-2001-00441 HIGH PRESSURE LIQUID CHROMATOGRAPHY	69-65-8

**COMMENTS:**

- \* CONCENTRATION CALCULATED USING AIR VOLUMES SUPPLIED BY CLIENT
- \* UNLESS OTHERWISE NOTED, SAMPLES RECEIVED IN GOOD CONDITION
- \* MODIFICATIONS MAY BE MADE TO ABOVE METHODS TO OPTIMIZE RESULTS (AVAILABLE UPON REQUEST)
- \* RESULTS ARE STRICTLY LIMITED TO SAMPLES ANALYZED

Respectfully submitted,

William M. Walsh, CIH, ROH  
Vice President, Laboratory Services

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REPORT DATE DEC 14, 2007  
SAMPLES REC'D DEC 05, 2007  
REQUEST NUMBER 511453  
PAGE NUMBER 5 OF 5

REQUEST CLIENT COMMENTS:

REQUEST LAB COMMENTS:

REF: P.O.# 991960905.

UNLESS OTHERWISE NOTED, ALL QC CRITERIA WERE MET. NO FENTANYL DETECTED ON LABORATORY BLANK.

Respectfully submitted,

William M. Walsh, CIH, ROH  
Vice President, Laboratory Services

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## Laboratory Analysis Report

Industrial Hygiene Laboratory  
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**TO:**

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700 EUBANKS DR.  
VACAVILLE, CA 95688  
USA

REPORT DATE JAN 03, 2008  
SAMPLES REC'D DEC 24, 2007  
REQUEST NUMBER 506993  
PAGE NUMBER 1 OF 8

SAMPLE	AIR VOLUME / ANALYSIS REQUESTED	MEDIA TYPE	/ RESULTS	ANALYZED DATE
27079546	347.83 Liters MANNITOL	25mm Glass Fiber Filter Micrograms	< 0.001 Micrograms/Cubic Meter	JAN 03, 2008 < 0.0029
27079535	388 Liters MANNITOL	25mm Glass Fiber Filter Micrograms	< 0.001 Micrograms/Cubic Meter	JAN 03, 2008 < 0.0026
27079537	387.35 Liters MANNITOL	25mm Glass Fiber Filter Micrograms	< 0.001 Micrograms/Cubic Meter	JAN 03, 2008 < 0.0026
27079533	380 Liters MANNITOL	25mm Glass Fiber Filter Micrograms	< 0.001 Micrograms/Cubic Meter	JAN 03, 2008 < 0.0026
27079551	389.12 Liters MANNITOL	25mm Glass Fiber Filter Micrograms	< 0.001 Micrograms/Cubic Meter	JAN 03, 2008 < 0.0026

**COMMENTS:**

IF PRESENT, DE MEANS DESORPTION EFFICIENCY

Respectfully submitted,

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Vice President, Laboratory Services

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USA

REPORT DATE JAN 03, 2008  
SAMPLES REC'D DEC 24, 2007  
REQUEST NUMBER 506993  
PAGE NUMBER 2 OF 8

SAMPLE	AIR VOLUME / ANALYSIS REQUESTED	MEDIA TYPE	/ RESULTS	ANALYZED DATE
27085127	384.75 Liters MANNITOL	25mm Glass Fiber Filter Micrograms	< 0.001 Micrograms/Cubic Meter	JAN 03, 2008 < 0.0026
27085130	385.51 Liters MANNITOL	25mm Glass Fiber Filter Micrograms	< 0.001 Micrograms/Cubic Meter	JAN 03, 2008 < 0.0026
27079543	377.15 Liters MANNITOL	25mm Glass Fiber Filter Micrograms	< 0.001 Micrograms/Cubic Meter	JAN 03, 2008 < 0.0027
27079538	434.65 Liters MANNITOL	25mm Glass Fiber Filter Micrograms	< 0.001 Micrograms/Cubic Meter	JAN 03, 2008 < 0.0023
27079541	379.24 Liters MANNITOL	25mm Glass Fiber Filter Micrograms	< 0.001 Micrograms/Cubic Meter	JAN 03, 2008 < 0.0026

**COMMENTS:**

IF PRESENT, DE MEANS DESORPTION EFFICIENCY

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SAMPLES REC'D DEC 24, 2007  
REQUEST NUMBER 506993  
PAGE NUMBER 3 OF 8

SAMPLE	AIR VOLUME / ANALYSIS REQUESTED	MEDIA TYPE	/ RESULTS	ANALYZED DATE
27079534	360.35 Liters MANNITOL	25mm Glass Fiber Filter Micrograms	< 0.001 Micrograms/Cubic Meter	JAN 03, 2008 < 0.0028
27079552	188.48 Liters MANNITOL	25mm Glass Fiber Filter Micrograms	< 0.001 Micrograms/Cubic Meter	JAN 03, 2008 < 0.0053
27079547	248 Liters MANNITOL	25mm Glass Fiber Filter Micrograms	< 0.001 Micrograms/Cubic Meter	JAN 03, 2008 < 0.004
27085084	216 Liters MANNITOL	25mm Glass Fiber Filter Micrograms	< 0.001 Micrograms/Cubic Meter	JAN 03, 2008 < 0.0046

**COMMENTS:**

IF PRESENT, DE MEANS DESORPTION EFFICIENCY

Respectfully submitted,

William M. Walsh, CIH, ROH  
Vice President, Laboratory Services

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USA

REPORT DATE JAN 03, 2008  
SAMPLES REC'D DEC 24, 2007  
REQUEST NUMBER 506994  
PAGE NUMBER 4 OF 8

SAMPLE	AIR VOLUME / ANALYSIS REQUESTED	MEDIA TYPE / RESULTS	ANALYZED DATE
27085102	MANNITOL (BLANK)	25mm Glass Fiber Filter Micrograms < 0.001  NONE DETECTED	JAN 03, 2008
27079539	261.37 Liters MANNITOL	25mm Glass Fiber Filter Micrograms < 0.001	JAN 03, 2008 Micrograms/Cubic Meter < 0.0038
27085106	47.33 Liters MANNITOL	25mm Glass Fiber Filter Micrograms < 0.001	JAN 03, 2008 Micrograms/Cubic Meter < 0.021
27075027	262.6 Liters MANNITOL	25mm Glass Fiber Filter Micrograms < 0.001	JAN 03, 2008 Micrograms/Cubic Meter < 0.0038
27079550	48.48 Liters MANNITOL	25mm Glass Fiber Filter Micrograms < 0.001	JAN 03, 2008 Micrograms/Cubic Meter < 0.021

**COMMENTS:**

IF PRESENT, DE MEANS DESORPTION EFFICIENCY

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REPORT DATE JAN 03, 2008  
SAMPLES REC'D DEC 24, 2007  
REQUEST NUMBER 506994  
PAGE NUMBER 5 OF 8

SAMPLE	AIR VOLUME / ANALYSIS REQUESTED	MEDIA TYPE / RESULTS	ANALYZED DATE
27223343	MANNITOL	TX714 LARGE ALPHA SWAB Micrograms 8.2	JAN 03, 2008
27223344	MANNITOL	TX714 LARGE ALPHA SWAB Micrograms < 0.1	JAN 03, 2008
27228468	MANNITOL	TX714 LARGE ALPHA SWAB Micrograms < 0.1	JAN 03, 2008
27223347	MANNITOL	TX714 LARGE ALPHA SWAB Micrograms < 0.1	JAN 03, 2008
27228467	MANNITOL	TX714 LARGE ALPHA SWAB Micrograms 0.46	JAN 03, 2008

**COMMENTS:**

IF PRESENT, DE MEANS DESORPTION EFFICIENCY

Respectfully submitted,

William M. Walsh, CIH, ROH  
Vice President, Laboratory Services

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REQUEST NUMBER 506994  
PAGE NUMBER 6 OF 8

SAMPLE	AIR VOLUME / ANALYSIS REQUESTED	MEDIA TYPE / RESULTS	ANALYZED DATE
27228469	MANNITOL	TX714 LARGE ALPHA SWAB Micrograms 96	JAN 03, 2008

**COMMENTS:**

IF PRESENT, DE MEANS DESORPTION EFFICIENCY

Respectfully submitted,

William M. Walsh, CIH, ROH  
Vice President, Laboratory Services

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USA

REPORT DATE JAN 03, 2008  
SAMPLES REC'D DEC 24, 2007  
REQUEST NUMBER 506993  
PAGE NUMBER 7 OF 8

REPORTING LIMIT	ANALYSIS REQUESTED	METHODOLOGY	CAS #
.001 Micrograms	MANNITOL IOM2	NAT-2001-00441 HIGH PRESSURE LIQUID CHROMATOGRAPHY	69-65-8
.1 Micrograms	MANNITOL TX74	NAT-2001-00441 HIGH PRESSURE LIQUID CHROMATOGRAPHY	69-65-8

**COMMENTS:**

- \* CONCENTRATION CALCULATED USING AIR VOLUMES SUPPLIED BY CLIENT
- \* UNLESS OTHERWISE NOTED, SAMPLES RECEIVED IN GOOD CONDITION
- \* MODIFICATIONS MAY BE MADE TO ABOVE METHODS TO OPTIMIZE RESULTS (AVAILABLE UPON REQUEST)
- \* RESULTS ARE STRICTLY LIMITED TO SAMPLES ANALYZED

Respectfully submitted,

William M. Walsh, CIH, ROH  
Vice President, Laboratory Services

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VACAVILLE, CA 95688  
USA

REPORT DATE JAN 03, 2008  
SAMPLES REC'D DEC 24, 2007  
REQUEST NUMBER 506993  
PAGE NUMBER 8 OF 8

REQUEST CLIENT COMMENTS:

REQUEST LAB COMMENTS:

ASSUME SAMPLE # 2722347 IS SAMPLE # 2723347.

UNLESS OTHERWISE NOTED, ALL QC CRITERIA WERE MET.  
ASSUME SAMPLE # 2722347 IS SAMPLE # 2723347. NO  
MANNITOL PRESENT ON LAB BLANKS.

Respectfully submitted,

William M. Walsh, CIH, ROH  
Vice President, Laboratory Services

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