MICHIGAN DEPARTMENT OF ENVIRONMENT, GREAT LAKES, AND ENERGY

INTEROFFICE COMMUNICATION

TO: File

FROM: Amy Robinson

DATE: December 10, 2019

SUBJECT: Monthly Ethylene Oxide Sampling at Viant Medical, Inc. for September and October 2019

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 (outdoor) air impacts. Subsequent computer modeling by the Michigan Department of Environment, Great Lakes and Energy's Air Quality Division (AQD) showed impacts above the Initial Risk Screening Level (IRSL) of 0.0002 μ g/m³ and Secondary Risk Screening Level (SRSL) of 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 (Ramboll) 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. From August 2019 through February 2020, the AQD will collect a side by side outdoor (collocated) air sample with Viant at one location. Results of all sampling events are available on the website Michigan.gov/viant.

Sampling Details

Ambient air sampling for ethylene oxide was accomplished using USEPA's TO-15 summa canister method. USEPA's national contract laboratory, Eastern Research Group (ERG), performed the analysis. ERG's laboratory detection limit is $0.045 \ \mu g/m^3$. Since the screening levels are lower than the detection limit the current sampling method for ethylene oxide allows for, the sampling data will have to be carefully interpreted. For example, if a sample result is reported as non-detect (ND), it is possible the actual level could still be above the screening levels.

The USEPA and ERG are actively working to improve the laboratory test method for ethylene oxide. Recently, ERG performed a trial run of a different method to see if ethylene oxide could be detected at lower levels. The <u>August 2019</u> sampling report utilized this updated method. However, after analyzing a few months' worth of data using the updated method, ERG determined the older method was more accurate in sensing ethylene oxide at or near the detection limit. Because

accuracy of data is very important, ERG went back to using the previous method of analysis. For consistency of data, the August sample was reprocessed, and the results were included in the laboratory report attached to this memo. The attachment contains August, September and October results.

Ramboll collected five samples over a 24-hour period on September 10, 2019 and on October 16, 2019. The AQD co-located one sample during both Viant sampling events. The AQD used 6-liter evacuated summa canisters which were sampled for 24 hours using fixed orifice regulators.

Results

Ramboll's sample results from September are on page 2 of the report named "Ambient Air Sampling at Viant Medical Facility, Grand Rapids, Michigan September 2019 Sampling Events Results". Ramboll's sampling results from October are on page 2 of the report named "Ambient Air Sampling at Viant Medical Facility, Grand Rapids, Michigan October 2019 Sampling Events Results". Ramboll's results for both months are similar to the AQD's <u>Phase I</u> and <u>Phase II</u> sampling results.

The results from the AQD's collocated canisters are on page 4 and 5 of the <u>ERG</u> <u>lab report</u>. The goal is to collocate the AQD canister in the predicted downwind direction for the day of sampling, therefore the co-located sampling site may change from month to month. September and October sampling locations can be seen in Figure 1.

The USEPA has established criteria for comparing data from different laboratories. If values from two different laboratories are within \pm 20%, then the laboratories have good comparability. It is difficult to make any determinations about the laboratories with just a few samples. The September and October sample results, when comparing Ramboll and ERG are outside of the \pm 20% criteria. As additional data is received, a better determination of laboratory comparability can be made.



Figure 1: Map of EGLE AQD ethylene oxide sample locations

12/2019

AMBIENT AIR SAMPLING AT VIANT MEDICAL FACILITY, GRAND RAPIDS, MICHIGAN SEPTEMBER 2019 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 October 2019

Project Number 1690010876

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2019

APPENDICES

- Attachment A: Air Sampling Program Results Summary
- Attachment B: Photographs of Sampling Locations
- Attachment C: Laboratory Analytical Report
- Attachment 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 September 2019 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 September 10 and 11, 2019, and included the collection of five ambient air samples¹ and one indoor air (IA) sample that were submitted for laboratory analysis of ethylene oxide (EtO). The sampling was the third monthly event performed in accordance with the scope of work in the April 2019 Ambient Air Sampling Work Plan (the "April 2019 Work Plan") prepared by Ramboll. The sections below describe the sampling methodology and results from the September 2019 sampling event.

2. SAMPLING LOCATIONS

The five sampling locations selected during this event were the same locations sampled by Ramboll during previous events. Location #4 was selected for the placement of co-located samples. Sampling locations are depicted on Figure 1 and photographs of each sample are included in Attachment A.

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). The canisters were secured to the same fixtures that were used during previous sampling events for sample collection within the breathing zone (approximately 5-6 feet). The co-located sample canister inlets at Location #4 were located 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 July 2019 sampling report. After the successful completion of the shut-in test at each location, 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 were variable, blowing primarily from the southwest and south, during the 24-hour sampling period, which began September 10, 2019 and ended September 11, 2019.

After approximately 24 hours from the start of the event, the valves on the canisters were closed, final field measurements were recorded, and samples 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 canister samples on September 12, 2019 and analyzed them between September 13 and 18, 2019.

Additionally, the Michigan Department of Environment, Great Lakes, and Energy (EGLE) collected one canister sample at Location #4 during the same 24-hour time period as Ramboll's samples and sent the sample to its own contract laboratory for analysis.

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, the canister inlets were placed one foot from each other.

4. **RESULTS**

Table 1: Outdoor Air Sampling Results, September 10-11, 2019						
Sample Location ID	On-Site	Location Description	EtO Concentration (μg/m ³)	Sample- Specific MDL (µg/m³)		
1	Yes	South of building in parking lot	0.38	0.047		
2	Yes	West of building, along western property boundary	0.51	0.047		
3	No	Northwest of building along Watson Street Southwest	0.40	0.046		
4 (co- located samples)	Yes	North of building, northern corner of parking lot	0.90; 0.76 (co-located sample)	0.047; 0.046		

The results from the September 2019 sampling event are reported in Table 1 and Table 2.

Table 2: Indoor Air Sampling Results, September 10-11, 2019							
Sample Location IDLocation DescriptionEtO Concentration $(\mu g/m^3)$ Sample- Specific MDL $(\mu g/m^3)$							
IA							

EtO was detected in all samples collected during the September 2019 event. The EtO concentration in outdoor ambient air samples ranged from 0.38 micrograms per cubic meter (μ g/m³) at Location #1 to 0.90 μ g/m³ at Location #4³ (Figure 1). 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.⁴ According to the meteorological data, winds were generally blowing from the southwest and south (Figure 2). Wind speed varied between 0 and 12 miles per hour (mph). The EtO concentration inside the scrubber room was 710 μ g/m³. A summary of results from this and prior sampling events is provided in Appendix A.

5. QUALITY ASSURANCE

Ramboll evaluated data quality based on acceptable criteria specified by USEPA for precision, completeness, bias, and sensitivity in accordance with the Ambient Air Sampling Work Plan. To evaluate the repeatability of sampling procedures, one co-located sample was collected at Location #4 during this investigation. The difference in concentrations of EtO detected in these co-located samples was 16.9% and within the acceptable range of 25%, as defined in the April 2019 Work Plan.

 $^{^3}$ The detected concentration of EtO in the co-located sample collected at this location was 0.76 $\mu g/m^3.$

⁴ The Grand Rapids – Monroe Street air monitoring site is part of the state's air monitoring network as well as the federal NCore multi-pollutant monitoring network. Meteorological measurements collected at that site are subject to quality assurance procedures in the Quality Assurance Handbook for Air Pollution Measurement Systems, Volume IV: Meteorological Measurements Version 2.0.

Additionally, a laboratory replicate sample analysis of the sample collected at Location #1 was performed. In this replicate analysis, the concentrations of EtO detected in both the original and replicate sample were identical ($0.38 \ \mu g/m^3$); thus, the replicate sample precision fell within the acceptable range of 25%. Given the sensitivity of the laboratory analytical method, the laboratory diluted the sample collected inside the scrubber room, which increased the Minimum Detection Limit (MDL) above the target MDL for this sample. A summary of all quality assurance criteria related to the September 2019 sampling event is provided in Table 2 below.

0	Data Ovalita	F	0	Contoucher	0
Quality Control Sample	Data Quality Indicators (DQIs)	Frequency	Acceptance Criteria	September 2019 Outcome	Corrective Action
Co-located sample	Precision	1 per day	Within 25%	16.9%	N/A
Replicate sample	Precision	1 per batch	Within 25% for 0.0% sample concentrations greater than five times reporting limit		N/A
Valid sample count	Completeness	N/A	85% or more of total samples	100% (100% for total sampling program)	N/A
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	N/A

6. CONCLUSIONS

EtO was detected at concentrations in ambient air surrounding the Viant facility at concentrations between 0.38 μ g/m³ and 0.90 μ g/m³ during the September 2019 sampling event, with the highest concentrations observed in the predominant downwind direction relative to the site building.

FIGURE 1 MAP OF SAMPLING RESULTS

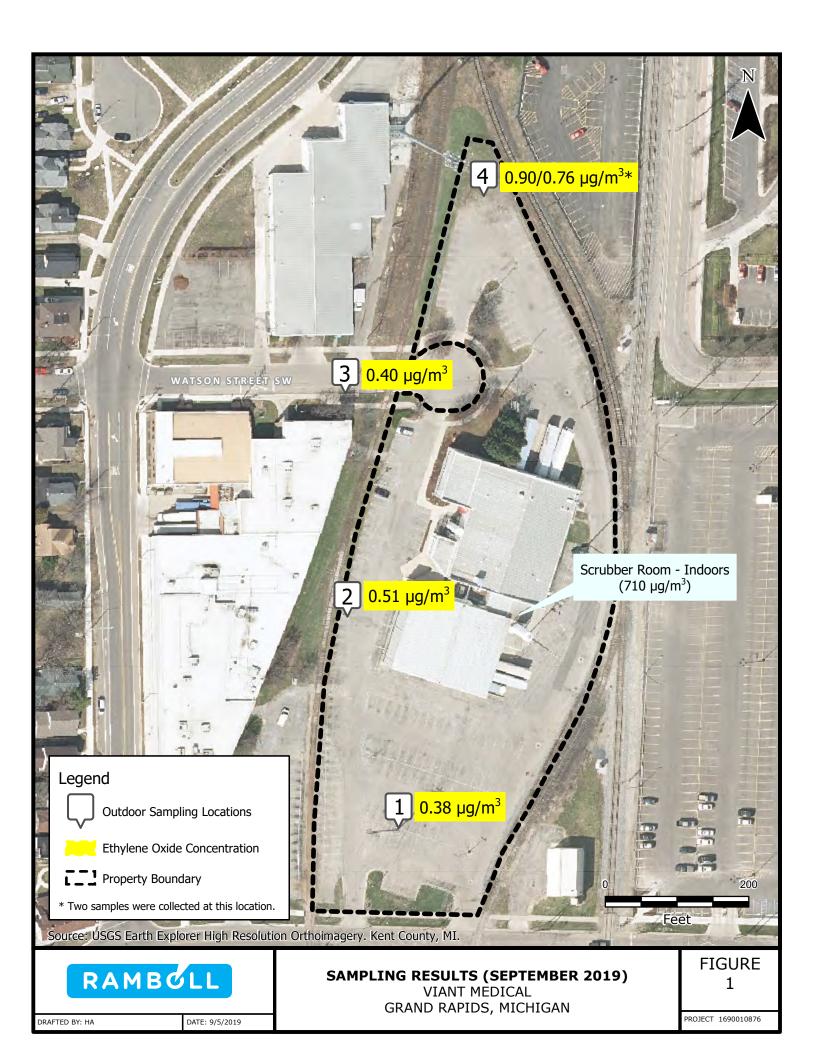
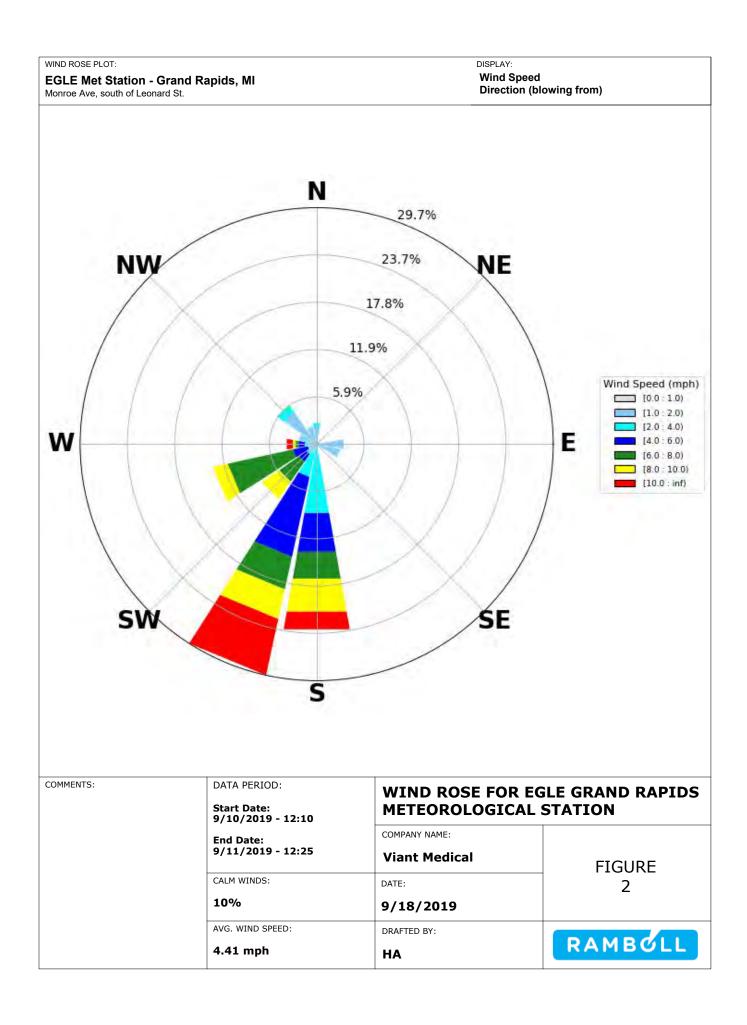


FIGURE 2 WIND ROSE



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	

Notes: /= Quality control sampling data is separated by a slash (/) ^c = Co-located sample Note 1 = Result represents an average concentration over a 21-hour period

Viant Medical 520 Watson Street Southwest, Grand Rapids, MI

Ethylene Oxide Concentrations ($\mu g/m^3)$ 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

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

APPENDIX B PHOTOGRAPHS OF SAMPLING LOCATIONS



Photo 1: View of sample collection at location #1, facing south.



Photo 2: View of sample collection at location #2, facing west.



Site Photographs Viant Medical 520 Watson Street Southwest, Grand Rapids, Michigan September 2019



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



Photo 4: View of co-located sample collection at location #4, facing north. Sample collected by the Michigan Department of Environment, Great Lakes, and Energy (EGLE) also pictured (center canister).



Site Photographs Viant Medical 520 Watson Street Southwest, Grand Rapids, Michigan September 2019





APPENDIX C LABORATORY ANALYTICAL REPORT



Air Toxics

9/25/2019 Ms. Christine Ng Ramboll 4350 N. Fairfax Drive Suite 300 Arlington VA 22203

Project Name: Viant Medical Grand Rapids Project #: 1690010876 Workorder #: 1909255

Dear Ms. Christine Ng

The following report includes the data for the above referenced project for sample(s) received on 9/12/2019 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

A Eurofins Lancaster Laboratories Company

180 Blue Ravine Road, Suite B Folsom, CA 95630



Air Toxics

WORK ORDER #: 1909255

Work Order Summary

CLIENT:	Ms. Christine Ng Ramboll 4350 N. Fairfax Drive Suite 300 Arlington, VA 22203	BILL TO:	Accounts Payable-Arlington VA Ramboll 4350 N. Fairfax Drive Suite 300 Arlington, VA 22203
PHONE:	703-516-2382	P.O. #	WO-2019-ARL-01
FAX:	703-516-2302	PROJECT #	1690010876 Viant Medical Grand Rapids
DATE RECEIVED:	09/12/2019	CONTACT:	Ausha Scott
DATE COMPLETED:	09/24/2019	continent	i usiu soot

			RECEIPT	FINAL
FRACTION #	NAME	<u>TEST</u>	VAC./PRES.	PRESSURE
01A	20190910-IA	Modified TO-15 SIM	7.6 "Hg	5 psi
02A	20190910-1	Modified TO-15 SIM	7.1 "Hg	4.8 psi
02AA	20190910-1 Lab Duplicate	Modified TO-15 SIM	7.1 "Hg	4.8 psi
03A	20190910-2	Modified TO-15 SIM	6.9 "Hg	5 psi
04A	20190910-3	Modified TO-15 SIM	6.7 "Hg	4.9 psi
05A	20190910-4	Modified TO-15 SIM	7.1 "Hg	5 psi
06A	20190910-DUP	Modified TO-15 SIM	6.5 "Hg	5.1 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>09/24/19</u>

This report shall not be reproduced, except in full, without the written approval of Eurofins Air Toxics, Inc. 180 BLUE RAVINE ROAD, SUITE B FOLSOM, CA - 95630 (916) 985-1000 . (800) 985-5955 . FAX (916) 985-1020 **Air Toxics**

LABORATORY NARRATIVE EPA TO-15 Ethylene oxide (SIM) Ramboll Workorder# 1909255

Six 6 Liter Summa Canister (100% SIM Ambient) samples were received on September 12, 2019. 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.

This workorder was independently validated prior to submittal using 'USEPA National Functional Guidelines' as generally applied to the analysis of volatile organic compounds in air. A rules-based, logic driven, independent validation engine was employed to assess completeness, evaluate pass/fail of relevant project quality control requirements and verification of all quantified amounts.

Receiving Notes

eurofins 🚯

There were no receiving discrepancies.

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.

Dilution was performed on sample 20190910-IA due to the presence of high level target species.

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

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MODIFIED EPA METHOD TO-15 GC/MS SIM

Viant Medical Grand Rapids

Air Toxics

Client ID: Lab ID: Date/Time Collected: Media:	20190910-IA 1909255-01A 9/11/19 12:10 PM 6 Liter Summa Canister (100% SIM Ambier	Date/Time A Dilution Fac Instrument/F	tor:	9/18/19 11:11 PM 28.7 msd30.i / 30091819sim	
Compound	CAS#	MDL (ug/m3)	LOD (ug/m:	Rpt. Limit 3) (ug/m3)	Amount (ug/m3)
Ethylene Oxide	75-21-8	0.77	D	2.6	710

🛟 eurofins

MODIFIED EPA METHOD TO-15 GC/MS SIM

Viant Medical Grand Rapids

Air Toxics

Client ID: Lab ID: Date/Time Collected: Media:	20190910-1 1909255-02A 9/11/19 12:24 PM 6 Liter Summa Canister (100% SIM Ambier	Date/Time A Dilution Fac Instrument/I	tor:	9/13/19 07:33 PM 1.74 msd30.i / 30091308sim	
Compound	CAS#	MDL (ug/m3)	LOD (ug/m3	Rpt. Limit) (ug/m3)	Amount (ug/m3)
Ethylene Oxide	75-21-8	0.047	D	0.16	0.38

🔅 eurofins

Air Toxics

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

Client ID: Lab ID: Date/Time (Media:

ical Grand R	apids			
Collected:	20190910-1 Lab Duplicate 1909255-02AA 9/11/19 12:24 PM 6 Liter Summa Canister (100% SIM Ambier	Date/Time Analyzed: Dilution Factor: Instrument/Filename:	9/13/19 08:18 PM 1.74 msd30.i / 30091309sim	

Compound	CAS#	MDL (ug/m3)	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)	
Ethylene Oxide	75-21-8	0.047	D	0.16	0.38	

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MODIFIED EPA METHOD TO-15 GC/MS SIM

Viant Medical Grand Rapids

Air Toxics

Client ID: Lab ID: Date/Time Collected: Media:	20190910-2 1909255-03A 9/11/19 12:22 PM 6 Liter Summa Canister (100% SIM Ambier	Date/Time A Dilution Fac Instrument/F	tor:	9/13/19 09:02 PM 1.74 msd30.i / 30091310sim	
Compound	CAS#	MDL (ug/m3)	LOD (ug/m	•	Amount (ug/m3)
Ethylene Oxide	75-21-8	0.047	D	0.16	0.51

🛟 eurofins

MODIFIED EPA METHOD TO-15 GC/MS SIM

Viant Medical Grand Rapids

Air Toxics

Client ID: Lab ID: Date/Time Collected: Media:	20190910-3 1909255-04A 9/11/19 12:19 PM 6 Liter Summa Canister (100% SIM Ambier	Date/Time A Dilution Fac Instrument/F	tor:	9/13/19 09:46 PM 1.72 msd30.i / 30091311sim	
		MDL	LOD	Rpt. Limit	Amount
Compound	CAS#	(ug/m3)	(ug/m3) (ug/m3)	(ug/m3)
Ethylene Oxide	75-21-8	0.046	D	0.15	0.40

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MODIFIED EPA METHOD TO-15 GC/MS SIM

Viant Medical Grand Rapids

Air Toxics

Client ID: Lab ID: Date/Time Collected: Media:	20190910-4 1909255-05A 9/11/19 12:16 PM 6 Liter Summa Canister (100% SIM Ambier	Date/Time A Dilution Fac Instrument/F	tor:	9/13/19 10:30 PM 1.76 msd30.i / 30091312sim		
Common d	040#	MDL	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)	
Compound Ethylene Oxide	CAS# 75-21-8	(ug/m3) 0.047	(ug/ms) D	0.16	0.90	

🛟 eurofins

0.15

Air Toxics

0.76

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

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75-21-8

Client ID: Lab ID: Date/Time Collected: Media:	20190910-DUP 1909255-06A 9/11/19 12:16 PM 6 Liter Summa Canister (100% SIM Ambier	Date/Time A Dilution Fac Instrument/F	tor: 1.	13/19 11:15 PM 72 sd30.i / 30091313sim	
Compound	CAS#	MDL (ug/m3)	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)

0.046

D

D: Analyte not within the DoD scope of accreditation.

🔅 eurofins

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

Client ID:	Lab Blank				
Lab ID:	1909255-07A	Date/Time Analyzed: 9/13 Dilution Factor: 1.00		13/19 05:05 PM	
Date/Time Collected	NA - Not Applicable			00	
Media:	NA - Not Applicable	Instrument/F	ilename: ma	sd30.i / 30091307sim	
		MDL	LOD	Rpt. Limit	Amount
Compound	CAS#	MDL (ug/m3)	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)

🔅 eurofins

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

Air Toxics

Client ID: Lab ID: Date/Time Collected: Media:	Lab Blank 1909255-07B NA - Not Applicable NA - Not Applicable	Dilution F	e Analyzed: Factor: nt/Filename:	9/18/19 12:12 PM 1.00 msd30.i / 30091806sima	
		MDL	LOD	Rpt. Limit	Amount
Compound	CAS#	(ug/m3)	(ug/m:	3) (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:** 1909255-08A Date/Time Analyzed: Lab ID: 9/13/19 11:41 AM Date/Time Collected: NA - Not Applicable **Dilution Factor:** 1.00 NA - Not Applicable msd30.i / 30091302sim Media: Instrument/Filename: %Recovery Compound CAS#

99

D: Analyte not within the DoD scope of accreditation.

75-21-8

🔅 eurofins **Air Toxics** MODIFIED EPA METHOD TO-15 GC/MS SIM Viant Medical Grand Rapids CCV **Client ID:** 1909255-08B Date/Time Analyzed: Lab ID: 9/18/19 09:02 AM Date/Time Collected: NA - Not Applicable **Dilution Factor:** 1.00 NA - Not Applicable msd30.i / 30091802sim Media: Instrument/Filename: %Recovery Compound CAS#

109

D: Analyte not within the DoD scope of accreditation.

75-21-8

🛟 eurofins **Air Toxics** MODIFIED EPA METHOD TO-15 GC/MS SIM Viant Medical Grand Rapids LCS **Client ID:** 1909255-09A Date/Time Analyzed: Lab ID: 9/13/19 12:24 PM Date/Time Collected: NA - Not Applicable **Dilution Factor:** 1.00 NA - Not Applicable msd30.i / 30091303sim Media: Instrument/Filename: %Recovery Compound CAS#

111

D: Analyte not within the DoD scope of accreditation.

75-21-8

🛟 eurofins **Air Toxics** MODIFIED EPA METHOD TO-15 GC/MS SIM Viant Medical Grand Rapids LCSD **Client ID:** 1909255-09AA Date/Time Analyzed: Lab ID: 9/13/19 04:21 PM Date/Time Collected: NA - Not Applicable **Dilution Factor:** 1.00 NA - Not Applicable msd30.i / 30091306sim Media: Instrument/Filename: %Recovery Compound CAS#

123

D: Analyte not within the DoD scope of accreditation.

75-21-8

Ethylene Oxide

* % Recovery is calculated using unrounded analytical results.

🛟 eurofins **Air Toxics** MODIFIED EPA METHOD TO-15 GC/MS SIM Viant Medical Grand Rapids LCS **Client ID:** 1909255-09B Date/Time Analyzed: Lab ID: 9/18/19 09:43 AM Date/Time Collected: NA - Not Applicable **Dilution Factor:** 1.00 NA - Not Applicable msd30.i / 30091803sim Media: Instrument/Filename: %Recovery Compound CAS#

121

D: Analyte not within the DoD scope of accreditation.

75-21-8

Ethylene Oxide

* % Recovery is calculated using unrounded analytical results.

🛟 eurofins **Air Toxics** MODIFIED EPA METHOD TO-15 GC/MS SIM Viant Medical Grand Rapids LCSD **Client ID:** 1909255-09BB Date/Time Analyzed: Lab ID: 9/18/19 10:25 AM Date/Time Collected: NA - Not Applicable **Dilution Factor:** 1.00 NA - Not Applicable msd30.i / 30091804sim Media: Instrument/Filename: %Recovery Compound CAS#

125

D: Analyte not within the DoD scope of accreditation.

75-21-8

Ethylene Oxide

* % Recovery is calculated using unrounded analytical results.

APPENDIX D LABORATORY CHAIN OF CUSTODY

Securofins Air Toxics	Analysis Request /Canister	For Labor	lest /Canister	Chain of		Oustody			20	2 boxes in shipned	ship	Ş.	
180 Blue Ravine Rd. Suite B, Folsom, CA 95630 Phone (800) 985-5955; Fax (916) 351-8279	30 PtD:	Workorder #	(* #:	19	1909255	0.			g	page-of			
Client: Ramboll		Special In	Special Instructions/Notes:					Turnaro	Ind Time	Turnaround Time (Rush surcharges may apply)	rges may	apply)	
Viant Medical Gran	Rapids	M	Multified T	70 - 15	SIH		Standard	rd 🗸		Rush		(specify)	
lanager: Christine Ng	Project # 169000876						Car	Canister Vacuum/Pressure	cuum/Pr	essure	Reques	Requested Analyses	ës
Nick Mar								r	Lab (Lab Use Only			
Site Name: Visant Medical							g)	;) 			2		Dagsen inda
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			Date	Time	Date	Time	Initia	Fina	Reco	Gas:	E+ C		
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			Lab Use Only	on							-		
Shipper Name:	Custody Seals Intact?	Yes	No	None								and the second	
any kind. Relinquishing signature also indicates agreement to hold harmless, defend, and indemnify Eurofins Air Toxics against any	ture on this document ind ement to hold harmless, i	dicates that sar defend, and inc	nples are shipped lemnify Eurofins /	in complian dr Toxics aga		licable local, s h, demand, or	state, Fed action, of	eral, and any kind	internation related	It applicable local, State, Federal, and international taws, regulations, and ordinances of claim, demand, or action, of any kind, related to the collection, handling, of shipping of	ations, and handling,	f ordinance of shipping	l of
		sar	samples. D.O.T Hotline (800) 467-4922	ne (800) 467	-4922						1	-	:

AMBIENT AIR SAMPLING AT VIANT MEDICAL FACILITY, GRAND RAPIDS, MICHIGAN OCTOBER 2019 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 December 2019

Project Number 1690010876

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2019

APPENDICES

- Appendix A: Air Sampling Program Results Summary
- 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 October 2019 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 October 16 and 17, 2019, and included the collection of five 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. The sections below describe the sampling methodology and results from the October 2019 sampling event.

2. SAMPLING LOCATIONS

The five sampling locations selected during this event were the same locations sampled by Ramboll during previous events. Location #1 was selected for the placement of co-located samples, 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). The canisters were secured to the same fixtures that were used during previous sampling events for sample collection within the breathing zone (approximately 5-6 feet). The co-located canister inlets at Location #1 were approximately 2 feet² 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 northwest during the 24-hour sampling period, which began October 16, 2019 and ended October 17, 2019.

After approximately 24 hours from the start of the event, the valves on the canisters were closed, final field measurements were recorded, and samples 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 October 18, 2019 and analyzed the samples between October 21 and 23, 2019.

Additionally, the Michigan Department of Environment, Great Lakes, and Energy (EGLE) collected one canister sample at Location #1 in the same 24-hour time period as Ramboll's samples, which was sent to a different contract laboratory for analysis and will be discussed separately by EGLE.

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 #1, the canister inlets were placed two feet from each other.

4. **RESULTS**

Table 1: Ou	utdoor Air	Sampling Results, October 1	6-17, 2019	
Sample Location ID	On-Site	Location Description	EtO Concentration (μg/m ³)	Sample- Specific MDL (μg/m³)
1 (co- located samples)	Yes	South of building in parking lot	0.20; 0.20 (co-located sample)	0.044; 0.044
2	Yes	West of building, along western property boundary	0.15 J	0.054
3	No	Northwest of building along Watson Street Southwest	0.34	0.044
4	Yes	North of building, northern corner of parking lot	0.16	0.043
J = Laborato	ory-estimate	ed value below the Reporting Li	imit but above the MI	DL.

The results from the October 2019 Ramboll sampling event are reported in Tables 1 and 2.

Table 2: Indoor	Air Sampling Results, October	16-17, 2019	
Sample Location ID	Location Description	EtO Concentration (µg/m³)	Sample- Specific MDL (µg∕m³)
IA	Scrubber room	590	0.48

EtO was detected in all samples collected during the October 2019 event. The EtO concentration in outdoor ambient air samples ranged from 0.15 micrograms per cubic meter (μ g/m³) at Location #2 to 0.34 μ g/m³ at Location #3 (Figure 1). 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 northwest during the sampling event. Wind speeds varied between 1 and 16 miles per hour (mph). The EtO concentration inside the scrubber room was 590 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 #1 during this investigation. The same concentration of EtO was detected in both canisters for the co-located sample; thus, the calculated difference in values (0%) is in the acceptable range of within 25%.

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.

Additionally, 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 9.5% (using the calculated average detected concentration as the denominator), which also is in the acceptable range of within 25%. Given the sensitivity of the laboratory analytical method, the laboratory diluted the sample collected inside the scrubber room, which increased the Minimum Detection Limit (MDL) above the target MDL for this sample. A summary of all quality assurance criteria related to the October 2019 sampling event is provided in Table 3 below.

Table 3: Qual	ity Control Crite	ria for TO-15 Samp	le Collection and Ar	nalysis, October 1	6-17, 2019
Quality Control Sample	Data Quality Indicators (DQIs)	Frequency	Acceptance Criteria	October 2019 Outcome	Corrective Action
Co-located sample	Precision	1 per day	Within 25%	0.0%	N/A
Replicate sample	Precision	1 per batch	Within 25% for sample concentrations greater than five times reporting limit	9.5%	N/A
Valid sample count	Completeness	N/A	85% or more of total samples	100% (100% for total sampling program)	N/A
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	N/A

6. CONCLUSIONS

EtO was detected at concentrations in ambient air surrounding the Viant facility at concentrations between 0.15 μ g/m³ and 0.34 μ g/m³ during the October 2019 sampling event. No correlation was apparent between sample concentrations and predominant wind direction, as was evident during prior monthly sampling events.

FIGURE 1 MAP OF SAMPLING RESULTS

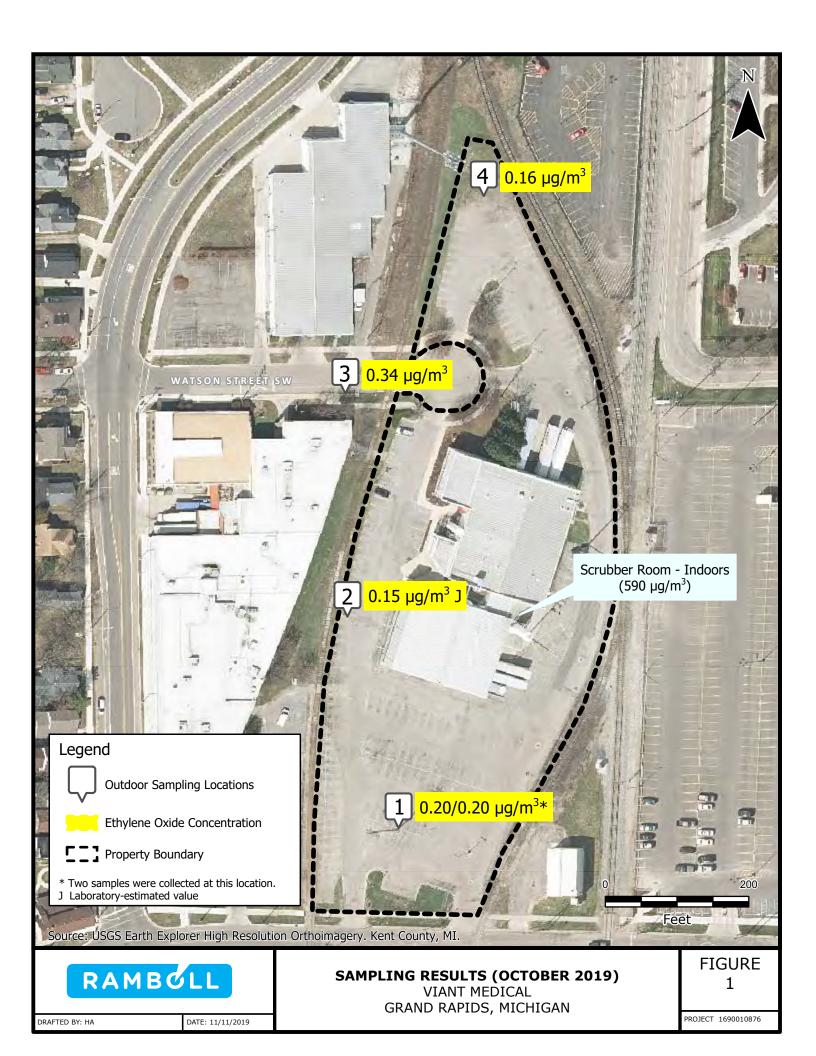
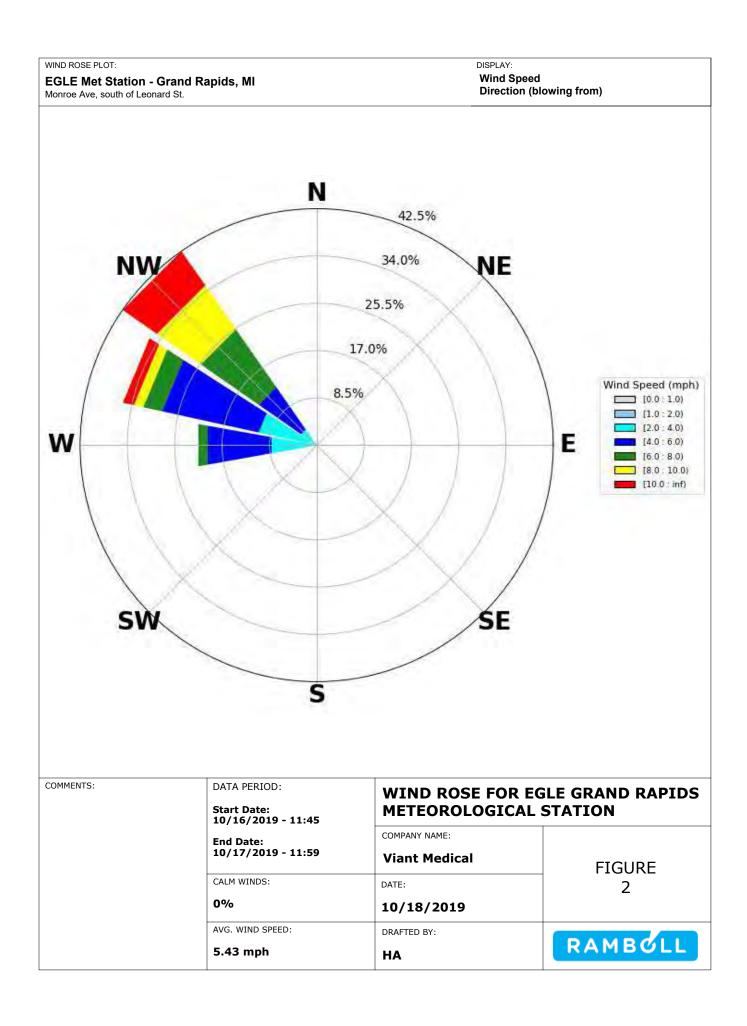


FIGURE 2 WIND ROSE



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 a	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	

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

Viant Medical 520 Watson Street Southwest, Grand Rapids, MI

Ethylene Oxide Concentrations ($\mu g/m^3)$ 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

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

APPENDIX B PHOTOGRAPHS OF SAMPLING LOCATIONS



Photo 1: View of co-located sample collection at location #1, facing south. Sample collected by the Michigan Department of Environment, Great Lakes, and Energy (EGLE) also pictured (center canister).



Photo 2: View of sample collection at location #2, facing west.



Site Photographs Viant Medical 520 Watson Street Southwest, Grand Rapids, Michigan October 2019



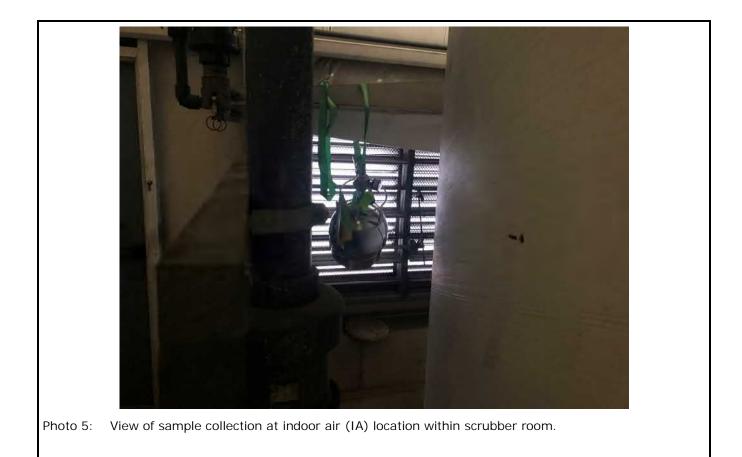
Photo 3: View of sample collection at location #3, facing east.



Photo 4: View of sample collection at location #4, facing south.



Site Photographs Viant Medical 520 Watson Street Southwest, Grand Rapids, Michigan October 2019





APPENDIX C LABORATORY ANALYTICAL REPORT



Air Toxics

10/31/2019 Ms. Christine Ng Ramboll 4350 N. Fairfax Drive Suite 300 Arlington VA 22203

Project Name: Viant Medical-Grand Rapids Project #: 1690010876 Workorder #: 1910464

Dear Ms. Christine Ng

The following report includes the data for the above referenced project for sample(s) received on 10/18/2019 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,

Scott

Ausha Scott Project Manager

180 Blue Ravine Road, Suite B Folsom, CA 95630



Air Toxics

WORK ORDER #: 1910464

Work Order Summary

CLIENT:	Ms. Christine Ng Ramboll 4350 N. Fairfax Drive Suite 300 Arlington, VA 22203	BILL TO:	Accounts Payable-Arlington VA Ramboll 4350 N. Fairfax Drive Suite 300 Arlington, VA 22203
PHONE:	703-516-2382	P.O. #	WO-2019-ARL-01
FAX:	703-516-2302	PROJECT #	1690010876 Viant Medical-Grand
DATE RECEIVED:	10/18/2019	CONTACT:	Rapids Ausha Scott
DATE COMPLETED:	10/31/2019		

			RECEIPT	FINAL
FRACTION #	NAME	<u>TEST</u>	VAC./PRES.	PRESSURE
01A	20191016-IA	Modified TO-15 SIM	7.5 "Hg	5 psi
02A	20191016-1	Modified TO-15 SIM	5.5 "Hg	5 psi
02AA	20191016-1 Lab Duplicate	Modified TO-15 SIM	5.5 "Hg	5 psi
03A	20191016-DUP	Modified TO-15 SIM	5.5 "Hg	5 psi
04A	20191016-2	Modified TO-15 SIM	10.0 "Hg	5 psi
05A	20191016-3	Modified TO-15 SIM	5.5 "Hg	5 psi
06A	20191016-4	Modified TO-15 SIM	5.0 "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>10/31/19</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# 1910464

Six 6 Liter Summa Canister (EO) samples were received on October 18, 2019. 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.

This workorder was independently validated prior to submittal using 'USEPA National Functional Guidelines' as generally applied to the analysis of volatile organic compounds in air. A rules-based, logic driven, independent validation engine was employed to assess completeness, evaluate pass/fail of relevant project quality control requirements and verification of all quantified amounts.

Receiving Notes

There were no receiving discrepancies.

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.

Dilution was performed on sample 20191016-IA due to the presence of high level target species.

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:	20191016-IA 1910464-01A : 10/17/19 11:38 AM 6 Liter Summa Canister (EO)	Date/Time A Dilution Fac Instrument/F	tor:	10/23/19 01:42 AM 17.9 msd30.i / 30102222sim	
Compound	CAS#	MDL (ug/m3)	LOD (ug/m3	Rpt. Limit) (ug/m3)	Amount (ug/m3)
Ethylene Oxide	75-21-8	0.48	D	1.6	590

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

Air Toxics

Client ID: Lab ID: Date/Time Collected: Media:	20191016-1 1910464-02A : 10/17/19 11:48 AM 6 Liter Summa Canister (EO)	Date/Time A Dilution Fac Instrument/F	tor:	10/21/19 05:22 PM 1.64 msd30.i / 30102110sim	
Compound	0404	MDL (ug/m3)	LOD (ug/m3	Rpt. Limit) (ug/m3)	Amount (ug/m3)
Compound Ethylene Oxide	CAS# 75-21-8	0.044	D	0.15	0.20

Air Toxics

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

Client ID: Lab ID: Date/Time Collected: Media:	20191016-1 Lab Duplicate 1910464-02AA 10/17/19 11:48 AM 6 Liter Summa Canister (EO)	Date/Time A Dilution Fac Instrument/F	tor: 1	0/21/19 06:06 PM .64 nsd30.i / 30102111sim	
Compound	CAS#	MDL (ug/m3)	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	75-21-8	0.044	D	0.15	0.22

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

Air Toxics

Client ID: Lab ID: Date/Time Collected: Media:	20191016-DUP 1910464-03A : 10/17/19 11:48 AM 6 Liter Summa Canister (EO)	Date/Time A Dilution Fac Instrument/F	tor:	10/21/19 06:50 PM 1.64 msd30.i / 30102112sim	
Compound	CAS#	MDL (ug/m3)	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	75-21-8	0.044	D	0.15	0.20

0.18

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

Air Toxics

0.15 J

Client ID: Lab ID: Date/Time Collected Media:	20191016-2 1910464-04A d: 10/17/19 11:53 AM 6 Liter Summa Canister (EO)	Date/Time A Dilution Fac Instrument/F	tor:	10/21/19 07:33 PM 2.01 msd30.i / 30102113sim	
Compound	CAS#	MDL (ug/m3)	LOD (ug/m3	Rpt. Limit) (ug/m3)	Amount (ug/m3)

0.054

D

J = Estimated value.

Ethylene Oxide

D: Analyte not within the DoD scope of accreditation.

75-21-8

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

Air Toxics

Client ID: Lab ID: Date/Time Collected Media:	20191016-3 1910464-05A : 10/17/19 11:57 AM 6 Liter Summa Canister (EO)	Date/Time A Dilution Fac Instrument/F	tor:	10/21/19 08:17 PM 1.64 msd30.i / 30102114sim	
Compound	CAS#	MDL (ug/m3)	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	75-21-8	0.044	D	0.15	0.34

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

Client ID:

Date/Time Analyzed: 10/21/19 09:01 PM

Lab ID: Date/Time Collected: Media:	1910464-06A : 10/17/19 11:59 AM 6 Liter Summa Canister (EO)	Date/Time A Dilution Fac Instrument/F	tor:	10/21/19 09:01 PM 1.61 msd30.i / 30102115sim	
Compound	CAS#	MDL (ug/m3)	LOD (ug/m3	Rpt. Limit 3) (ug/m3)	Amount (ug/m3)
Ethylene Oxide	75-21-8	0.043	D	0.14	0.16

D: Analyte not within the DoD scope of accreditation.

20191016-4

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

Air Toxics

Client ID: Lab ID: Date/Time Collected Media:	Lab Blank 1910464-07A : NA - Not Applicable NA - Not Applicable	Dilution F	e Analyzed: actor: ht/Filename:	10/21/19 03:19 PM 1.00 msd30.i / 30102108sim	
Compound	CAS#	MDL (ug/m3)	LOD (ug/m3	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	75-21-8	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 1910464-07B NA - Not Applicable NA - Not Applicable	Date/Time A Dilution Fac Instrument/F	tor:	10/22/19 02:43 PM 1.00 msd30.i / 30102208sim	
		MDL	LOD	Rpt. Limit	Amount
Compound	CAS#	(ug/m3)	(ug/m	3) (ug/m3)	(ug/m3)
Ethylene Oxide	75-21-8	0.027	D	0.090	Not Detected

🛟 eurofins MODIFIED EPA METHOD TO-15 GC/MS SIM **Air Toxics** Viant Medical-Grand Rapids CCV **Client ID:** 1910464-08A Date/Time Analyzed: Lab ID: 10/21/19 10:37 AM Date/Time Collected: NA - Not Applicable **Dilution Factor:** 1.00 NA - Not Applicable msd30.i / 30102102sim Media: Instrument/Filename: Г

Compound	CAS#	%Recovery
Ethylene Oxide	75-21-8	103

🛟 eurofins MODIFIED EPA METHOD TO-15 GC/MS SIM **Air Toxics** Viant Medical-Grand Rapids CCV **Client ID:** 1910464-08B Date/Time Analyzed: Lab ID: 10/22/19 10:36 AM Date/Time Collected: NA - Not Applicable **Dilution Factor:** 1.00 NA - Not Applicable msd30.i / 30102203sim Media: Instrument/Filename:

Compound	CAS#	%Recovery
Ethylene Oxide	75-21-8	98

🔅 eurofins MODIFIED EPA METHOD TO-15 GC/MS SIM **Air Toxics** Viant Medical-Grand Rapids LCS **Client ID:** 1910464-09A Date/Time Analyzed: Lab ID: 10/21/19 01:29 PM Date/Time Collected: NA - Not Applicable **Dilution Factor:** 1.00 NA - Not Applicable msd30.i / 30102106sim Media: Instrument/Filename:

Compound	CAS#	%Recovery
Ethylene Oxide	75-21-8	130

D: Analyte not within the DoD scope of accreditation.

🔅 eurofins MODIFIED EPA METHOD TO-15 GC/MS SIM **Air Toxics** Viant Medical-Grand Rapids LCSD **Client ID:** 1910464-09AA Date/Time Analyzed: Lab ID: 10/21/19 02:10 PM Date/Time Collected: NA - Not Applicable **Dilution Factor:** 1.00 NA - Not Applicable msd30.i / 30102107sim Media: Instrument/Filename:

Compound	CAS#	%Recovery
Ethylene Oxide	75-21-8	118

D: Analyte not within the DoD scope of accreditation.

🔅 eurofins MODIFIED EPA METHOD TO-15 GC/MS SIM **Air Toxics** Viant Medical-Grand Rapids LCS **Client ID:** 1910464-09B Date/Time Analyzed: Lab ID: 10/22/19 11:17 AM Date/Time Collected: NA - Not Applicable **Dilution Factor:** 1.00 NA - Not Applicable msd30.i / 30102204sim Media: Instrument/Filename:

Compound	CAS#	%Recovery
Ethylene Oxide	75-21-8	117

D: Analyte not within the DoD scope of accreditation.

🔅 eurofins MODIFIED EPA METHOD TO-15 GC/MS SIM **Air Toxics** Viant Medical-Grand Rapids LCSD **Client ID:** 1910464-09BB Date/Time Analyzed: Lab ID: 10/22/19 11:58 AM Date/Time Collected: NA - Not Applicable **Dilution Factor:** 1.00 NA - Not Applicable msd30.i / 30102205sim Media: Instrument/Filename:

Compound	CAS#	%Recovery
Ethylene Oxide	75-21-8	122

D: Analyte not within the DoD scope of accreditation.

APPENDIX D LABORATORY CHAIN OF CUSTODY

180 Blue Ravine Rd. Suite B, Folsom, CA 95630 Phone (800) 985-5955; Fax (916) 351-8279	PID: X	Workorder #:	NA	jaard	910464			page-of-	
Client: Rambell		Special Instructions/Notes	ions/Notes:				Turnaro	Turnaround Time (Rush surcharges may apply)	harges may apply)
Project Name: Viant Medical - Grand Rapids		Modified TO-15	21-01	SIM for	ethylew	Standard	ard	Rush	(specify)
Project Manager: Christine No Project #	A80101631	oxide				C3	inister Va	Canister Vacuum/Pressure	Requested Analyses
Sampler: Nick Martin								Lab Use Only	*
Site Name: Vint Medice (g)	j)	e	Xi Le
Lab Field Sample Identification(Location)	Can # Con	Flow Controller #	Start Sampling Information		Stop Sampling Information	al (in Hg	al (in Hg)	eipt al (psig) : N ₂ / He	ylene Q
			Date Time	ne Date	Time	Initia	Fina	Rec Fina Gas	Ełł
01A 20191016-IN 64	54 25 25	10754 10/1	10/16/19 1145	5 10/17/1	19 1138	28	8		<
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Relinquished by Kignature Athliation) / Ramboll	Date	Date 10/17/19	Time 300	Receiveq	Received by: (Sigpentre/Affiliation		77	Date	lic Dq Ur
Relinquished by: (Signature/Affiliation)	Date		Time	Receivec	Received by: (Signature/Affiliation)	filiation)		Date	
Relinquished by: (Signature/Affiliation)	Date		Time	Receivec	Received by: (Signature/Affiliation)	ffiliation)	********	Date	Time
$\sim hc$			Lab Use Only	nly -				-	
Shipper Name: $\mathcal{H}\mathcal{A}\mathcal{K}$ Custody	Custody Seals Intact?	Yes	No	None					



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

December 02, 2019

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 08/14/19 10:12 through 10/18/19 10:09.

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 <u>julie.swift@erg.com</u> and delete the report without retaining any copies.

NERG

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: 12/02/19 10:32

 SUBMITTED: 08/14/19 to 10/18/19

 AQS SITE CODE:

 SITE CODE:

 Viant EtO

ANALYTICAL REPORT FOR SAMPLES

SampleName	LabNumber	<u>Matrix</u>	<u>Sampled</u>	<u>Received</u>
Viant	9081452-01	Air	08/13/19 12:00	08/14/19 10:12
Viant	9091304-01	Air	09/11/19 12:16	09/13/19 10:33
Viant	9101801-01	Air	10/17/19 11:48	10/18/19 10:09

Eastern Research Group

NERG	CERTIFICATE OF	ANALYSIS
U.S. Environmental Protection Agency,	Region 5	FILE #: 4173.00
PO Box 30260		REPORTED: 12/02/19 10:32
Lansing, MI 48909		SUBMITTED: 08/14/19 to 10/18/19
ATTN: Ms. Amy Robinson		AQS SITE CODE:
PHONE: (517) 241-2198 FAX: (312)	886-5824	SITE CODE: Viant EtO
Description: Viant	Lab ID: 9081452-03	Sampled: 08/13/19 12:00
Pressure @ Receipt: 2.00" Hg	Canister #: SAT032	Received: 08/14/19 10:12
Comments:		Analyzed: 08/19/19 19:51
	Air Toxics by EPA Compend esults <u>MDL</u> v ug/m³ <u>Flag</u> ppbv	lium Method TO-15

<u>ppbv ug/m³</u> Flag <u>ppbv</u> Ethylene oxide 1.82 3.29 0.0250

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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 3 of 10

NERG C	CERTIFICATE OF	ANALYSIS
U.S. Environmental Protection Agency, Re	gion 5	FILE #: 4173.00
PO Box 30260		REPORTED: 12/02/19 10:32
Lansing, MI 48909		SUBMITTED: 08/14/19 to 10/18/19
ATTN: Ms. Amy Robinson		AQS SITE CODE:
PHONE: (517) 241-2198 FAX: (312) 88	36-5824	SITE CODE: Viant EtO
Description: Viant	Lab ID: 9091304-0	01 Sampled: 09/11/19 12:16
Pressure @ Receipt: 11.50" Hg	Canister #: SAT171	Received: 09/13/19 10:33
Comments:		Analyzed: 09/17/19 05:10
Res	ir Toxics by EPA Compen ults MDI ug/m³ Flag ppb	<u>L</u>

0.0250

Ethylene oxide

0.254

0.46

NERG CE	CERTIFICATE OF ANALYSIS				
U.S. Environmental Protection Agency, Regio	n 5	FILE #: 4173.0	00		
PO Box 30260		REPORTED: 12	2/02/19 10:32		
Lansing, MI 48909		SUBMITTED:	08/14/19 to 10/18/19		
ATTN: Ms. Amy Robinson		AQS SITE COD	DE:		
PHONE: (517) 241-2198 FAX: (312) 886-	5824	SITE CODE:	Viant EtO		
Description: Viant	Lab ID: 9101801-0	1	Sampled: 10/17/19 11:48		
Pressure @ Receipt: 0" Hg	Canister #: SAT168		Received: 10/18/19 10:09		
Comments:			Analyzed: 10/22/19 00:24		
Air <u>Result</u> <u>Analyte ppbv uc</u>			ro-15		

0.0250

<u>ppbv_ug/m³</u> Flag Ethylene oxide 0.0656 0.12

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Page 5 of 10

U.S. Environmental Protection Agency, Region 5

PO Box 30260

Lansing, MI 48909

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

FILE #: 4173.00

REPORTED: 12/02/19 10:32

SUBMITTED: 08/14/19 to 10/18/19

AQS SITE CODE:

SITE CODE: Viant EtO

Analyte	Result	Units	Source Result	RPD	RPD Limit	Notes
ir Toxics by EPA Compend	lium Method TO-15	- Ouality Contro	ol			
Batch B9H1908 - Summa Can		2				
Blank (B9H1908-BLK1)	,		Prepared: 08/14/19 An	alyzed: 08/19/19)	
Acetylene	ND	ppbv		- /		U
Propylene	ND	ppbv				U
Dichlorodifluoromethane	ND	ppbv				U
Chloromethane	ND	ppbv				U
Dichlorotetrafluoroethane	ND	ppbv				U
Vinyl chloride	ND	ppbv				U
1,3-Butadiene	ND	ppbv				U
Ethylene oxide	ND	ppbv				U
Bromomethane	ND	ppbv				U
Chloroethane	ND	ppbv				U
Acetonitrile	ND	ppbv				Ŭ
Acrolein	ND	ppbv				U
Trichlorofluoromethane	ND	ppbv				Ŭ
Acrylonitrile	ND	ppbv				Ŭ
1,1-Dichloroethene	ND	ppbv				U
Dichloromethane	ND	ppbv				U
Carbon Disulfide	ND	ppbv				Ŭ
Trichlorotrifluoroethane	ND	ppbv				U
trans-1,2-Dichloroethylene	ND	ppbv				U
1,1-Dichloroethane	ND	ppbv				Ŭ
Methyl tert-Butyl Ether	ND	ppbv				U
Chloroprene	ND	ppbv				U
cis-1,2-Dichloroethylene	ND	ppbv				U
Bromochloromethane	ND	ppbv				U
Chloroform	ND	ppbv				Ŭ
Ethyl tert-Butyl Ether	ND	ppbv				U
1,2-Dichloroethane	ND	ppbv				U
1,1,1-Trichloroethane	ND	ppbv				U
Benzene	ND	ppbv				U
Carbon Tetrachloride	ND	ppbv				U
tert-Amyl Methyl Ether	ND	ppbv				U
1,2-Dichloropropane	ND	ppbv				U
Ethyl Acrylate	ND	ppbv				U
Bromodichloromethane	ND	ppbv				U
Trichloroethylene	ND	ppbv				U
Methyl Methacrylate	ND	ppbv				U
cis-1,3-Dichloropropene	ND	ppbv				U

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FILE #: 4173.00

REPORTED: 12/02/19 10:32

SUBMITTED: 08/14/19 to 10/18/19

AQS SITE CODE:

SITE CODE: Viant EtO

Analyte	Result	Units	Source Result RP	RPD D Limit	Notes
Air Toxics by EPA Compendiun		- Quality Con	trol		
Batch B9H1908 - Summa Canistei	r Prep				
Blank (B9H1908-BLK1) Continu	ed		Prepared: 08/14/19 Analyzed: 08/1	9/19	
Methyl Isobutyl Ketone	ND	ppbv	· · · ·		U
trans-1,3-Dichloropropene	ND	ppbv			U
1,1,2-Trichloroethane	ND	ppbv			U
Toluene	ND	ppbv			U
Dibromochloromethane	ND	ppbv			U
1,2-Dibromoethane	ND	ppbv			U
n-Octane	ND	ppbv			U
Tetrachloroethylene	ND	ppbv			U
Chlorobenzene	ND	ppbv			U
Ethylbenzene	ND	ppbv			U
m,p-Xylene	ND	ppbv			U
Bromoform	ND	ppbv			U
Styrene	ND	ppbv			U
1,1,2,2-Tetrachloroethane	ND	ppbv			U
o-Xylene	ND	ppbv			U
1,3,5-Trimethylbenzene	ND	ppbv			U
1,2,4-Trimethylbenzene	ND	ppbv			U
m-Dichlorobenzene	ND	ppbv			U
p-Dichlorobenzene	ND	ppbv			U
o-Dichlorobenzene	ND	ppbv			U
1,2,4-Trichlorobenzene	ND	ppbv			U
Hexachloro-1,3-butadiene	ND	ppbv			U
Batch B9I1303 - Summa Canister	Prep				
Blank (B9I1303-BLK1)	,		Prepared: 09/13/19 Analyzed: 09/1	6/19	
Ethylene oxide	ND	ppbv	,		U
Batch B9J2105 - Summa Canister	Prep				
Blank (B9J2105-BLK1)			Prepared & Analyzed: 10/21/19		
Ethylene oxide	ND	ppbv			U

NERG	CERTIFICATE OF	ANALYSIS
U.S. Environmental Protection Agency,	Region 5	FILE #: 4173.00
PO Box 30260		REPORTED: 12/02/19 10:32
Lansing, MI 48909		SUBMITTED: 08/14/19 to 10/18/19
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	dium Method TO-15	- Quality Co	ntrol		
Sequence 1908051					
Calibration Check (1908051-CCV1)			Prepared & Analyzed: 08/19/19		
Acetylene	2.10	ppbv	-12.4	30.00	
Propylene	2.40	ppbv	-2.0	30.00	
Dichlorodifluoromethane	2.34	ppbv	-1.9	30.00	
Chloromethane	2.25	ppbv	-9.3	30.00	
Dichlorotetrafluoroethane	2.67	ppbv	9.6	30.00	
Vinyl chloride	2.32	ppbv	-7.2	30.00	
1,3-Butadiene	2.29	ppbv	-7.2	30.00	
Ethylene oxide	2.69	ppbv	7.7	30.00	
Bromomethane	2.43	ppbv	-3.0	30.00	
Chloroethane	2.45	ppbv	-1.9	30.00	
Acetonitrile	2.22	ppbv	-12.4	30.00	
Acrolein	2.36	ppbv	-2.6	30.00	
Trichlorofluoromethane	2.26	ppbv	-9.7	30.00	
Acrylonitrile	2.31	ppbv	-7.5	30.00	
1,1-Dichloroethene	2.61	ppbv	6.8	30.00	
Dichloromethane	2.54	ppbv	2.6	30.00	
Carbon Disulfide	2.44	ppbv	-1.7	30.00	
Trichlorotrifluoroethane	2.62	ppbv	7.2	30.00	
trans-1,2-Dichloroethylene	2.50	ppbv	1.5	30.00	
1,1-Dichloroethane	2.57	ppbv	5.8	30.00	
Methyl tert-Butyl Ether	2.69	ppbv	5.7	30.00	
Chloroprene	2.49	ppbv	0.3	30.00	
cis-1,2-Dichloroethylene	2.32	ppbv	-7.3	30.00	
Bromochloromethane	2.38	ppbv	-3.7	30.00	
Chloroform	2.61	ppbv	4.6	30.00	
Ethyl tert-Butyl Ether	2.48	ppbv	-3.5	30.00	
1,2-Dichloroethane	2.51	ppbv	0.7	30.00	
1,1,1-Trichloroethane	2.28	ppbv	-7.7	30.00	
Benzene	2.46	ppbv	-2.1	30.00	
Carbon Tetrachloride	2.66	ppbv	5.7	30.00	
tert-Amyl Methyl Ether	2.27	ppbv	-12.7	30.00	
1,2-Dichloropropane	2.26	ppbv	-10.9	30.00	
Ethyl Acrylate	2.09	ppbv	-17.5	30.00	
Bromodichloromethane	2.12	ppbv	-17.0	30.00	

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NERG	CERTIFICATE OF	ANALYSIS		
U.S. Environmental Protection Agency, Region 5		FILE #: 4173.00		
PO Box 30260		REPORTED: 12/02/19 10:32		
Lansing, MI 48909		SUBMITTED: 08/14/19 to 10/18/19		
ATTN: Ms. Amy Robinson		AQS SITE CODE:		
PHONE: (517) 241-2198 FAX: (312) 886-5824	SITE CODE: Viant EtO		

nalyte	Result	Units	% Difference	Limit (%)	Notes
ir Toxics by EPA Compendi	um Method TO-15 -	Quality Cor	ntrol		
Sequence 1908051					
Calibration Check (1908051-CCV1) Continued		Prepared & Analyzed: 08/19/19			
Trichloroethylene	2.19	ppbv	-13.2	30.00	
Methyl Methacrylate	2.01	ppbv	-20.7	30.00	
cis-1,3-Dichloropropene	2.37	ppbv	-6.7	30.00	
Methyl Isobutyl Ketone	2.05	ppbv	-19.1	30.00	
trans-1,3-Dichloropropene	2.20	ppbv	-10.5	30.00	
1,1,2-Trichloroethane	2.24	ppbv	-9.6	30.00	
Toluene	2.45	ppbv	0.5	30.00	
Dibromochloromethane	2.43	ppbv	-4.5	30.00	
1,2-Dibromoethane	2.40	ppbv	-3.9	30.00	
n-Octane	2.39	ppbv	-5.0	30.00	
Tetrachloroethylene	2.53	ppbv	1.8	30.00	
Chlorobenzene	2.37	ppbv	-3.9	30.00	
Ethylbenzene	2.48	ppbv	-0.8	30.00	
m,p-Xylene	5.01	ppbv	0.7	30.00	
Bromoform	2.49	ppbv	-2.1	30.00	
Styrene	2.38	ppbv	-4.8	30.00	
1,1,2,2-Tetrachloroethane	2.22	ppbv	-12.3	30.00	
o-Xylene	2.54	ppbv	4.1	30.00	
1,3,5-Trimethylbenzene	2.42	ppbv	-4.2	30.00	
1,2,4-Trimethylbenzene	2.29	ppbv	-3.8	30.00	
m-Dichlorobenzene	1.89	ppbv	-21.2	30.00	
p-Dichlorobenzene	2.18	ppbv	-16.5	30.00	
o-Dichlorobenzene	2.15	ppbv	-13.8	30.00	
1,2,4-Trichlorobenzene	2.26	ppbv	-9.0	30.00	
Hexachloro-1,3-butadiene	2.32	ppbv	-7.4	30.00	
Sequence 1909031					
Calibration Check (1909031-	CCV1)		Prenared: 09/12/10	Analyzed: 09/16/19	
Ethylene oxide	2.71	ppbv	8.4	30.00	
Sequence 1910046	=	P		50.00	
	CCV(1)		Droparad Q Analise	d. 10/21/10	
Calibration Check (1910046- Ethylene oxide	2.21	Prepared & Analyzed: 10/21/19 ppbv -10.3 30.00			

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CERTIFICATE OF ANALYSIS

U.S. Environmental Protection Agency, Region 5

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Lansing, MI 48909

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 FILE #: 4173.00

 REPORTED: 12/02/19 10:32

 SUBMITTED: 08/14/19 to 10/18/19

 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 tert butyl ether, ethylene oxide, hexachloro-1,3-butadiene, n-octane, propylene, tert amyl methyl ether, tetrachloroethylene, trans-1,2-dichloroethylene, trichlorofluoromethane, and trichlorotrufluoroethane.

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