INTEROFFICE COMMUNICATION

TO: File

FROM: Amy Robinson

DATE: March 13, 2020

SUBJECT: Monthly Ethylene Oxide Sampling at Viant Medical, Inc. for January 2020

Overview

Viant Medical, Inc. (Viant) in Grand Rapids, Michigan was identified by the United States Environmental Protection Agency (USEPA) National Air Toxics Assessment (NATA) as having elevated ethylene oxide ambient air impacts. Subsequent computer modeling by the Air Quality Division (AQD) showed impacts above the Initial Risk Screening Level (IRSL) at 0.0002 μ g/m³ and Secondary Risk Screening Level (SRSL) at 0.002 μ g/m³. To ascertain the accuracy of the computer model, the AQD initially conducted a <u>Phase I</u> (limited monitoring) sampling study for ethylene oxide in the vicinity of Viant in November 2018. A more robust <u>Phase II</u> sampling effort was conducted in March 2019 near the facility, on the Grand Valley State University campus, locations in the City of Grand Rapids, and several upwind and downwind locations.

As part of a compliance plan related to an enforcement action, Viant has agreed to conduct monthly perimeter sampling for ethylene oxide. Viant contracted with Ramboll US Corporation to conduct ambient air sampling at four outdoor locations as well as one indoor location on a once per month basis. The monthly sampling began in July 2019 and will continue through February 2020. The AQD began collecting a side by side outdoor air sample with Viant at one location starting in August 2019 and will continue through February 2020. The EPA has established criteria for comparing data from different laboratories. If values from two different laboratories are within ± 20%, then the laboratories have good comparability. Results of all sampling events are available on the website www.michigan.gov/viant

Sampling Details

Ambient air monitoring for ethylene oxide was accomplished using the EPA TO-15 Summa canister method. The EPA's National Contract Laboratory, Eastern Research Group (ERG), performed the analysis. ERG's laboratory detection limit is 0.045 μ g/m³. Since the SRSL is lower than the detection limit of the current method for ethylene oxide, the monitoring data will have to be carefully interpreted. For example, if a sample result is reported as non-detect, it is possible that the actual level could still be above the SRSL.

Results

The Ramboll US Corporation (Ramboll) collected five samples over a 24-hour period on January 22, 2020. Ramboll collects a duplicate canister at one location each month. The AQD received the Viant results in March 2020. The results from the January sampling are

on page 2 of the report named "Ambient Air Sampling at Viant Medical Facility, Grand Rapids, Michigan January 2020 Sampling Events Results" (Viant Report) and likewise on page 2 of the December Viant Report. The results from the AQD canister collected in January are on page 2 of the ERG lab report.

The results of the January samples collected by Ramboll and the AQD are similar to the results observed during the AQD's Phase I and II sampling events in the greater Grand Rapids community. The AQD canister was located at site #4 with two Ramboll canisters. Due to a large snow bank this site was moved approximately 90 feet to the south of the previous site #4. The AQD canister result was 0.17 ug/m³ whereas the Ramboll canisters were 0.12 and 0.12 ug/m³. The laboratory flagged the results for the Ramboll canisters with a J Flag. This means that they are estimated values because they are lower than the laboratories reporting limit. The difference between the laboratories is greater than the EPA recommended +/- 20% criteria. This could be caused by the estimated value of the Ramboll samples. The wind direction on the January sample day was from the south, blowing to the north. Site #4 is on the north side of the facility.



Eastern Research Group 601 Keystone Park Drive Suite 700 Morrisville, NC 27560

February 20, 2020

Ms. Amy Robinson U.S. Environmental Protection Agency, Region 5 PO Box 30260 Lansing, MI 48909 Project Name: Viant EtO

Dear Ms. Amy Robinson,

This report contains the analytical results for the sample(s) received under chain(s) of custody by Eastern Research Group on 01/27/20 11:14.

The test results in this report are in compliance with NELAC accreditation requirements for the certified parameters. All analyses were performed as described in the US EPA-approved QAPP, under the contract for UATMP, NATTS, CSATAM, PAMS and NMOC support (US EPA Contract No. EP-D-14-030). This cover page is an integral part of this report, and any exceptions or comments are noted on the last page.

Release of the data contained in this data package and in the data submitted in the electronic data deliverable, has been authorized by the Program Manager, or the Program Manager's designee as verified by the following signature.

The issuance of the final Certificate of Analysis takes precedence over any previous Report. If you have any questions, please contact me at 919-468-7924.

Sincerely,

Julie Swift Program Manager julie.swift@erg.com

The information contained in this report and its attachment(s) are intended only for the use of the individual to whom it is addressed and may contain information that is privileged, confidential, or exempt from disclosure. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this report is strictly prohibited. If you have received this report in error, please notify julie.swift@erg.com and delete the report without retaining any copies.

NERG

CERTIFICATE OF ANALYSIS

U.S. Environmental Protection Agency, Region 5		FILE #: 4173	3.00
PO Box 30260		REPORTED:	02/20/20 12:50
Lansing, MI 48909		SUBMITTED:	01/27/20
ATTN: Ms. Amy Robinson		AQS SITE CO	DE:
PHONE: (517) 241-2198	FAX: (312) 886-5824	SITE CODE:	Viant EtO

ANALYTICAL REPORT FOR SAMPLES

<u>SampleName</u> Viant	<u>LabNumber</u> 0012723-01	<u>Matrix</u> Air	<u>Sampled</u> 01/23/20 11:00	<u>Received</u> 01/27/20 11:14
Description: Viant	La	bID: 0012723-	.01	Sampled: 01/23/20 11:00
Pressure @ Receipt:	O" Hg Ca	nister #: SAT17	4	Received: 01/27/20 11:14
Comments: Receive	d at ambient			Analyzed: 01/27/20 20:18
	Air Toxic	s by EPA Compe	ndium Method TO-15	
	Results	M	<u>DL</u>	
<u>Analyte</u>	<u>ppbv_ug/m³</u>	<u>Flag</u> pp	VC	
Ethylene oxide	0.0916 0.17	0.02	50	

Eastern Research Group

The results in this report apply only to the samples analyzed in accordance with the chain of custody document. This analytical report must be reproduced in its entirety.

CERTIFICATE OF ANALYSIS

U.S. Environmental Protection Agency, Region 5	FILE #: 4173.00
PO Box 30260	REPORTED: 02/20/20 12:50
Lansing, MI 48909	SUBMITTED: 01/27/20
ATTN: Ms. Amy Robinson	AQS SITE CODE:
PHONE: (517) 241-2198 FAX: (312) 886-5824	SITE CODE: Viant EtO

Analyte	Result	Units	Source Result	RPD	RPD Limit	Notes
Air Toxics by EPA Compendium Batch B0A2709 - Summa Canister F		uality Control				
Blank (B0A2709-BLK1)			Prepared: 01/23/20 Ana	alyzed: 01/27/20		
Ethylene oxide	ND	ppbv				U

Eastern Research Group

ERG

The results in this report apply only to the samples analyzed in accordance with the chain of custody document. This analytical report must be reproduced in its entirety.

CERTIFICATE OF ANALYSIS

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U.S. Environmental Protection Agency, Region 5	FILE #: 4173.00
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ATTN: Ms. Amy Robinson	AQS SITE CODE:
PHONE: (517) 241-2198 FAX: (312) 886-5824	SITE CODE: Viant EtO

Analyte	Result	Units	% Difference	Limit (%)	Notes
Air Toxics by EPA Compen- Sequence 2001074	dium Method TO-15 - Q	uality Control			
Calibration Check (2001074	4-CCV1)	Pi	repared & Analyze	d: 01/27/20	
Ethylene oxide	2.56	ppbv	2.4	30.00	

Eastern Research Group

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NERG

CERTIFICATE OF ANALYSIS

U.S. Environmental Protection Agency, Region 5

PO Box 30260

Lansing, MI 48909

ATTN: Ms. Amy Robinson

PHONE: (517) 241-2198 **FAX:** (312) 886-5824

 FILE #: 4173.00

 REPORTED: 02/20/20 12:50

 SUBMITTED: 01/27/20

 AQS SITE CODE:

 SITE CODE:

 Viant EtO

Notes and Definitions

U	Under Detection Limit
ND	Analyte NOT DETECTED

NR Not Reported

MDL Method Detection Limit

RPD Relative Percent Difference

Note: The test results meet all requirements of NELAC; however the following analytes are not accredited: 1,2,4-trimethylbenzene, 1,2-dibromoethane, 1,2-dichloropropane, 1,3,5-trimethylbenzene, 1,3-butadiene, acetylene, acrolein, bromochloromethane, bromodichloromethane, bromoform, carbon disulfide, dibromochloromethane, dichlorodifluoromethane, dichlorotetrafluoroethane, ethyl acrylate, ethyl tert butyl ether, ethylene oxide, hexachloro-1,3-butadiene, n-octane, propylene, tert amyl methyl ether, tetrachloroethylene, trans-1,2-dichloroethylene, trichlorofluoromethane, and trichlorotrufluoroethane.

Eastern Research Group

The results in this report apply only to the samples analyzed in accordance with the chain of custody document. This analytical report must be reproduced in its entirety.

Page 5 of 5

AMBIENT AIR SAMPLING AT VIANT MEDICAL FACILITY, GRAND RAPIDS, MICHIGAN JANUARY 2020 SAMPLING EVENT RESULTS

Prepared For: Hogan Lovells US LLP Denver, CO

On Behalf Of: Viant Medical Grand Rapids, MI

Prepared By: Ramboll US Corporation Arlington, VA

Date March 2020

Project Number 1690010876

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2020

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- Appendix B: Photographs of Sampling Locations
- Appendix C: Laboratory Analytical Report
- Appendix D: Laboratory Chain of Custody

1. INTRODUCTION

Ramboll US Corporation (Ramboll) has prepared this report to summarize the sampling procedures and results of Ramboll's January 2020 air sampling event at the Viant Medical (Viant) facility located at 520 Watson Street Southwest in Grand Rapids, Michigan (the "facility" or the "site"). The sampling event was completed during a 24-hour period between January 22 and 23, 2020, and included the collection of five outdoor ambient air samples¹ and one indoor air (IA) sample, which were submitted for laboratory analysis of ethylene oxide (EtO). The sampling was performed in accordance with the scope of work outlined in the April 2019 Ambient Air Sampling Work Plan (the "April 2019 Work Plan") prepared by Ramboll. This sampling event was the first monthly event to take place after EtO sterilization operations at the facility ceased in late December 2019. The sections below describe the sampling methodology and results from the January 2020 sampling event.

2. SAMPLING LOCATIONS

Four out of the five sampling locations, including Locations #1, #2, #3, and the indoor air sampling location, were the same locations sampled by Ramboll during previous events. Due to the presence of a large pile of snow surrounding the light pole used for Location #4 (north of the site building) during previous events, an alternative location was chosen for this event. The alternative Location #4 (or "#4-Alt") was a light pole located approximately 90 feet to the south of the original Location #4. Co-located samples were collected from Location #4-Alt, resulting in the collection of six samples in total. Sampling locations are depicted on Figure 1 and photographs of each sample are included in Appendix B.

3. METHODOLOGY

All six samples were collected using individually certified 6-liter stainless steel SUMMA® canisters equipped with individually certified 24-hour mass flow controllers provided by Eurofins Air Toxics (EAT). Except for Location #4-Alt, as noted above, the canisters were secured to the same fixtures that were used during previous sampling events for sample collection within the breathing zone. The co-located canister inlets at Location #4-Alt were approximately 1-foot² away from each other.

Prior to sample collection at each location, a shut-in test was performed on each canister and mass flow controller using the methods described in the initial July 2019 sampling report. After the successful completion of each shut-in test, the valve on the canister was opened to begin collection of the 24-hour integrated sample. The recordkeeping and canister pressure monitoring methods used in the field during this event are the same as those described previously. The winds primarily blew from the south and south-southeast during the 24-hour sampling period, which began January 22, 2020, and ended January 23, 2020.

Final canister pressure should be under slight vacuum; if the final canister pressure is at ambient pressure at the end of the sampling period, it may be indicative of an equipment malfunction. The air pressure in one of the co-located canisters at Location #4-Alt reached ambient pressure prior to the

¹ One of the samples was a co-located sample.

² Because of the diameter of the utility pole used to secure the canisters at Location #4-Alt, the canister inlets were placed one foot from each other.

end of the 24-hour time period. Sampling of this canister was discontinued approximately 22.5 hours after sample collection began. As such, the sampling result from this canister may be suspect. After approximately 24 hours from the start of the event, the valves on the other canisters were closed, and final field measurements were recorded. Sample canisters were shipped overnight to EAT in Folsom, California for analysis of EtO using the methods specified in the April 2019 Work Plan. The laboratory received the canisters on January 24, 2020 and analyzed the samples between January 27 and 28, 2020.

Additionally, the Michigan Department of Environment, Great Lakes, and Energy (EGLE) collected one canister sample at Location #4-Alt in the same 24-hour time period as Ramboll's samples. EGLE's canister was sent to a different contract laboratory for analysis and will be discussed separately by EGLE.

4. **RESULTS**

Table 1: Outdoor Air Sampling Results, January 22-23, 2020					
Sample Location ID	On-Site	Location Description	EtO Concentration (μg/m ³)	Sample- Specific MDL (µg∕m³)	
1YesSouth of building in parking lot0.087 J0.045					
2	Yes	West of building, along western property boundary	0.11 J	0.043	
3NoNorthwest of building along Watson Street Southwest0.11 J0.037					
4-Alt* (co- located samples)YesNorth of building, 90 feet south of the northern corner of parking lot0.12 **; 0.12 J (co-located sample)0.035; 0.039					
J = Laboratory-estimated value below the Reporting Limit but above the MDL. * = Located approximately 90 feet to the south of the original #4 location. ** = Canister air pressure reached ambient pressure prior to the end of the 24-hour sampling period; the result may not represent the average concentration during the entire sampling period.					

The results from the January 2020 Ramboll sampling event are reported in Tables 1 and 2.

Table 2: Indoor Air Sampling Results, January 22-23, 2020				
Sample Location ID	Location Description	EtO Concentration (µg/m³)	Sample- Specific MDL (μg/m³)	
IA	Scrubber room	0.35	0.049	

EtO was detected in all samples collected during the January 2020 event. The EtO concentration in outdoor ambient air samples ranged from 0.087 micrograms per cubic meter (μ g/m³) at Location #1 to 0.12 μ g/m³ at Location #4-Alt (Figure 1). All outdoor sample concentrations were reported at or below the laboratory reporting limit. EGLE provided meteorological data collected in five-minute

intervals from its Grand Rapids – Monroe Street air monitoring site, which is approximately 1.7 miles north-northeast of Viant.³ As evident from a wind rose prepared using the meteorological data (Figure 2), winds were generally blowing from the south and south-southeast during the sampling event. Wind speeds varied between 1 and 10 miles per hour (mph). The EtO concentration in the scrubber room was 0.35 μ g/m³. A summary of results from this and prior Ramboll sampling events is provided in Appendix A.

5. QUALITY ASSURANCE

Ramboll evaluated data quality based on acceptance criteria specified by USEPA for precision, completeness, bias, and sensitivity in accordance with the April 2019 Work Plan. To evaluate the repeatability of sampling procedures, one co-located sample was collected at Location #4-Alt during this investigation. Although the same concentration of EtO was detected in both canisters used to collect the co-located sample (i.e., a calculated difference in values of 0%), the result from one of the canisters may not represent the average concentration during the entire sampling period, and thus, the results from these two canisters cannot be compared, and the repeatability of sampling procedures cannot be assessed for this event. To evaluate the repeatability of laboratory analytical methods, a laboratory replicate sample analysis of the sample collected at Location #1 was performed. In this replicate analysis, the difference in detected concentration of EtO was approximately 5.9% (using the calculated average detected concentration as the denominator), which is in the acceptable range of within 25%. A summary of all quality assurance criteria related to the January 2020 sampling event is provided in Table 3 below.

³ The Grand Rapids – Monroe Street air monitoring site is part of the state's air monitoring network as well as the federal NCore multipollutant monitoring network. Meteorological measurements collected at the site are subject to quality assurance procedures in the Quality Assurance Handbook for Air Pollution Measurement Systems, Volume IV: Meteorological Measurements Version 2.0.

Table 3: Quality Control Criteria for TO-15 Sample Collection and Analysis, January 22-23, 2020							
Quality Control Sample	Data Quality Indicators (DQIs)	Frequency	Acceptance Criteria	January 2020 Outcome	Corrective Action		
Co-located sample	Precision	1 per day	Within 25%	N/A^	N/A		
Replicate sample	Precision	1 per batch	Within 25% for sample concentrations greater than five times reporting limit	5.9%	N/A		
Valid sample count	Completeness	N/A	85% or more of total samples	100%⁺ (100% for total sampling program)			
Canister batch blank	Bias	After analysis of standards and prior to sample analysis, or when contamination is present.	Below the reporting limit	Below reporting limit of 0.090 μg/m ³	N/A		
Method Detection Limit	Sensitivity	1 per method modification	0.05 ppb (0.09 µg/m³) or less	N/A* (no change to method)	N/A		
Sampling period	Field QC	All samples	24 hours +/- 1 hour	All samples except one of the samples at Location #4- Alt, which was collected for 22.5 hours or less	None; All canisters had passed the leak checks and the observed canister pressures after a few hours into the start of the sampling period appeared normal.		

of one of the co-located samples may not be representative of the entire time period.

 $^{+}$ = A valid sample was collected at each of the sampling locations during this event. The previously mentioned issue with one of the co-located samples does not impact the completeness of the data.

* = Sample-specific MDLs noted in Tables 1 and 2 may be affected by dilution.

6. CONCLUSIONS

The January 2020 sampling event was the first monthly sampling event completed after the cessation of EtO sterilization operations at the facility. EtO was detected in ambient air surrounding the Viant facility at concentrations at or below reporting limits during the January 2020 sampling event.

FIGURE 1 MAP OF SAMPLING RESULTS

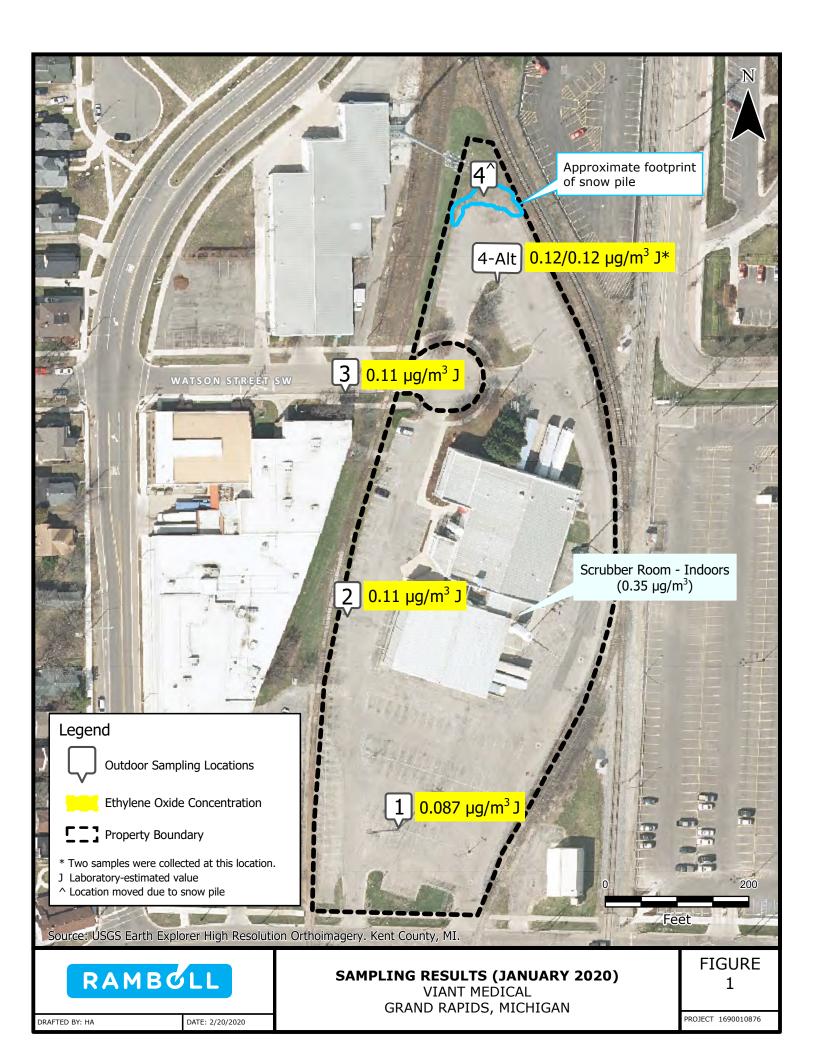
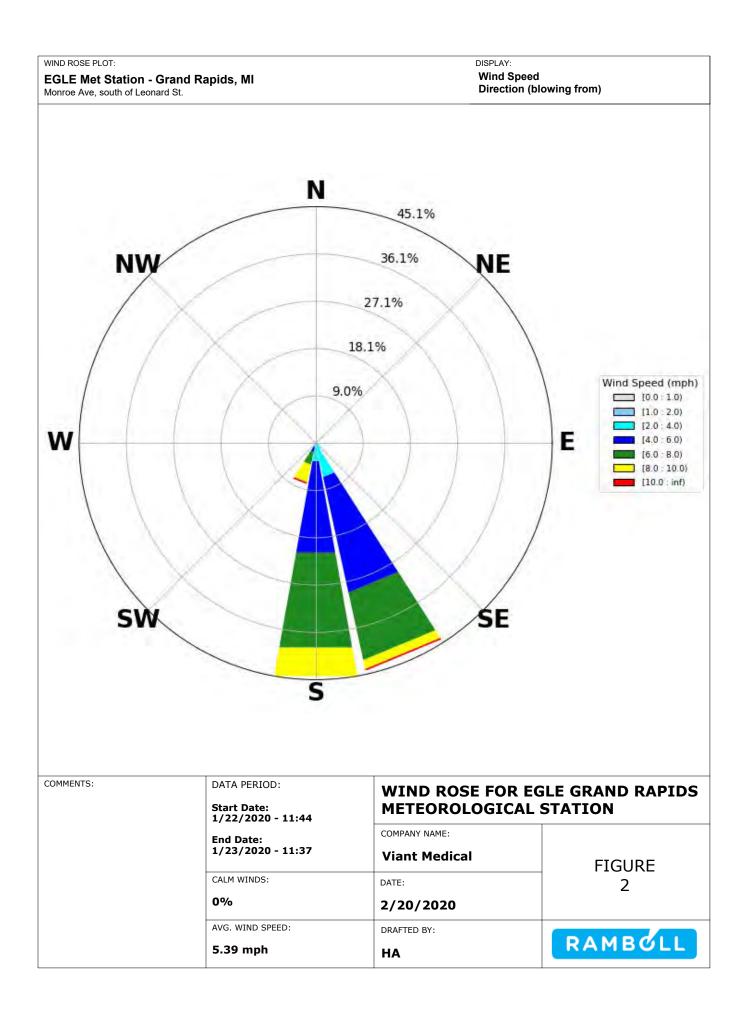


FIGURE 2 WIND ROSE



APPENDIX A AIR SAMPLING PROGRAM RESULTS SUMMARY

Viant Medical 520 Watson Street Southwest, Grand Rapids, MI

Ethylene Oxide Concentrations (μ g/m³) in Outdoor Air

		Location ID and Description				
		#1	#2	#3	#4	
Sample Dates (24-Hour Period)	Predominant Wind Direction(s) During Event	South of Building	West of Building	Northwest of Building (off-site along Watson Street SW)	North of Building	
7/9/2019 - 7/10/2019	SE	0.27	0.77	0.98	1.8 (Note 1)	
8/12/2019 - 8/13/2019	W, NW, N, NE	2.5	0.22	0.21	0.28 / 0.28 ^c	
9/10/2019 - 9/11/2019	SW, S	0.38	0.51	0.40	0.90 / 0.76 ^c	
10/16/2019 - 10/17/2019	NW	0.20 / 0.20 ^c	0.15 J	0.34	0.16	
11/19/2019 - 11/20/2019	SW	0.14 J	0.15 J	0.11 J	0.14 / 0.13 ^c J	
12/12/2019 - 12/13/2019	S	0.048 J	0.12 J	0.10 J	0.54 / 0.60 ^c	
1/22/2020 - 1/23/2020	S, SSE	0.087 J	0.11 J	0.11 J	0.12 / 0.12 ^c J (Note 2,3)	

Notes: /= Quality control sampling data is separated by a slash (/) ^c = Co-located sample J = Laboratory-estimated value Note 1 = Result represents an average concentration over a 21-hour period. Note 2 = An alternative Location #4 was selected due to an accumulated snow pile near the original Location #4. Note 3 = Air pressure of one of the canisters reached ambient pressure prior to the end of the 24-hour period, and therefore may not be representative of the entire sampling period.

Viant Medical 520 Watson Street Southwest, Grand Rapids, MI

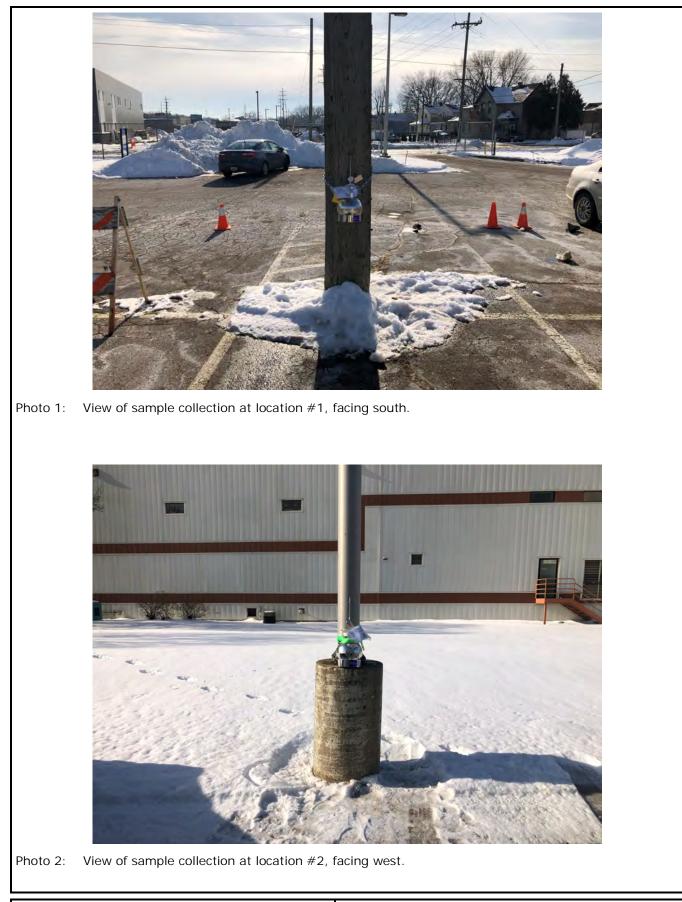
Ethylene Oxide Concentrations ($\mu\text{g/m}^3)$ in Indoor Air

	Location ID and Description
Sample Dates (24-Hour Period)	IA (Scrubber Room)
7/9/2019 - 7/10/2019	440 / 450 ^c
8/12/2019 - 8/13/2019	460
9/10/2019 - 9/11/2019	710
10/16/2019 - 10/17/2019	590
11/19/2019 - 11/20/2019	580
12/12/2019 - 12/13/2019	280
1/22/2020 - 1/23/2020	0.35

Notes:

/= Quality control sampling data is separated by a slash (/) ^c = Co-located sample

APPENDIX B PHOTOGRAPHS OF SAMPLING LOCATIONS





Site Photographs Viant Medical 520 Watson Street Southwest, Grand Rapids, Michigan January 2020



Photo 3: View of sample collection at location #3, facing north.



Photo 4: View of original location #4, facing north. Sampling location #4 was re-located ("#4-Alt") approximately 90 feet to the south due to the presence of the large snow pile pictured here.



Site Photographs Viant Medical 520 Watson Street Southwest, Grand Rapids, Michigan January 2020



Photo 5: View of sample collection at location #4-Alt (foreground) and original location #4 (background), facing north. Sample collected by EGLE also pictured (canister on right).

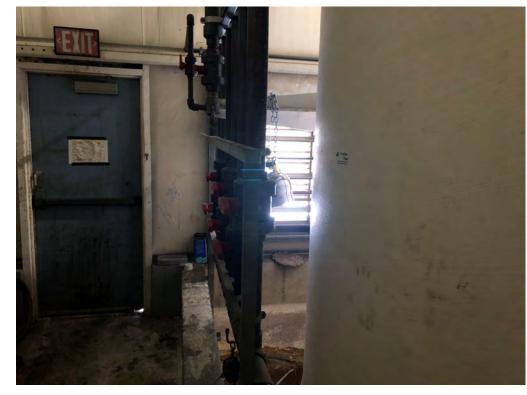


Photo 6: View of sample collection at indoor air (IA) location within scrubber room.



Site Photographs Viant Medical 520 Watson Street Southwest, Grand Rapids, Michigan January 2020

APPENDIX C LABORATORY ANALYTICAL REPORT



Air Toxics

2/6/2020 Ms. Christine Ng Ramboll 4350 N. Fairfax Drive Suite 300 Arlington VA 22203

Project Name: Viant Medical-Grand Rapids Project #: 1690010876 Workorder #: 2001554

Dear Ms. Christine Ng

The following report includes the data for the above referenced project for sample(s) received on 1/24/2020 at Air Toxics Ltd.

The data and associated QC analyzed by Modified TO-15 SIM are compliant with the project requirements or laboratory criteria with the exception of the deviations noted in the attached case narrative.

Thank you for choosing Eurofins Air Toxics Inc. for your air analysis needs. Eurofins Air Toxics Inc. is committed to providing accurate data of the highest quality. Please feel free to contact the Project Manager: Ausha Scott at 916-985-1000 if you have any questions regarding the data in this report.

Regards,

5.637-

Ausha Scott Project Manager

180 Blue Ravine Road, Suite B Folsom, CA 95630



Air Toxics

WORK ORDER #: 2001554

Work Order Summary

CLIENT:	Ms. Christine Ng Ramboll 4350 N. Fairfax Drive Suite 300 Arlington, VA 22203	BILL TO:	Accounts Payable Ramboll 333 West Wacker Drive Suite 2700 Chicago, IL 60606
PHONE:	703-516-2382	P.O. #	WO-2019-ARL-01
FAX:	703-516-2302	PROJECT #	1690010876 Viant Medical-Grand
DATE RECEIVED:	01/24/2020	CONTACT:	Rapids Ausha Scott
DATE COMPLETED:	02/06/2020		i usiu soou

			RECEIPT	FINAL
FRACTION #	NAME	<u>TEST</u>	VAC./PRES.	PRESSURE
01A	20200122-1	Modified TO-15 SIM	6.0 "Hg	5 psi
01AA	20200122-1 Lab Duplicate	Modified TO-15 SIM	6.0 "Hg	5 psi
02A	20200122-2	Modified TO-15 SIM	5.0 "Hg	5 psi
03A	20200122-3	Modified TO-15 SIM	1.0 "Hg	5 psi
04A	20200122-4	Modified TO-15 SIM	0.2 psi	5 psi
05A	20200122-DUP	Modified TO-15 SIM	2.0 "Hg	5 psi
06A	20200122-IA	Modified TO-15 SIM	8.0 "Hg	5 psi
07A	Lab Blank	Modified TO-15 SIM	NA	NA
07B	Lab Blank	Modified TO-15 SIM	NA	NA
08A	CCV	Modified TO-15 SIM	NA	NA
08B	CCV	Modified TO-15 SIM	NA	NA
09A	LCS	Modified TO-15 SIM	NA	NA
09AA	LCSD	Modified TO-15 SIM	NA	NA
09B	LCS	Modified TO-15 SIM	NA	NA
09BB	LCSD	Modified TO-15 SIM	NA	NA

Rayes Tude 6

Technical Director

CERTIFIED BY:

DATE: <u>02/06/20</u>

This report shall not be reproduced, except in full, without the written approval of Eurofins Air Toxics, LLC. 180 BLUE RAVINE ROAD, SUITE B FOLSOM, CA - 95630 (916) 985-1000 . (800) 985-5955 . FAX (916) 351-8279



Air Toxics

LABORATORY NARRATIVE EPA TO-15 Ethylene oxide (SIM) Ramboll Workorder# 2001554

Six 6 Liter Summa Canister (EO) samples were received on January 24, 2020. The laboratory performed analysis via EPA Method TO-15 using GC/MS in the SIM acquisition mode for the measurement of Ethylene oxide in ambient air.

Receiving Notes

Despite the use of flow controllers for sample collection, the final canister vacuum for sample 20200122-4 was measured at ambient pressure at the laboratory.

Analytical Notes

Ethylene Oxide is not included on the laboratory's NELAP scope of accreditation for TO-15 SIM. However, TO-15 method and NELAP quality requirements were met.

As per project specific client request the laboratory has reported estimated values for target compound hits that are below the Reporting Limit but greater than the Method Detection Limit. The canisters used for this project have been certified to the Reporting Limit for Ethylene Oxide. Concentrations that are below the level at which the canister was certified may be false positives.

Definition of Data Qualifying Flags

Nine qualifiers may have been used on the data analysis sheets and indicates as follows:

B - Compound present in laboratory blank greater than reporting limit (background subtraction not performed).

J - Estimated value.

S - Saturated peak.

Q - Exceeds quality control limits.

U - Compound analyzed for but not detected above the reporting limit, LOD, or MDL value. See data page for project specific U-flag definition.

UJ- Non-detected compound associated with low bias in the CCV

N - The identification is based on presumptive evidence.

CN - See Case Narrative

File extensions may have been used on the data analysis sheets and indicates as follows:

a-File was requantified

b-File was quantified by a second column and detector

r1-File was requantified for the purpose of reissue

MODIFIED EPA METHOD TO-15 GC/MS SIM

Viant Medical-Grand Rapids

Air Toxics

Client ID: Lab ID: Date/Time Collected Media:	20200122-1 2001554-01A : 1/23/20 11:25 AM 6 Liter Summa Canister (EO)	Date/Time A Dilution Fac Instrument/F	tor:	1/27/20 06:27 PM 1.68 msd30.i / 30012712sim	
Compound	CAS#	MDL (ug/m3)	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	75-21-8	0.045	D	0.15	0.087 J

J = Estimated value.

MODIFIED EPA METHOD TO-15 GC/MS SIM Viant Medical-Grand Rapids

Air Toxics

Client ID: Lab ID: Date/Time Collected: Media:	20200122-1 Lab Duplicate 2001554-01AA 1/23/20 11:25 AM 6 Liter Summa Canister (EO)	Date/Time A Dilution Fac Instrument/F	tor:	1/27/20 07 1.68 msd30.i / 3	:11 PM 0012713sim	
Compound	CAS#	MDL (ug/m3)	LOE (ug/m		Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	75-21-8	0.045	D	~,	0.15	0.082 J

J = Estimated value.

MODIFIED EPA METHOD TO-15 GC/MS SIM

Viant Medical-Grand Rapids

Air Toxics

Client ID: Lab ID: Date/Time Collected Media:	20200122-2 2001554-02A : 1/23/20 11:30 AM 6 Liter Summa Canister (EO)	Date/Time A Dilution Fac Instrument/F	tor: 1.	/27/20 07:55 PM 61 sd30.i / 30012714sim	
Compound	CAS#	MDL (ug/m3)	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	75-21-8	0.043	D	0.14	0.11 J

J = Estimated value.

MODIFIED EPA METHOD TO-15 GC/MS SIM

Viant Medical-Grand Rapids

Air Toxics

Client ID: Lab ID: Date/Time Collected Media:	20200122-3 2001554-03A I: 1/23/20 11:15 AM 6 Liter Summa Canister (EO)	Date/Time A Dilution Fac Instrument/F	tor:	1/27/20 08:39 PM 1.39 nsd30.i / 30012715sim	
Compound	CAS#	MDL (ug/m3)	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	75-21-8	0.037	D	0.12	0.11 J

J = Estimated value.

MODIFIED EPA METHOD TO-15 GC/MS SIM Viant Medical-Grand Rapids

Air Toxics

Client ID: Lab ID: Date/Time Collected: Media:	20200122-4 2001554-04A 1/23/20 10:23 AM 6 Liter Summa Canister (EO)	Date/Time A Dilution Fac Instrument/F	tor:	1/27/20 05:42 PM 1.32 msd30.i / 30012711sim	
Compound	CA5#	MDL (ug/m3)	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Compound Ethylene Oxide	CAS# 75-21-8	0.035	D	0.12	0.12

0.13

Air Toxics

0.12 J

MODIFIED EPA METHOD TO-15 GC/MS SIM Viant Medical-Grand Rapids

75-21-8

		MDL	LOD	Rpt. Limit 3) (ug/m3)	Amount (ug/m3)	
Date/Time Collected Media:	: 1/23/20 11:00 AM 6 Liter Summa Canister (EO)	Dilution Fac Instrument/F		1.44 msd30.i / 30012716sim		
		Date/Time A	nalyzed:	1/27/20 09:23 PM		

0.039

D

J = Estimated value.

Ethylene Oxide

MODIFIED EPA METHOD TO-15 GC/MS SIM Viant Medical-Grand Rapids

Air Toxics

Client ID: Lab ID: Date/Time Collected: Media:	20200122-IA 2001554-06A 1/23/20 11:37 AM 6 Liter Summa Canister (EO)	Date/Time A Dilution Fac Instrument/F	tor:	1/28/20 07:38 PM 1.83 msd30.i / 30012813sim	
Compound	CAS#	MDL (ug/m3)	LOD (ug/m3	Rpt. Limit) (ug/m3)	Amount (ug/m3)
Ethylene Oxide	75-21-8	0.049	D	0.16	0.35

MODIFIED EPA METHOD TO-15 GC/MS SIM Viant Medical-Grand Rapids

Air Toxics

Client ID: Lab ID: Date/Time Collected Media:	Lab Blank 2001554-07A I: NA - Not Applicable NA - Not Applicable		Date/Time / Dilution Fa Instrument	ctor:	1/27/20 12:20 PM 1.00 msd30.i / 30012706sim	
			MDL	LOD	Rpt. Limit	Amount
Compound		CAS#	(ug/m3)	(ug/m3) (ug/m3)	(ug/m3)
Ethylene Oxide	75	5-21-8	0.027	D	0.090	Not Detected

MODIFIED EPA METHOD TO-15 GC/MS SIM Viant Medical-Grand Rapids

Air Toxics

Client ID: Lab ID: Date/Time Collected Media:	Lab Blank 2001554-07B : NA - Not Applicable NA - Not Applicable	Dilution		1/28/20 02:08 PM 1.00 msd30.i / 30012807sim	
		MDL	LOD	Rpt. Limit	Amount
Compound	CAS#	(ug/m3)	(ug/m3)) (ug/m3)	(ug/m3)
Ethylene Oxide	75-21-8	0.027	D	0.090	Not Detected

🛟 eurofins **Air Toxics** MODIFIED EPA METHOD TO-15 GC/MS SIM Viant Medical-Grand Rapids CCV **Client ID:** 2001554-08A Date/Time Analyzed: Lab ID: 1/27/20 09:12 AM Date/Time Collected: NA - Not Applicable **Dilution Factor:** 1.00 NA - Not Applicable msd30.i / 30012702sim Media: Instrument/Filename: %Recovery Compound CAS#

72

D: Analyte not within the DoD scope of accreditation.

75-21-8

Ethylene Oxide

🛟 eurofins **Air Toxics** MODIFIED EPA METHOD TO-15 GC/MS SIM Viant Medical-Grand Rapids CCV **Client ID:** 2001554-08B Date/Time Analyzed: Lab ID: 1/28/20 10:01 AM Date/Time Collected: NA - Not Applicable **Dilution Factor:** 1.00 NA - Not Applicable msd30.i / 30012802sim Media: Instrument/Filename: %Recovery Compound CAS#

88

D: Analyte not within the DoD scope of accreditation.

75-21-8

Ethylene Oxide

🛟 eurofins **Air Toxics** MODIFIED EPA METHOD TO-15 GC/MS SIM Viant Medical-Grand Rapids LCS **Client ID:** 2001554-09A Date/Time Analyzed: Lab ID: 1/27/20 09:54 AM Date/Time Collected: NA - Not Applicable **Dilution Factor:** 1.00 NA - Not Applicable msd30.i / 30012703sim Media: Instrument/Filename: %Recovery Compound CAS#

94

D: Analyte not within the DoD scope of accreditation.

75-21-8

Ethylene Oxide

🛟 eurofins **Air Toxics** MODIFIED EPA METHOD TO-15 GC/MS SIM Viant Medical-Grand Rapids LCSD **Client ID:** 2001554-09AA Date/Time Analyzed: Lab ID: 1/27/20 10:36 AM Date/Time Collected: NA - Not Applicable **Dilution Factor:** 1.00 NA - Not Applicable msd30.i / 30012704sim Media: Instrument/Filename: %Recovery Compound CAS#

94

D: Analyte not within the DoD scope of accreditation.

75-21-8

Ethylene Oxide

🛟 eurofins **Air Toxics** MODIFIED EPA METHOD TO-15 GC/MS SIM Viant Medical-Grand Rapids LCS **Client ID:** 2001554-09B Date/Time Analyzed: Lab ID: 1/28/20 11:29 AM Date/Time Collected: NA - Not Applicable **Dilution Factor:** 1.00 NA - Not Applicable msd30.i / 30012804sim Media: Instrument/Filename: %Recovery Compound CAS#

81

D: Analyte not within the DoD scope of accreditation.

75-21-8

Ethylene Oxide

🛟 eurofins **Air Toxics** MODIFIED EPA METHOD TO-15 GC/MS SIM Viant Medical-Grand Rapids LCSD **Client ID:** 2001554-09BB Date/Time Analyzed: Lab ID: 1/28/20 12:13 PM Date/Time Collected: NA - Not Applicable **Dilution Factor:** 1.00 NA - Not Applicable msd30.i / 30012805sim Media: Instrument/Filename: %Recovery Compound CAS#

98

D: Analyte not within the DoD scope of accreditation.

75-21-8

Ethylene Oxide

APPENDIX D LABORATORY CHAIN OF CUSTODY

eurofins	Analysis Request /Canister Chain of For Laboratory Use Only	For Labor	lest /Caniste For Laboratory Use Only	ar Chai	n of Qu	Oustody					
180 Blue Ravine Rd. Suite B, Folsom, CA 95630 Phone (800) 985-5955: Fax (916) 351-8279	30 PID: <u>//k</u>	Workorder #:		2001554					~	page of -1	
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Sample Transportation Notice: Weiinquishing signature on this document indicates that samples are shipped in compliance with all applicable local. State, Federal, and international laws, regulations, and ordinances of any kind. Relinquishing signature also indicates agreement to hold harmless, defend, end indemnify Eurofins Air Toxics against any claim, demand, or action, of any kind, related to the collection, handling, of shipping of samples in the collection of the collect	ature on this document i sement to hold harmless	ndicates that sa , defen d, an d in	Imples are ship demnify Eurofi moles D.O.T.F	ped in complic ns Air Toxics a totline (800) 4	ance with all a against any cla 67-4022	oplicable local im, demand, c	, State, Fe or action,	ederal, ar of any kir	id interna id, relate	tional laws, regu d to the collection	Relinquishing signature on this document indicates that samples are shipped in compliance with all applicable local. State, Federal, and international laws, regulations, and ordinances of also indicates agreement to hold harmless, defend, and indemnify Eurofins Air Toxics against any claim, demand, or action, of any kind, related to the collection, handling, of shipping of samples D.O.T. Hotline (200) 467-4672
		sa	samples. D.O.T Hotline (800) 467-4922	10tline (800) 4	67-4922						