

# MICHIGAN DEPARTMENT OF ENVIRONMENT, GREAT LAKES, AND ENERGY

## INTEROFFICE COMMUNICATION

TO: File

FROM: Amy Robinson

DATE: April 13, 2020

SUBJECT: Monthly Ethylene Oxide Sampling at Viant Medical, Inc. for February 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  $0.0002 \mu\text{g}/\text{m}^3$  and Secondary Risk Screening Level (SRSL) at  $0.002 \mu\text{g}/\text{m}^3$ . To ascertain the accuracy of the computer model, the AQD initially conducted a [Phase I](#) (limited monitoring) sampling study for ethylene oxide in the vicinity of Viant in November 2018. A more robust [Phase II](#) 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  $\pm 20\%$ , then the laboratories have good comparability. Results of all sampling events are available on the website [www.michigan.gov/viant](http://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  $0.045 \mu\text{g}/\text{m}^3$ . 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 February 26, 2020. Ramboll collects a duplicate canister at one location each month. The AQD received the Viant results in April 2020. The results from the February sampling are on page 2 of the report named "Ambient Air Sampling at Viant Medical Facility, Grand Rapids, Michigan February 2020 Sampling Events Results" (Viant Report). The results from the AQD canister collected in February are on page 2 of the ERG lab report.

The results of the February 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 #1 with two Ramboll canisters. The AQD canister result was  $0.39 \mu\text{g}/\text{m}^3$  whereas the Ramboll canisters were  $0.11 \mu\text{g}/\text{m}^3$  and ND (non-Detect). 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  $\pm 20\%$  criteria. This could be caused by the estimated value of the Ramboll samples. The wind direction on the February sample day was from the north-northeast, blowing to the south-southwest. Site #1 is on the south side of the facility.



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

March 24, 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 02/28/20 13:09.

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](mailto: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](mailto:julie.swift@erg.com) and delete the report without retaining any copies.



## 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: 03/24/20 12:47

SUBMITTED: 02/28/20

AQS SITE CODE:

SITE CODE: Viant EtO

### ANALYTICAL REPORT FOR SAMPLES

<u>SampleName</u>	<u>LabNumber</u>	<u>Matrix</u>	<u>Sampled</u>	<u>Received</u>
Viant	0022812-01	Air	02/25/20 23:57	02/28/20 13:09

<b>Description:</b> Viant	<b>Lab ID:</b> 0022812-01	<b>Sampled:</b> 02/25/20 23:57
<b>Pressure @ Receipt:</b> 0.00" Hg	<b>Canister #:</b> SAT018	<b>Received:</b> 02/28/20 13:09
<b>Comments:</b> Received at ambient		<b>Analyzed:</b> 03/05/20 00:48

### Air Toxics by EPA Compendium Method TO-15

<u>Analyte</u>	<u>Results</u>		<u>Flag</u>	<u>MDL</u>
	<u>ppbv</u>	<u>ug/m<sup>3</sup></u>		<u>ppbv</u>
Ethylene oxide	0.214	0.39		0.0250



## 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:** 03/24/20 12:47

**SUBMITTED:** 02/28/20

**AQS SITE CODE:**

**SITE CODE:** Viant EtO

Analyte	Result	Units	Source Result	RPD	RPD Limit	Notes
---------	--------	-------	------------------	-----	--------------	-------

### Air Toxics by EPA Compendium Method TO-15 - Quality Control

*Batch B0C0407 - Summa Canister Prep*

#### Blank (B0C0407-BLK1)

Prepared & Analyzed: 03/04/20

Ethylene oxide	ND	ppbv				U
----------------	----	------	--	--	--	---



## 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:** 03/24/20 12:47

**SUBMITTED:** 02/28/20

**AQS SITE CODE:**

**SITE CODE:** Viant EtO

Analyte	Result	Units	% Difference	Limit (%)	Notes
---------	--------	-------	--------------	-----------	-------

### Air Toxics by EPA Compendium Method TO-15 - Quality Control

*Sequence 2003013*

#### Calibration Check (2003013-CCV1)

Prepared & Analyzed: 03/04/20

Ethylene oxide	2.87	ppbv	14.6	30.00
----------------	------	------	------	-------



## 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:** 03/24/20 12:47

**SUBMITTED:** 02/28/20

**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 trichlorotrifluoroethane.

AMBIENT AIR SAMPLING AT VIAN T MEDICAL  
FACILITY, GRAND RAPIDS, MICHIGAN  
FEBRUARY 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  
April 2020

Project Number  
1690010876

## CONTENTS

1.	INTRODUCTION	1
2.	SAMPLING LOCATIONS	1
3.	METHODOLOGY	1
4.	RESULTS	2
5.	QUALITY ASSURANCE	3
6.	CONCLUSIONS	4

## FIGURES

Figure 1: Map of Sampling Results

Figure 2: Wind Rose

## TABLES

Table 1: Outdoor Air Sampling Results, February 25-26, 2020

Table 2: Indoor Air Sampling Results, February 25-26, 2020

Table 3: Quality Control Criteria for TO-15 Sample Collection and Analysis, February 25-26, 2020

## 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 February 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 February 25 and 26, 2020, and included the collection of five outdoor ambient air samples<sup>1</sup> 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 second monthly event to take place after EtO sterilization operations at the facility ceased in late December 2019, and was the final event scheduled in the April 2019 Work Plan. The sections below describe the sampling methodology and results from the February 2020 sampling event.

## 2. SAMPLING LOCATIONS

Each of the four outdoor sampling locations (i.e., Locations #1 through #4) selected during this event were the same locations sampled by Ramboll in 2019. Location #1 was selected for the placement of the co-located samples. The indoor sampling location selected for this event was relocated approximately 35 feet to the south of the original location but still within the scrubber room. The relocation was necessary because the support beam to which the indoor air sample canister was previously secured had been removed. Instead, the indoor air sample canister was secured to the exterior of a nearby tank located in the southern part of the scrubber room. Six samples, including the co-located sampling canisters, were collected in total during this sampling event. 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 the indoor sample location noted above, the canisters were secured to the same fixtures that have been previously used in 2019 for sample collection within the breathing zone. The co-located canister inlets at Location #1 were approximately 2 feet<sup>2</sup> 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 north-northeast during the 24-hour sampling period, which began February 25, 2020, and ended February 26, 2020.

---

<sup>1</sup> One of the samples was a co-located sample.

<sup>2</sup> 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.

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 February 27, 2020 and analyzed the samples between March 2 and 4, 2020.

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. EGLE's canister was sent to a different contract laboratory for analysis and will be discussed separately by EGLE.

## 4. RESULTS

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

Table 1: Outdoor Air Sampling Results, February 25-26, 2020				
Sample Location ID	On-Site	Location Description	EtO Concentration ( $\mu\text{g}/\text{m}^3$ )	Sample-Specific MDL ( $\mu\text{g}/\text{m}^3$ )
1 (co-located samples)	Yes	South of building in parking lot	0.11 J; ND (co-located sample)	0.069; 0.068
2	Yes	West of building, along western property boundary	ND	0.070
3	No	Northwest of building along Watson Street Southwest	0.099 J	0.061
4	Yes	North of building, northern corner of parking lot	0.098 J	0.065
J = Laboratory-estimated value below the Reporting Limit but above the MDL. ND = Not detected				

Table 2: Indoor Air Sampling Results, February 25-26, 2020			
Sample Location ID	Location Description	EtO Concentration ( $\mu\text{g}/\text{m}^3$ )	Sample-Specific MDL ( $\mu\text{g}/\text{m}^3$ )
IA	Scrubber room	0.19	0.076

EtO was detected in four out of five outdoor ambient air samples collected during the February 2020 event. EtO was not detected in one of the two co-located samples at Location #1 or in the sample collected at Location #2. The concentration of EtO in outdoor samples, where detected, ranged from 0.098 micrograms per cubic meter ( $\mu\text{g}/\text{m}^3$ ) at Location #4 to 0.11  $\mu\text{g}/\text{m}^3$  in the other co-located sample at Location #1 (Figure 1). All outdoor sample concentrations were reported 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.<sup>3</sup> As evident from a wind rose prepared using the meteorological data (Figure 2), winds were generally blowing from the north-northeast during the sampling event. Wind speeds varied between 3 and 13 miles per hour (mph). The EtO concentration in the scrubber room was 0.19 µg/m<sup>3</sup>. 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 (results shown in Table 1). In addition, one of the co-located samples was used for replicate analysis. No conclusions could be drawn from these tests as EtO was not present above detection limits in these samples. The laboratory also performed analyses of two sets of daily laboratory control samples (LCS) and laboratory control sample duplicates (LCSD) that contain known concentrations of EtO to demonstrate the repeatability of laboratory analytical methods. The results are reported in terms of the percent EtO recovered (i.e., detected) relative to the known concentration of EtO in the LCS and LCSD. The relative percent difference in detected concentrations of EtO was 1.03% for the LCS/LCSD set analyzed on March 2, and 0% for the LCS/LCSD set analyzed on March 3. Both results are in the acceptable range of within 25%. A summary of all quality assurance criteria related to the February 2020 sampling event is provided in Table 3 below.

---

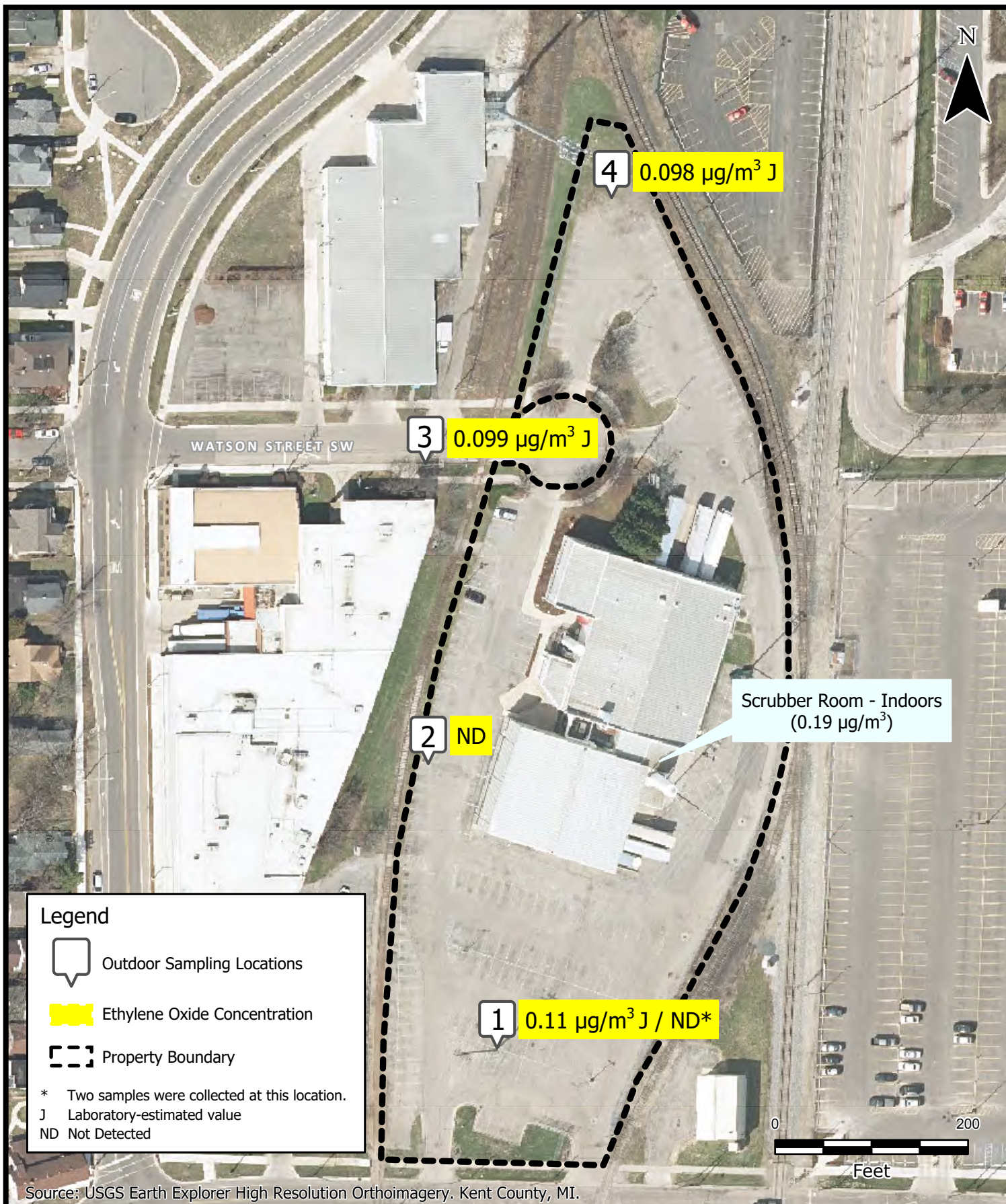
<sup>3</sup> The Grand Rapids – Monroe Street air monitoring site is part of the state's air monitoring network as well as the federal NCore multipollutant monitoring network. Meteorological measurements collected at the site are subject to quality assurance procedures in the Quality Assurance Handbook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

Table 3: Quality Control Criteria for TO-15 Sample Collection and Analysis, February 25-26, 2020					
Quality Control Sample	Data Quality Indicators (DQIs)	Frequency	Acceptance Criteria	February 2020 Outcome	Corrective Action
Co-located sample	Precision	1 per day	Within 25%	N/A <sup>+</sup>	N/A
Replicate sample <sup>**</sup>	Precision	1 per batch	Within 25% for sample concentrations greater than five times reporting limit	1.03% - March 2 0% - March 3	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 <sup>3</sup>	N/A
Method Detection Limit	Sensitivity	1 per method modification	0.05 ppb (0.09 µg/m <sup>3</sup> ) or less	N/A* (no change to method)	N/A
Sampling period	Field QC	All samples	24 hours +/- 1 hour	All samples	N/A
<sup>+</sup> = Unable to quantify due to lack of EtO detected in quality control samples. <sup>*</sup> = Sample-specific MDLs noted in Tables 1 and 2 may be affected by dilution. <sup>**</sup> = Laboratory analysis of LCS and LCSD were used to evaluate precision of analytical methods during this sampling event.					

## 6. CONCLUSIONS

The February 2020 sampling event was the second monthly sampling event completed after the cessation of EtO sterilization operations at the facility, and the final sampling event scheduled in the April 2019 Work Plan. EtO detected in ambient air samples from locations surrounding the Viant facility were below reporting limits during the February 2020 sampling event.

**FIGURE 1**  
**MAP OF SAMPLING RESULTS**



**SAMPLING RESULTS (FEBRUARY 2020)**  
 VIANT MEDICAL  
 GRAND RAPIDS, MICHIGAN

**FIGURE**  
**1**

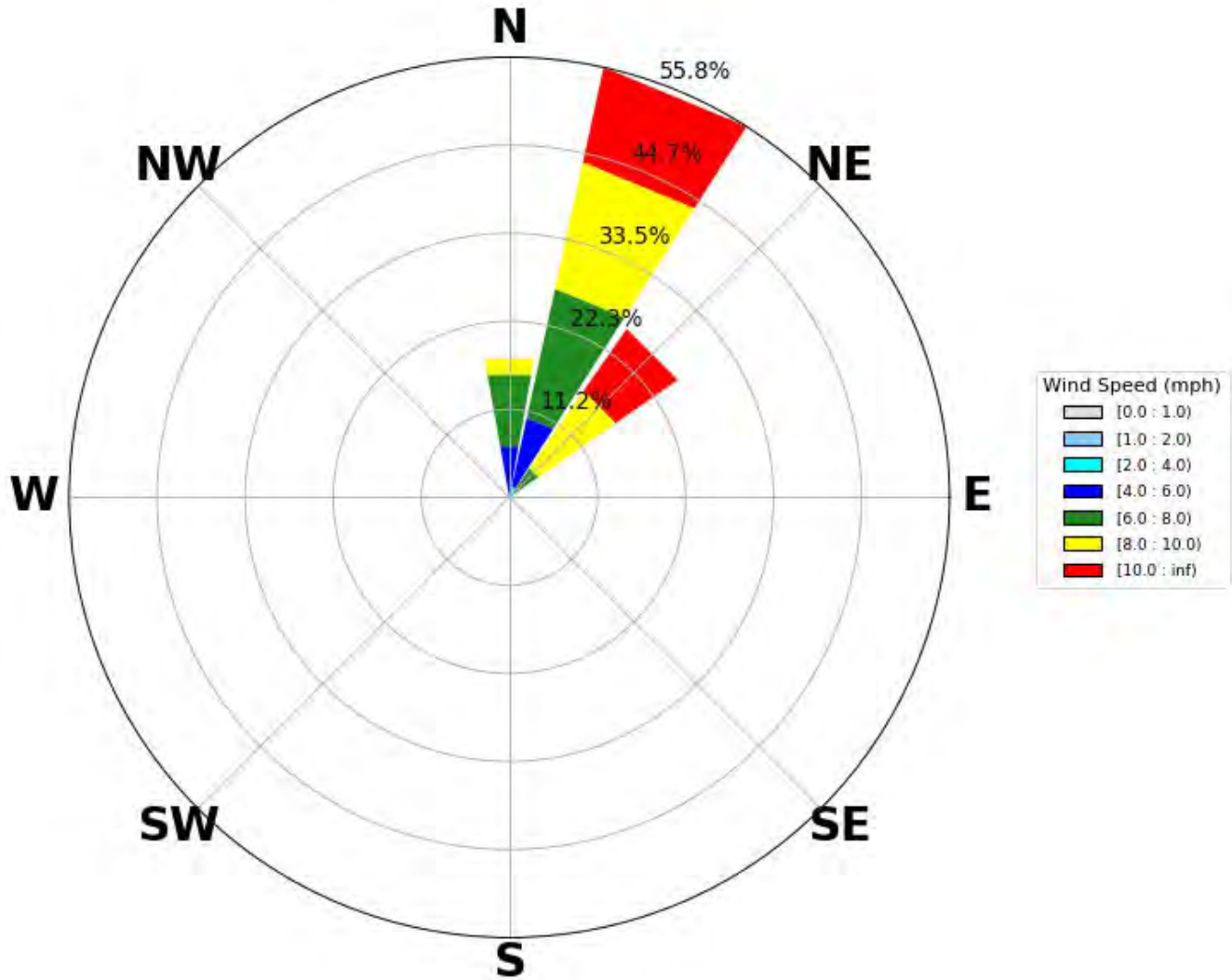
**FIGURE 2**  
**WIND ROSE**

WIND ROSE PLOT:

**EGLE Met Station - Grand Rapids, MI**  
Monroe Ave, south of Leonard St.

DISPLAY:

**Wind Speed**  
**Direction (blowing from)**



COMMENTS:

DATA PERIOD:

**Start Date:**  
**2/25/2020 - 11:21**

**End Date:**  
**2/26/2020 - 11:34**

CALM WINDS:

**0%**

AVG. WIND SPEED:

**7.64 mph**

## WIND ROSE FOR EGLE GRAND RAPIDS METEOROLOGICAL STATION

COMPANY NAME:

**Viant Medical**

DATE:

**3/11/2020**

DRAFTED BY:

**HA**

FIGURE  
2

**RAMBOLL**

**APPENDIX A**  
**AIR SAMPLING PROGRAM RESULTS**  
**SUMMARY**

Viant Medical  
520 Watson Street Southwest, Grand Rapids, MI

Ethylene Oxide Concentrations ( $\mu\text{g}/\text{m}^3$ ) 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 <sup>c</sup>
9/10/2019 - 9/11/2019	SW, S	0.38	0.51	0.40	0.90 / 0.76 <sup>c</sup>
10/16/2019 - 10/17/2019	NW	0.20 / 0.20 <sup>c</sup>	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 <sup>c</sup> J
12/12/2019 - 12/13/2019	S	0.048 J	0.12 J	0.10 J	0.54 / 0.60 <sup>c</sup>
1/22/2020 - 1/23/2020	S, SSE	0.087 J	0.11 J	0.11 J	0.12 / 0.12 <sup>c</sup> J (Note 2,3)
2/25/2020 - 2/26/2020	NNE	0.11 J / ND <sup>c</sup>	ND	0.099 J	0.098 J

**Notes:**

/ = Quality control sampling data is separated by a slash (/)

<sup>c</sup> = 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.

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

	Location ID and Description
Sample Dates (24-Hour Period)	IA (Scrubber Room)
7/9/2019 - 7/10/2019	440 / 450 <sup>c</sup>
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
2/25/2020 - 2/26/2020	0.19

Notes:

/ = Quality control sampling data is separated by a slash (/)

<sup>c</sup> = Co-located sample

## **APPENDIX B**

### **PHOTOGRAPHS OF SAMPLING LOCATIONS**



Photo 1: View of 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.



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



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



## Site Photographs

Viant Medical  
520 Watson Street Southwest, Grand Rapids, Michigan  
February 2020



Photo 5: View of scrubber room. The original indoor air (IA) sample location is in vicinity of the scissor lift. During this event, the IA sample was placed on the exterior of a tank in the back of the room.



Photo 6: View of sample collection at the IA location within scrubber room.

## **APPENDIX C**

### **LABORATORY ANALYTICAL REPORT**

3/7/2020

Ms. Christine Ng

Ramboll

4350 N. Fairfax Drive

Suite 300

Arlington VA 22203

Project Name: Viant Medical-Grand Rapids

Project #: 1690010876

Workorder #: 2002739

Dear Ms. Christine Ng

The following report includes the data for the above referenced project for sample(s) received on 2/27/2020 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,



Ausha Scott

Project Manager

# WORK ORDER #: 2002739

## Work Order Summary

<b>CLIENT:</b>	Ms. Christine Ng Ramboll 4350 N. Fairfax Drive Suite 300 Arlington, VA 22203	<b>BILL TO:</b>	Accounts Payable Ramboll 300 S. Wacker Drive Suite 1300 Chicago, IL 60606
<b>PHONE:</b>	703-516-2382	<b>P.O. #</b>	WO-2019-ARL-01
<b>FAX:</b>	703-516-2302	<b>PROJECT #</b>	1690010876 Viant Medical-Grand
<b>DATE RECEIVED:</b>	02/27/2020	<b>CONTACT:</b>	Rapids Ausha Scott
<b>DATE COMPLETED:</b>	03/07/2020		

<u>FRACTION #</u>	<u>NAME</u>	<u>TEST</u>	<u>RECEIPT VAC./PRES.</u>	<u>FINAL PRESSURE</u>
01A	20200225-1	Modified TO-15 SIM	4.0 "Hg	5 psi
02A	20200225-2	Modified TO-15 SIM	4.5 "Hg	5 psi
03A	20200225-3	Modified TO-15 SIM	0.5 "Hg	5 psi
04A	20200225-4	Modified TO-15 SIM	2.5 "Hg	5 psi
05A	20200225-IA	Modified TO-15 SIM	6.5 "Hg	5 psi
06A	20200225-DUP	Modified TO-15 SIM	3.5 "Hg	5 psi
06AA	20200225-DUP Lab Duplicate	Modified TO-15 SIM	3.5 "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

CERTIFIED BY:



Technical Director

DATE: 03/07/20

**LABORATORY NARRATIVE**  
**EPA TO-15 Ethylene oxide (SIM)**  
**Ramboll**  
**Workorder# 2002739**

Six 6 Liter Summa Canister (EO) samples were received on February 27, 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**

There were no receiving discrepancies.

**Analytical Notes**

As per client project requirements, the laboratory has reported estimated values for target compound hits that are below the Reporting Limit but greater than the Method Detection Limit. 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

<b>Client ID:</b>	20200225-1	<b>Date/Time Analyzed:</b>	3/2/20 09:53 PM
<b>Lab ID:</b>	2002739-01A	<b>Dilution Factor:</b>	1.55
<b>Date/Time Collected:</b>	2/26/20 11:26 AM	<b>Instrument/File name:</b>	msd2.i / 2030216sim
<b>Media:</b>	6 Liter Summa Canister (EO)		

Compound	CAS#	MDL (ug/m3)	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	75-21-8	0.069	D	0.14	0.11 J

J = Estimated value.

D: Analyte not within the DoD scope of accreditation.

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

<b>Client ID:</b>	20200225-2	<b>Date/Time Analyzed:</b>	3/4/20 12:46 AM
<b>Lab ID:</b>	2002739-02A	<b>Dilution Factor:</b>	1.58
<b>Date/Time Collected:</b>	2/26/20 11:29 AM	<b>Instrument/Filename:</b>	msd2.i / 2030318sim
<b>Media:</b>	6 Liter Summa Canister (EO)		

Compound	CAS#	MDL (ug/m3)	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	75-21-8	0.070	D	0.14	Not Detected

D: Analyte not within the DoD scope of accreditation.

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

<b>Client ID:</b>	20200225-3	<b>Date/Time Analyzed:</b>	3/3/20 08:04 PM
<b>Lab ID:</b>	2002739-03A	<b>Dilution Factor:</b>	1.36
<b>Date/Time Collected:</b>	2/26/20 11:24 AM	<b>Instrument/Filename:</b>	msd2.i / 2030311sim
<b>Media:</b>	6 Liter Summa Canister (EO)		

Compound	CAS#	MDL (ug/m3)	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	75-21-8	0.061	D	0.12	0.099 J

J = Estimated value.

D: Analyte not within the DoD scope of accreditation.

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

<b>Client ID:</b>	20200225-4	<b>Date/Time Analyzed:</b>	3/3/20 08:44 PM
<b>Lab ID:</b>	2002739-04A	<b>Dilution Factor:</b>	1.46
<b>Date/Time Collected:</b>	2/26/20 11:30 AM	<b>Instrument/File name:</b>	msd2.i / 2030312sim
<b>Media:</b>	6 Liter Summa Canister (EO)		

Compound	CAS#	MDL (ug/m3)	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	75-21-8	0.065	D	0.13	0.098 J

J = Estimated value.

D: Analyte not within the DoD scope of accreditation.

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

<b>Client ID:</b>	20200225-IA	<b>Date/Time Analyzed:</b>	3/3/20 09:25 PM
<b>Lab ID:</b>	2002739-05A	<b>Dilution Factor:</b>	1.71
<b>Date/Time Collected:</b>	2/26/20 11:34 AM	<b>Instrument/Filename:</b>	msd2.i / 2030313sim
<b>Media:</b>	6 Liter Summa Canister (EO)		

Compound	CAS#	MDL (ug/m3)	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	75-21-8	0.076	D	0.15	0.19

D: Analyte not within the DoD scope of accreditation.

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

<b>Client ID:</b>	20200225-DUP	<b>Date/Time Analyzed:</b>	3/3/20 06:44 PM
<b>Lab ID:</b>	2002739-06A	<b>Dilution Factor:</b>	1.52
<b>Date/Time Collected:</b>	2/26/20 11:26 AM	<b>Instrument/Filename:</b>	msd2.i / 2030309sim
<b>Media:</b>	6 Liter Summa Canister (EO)		

Compound	CAS#	MDL (ug/m3)	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	75-21-8	0.068	D	0.14	Not Detected

D: Analyte not within the DoD scope of accreditation.

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

<b>Client ID:</b>	20200225-DUP Lab Duplicate	<b>Date/Time Analyzed:</b>	3/3/20 07:24 PM
<b>Lab ID:</b>	2002739-06AA	<b>Dilution Factor:</b>	1.52
<b>Date/Time Collected:</b>	2/26/20 11:26 AM	<b>Instrument/Filename:</b>	msd2.i / 2030310sim
<b>Media:</b>	6 Liter Summa Canister (EO)		

Compound	CAS#	MDL (ug/m3)	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	75-21-8	0.068	D	0.14	Not Detected

D: Analyte not within the DoD scope of accreditation.

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

<b>Client ID:</b>	Lab Blank	<b>Date/Time Analyzed:</b>	3/2/20 03:54 PM
<b>Lab ID:</b>	2002739-07A	<b>Dilution Factor:</b>	1.00
<b>Date/Time Collected:</b>	NA - Not Applicable	<b>Instrument/Filename:</b>	msd2.i / 2030208sim
<b>Media:</b>	NA - Not Applicable		

Compound	CAS#	MDL (ug/m3)	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	75-21-8	0.045	D	0.090	Not Detected

D: Analyte not within the DoD scope of accreditation.

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

<b>Client ID:</b>	Lab Blank	<b>Date/Time Analyzed:</b>	3/3/20 04:42 PM
<b>Lab ID:</b>	2002739-07B	<b>Dilution Factor:</b>	1.00
<b>Date/Time Collected:</b>	NA - Not Applicable	<b>Instrument/Filename:</b>	msd2.i / 2030306sim
<b>Media:</b>	NA - Not Applicable		

Compound	CAS#	MDL (ug/m3)	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	75-21-8	0.045	D	0.090	Not Detected

D: Analyte not within the DoD scope of accreditation.

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

<b>Client ID:</b>	CCV	<b>Date/Time Analyzed:</b>	3/2/20 10:56 AM
<b>Lab ID:</b>	2002739-08A	<b>Dilution Factor:</b>	1.00
<b>Date/Time Collected:</b>	NA - Not Applicable	<b>Instrument/Filename:</b>	msd2.i / 2030202sim
<b>Media:</b>	NA - Not Applicable		

Compound	CAS#	%Recovery
Ethylene Oxide	75-21-8	74

D: Analyte not within the DoD scope of accreditation.

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

<b>Client ID:</b>	CCV	<b>Date/Time Analyzed:</b>	3/3/20 10:48 AM
<b>Lab ID:</b>	2002739-08B	<b>Dilution Factor:</b>	1.00
<b>Date/Time Collected:</b>	NA - Not Applicable	<b>Instrument/Filename:</b>	msd2.i / 2030302sim
<b>Media:</b>	NA - Not Applicable		

Compound	CAS#	%Recovery
Ethylene Oxide	75-21-8	86

D: Analyte not within the DoD scope of accreditation.

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

<b>Client ID:</b>	LCS	<b>Date/Time Analyzed:</b>	3/2/20 11:32 AM
<b>Lab ID:</b>	2002739-09A	<b>Dilution Factor:</b>	1.00
<b>Date/Time Collected:</b>	NA - Not Applicable	<b>Instrument/Filename:</b>	msd2.i / 2030203sim
<b>Media:</b>	NA - Not Applicable		

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

D: Analyte not within the DoD scope of accreditation.

\* % Recovery is calculated using unrounded analytical results.

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

<b>Client ID:</b>	LCSD	<b>Date/Time Analyzed:</b>	3/2/20 12:15 PM
<b>Lab ID:</b>	2002739-09AA	<b>Dilution Factor:</b>	1.00
<b>Date/Time Collected:</b>	NA - Not Applicable	<b>Instrument/Filename:</b>	msd2.i / 2030204sim
<b>Media:</b>	NA - Not Applicable		

Compound	CAS#	%Recovery
Ethylene Oxide	75-21-8	97

D: Analyte not within the DoD scope of accreditation.

\* % Recovery is calculated using unrounded analytical results.

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

<b>Client ID:</b>	LCS	<b>Date/Time Analyzed:</b>	3/3/20 11:25 AM
<b>Lab ID:</b>	2002739-09B	<b>Dilution Factor:</b>	1.00
<b>Date/Time Collected:</b>	NA - Not Applicable	<b>Instrument/Filename:</b>	msd2.i / 2030303sim
<b>Media:</b>	NA - Not Applicable		

Compound	CAS#	%Recovery
Ethylene Oxide	75-21-8	102

D: Analyte not within the DoD scope of accreditation.

\* % Recovery is calculated using unrounded analytical results.

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

<b>Client ID:</b>	LCSD	<b>Date/Time Analyzed:</b>	3/3/20 12:02 PM
<b>Lab ID:</b>	2002739-09BB	<b>Dilution Factor:</b>	1.00
<b>Date/Time Collected:</b>	NA - Not Applicable	<b>Instrument/Filename:</b>	msd2.i / 2030304sim
<b>Media:</b>	NA - Not Applicable		

Compound	CAS#	%Recovery
Ethylene Oxide	75-21-8	102

D: Analyte not within the DoD scope of accreditation.

\* % Recovery is calculated using unrounded analytical results.

## **APPENDIX D**

### **LABORATORY CHAIN OF CUSTODY**

