Are Chemical Constituents Exhaled in a Room Where e-Vapor Products are Used?

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Passive Vaping Evidence Gaps

"Little is known about the environmental impact of e-cigarettes."

"A study evaluating the indoor air quality in other various locations (e.g., car, home, office, school and public indoor areas such as transit stations) during and after e-cigarette use provides important information about environmental impacts. This information should be collected using a representative sample of the e-cigarette products currently available."

Source: Hoshing Chang, Tobacco Control (2014), 23:ii54-ii58

Questions to be Addressed

- What are the levels of e-vapor constituents in room air where e-vapor products are used?
- What is the exposure to e-vapor constituents in non-users?
- If there is measurable exposure to e-vapor constituents in non-users, what is the potential for harm from this level of exposure?

ALCS Approach to Address These Questions

- Review and monitor published literature
- Conduct studies to generate data
  - Two initial pilot studies
  - Controlled clinical study
- Develop a computational model to predict air levels of e-vapor constituents under different conditions
- Assess risk to non-users based on evidence collected from studies and model based predictions

Study Design

Objectives:

1. To evaluate the exhaled breath, room air and surface levels of selected constituents following the use of various types of e-vapor products and conventional cigarettes under controlled and *ad lib* conditions.
2. To generate input parameters for validation of a computational model

- Study Design
  - Open-label, single-center, observational study
- Study Participants (Total n=40)
  - Healthy males and females, 21 years and older
  - Current daily e-vapor users (n=20)
  - Current daily refillable tank users (n=10)
  - Current daily conventional cigarette smokers (n=10)

Study Design

- Products Tested
  - MarkTen® 2.5%[a] Classic Electronic Cigarette (M10)
  - Prototype Electronic Cigarette 2.4%[a,b] (GS)
  - Ego-Tank and subjects' own e-liquids (Tank)
  - Conventional cigarettes, subjects' own cigarettes (CIG)

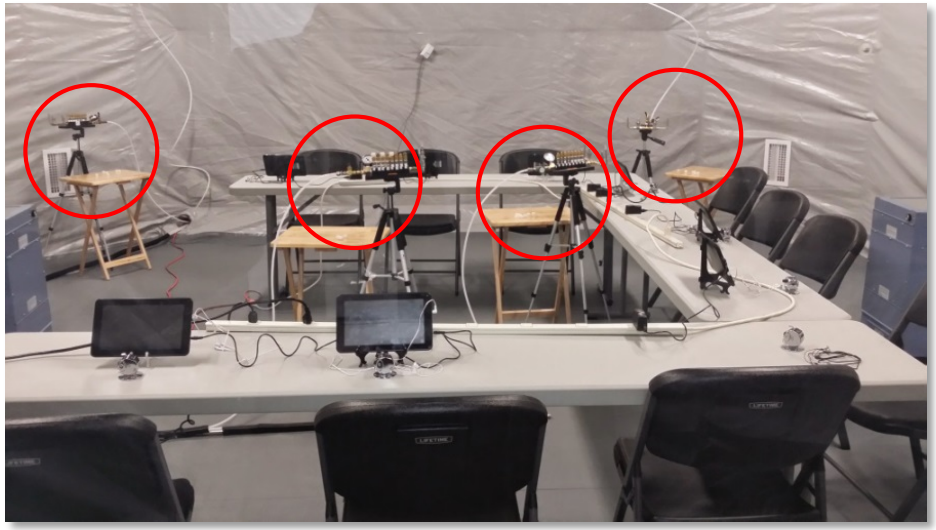
- Investigations
  - Exhaled Breath Samples (EBS)
  - Room Air Samples (RAS)
  - Surface Samples (SS)

[a] Percent of USP grade nicotine w/w
[b] Similar to commercial GreenSmoke® electronic cigarettes

Study Conduct

Exposure Room

inflamax RESEARCH



Volume 113 m^3
Air exchange rate 2.25/hour

HIGH POINT clinicaltrialscenter

Clinical site for study conduct

ENTHALPY analytical, inc. chromatography services

Sample collection and analysis

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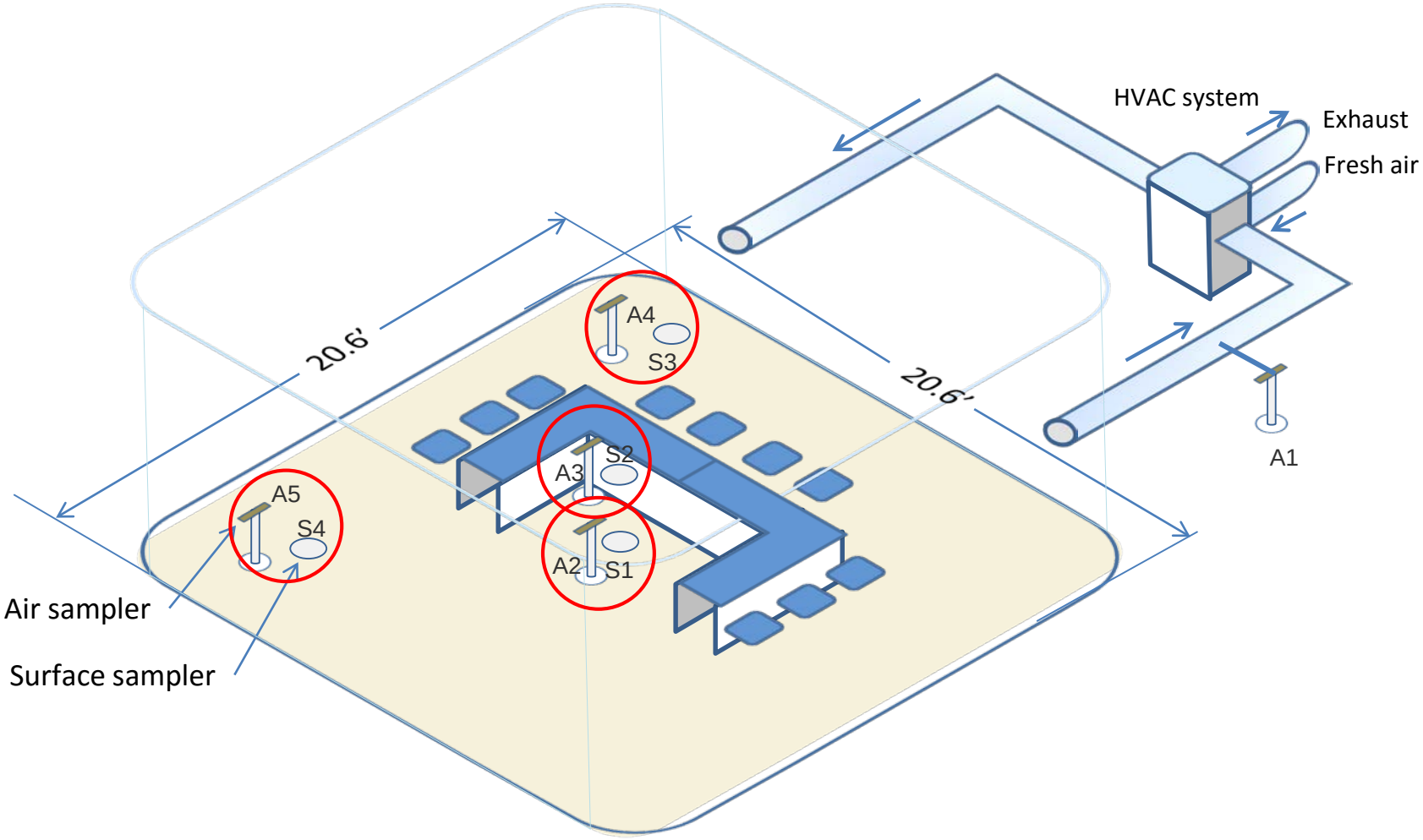
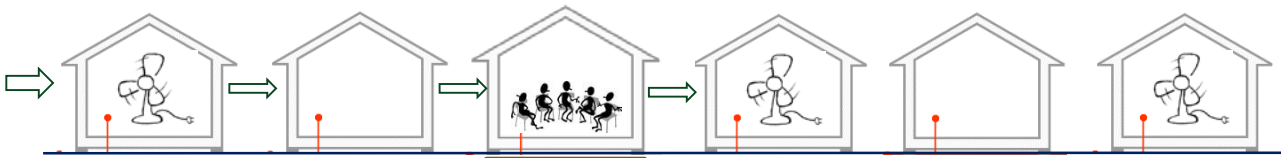
Sampling Stations



Sample Collection – M10 & GS

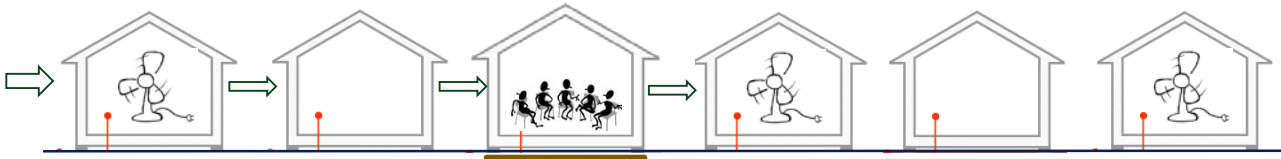
DAY 1



Air wash	Background-1	***Baseline***	Air Wash	Background-2	Air Wash
->>----------	2 h	4 h	2 h	2 h	----------->>

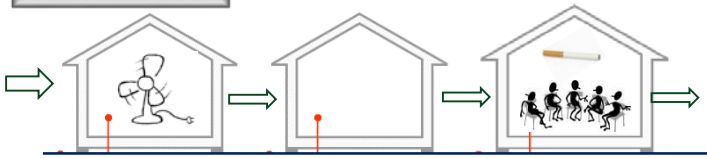
Sample Collection – M10 & GS

DAY 1



Air wash	Background-1	***Baseline***	Air Wash	Background-2	Air Wash
->>----------	2 h	4 h	2 h	2 h	----------->>

DAY 2



Air wash	Background-3	***Controlled Use***
		80 puffs per person 4 h
->>----------	2 h	

Controlled Use = 10 puffs, 5 sec puff duration every 30 mins

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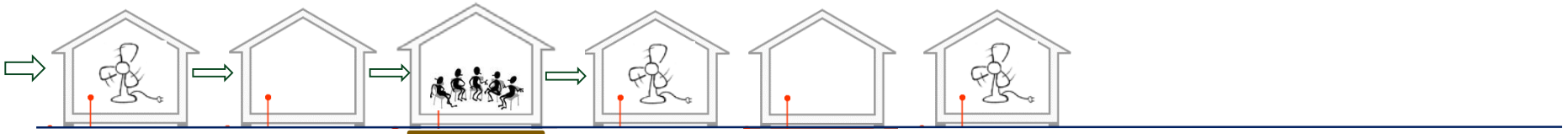
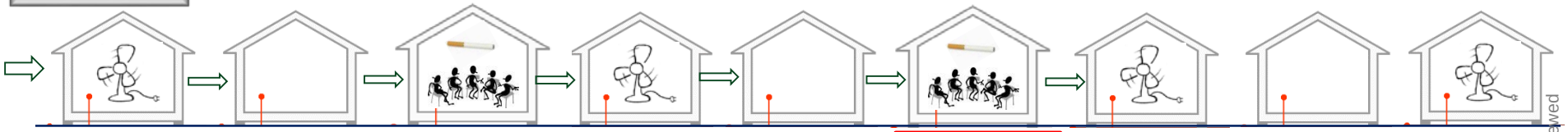
Sample Collection – M10 & GS

DAY 1



Air wash	Background-1	***Baseline***	Air Wash	Background-2	Air Wash
->>----------	2 h	4 h	2 h	2 h	----------->>

DAY 2



Air wash	Background-3	***Controlled Use***	Air Wash	Background-4	***Ad lib Use***	Air Wash	Background-5	Air Wash
		80 puffs per person						
->>----------	2 h	4 h	2 h	2 h	4 h	2 h	2 h	-------->>

Ad Lib Use = Product use under naturalistic settings

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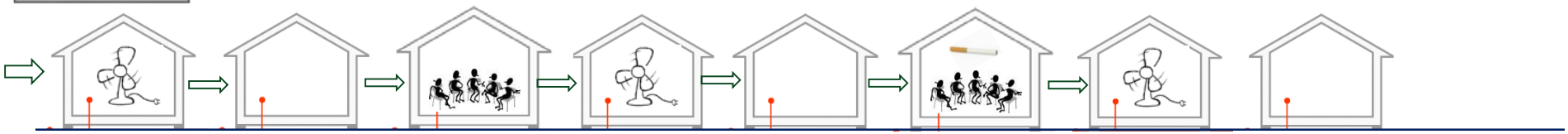
Sample Collection – Tank & Cig

DAY 1



Air wash	Background-1	***Baseline***	Air Wash	Background-2	***Ad lib Use***	Air Wash	Background-3
->>----------	2 h	4 h	2 h	2 h	4 h	2 h	2 h

Ad Lib Use = Product use under naturalistic settings

Constituents Analyzed

Constituent	EBS	RAS	SS
Propylene glycol and glycerin (ISO 16200-1)			
nicotine	√	√	√
propylene glycol	√	√	√
glycerol	√	√	√
Carbonyl compounds (ISO 16000-3 & EPA TO-11A)			
formaldehyde	√	√	
crotonaldehyde		√	
o-tolualdehyde		√	
acetaldehyde	√	√	
butyraldehyde (butanal)		√	
m&p-tolualdehyde		√	
acetone		√	
benzaldehyde		√	
propionaldehdye		√	
isovaleraldehyde		√	
hexanaldehyde (aka hexaldehyde)		√	
valeraldehyde		√	
2, 5-dimethylbenzaldehyde		√	
methyl ethyl ketone (MEK)		√	
acrolein	√	√	

Constituent	EBS	RAS	SS
Volatile organic compounds (ISO-16000-6)			
1,3-butadiene		√	
benzene		√	
isoprene		√	
toluene		√	
furan		√	
ethylene oxide		√	
vinyl chloride		√	
propylene oxide		√	
nitromethane		√	
2-nitropropane		√	
vinyl acetate		√	
ethylbenzene		√	
Trace metals (EPA IO-2.1 & 3.5)			
arsenic		√	
cadmium		√	
chromium		√	
nickel		√	

EBS=Exhaled Breath Samples; RA= Room Air Samples; SS=Surface Samples

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Constituents Analyzed

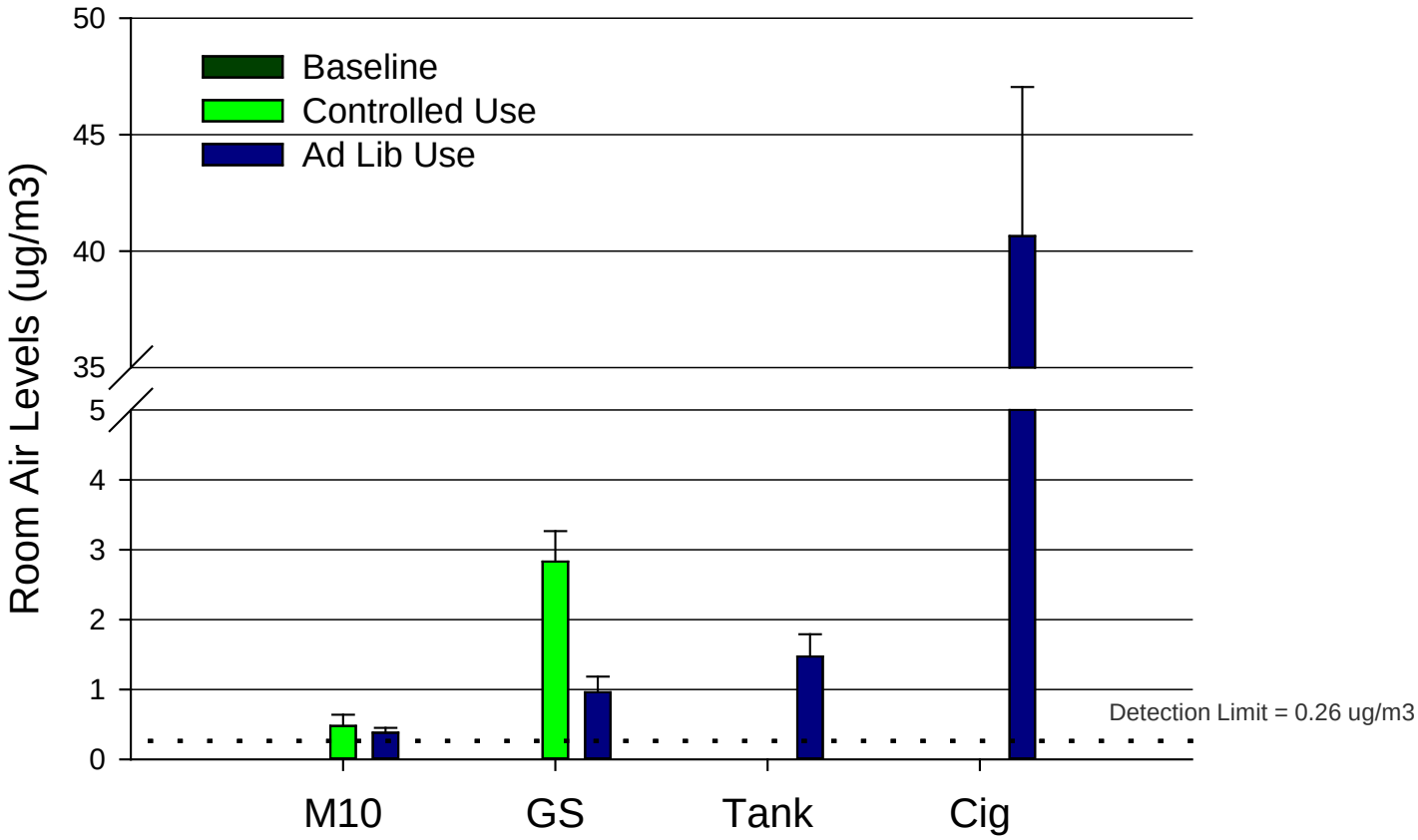
Constituent	EBS	RAS	SS
Propylene glycol and glycerin (ISO 16200-1)			
nicotine	√	√	√
propylene glycol	√	√	√
glycerin	√	√	√
Carbonyl compounds (ISO 16000-3 & EPA TO-11A)			
formaldehyde	√	√	
crotonaldehyde		√	
o-tolualdehyde		√	
acetaldehyde	√	√	
butyraldehyde (butanal)		√	
m&p-tolualdehyde		√	
acetone		√	
benzaldehyde		√	
propionaldehdye		√	
isovaleraldehyde		√	
hexanaldehyde (aka hexaldehyde)		√	
valeraldehyde		√	
2, 5-dimethylbenzaldehyde		√	
methyl ethyl ketone (MEK)		√	
acrolein	√	√	

Constituent	EBS	RAS	SS
Volatile organic compounds (ISO-16000-6)			
1,3-butadiene		√	
benzene		√	
isoprene		√	
toluene		√	
furan		√	
ethylene oxide		√	
vinyl chloride		√	
propylene oxide		√	
nitromethane		√	
2-nitropropane		√	
vinyl acetate		√	
ethylbenzene		√	
Trace metals (EPA IO-2.1 & 3.5)			
arsenic		√	
cadmium		√	
chromium		√	
nickel		√	

EBS=Exhaled Breath Samples; RA= Room Air Samples; SS=Surface Samples

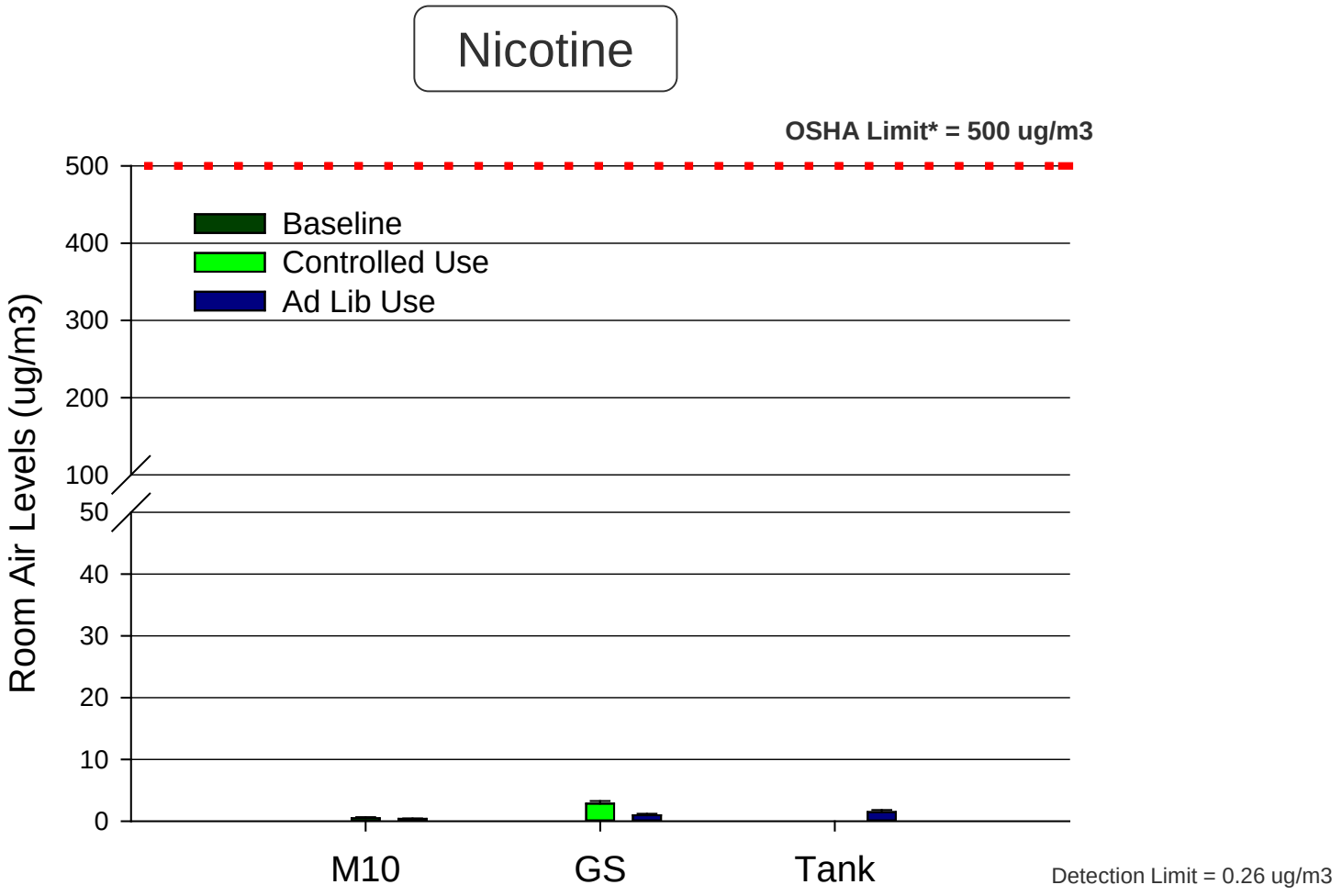
Room Air Levels

Nicotine



Data shown as average of n=4 sampling stations ± SD

Room Air Levels



* Source: Occupational Safety and Health Administration Regulations (Standards – 29 CFR 1910.1000) Table Z-1 Limits for Air Contaminants Value shown as 8-hour time weighted average permissible exposure limit

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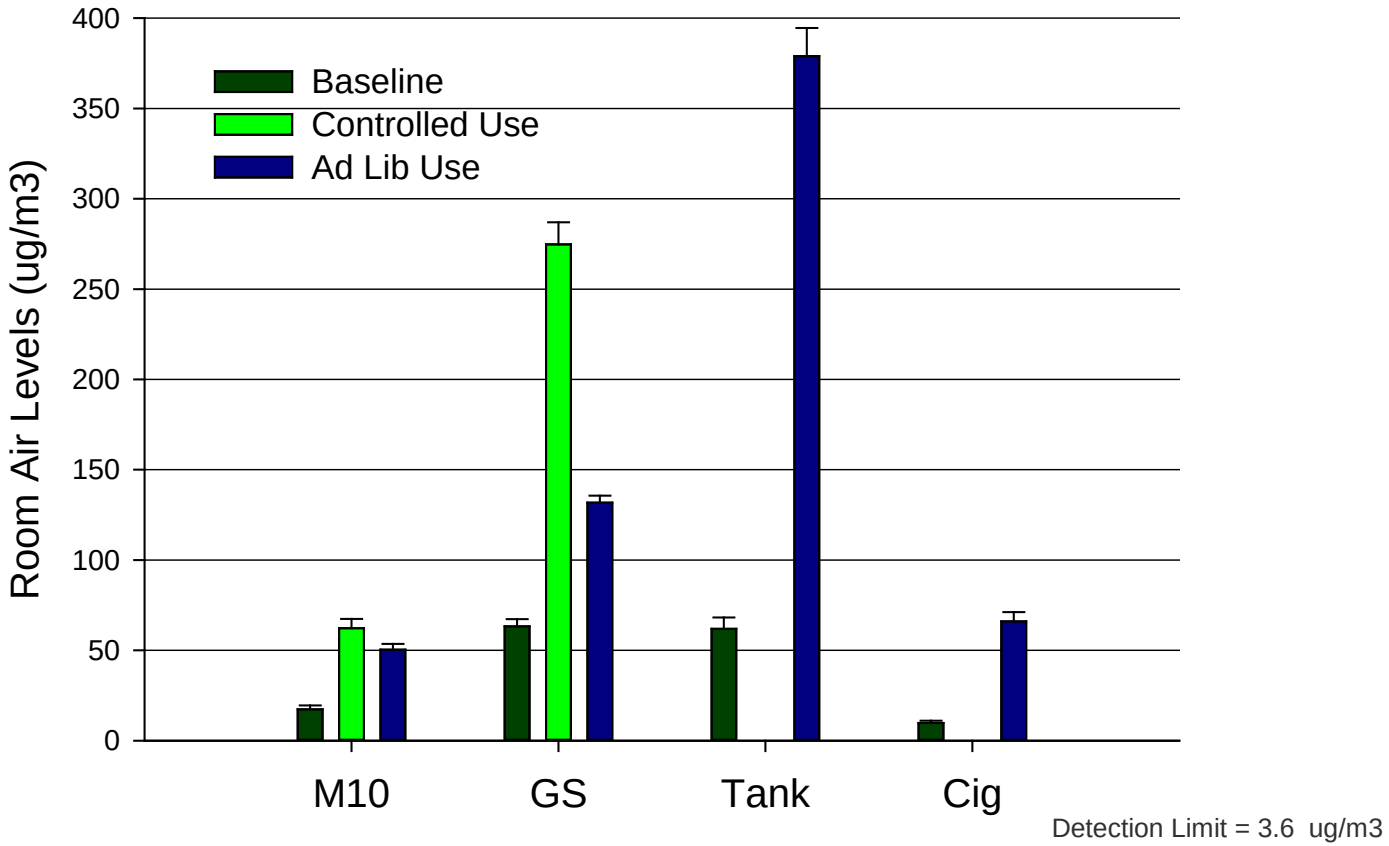
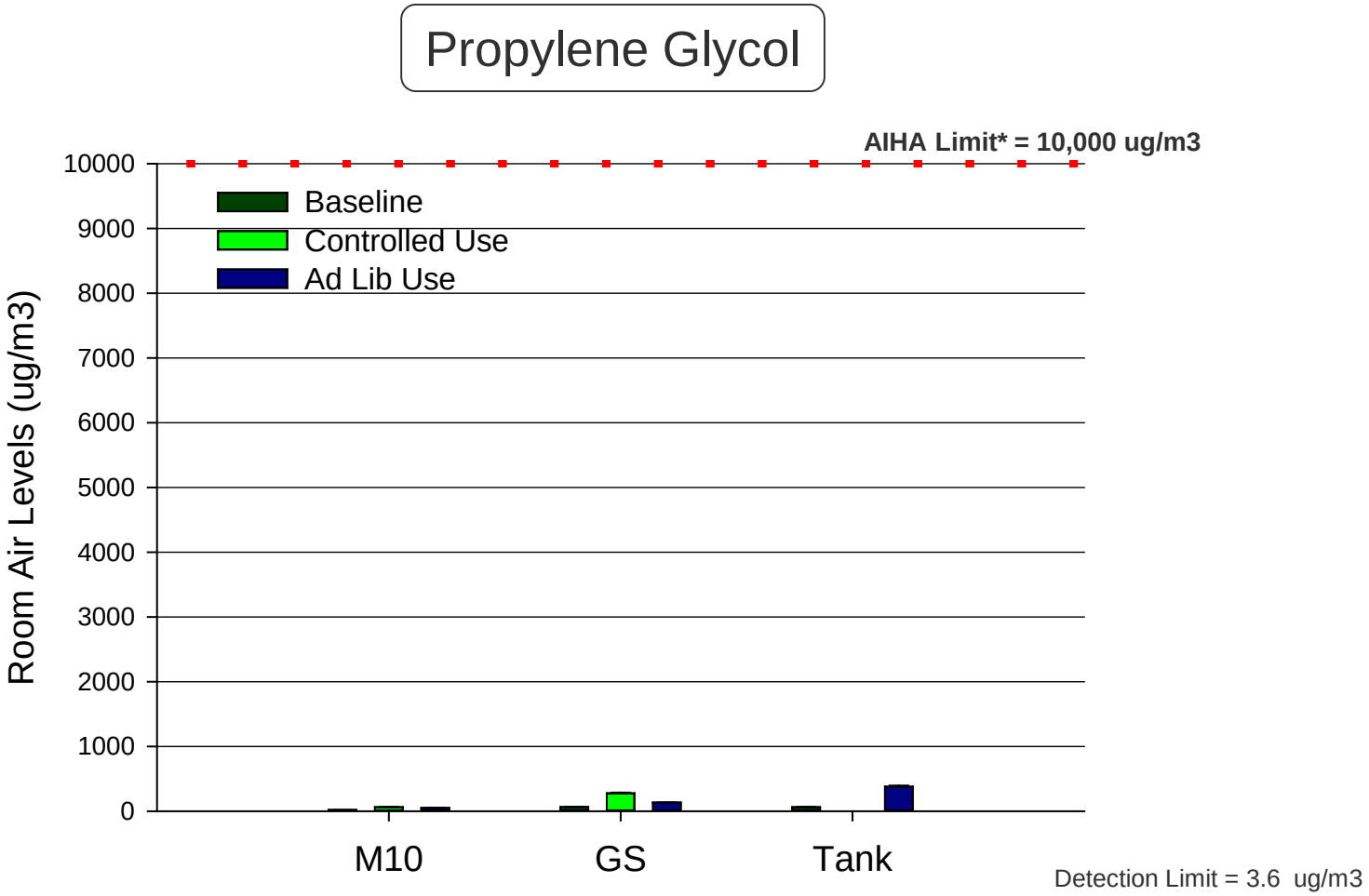
Room Air Levels

Propylene Glycol



Detection Limit = 3.6 ug/m3

Room Air Levels



* Source: American Industrial Hygiene Association (AIHA) 2013 ERPG/WEEL Handbook
Value shown as 8-hour time weighted average permissible exposure limit

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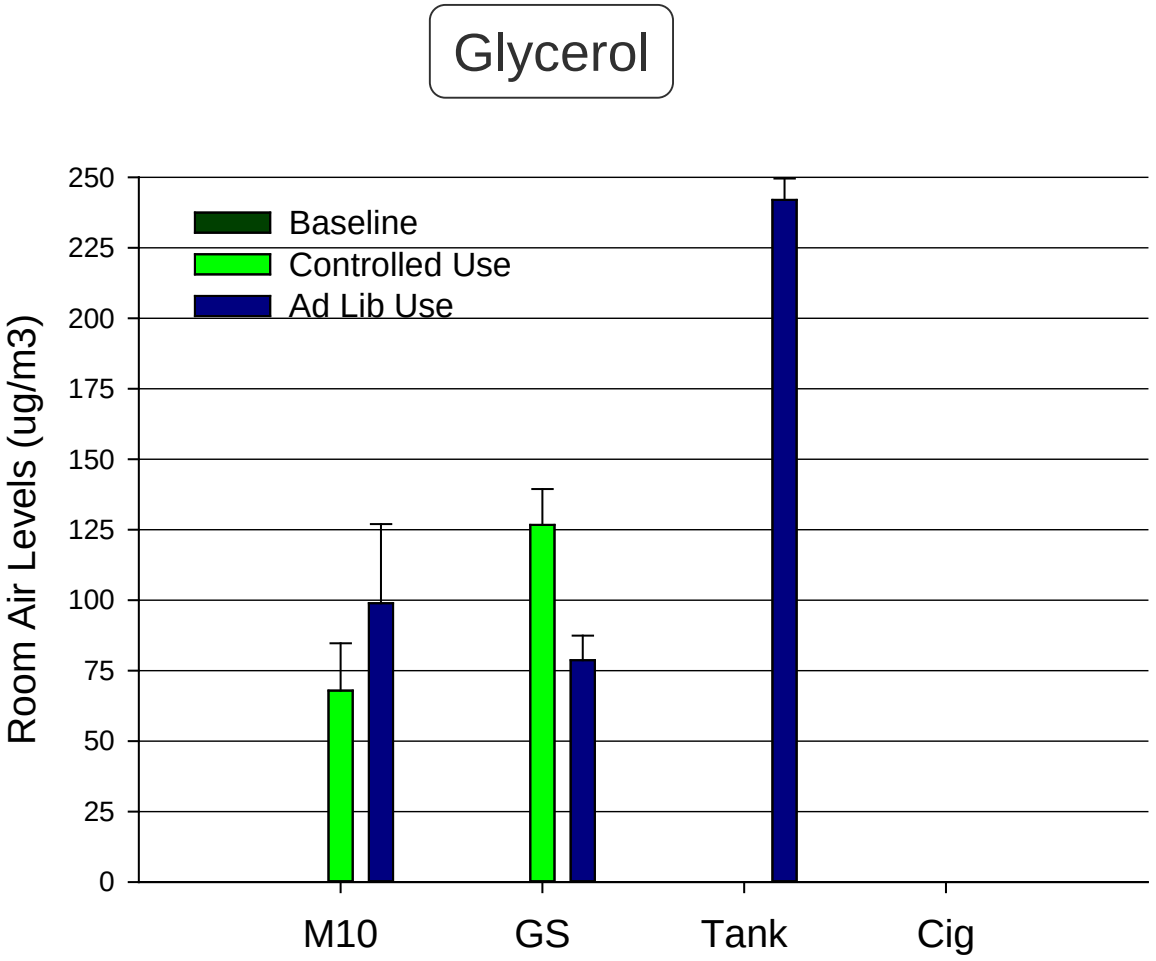
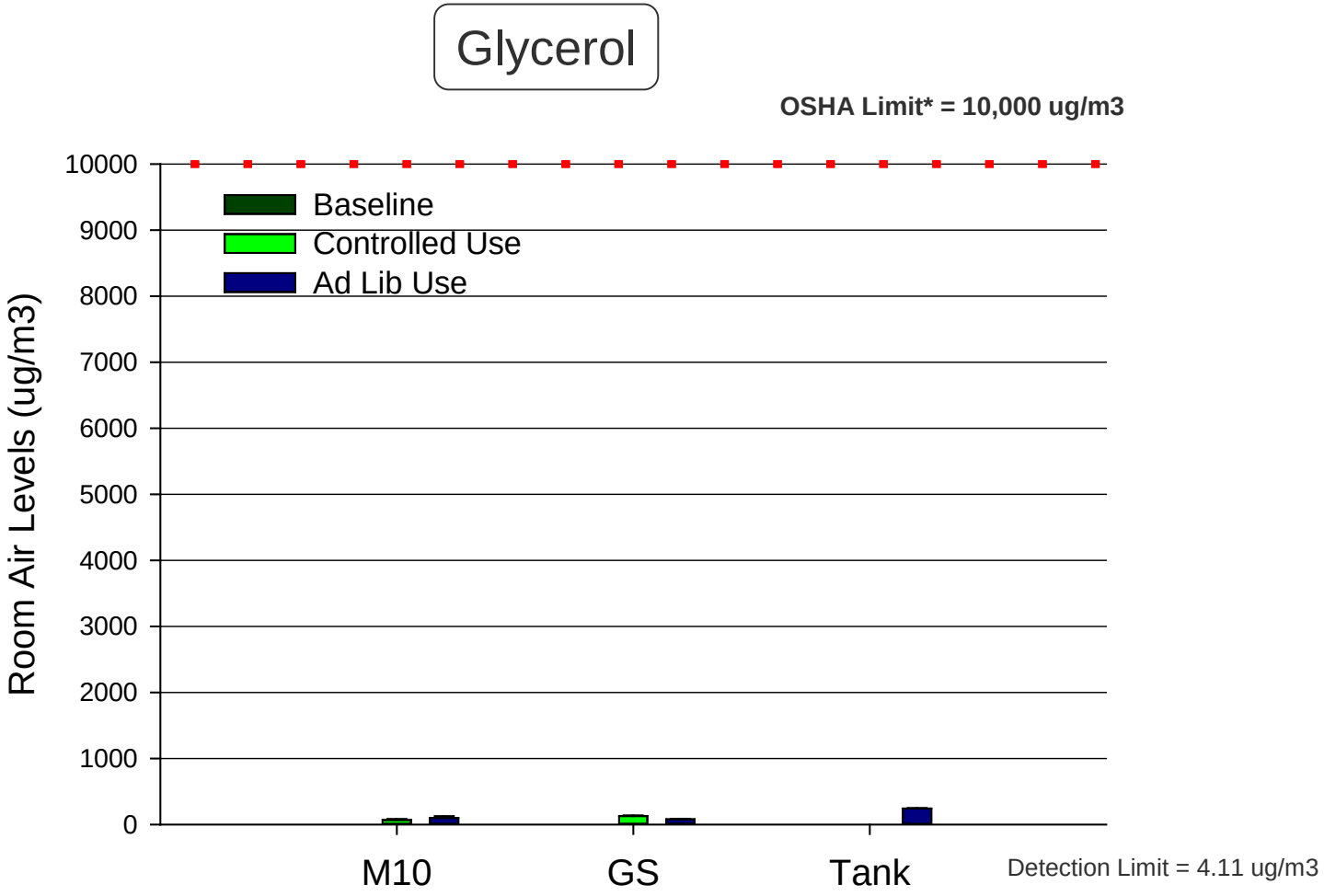
Room Air Levels



Detection Limit = 4.11 ug/m3

Room Air Levels



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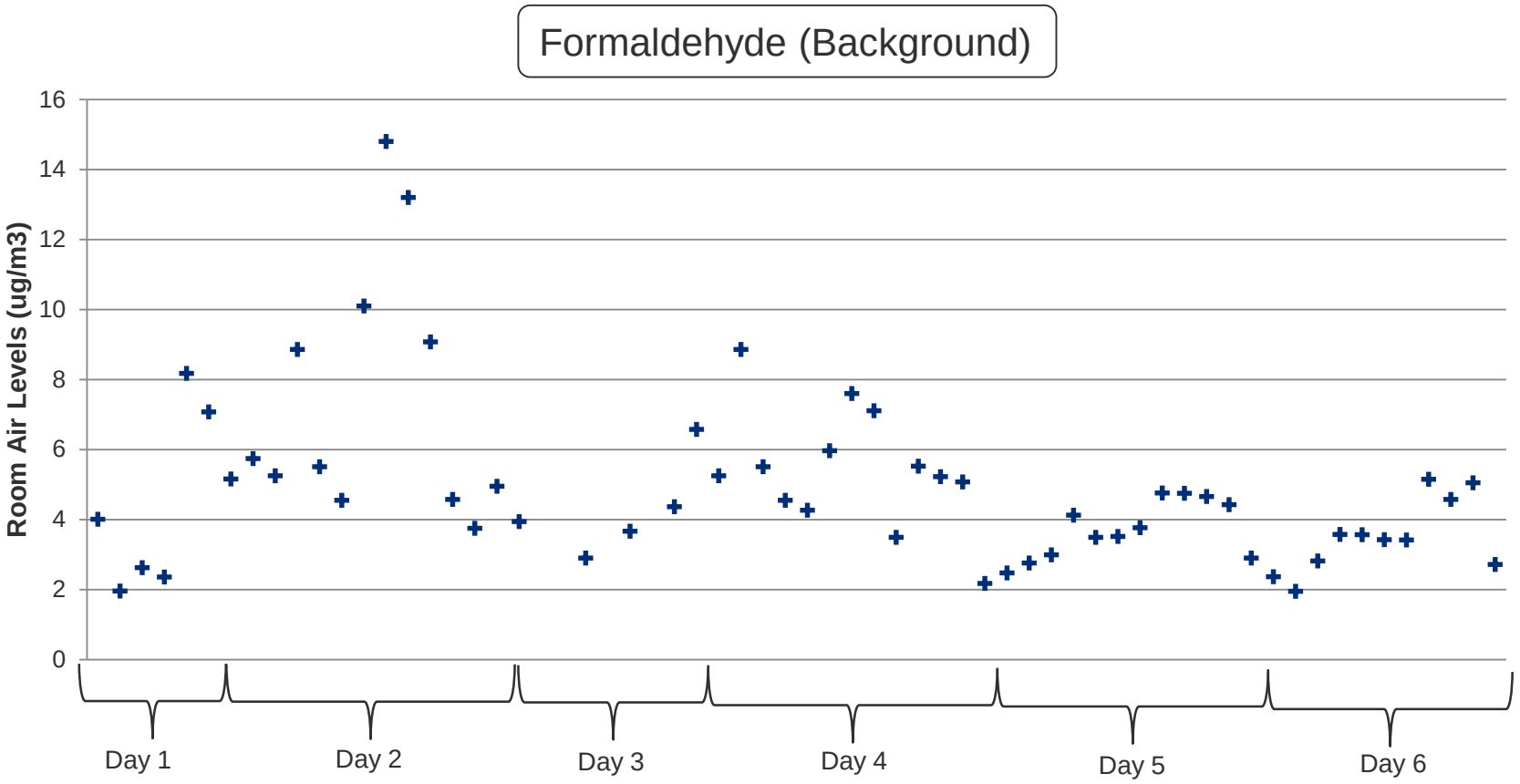
Room Air Levels



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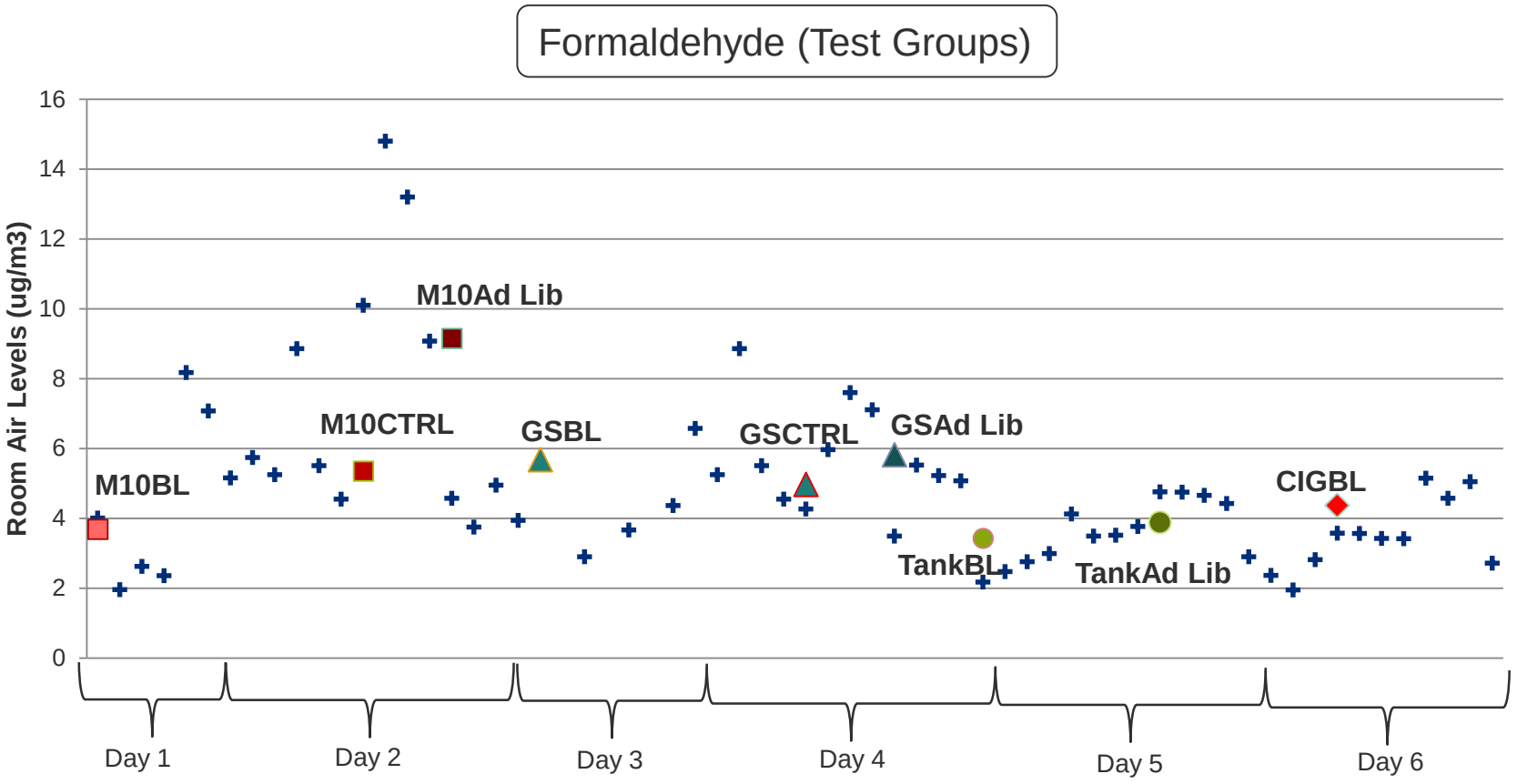
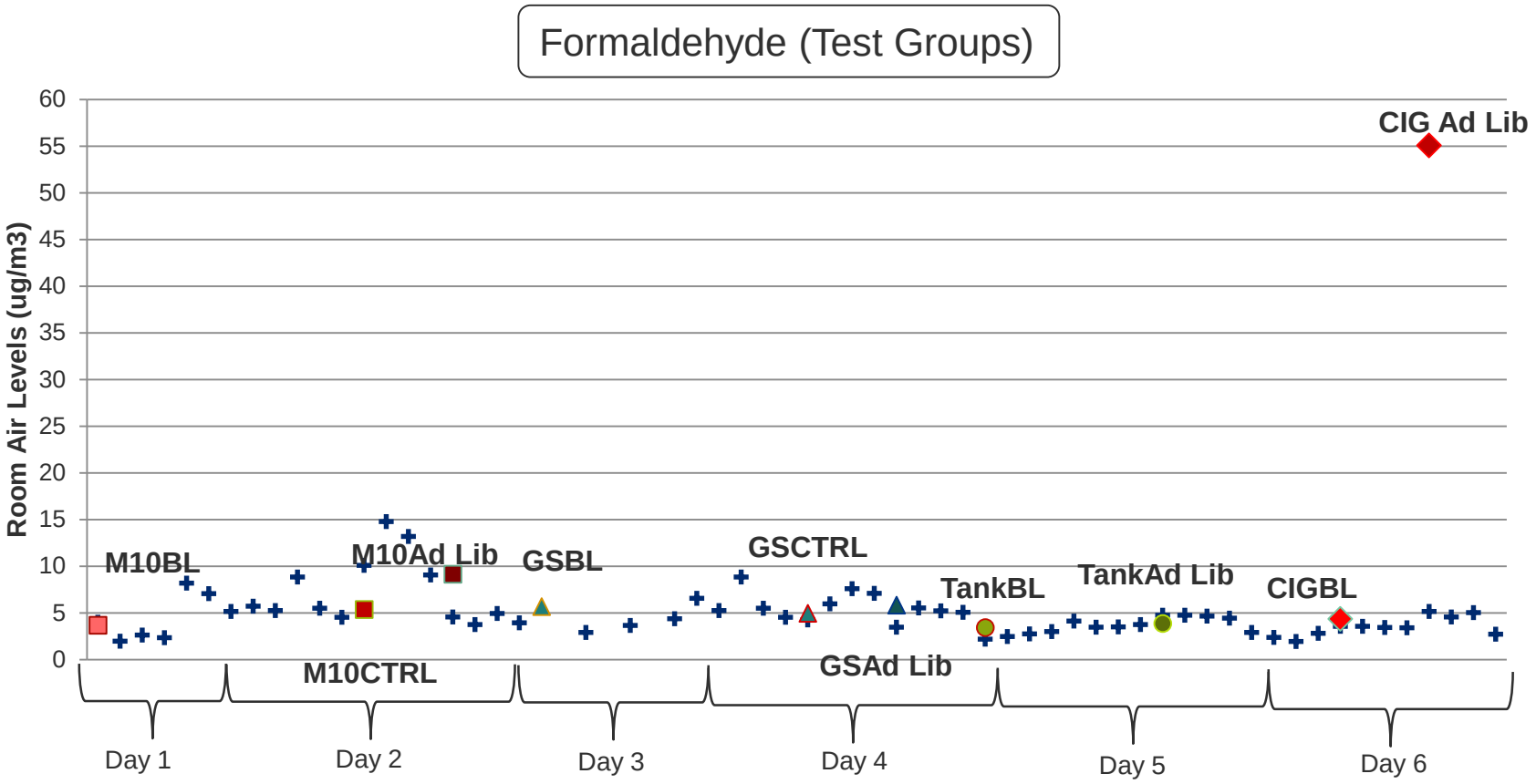
Room Air Levels



M10 = Mark-Ten® 2.5% Classic; GS = Prototype Electronic Cigarette 2.4%[A]; Tank = Ego-T Tank and subjects' own e-liquids; CIG= Conventional cigarettes, subjects' own cigarettes ; BL=Baseline; CTRL=Controlled Use; Ad Lib = Ad lib use

[A] Similar to commercial GreenSmoke® electronic cigarettes

Room Air Levels



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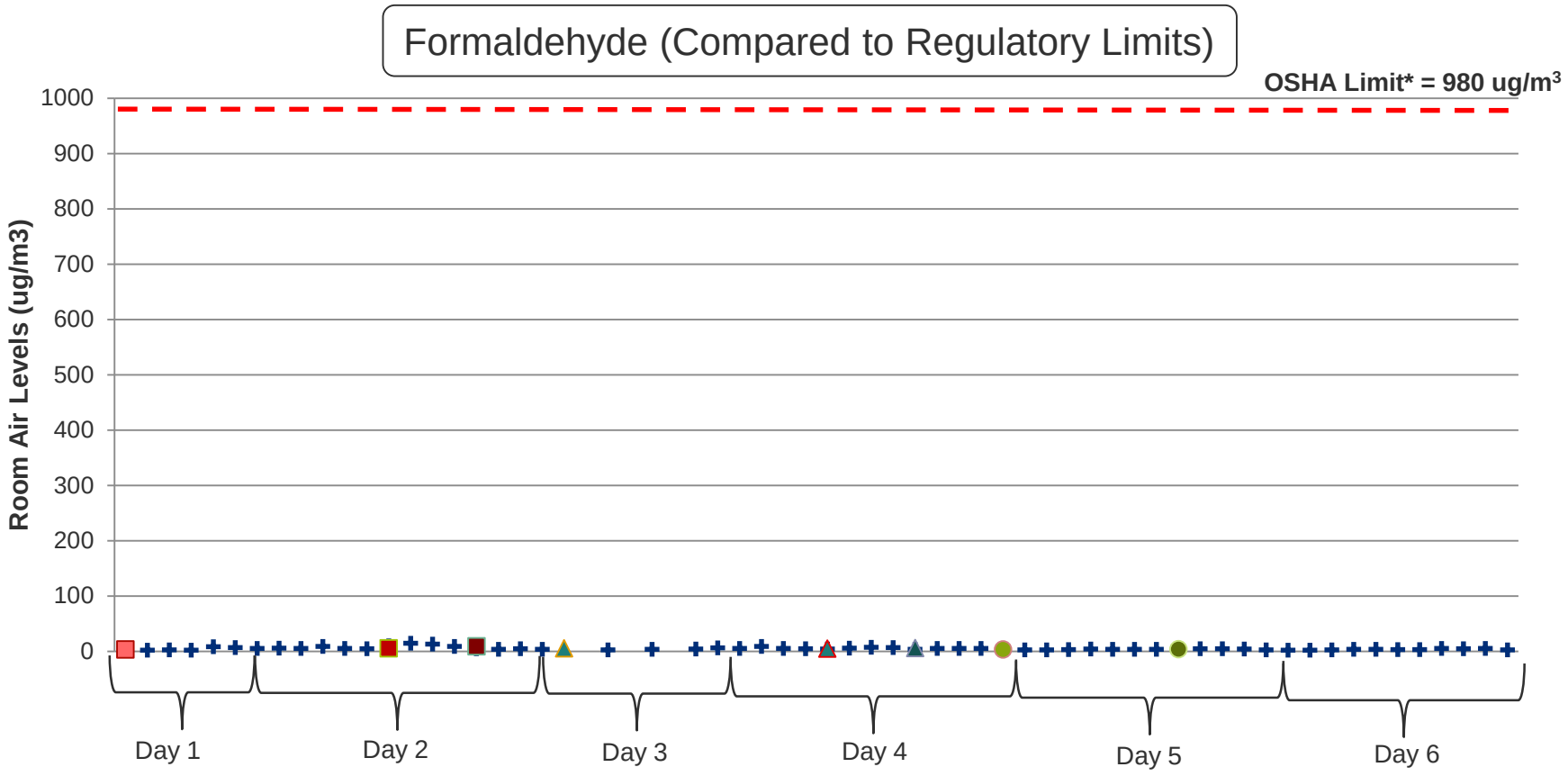
Room Air Levels



*Source: Occupational Safety and Health Administration Regulations (Standards – 29 CFR 1910.1000) Table Z-1 Limits for Air Contaminants
Value shown as 8-hour time weighted average permissible exposure limit

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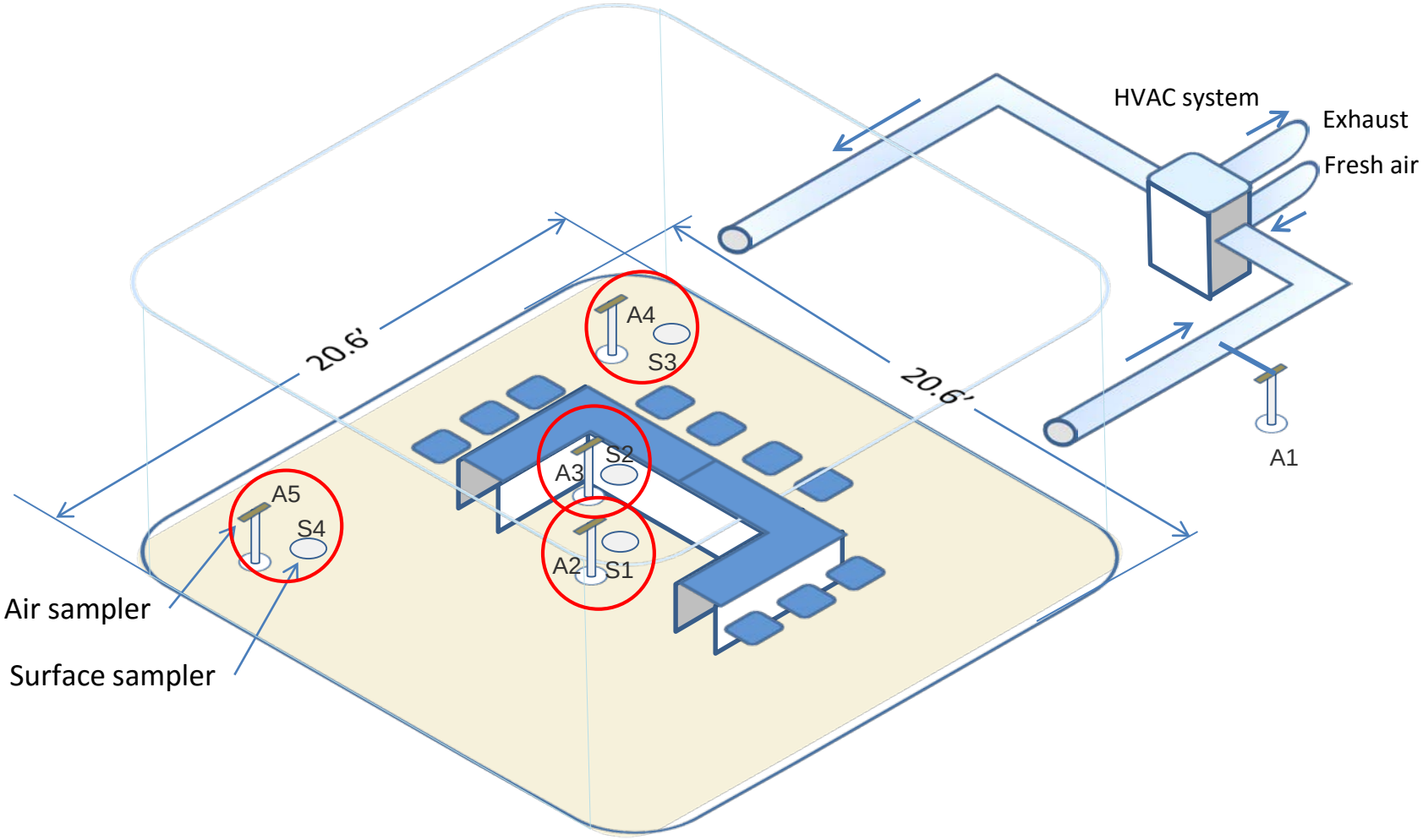
Sampling Stations



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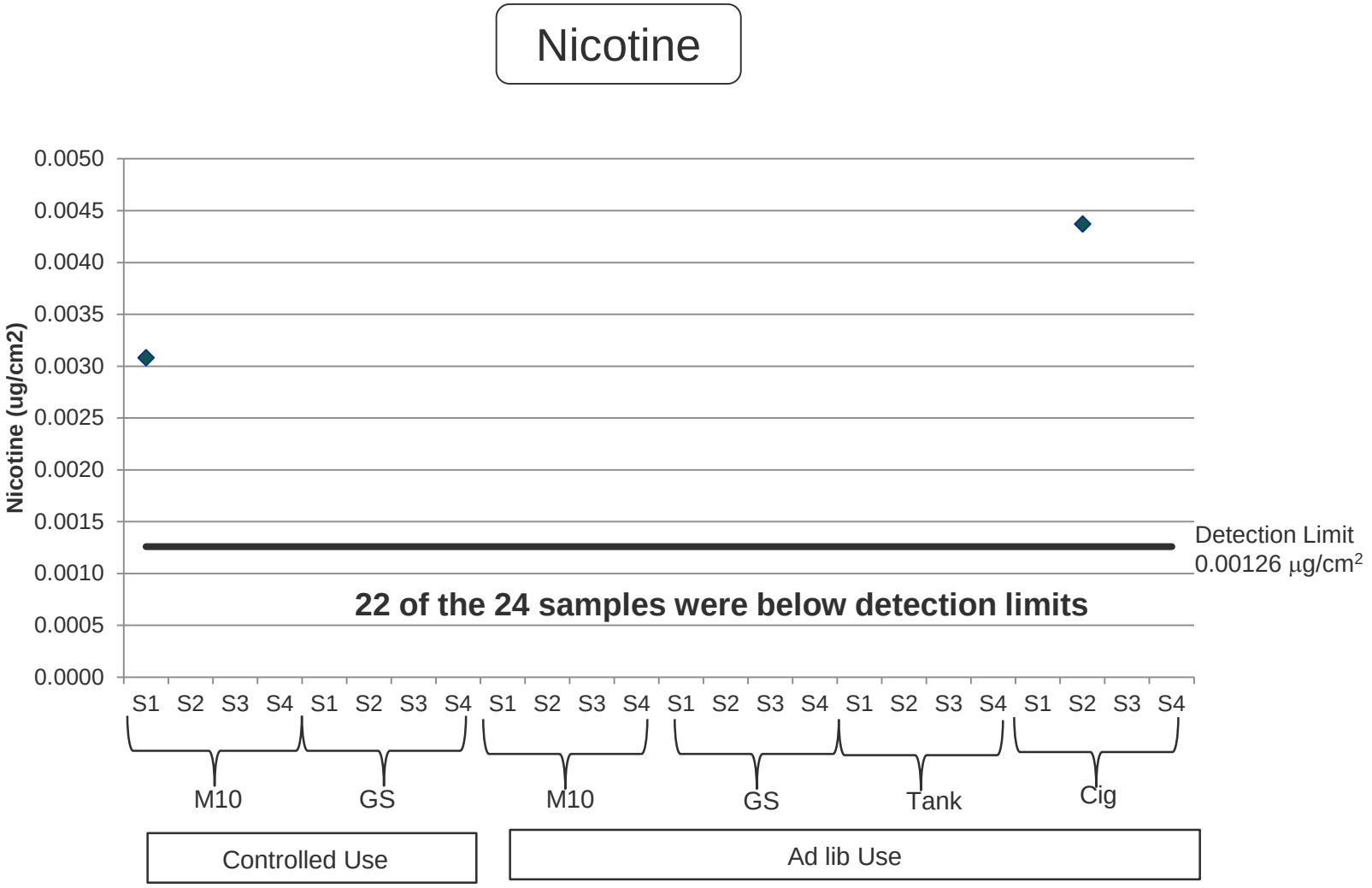
Surface Sample Levels



Conclusions

- Under study conditions with the products tested
  - Room air levels of constituents during the use e-vapor products were several fold below the current occupational regulatory and consensus limits[a]
  - Surface sample results suggest that thirdhand exposure of non-users to nicotine is unlikely
- Further research is needed to determine the exposure to e-vapor constituents in non-users under different conditions of use and the potential for harm associated with this exposure

[a] Workplace exposure limits to airborne contaminants set by Occupational Safety and Health Administration (OSHA) for Nicotine, Glycerol and Formaldehyde; American Industrial Hygiene Association (AIHA) for Propylene Glycol.