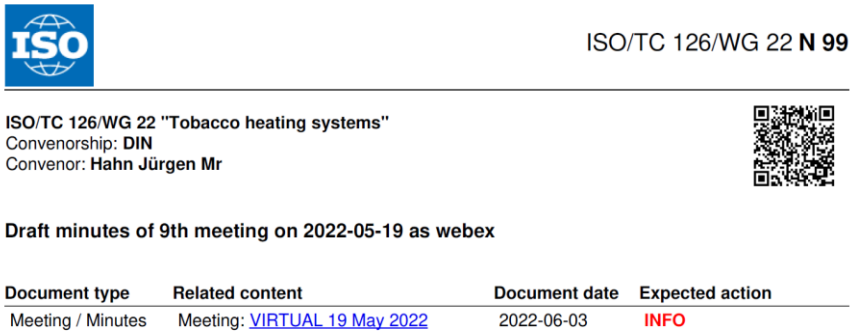
Draft minutes of 9th meeting of ISO/TC 126/WG 22



ISO/TC 126/WG 22 **N 99**

ISO/TC 126/WG 22 "Tobacco heating systems"
Convenorship: **DIN**
Convenor: **Hahn Jürgen Mr**

Draft minutes of 9th meeting on 2022-05-19 as webex

Document type	Related content	Document date	Expected action
Meeting / Minutes	Meeting: VIRTUAL 19 May 2022	2022-06-03	INFO

Mr HYODO explained that if the proficiency study is finalised within CORESTA then this should be shared within WG 22 in order to discuss the next steps. There was an agreement that it should be waited for the results of the proficiency study of CORESTA and then they should be discussed within WG 22 before planning the next steps.

Heated Tobacco Products (HTP) Task Force: Proficiency Study for Propylene Glycol, Glycerin, Nicotine, CO, NO, NOx, ACM, and DML in HTP Aerosol

Taryn Winner / Takatsugu Hyodo

ISO/TC 126/WG 22 meeting
December 6, 2022

Contents

- Proposals from CORESTA HTP Task Force to WG 22
- Executive summary of the study
- Study overview
- Results
- Discussions
- Conclusions
- Recommendations

Proposal from CORESTA HTP TF to WG 22

- **Collaboration between CORESTA and ISO**
  - **Discussion at WG 22 to be based on the outcomes from this proficiency study**
    - Most widely used method among labs can be the candidate for the basis of CRMs and **ISO methods** for propylene glycol, glycerin, **nicotine**, **nitrogen oxide**, **nitrogen oxides**, **carbon monoxide**, **aerosol collected mass** and device mass loss when applicable.

(Section 7. Recommendations)

Executive summary of the study

- A proficiency study with seventeen participants covering 4 HTP products was successfully executed.
- While there were minor deviations from nearly uniform methodology, it does not appear these deviations resulted in any meaningful differences with the exception of perhaps NO in cHTP products.
- Due to the uniformity of the selected analytical methods, the data for 4 HTP products can be considered as both a proficiency study and a collaborative study.

(Section 6. Conclusion)

Executive summary of the study

(Section 7. Recommendations)

- **Prepare CORESTA Recommended Methods**
  - **Most widely used method among labs can be the candidate for the basis of CRMs, which are as follows.**
  - **Repeatability and reproducibility from this proficiency study can be used.** *(calculation with data only from each method below)*

(Section 7. Table 23)

Analytes	Trapping	Extraction	Separation / Detection
PG, Gly, Nicotine	CFP	Isopropanol	GC-FID
CO	Gas bags	---	NDIR
NO & NOx	Gas bags or online	---	Chemiluminescence

Study overview

(Cover page)

- Study Coordinators: Taryn Winner & Takatsugu Hyodo
- Protocol Author: Maxim Belushkin
- Statistician: Hsiao-Pin Liu with support from Michael Morton and Hannah Grisevich
- Four products:
  - eHTP - Philip Morris and British American Tobacco
  - aHTP - Japan Tobacco
  - cHTP - RJ Reynolds Tobacco

(3.1 Participation Table 2)

Study overview

(4.1. Methods)

- 17 laboratories returned data
- Shipping issues created limited product availability for some
- Technical capabilities limited analytes for some
- Analytes:
  - CO, NO, NO_x
  - Propylene Glycol, Glycerin, Nicotine
  - Aerosol Collected Mass (ACM)
  - Device Mass Loss (DML) - *aHTP only*

(2. Introduction)

Study overview

Timeline:

- **2020 Q4:** Product shipped from manufacturers to Laboratories
- **2021 Q2:** Labs perform analysis after receiving all samples
- **2021 Q3&4:** Data to Stats & study complete
- **2022 Q1-3:** Report drafted
- **2022 Q3:** Report publication on CORESTA website

(https://www.coresta.org/proficiency-study-propylene-glycol-glycerin-nicotine-co-no-nox-acm-and-dml-htp-aerosol-36692.html)

Outline

- Labs and manufacturers
- Method tables
- Figures (ranked charts per Analyte and Product)
- Repeatability and reproducibility values

- Z-score (Appendix)

Labs and manufacturers

Participating Laboratories
Altria
ASL Analytic Service Laboratory GmbH
JTI-Ökolab, Vienna
China National Tobacco Quality Supervision and Test Centre
Compañía Industrial de Tabacos Monte Paz SA
Enthalpy Analytical Inc.
Essentra
Japan Tobacco Inc.
Kentucky Tobacco Research & Development Center
KT&G Research institute
SWM intl/co LTR Industries Usine Le Mans
Philip Morris Izhora
Philip Morris Manufacturing & Technology Bologna S.p.A.
Philip Morris Products S.A. R&D Innovation Cube T0134
R&D Centre of China Tobacco Yunnan Industrial Co. Ltd.
RJ Reynolds Tobacco Co.
Shanghai New Tobacco Product Research Institute of CNTC

Manufacturers	HTP Product
Philip Morris International	eHTP-1
British American Tobacco	eHTP-2
RJ Reynolds Tobacco Co.	cHTP
Japan Tobacco	aHTP

(3.1 Participation Table 1 and 2)

Method table for PG, Gly and Nic

Lab	Linear or Rotary Smoke	Pad and/or Impinger(s)	Method of Extraction	Method of Separation	Method of Detection	eHTP consumables/rep	cHTP consumables/rep	aHTP consumables/rep
1	Linear	CFP	Isopropanol	GC	FID	3	2	1
2	Linear	CFP	Isopropanol	GC	FID	3	3	1
3	Not Reported	CFP	Methanol	GC	FID	3		1
4	Linear	CFP	Isopropanol	GC	FID	3	3	
5	Linear	CFP	Isopropanol	GC	FID	12		
6	Linear	CFP	Isopropanol/octadecane/ethanol	GC	FID	5	2	1
7	Linear	CFP	Isopropanol	GC	FID	3	3	3
8	Linear	CFP	Isopropanol	GC	FID	3	3	
9	Linear	CFP	Isopropanol	GC	FID	2	2	1
10	Linear	CFP	Isopropanol	GC	FID	3	3	1
11	Linear	CFP	Isopropanol	GC	FID	3	2	
12	Linear	CFP	Isopropanol	GC	FID	3	3	3
13	Linear	CFP	Methanol	GC	FID	3	3	
15	Linear	CFP	Isopropanol	GC	FID	4	4	
16								
17	Linear	CFP	Isopropanol	GC	FID	3 eHTP-1 / 5 eHTP-2	5	1
18	Linear	CFP and 1 impinger with methanol (impinger for PG only)	Isopropanol	GC	MS	5	2	1

(4.1 Methods Table 3)

Method table for ACM and DML

Lab	Linear or Rotary Smoke	Pad and/or Impinger(s), and/or Gas Bag	Method of Detection	ACM eHTP consumables/rep	ACM cHTP consumables/rep	ACM aHTP consumables/rep
1	Linear	CFP	Balance	3	2	1
2	Linear	CFP	Balance	3	3	1
3	Not Reported	CFP	Balance	3		1
4	Linear	CFP	Balance	3	3	
5	Linear	CFP	Balance	5		
6	Linear	CFP	Balance	5	2	1
7	Linear	CFP	Balance	3	3	3
8	Linear	CFP	Balance	3	3	1
9	Linear	CFP	Balance	2	2	1
10	Linear	CFP	Balance	3	3	1
11	Linear	CFP	Balance	3	2	
12	Linear	CFP	Balance	3	3	3
13	Linear	CFP	Balance	3	3	
15	Linear	CFP	Balance	4	4	
16	Rotary	CFP	Balance	5	5	2
17	Linear	CFP	Balance	3 eHTP-1 / 5 eHTP-2	5	1
18	Linear	CFP	Balance	5	2	1

Linear or Rotary Smoke	Method of Detection	DML aHTP consumables/rep
Linear	Balance	1
Not Reported	Balance	1
Linear	Balance	1
Linear	Balance	3
Linear	Balance	1
Linear	Balance	1
Linear	Balance	1
Linear	Balance	3
Rotary	Balance	2
Linear	Balance	1
Linear	Balance	1

(4.1 Methods Table 6 and 7)

Method table for CO

Lab	Linear or Rotary Smoke	Pad and/or Impinger(s), and/or Gas Bag	Method of Detection	eHTP consumables/rep	cHTP consumables/rep	aHTP consumables/rep
1	Linear	Gas Bag	NDIR Analyzer	3	2	1
2	Linear	Gas Bag	NDIR Analyzer	3	3	1
3	Not Reported	Gas Bag	NDIR Analyzer	3		Not Reported
4	Linear	Gas Bag	NDIR Analyzer	3	3	
5	Linear	Gas Bag	NDIR Analyzer	12		
6	Linear	Gas Bag	NDIR Analyzer	5	2	1
7	Linear	Gas Bag	NDIR Analyzer	3	3	3
8	Linear	Gas Bag	NDIR Analyzer	3	3	3
9	Linear	Gas bag	NDIR Analyzer	2	2	1
10	Linear	Gas bag	NDIR Analyzer	3	3	1
11						
12	Linear	Gas Bag	NDIR Analyzer	3	3	3
13	Linear	Gas Bag	NDIR Analyzer	3	3	
15	Linear	Gas Bag	NDIR Analyzer	4	4	
16	Rotary	Gas Bag	NDIR Analyzer	5	5	2
17	Linear	Gas Bag	NDIR Analyzer	3 eHTP-1 / 5 eHTP-2	5	1
18	Linear	Gas bag	NDIR Analyzer	5	2	1

(4.1 Methods Table 4)

Method table for NO and NO_x

Lab	Linear or Rotary Smoke	Pad and/or Impinger(s), and/or Gas Bag	Method of Detection	eHTP consumables/rep	cHTP consumables/rep	aHTP consumables/rep
1	Rotary	Gas Bag	Chemiluminescence	5	2	1
2	Single Port	Online	Chemiluminescence	1	1	1
3						
4	Linear	Gas Bag	Chemiluminescence	3	3	
5	Linear	Gas Bag	Chemiluminescence	20		
6						
7	Linear	Gas Bag	Chemiluminescence	3	3	3
8	Single Port	Online	Chemiluminescence	1	1	1
9	Single Port	Gas Bag	Chemiluminescence	1		1
10	Linear	Gas Bag	Chemiluminescence	3	3	1
11						
12	Linear	Gas Bag	Chemiluminescence	3	3	3
13						
15						
16	Rotary	Online	Chemiluminescence	5	5	2
17	Linear	Gas Bag	Chemiluminescence	5 eHTP-1 / 3 eHTP-2	3	
18	Linear	Gas Bag	Chemiluminescence	5	2	1

(4.1 Methods Table 5)

Ranked Charts per Analyte and Product

- For PG, Gly and Nic
  - Indicates use of mass spectrometry (MS) vs FID →
  - Indicates use of methanol vs isopropanol →
  - Indicates use of isopropanol/octadecane/ethanol vs isopropanol →
- For NO & NOx
  - Indicates use of online collection →
- For all other analytes a similar analytical method is used
- For labs with results which were below analytical limits: <
- For labs which did not return data: X

(4.2 Data plots Figure 1-8)

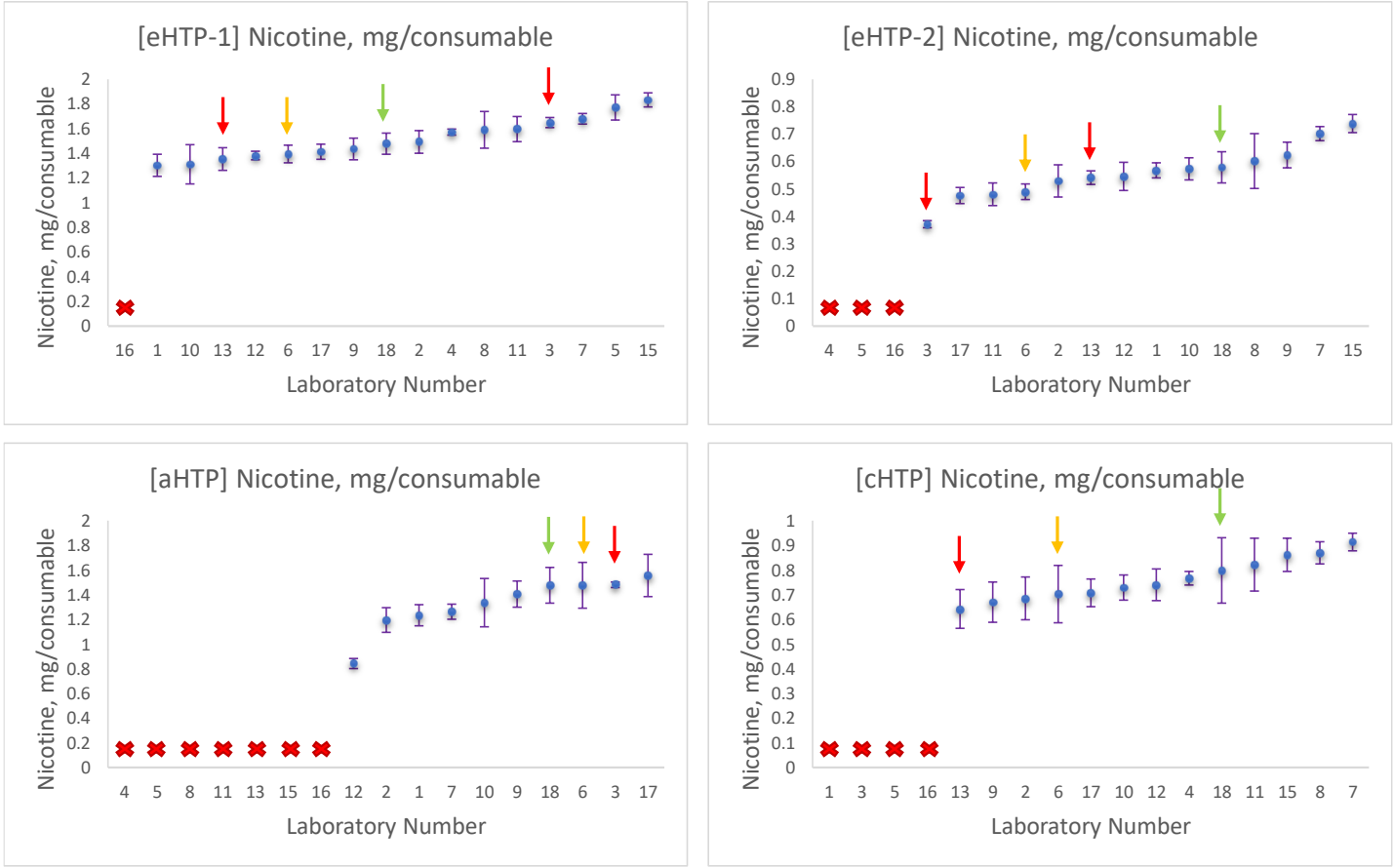


Figure 3. Nicotine results. Symbols indicate: (red X) did not return data, (green arrow) use of mass spectrometry vs FID for detection, (red arrow) use of methanol vs isopropanol for extraction, (orange arrow) use of isopropanol/octadecane/ethanol vs isopropanol for extraction.

(4.2 Data plots)

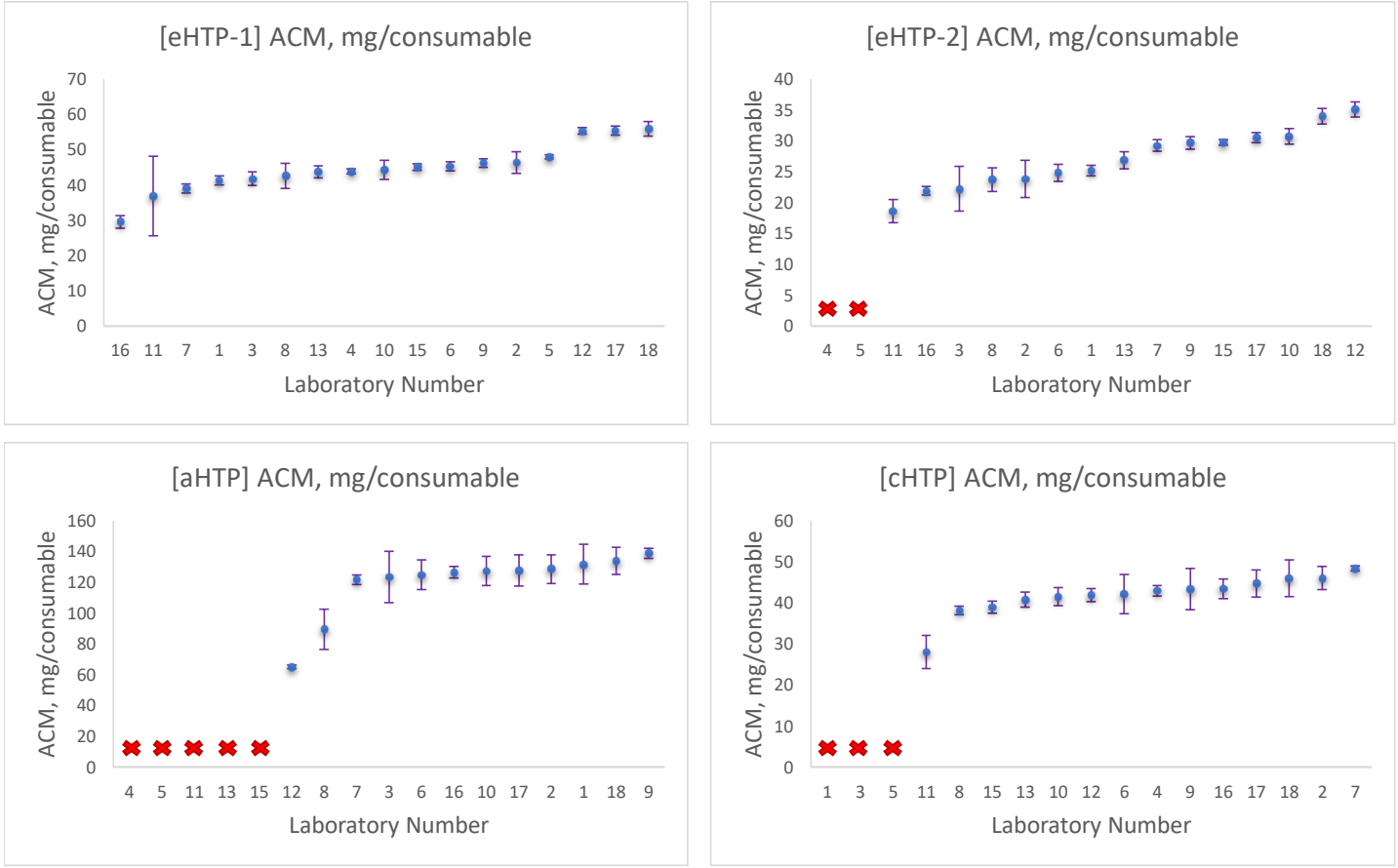


Figure 7. Aerosol collected mass results. Symbols indicate (red X) did not return data.

(4.2 Data plots)

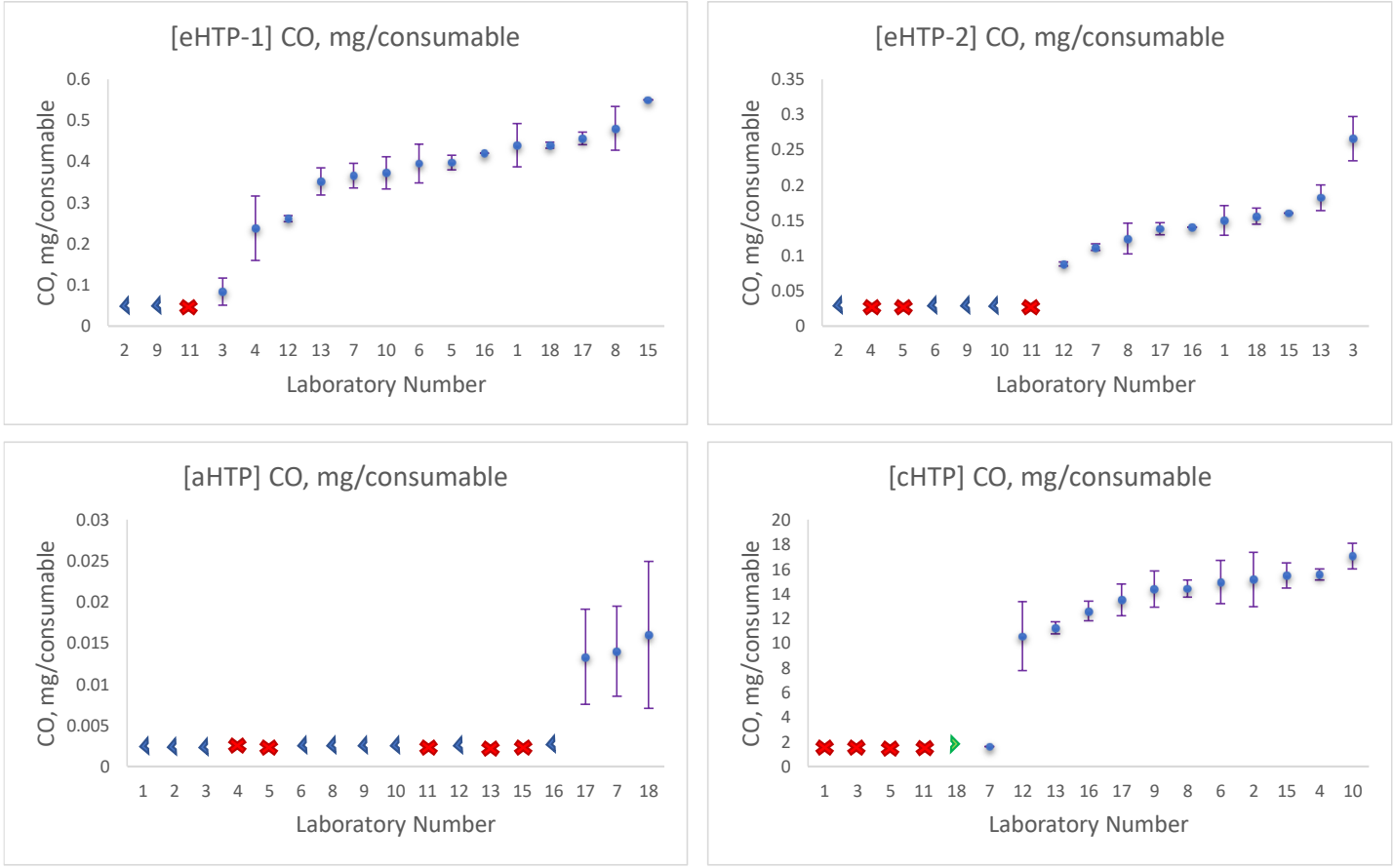


Figure 4. Carbon monoxide results. Symbols indicate (red X) did not return data, (blue "less than" sign) analyte below method LOQ or LOD, (green "greater than" sign) analyte greater than method LOQ.

(4.2 Data plots)

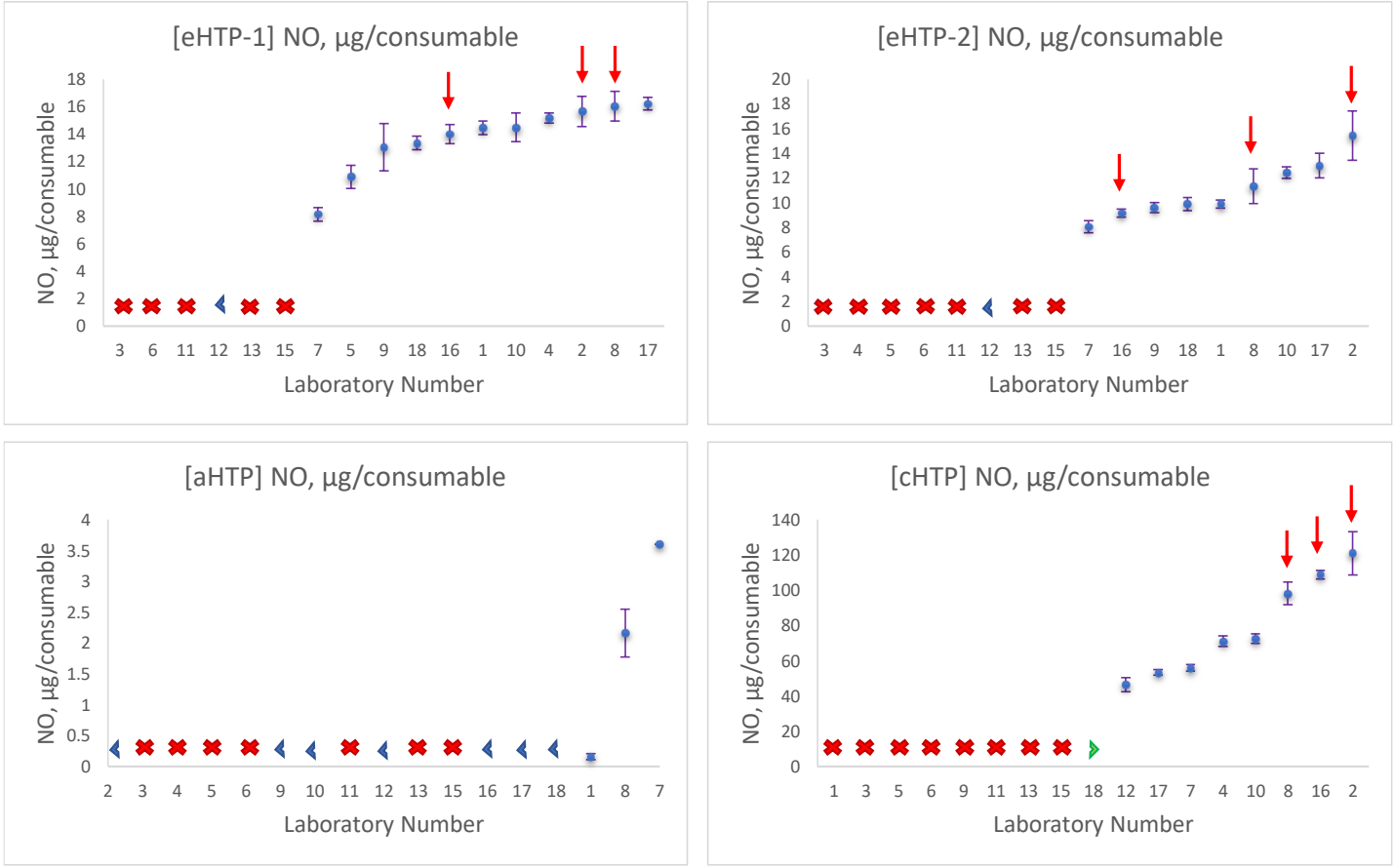


Figure 5. Nitrogen oxide results. Symbols indicate (red X) did not return data, (blue "less than" sign) analyte below method LOQ or LOD, (green "greater than" sign) analyte greater than method LOQ, (red arrow) use of online collection/detection vs gas bag collection.

(4.2 Data plots)

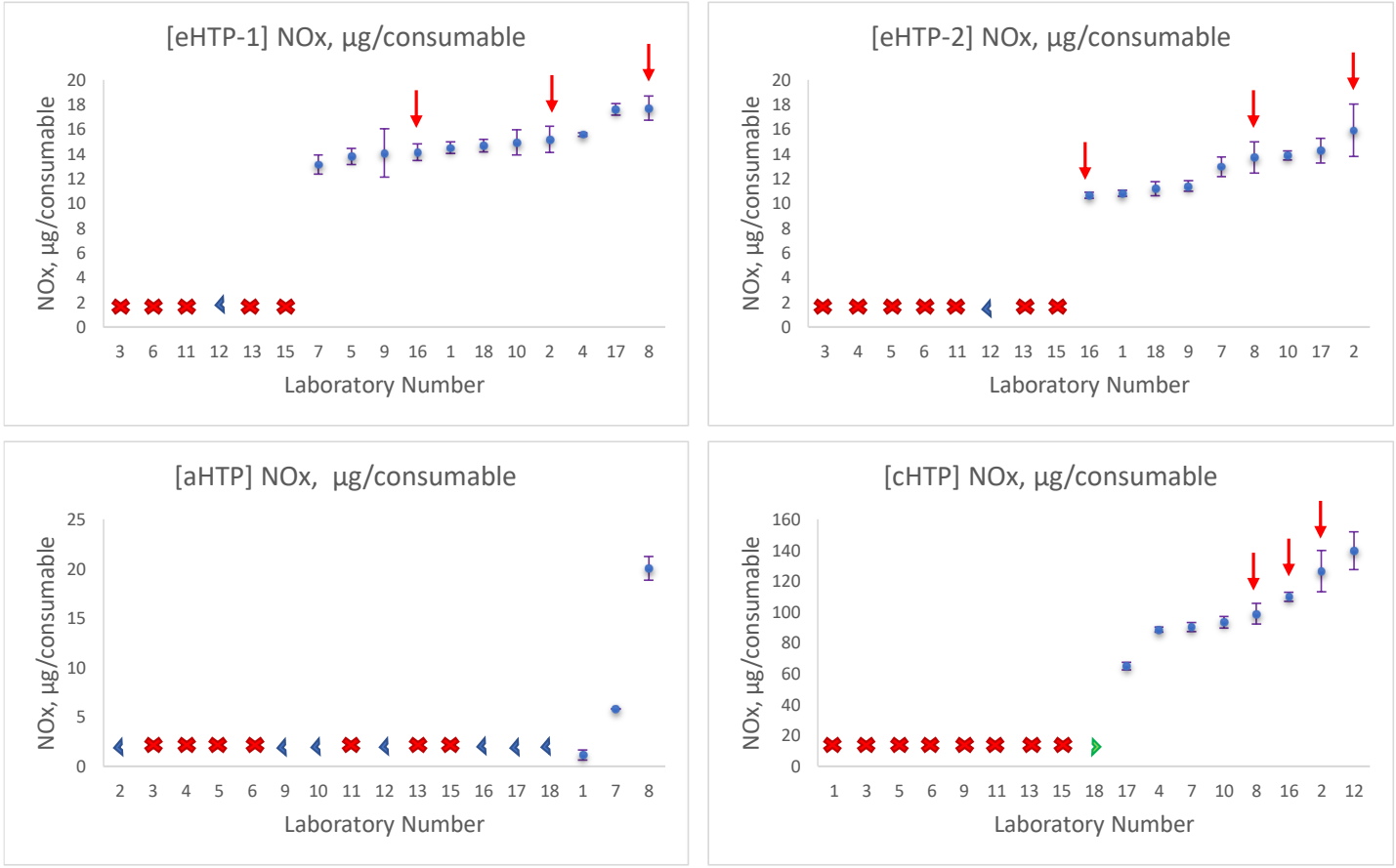


Figure 6. Nitrogen oxides results. Symbols indicate (red X) did not return data, (blue "less than" sign) analyte below method LOQ or LOD, (green "greater than" sign) analyte greater than method LOQ, (red arrow) use of online collection/detection vs gas bag collection.

(4.2 Data plots)

r and R values

- **Statistical analysis does not include data for labs which were below analytical limits** *(4.3.1 Exclusion of Outliers)*
- **ISO 5725-2:1994**
- **Outliers were removed sequentially by:**
  1. **Cochran Outlier Test (1st pass)**
  2. **Grubbs Outlier Test (2nd pass, 3rd pass, 4th pass and so on as needed)**
- **r and R data for the following:**
  - **PG, Gly and Nic with labs 3, 6, 13 and 18 excluded due to the method differences**
  - **CO, NO, NO_x, ACM and DML all labs** *(4.3 Statistical Analysis)*

r & R values for Nicotine

Table 10. Estimates of test sample mean, standard deviations and repeatability and reproducibility for nicotine.

Analyte	Product	N° of Labs*	Mean mg/consumable	r	% r	R	% R	rSD (σ_r)	RSD (σ_R)
Nicotine	eHTP-1	12	1,53	0,260	17,0	0,538	35,1	0,093	0,192
Nicotine	eHTP-2	9	0,58	0,114	19,6	0,275	47,3	0,041	0,098
Nicotine	aHTP	7	1,26	0,338	26,8	0,690	54,7	0,121	0,247
Nicotine	cHTP	10	0,78	0,186	24,0	0,290	37,4	0,066	0,104

(4.3.2 Calculation of r&R)

Labs 3, 6, 13, 18 Excluded

r & R values for ACM

Table 15. Estimates of test sample mean, standard deviations and repeatability and reproducibility for aerosol collected mass.

Analyte	Product	N° of Labs*	Mean mg/consumable	r	% r	R	% R	rSD (σ_r)	RSD (σ_R)
ACM	eHTP-1	16	45,26	5,148	11,4	19,08	42,2	1,839	6,814
ACM	eHTP-2	13	27,73	3,449	12,4	13,62	49,1	1,232	4,863
ACM	aHTP	12	119,82	26,74	22,3	63,80	53,2	9,551	22,78
ACM	cHTP	13	42,90	8,105	18,9	10,80	25,2	2,894	3,857

(4.3.2 Calculation of r&R)

r & R values for CO

Table 12. Estimates of test sample mean, standard deviations and repeatability and reproducibility for carbon monoxide.

Analyte	Product	N° of Labs*	Mean mg/consumable	r	% r	R	% R	rSD (σ_r)	RSD (σ_R)
CO	eHTP-1	13	0,39	0,089	23,0	0,330	85,4	0,032	0,118
CO	eHTP-2	9	0,14	0,037	26,5	0,084	60,5	0,013	0,030
CO	aHTP	3*	-	-	-	-	-	-	-
CO	cHTP	11	14,08	4,083	29,0	6,581	46,8	1,458	2,350

*: The (-) symbol indicates r & R are not recommended due to only three laboratories' data.

(4.3.2 Calculation of r&R)

r & R values for NO & NOx

Table 13. Estimates of test sample mean, standard deviations and repeatability and reproducibility for nitrogen oxide.

Analyte	Product	N° of Labs*	Mean µg/consumable	r	% r	R	% R	rSD (σ_r)	RSD (σ_R)
NO	eHTP-1	11	13,77	2,500	18,2	7,120	51,7	0,893	2,543
NO	eHTP-2	7	10,29	1,542	15,0	5,176	50,3	0,551	1,848
NO	aHTP	2*	-	-	-	-	-	-	-
NO	cHTP	7	72,31	9,814	13,6	66,27	91,7	3,505	23,67

*: The (-) symbol indicates r & R are not recommended due to only two laboratories' data.

Table 14. Estimates of test sample mean, standard deviations and repeatability and reproducibility for nitrogen oxides.

Analyte	Product	N° of Labs*	Mean µg/consumable	r	% r	R	% R	rSD (σ_r)	RSD (σ_R)
NOx	eHTP-1	10	15,14	2,052	13,6	4,591	30,3	0,733	1,640
NOx	eHTP-2	8	12,37	1,980	16,0	4,560	36,8	0,707	1,628
NOx	aHTP	2*	-	-	-	-	-	-	-
NOx	cHTP	8	101,47	20,25	20,0	68,07	67,1	7,232	24,31

*: The (-) symbol indicates r & R are not recommended due to only two laboratories' data.

(4.3.2 Calculation of r&R)

Discussions

(5.2 Relationship Between Methods and Yields)

- **Relationship between methods and data**
  - **In general, nearly every laboratory ran essentially the same method with a few exceptions.**
  - **There did not appear to be any significant differences in their results compared to the other laboratories (with the noted exception of NO in cHTP).**
  - **It was discovered that each laboratory had developed analytical methods for analytes in HTP aerosol based on the method used for cigarette smoke and/or e-cigarette aerosol testing, mostly either ISO methods or CRMs.**

→ **Therefore, this proficiency study can be regarded as collaborative study.**

Discussions

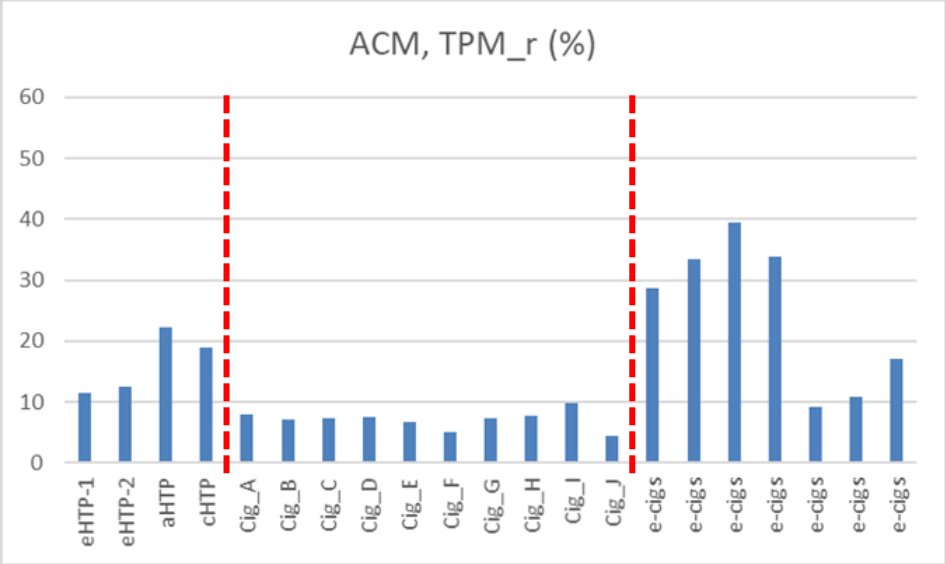
- **Magnitude of variability compared with other product category**
  - There is no benchmark data in the past HTP studies to assess the magnitude of yield variability.
  - r and R data from other product categories such as cigarettes and e-cigarettes were used for the assessment.
  - The magnitudes of ACM yields variability on HTP were generally comparable with the ones from cigarettes (TPM) and e-cigarettes.
  - Regarding nicotine and CO, r & R of HTP tended to be higher than the ones from cigarettes, and nearly the same level as e-cigarettes.

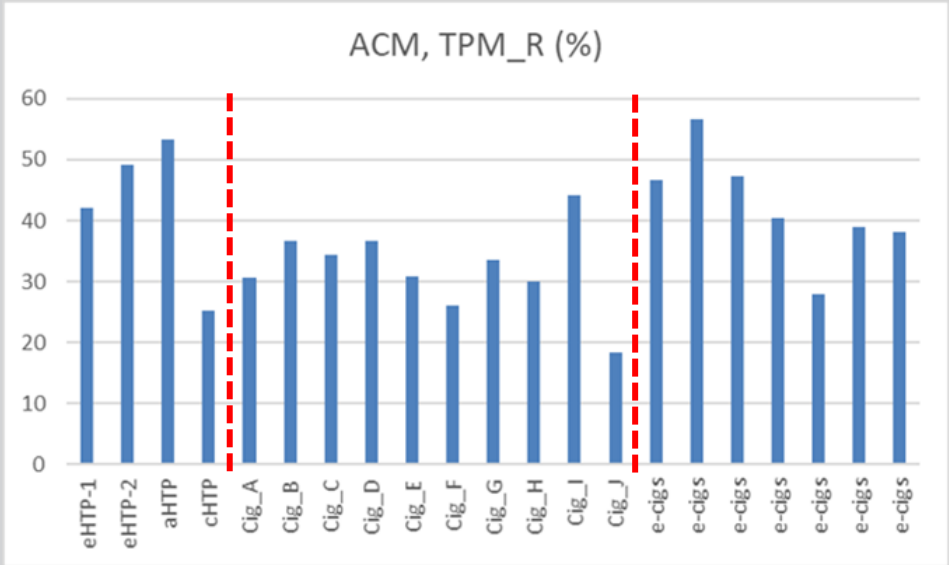
→ **This is a snapshot, and it is important to collect data continuously.**

(5.5 Magnitude of Variability Compared with Other Product Category)

Discussions

- r and R for ACM/TPM yields of HTP, e-cigarettes, and cigarettes.





(5.5 Magnitude of Variability Compared with Other Product Category Figure 9)

Discussions

- **Nitric oxide (NO) and nitrogen oxides (NOx)**
  - Three labs selected online chemiluminescence detection while the other labs collected the aerosol in gas bags, then measured the concentrations using chemiluminescence.
  - There does seem to be higher trending data for the labs utilizing the online collection method on the concentration of NO in the cHTP product, although no such tendency for aHTP and eHTP products.
  - The conversion, NO oxidized into NOx, is not only time-based but is also influenced by NO/NOx concentrations as well as other gases which many be present in the mixture (Rickert et al., 1987).

→ **CORESTA HTP TF agreed that trapping with gas bags and online measures could both be included in the CRM.**

(5.2.1 Nitric oxide (NO) and nitrogen oxides (NOx))

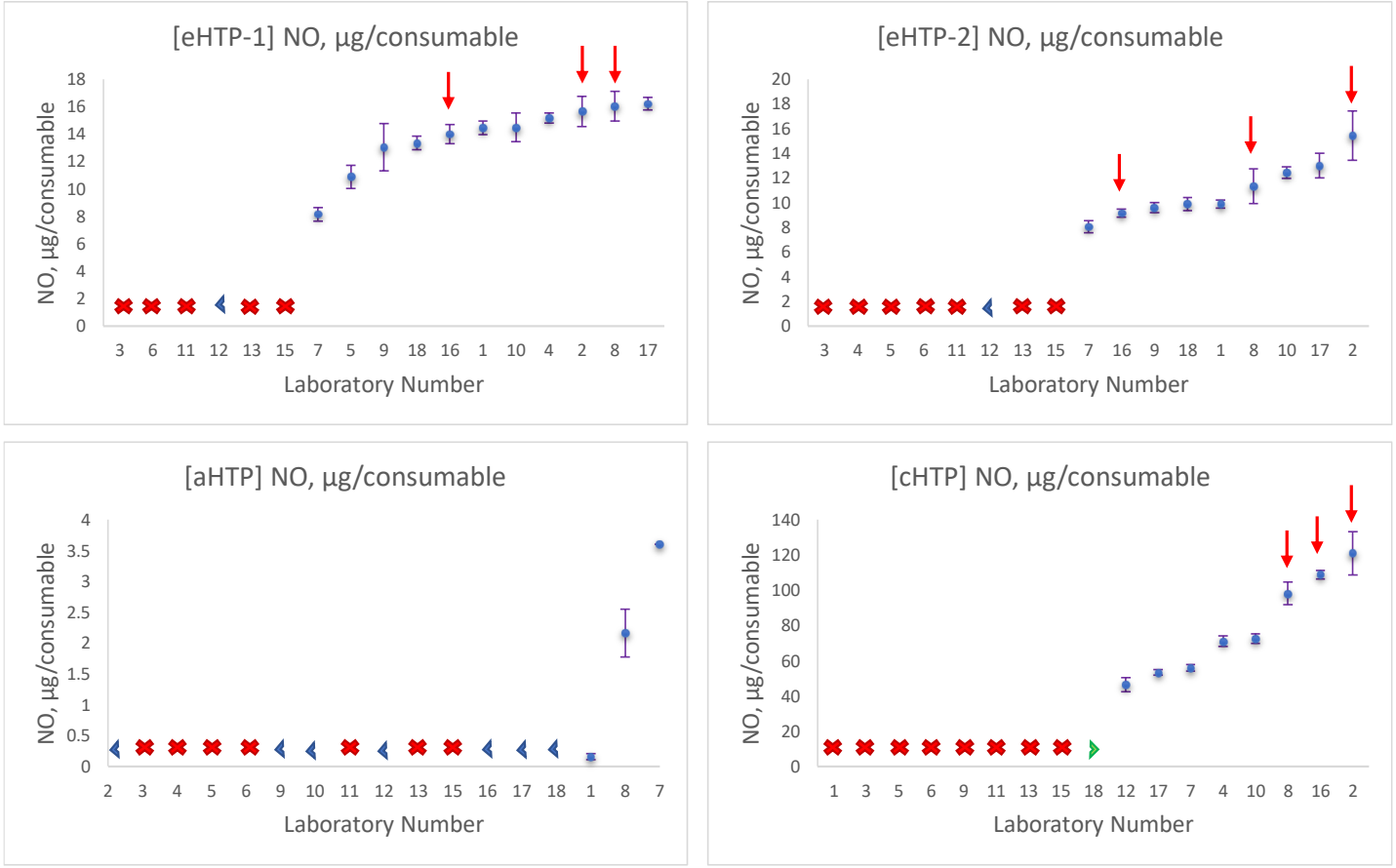


Figure 5. Nitrogen oxide results. Symbols indicate (red X) did not return data, (blue "less than" sign) analyte below method LOQ or LOD, (green "greater than" sign) analyte greater than method LOQ, (red arrow) use of online collection/detection vs gas bag collection.

Discussions

- **Analyte yields close to or below LOQ**
  - For example, NO analysis from the aHTP product returned 3 values above LOQ, therefore, r and R values were not robust and recommended. However, the other subcategories did return enough data to generate r and R values. *(5.1 Analyte Yields Close to or Below LOQ)*
  - The low levels of a particular analyte for any given subcategory are attributed to the nature of the product(s) rather than the method suitability. *(5.1 Analyte Yields Close to or Below LOQ)*
  - For all labs, the analytical method was not altered based on the subcategory of HTP product analyzed. *(4.1 Methods)*

→ **No specific method per HTP subcategory for any of the analytes in this study is recommended.**

Conclusion

- A proficiency study with seventeen participants covering 4 HTP products was successfully executed.
- While there were minor deviations from nearly uniform methodology, it does not appear these deviations resulted in any meaningful differences with the exception of perhaps NO for cHTP products.
- Due to the uniformity of the selected analytical methods, the data for 4 HTP products can be considered as both a proficiency study and a collaborative study.

Recommendations

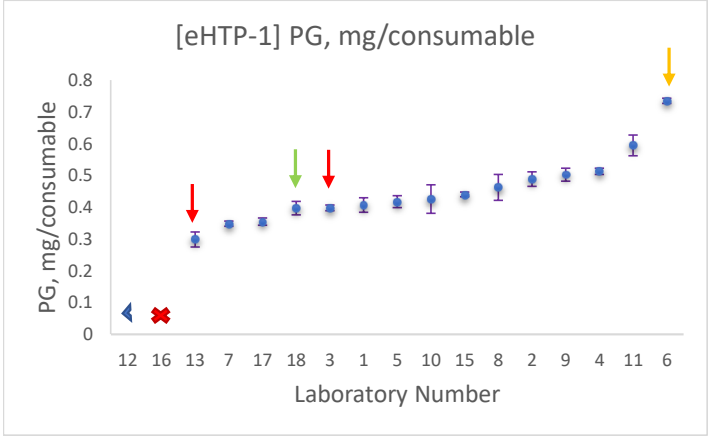
- **Prepare CORESTA Recommended Methods**
  - **Most widely used method among labs can be the candidate for the basis of CRMs, which are as follows.**
  - **Repeatability and reproducibility from this proficiency study can be used.** *(calculation with data only from each method below)*

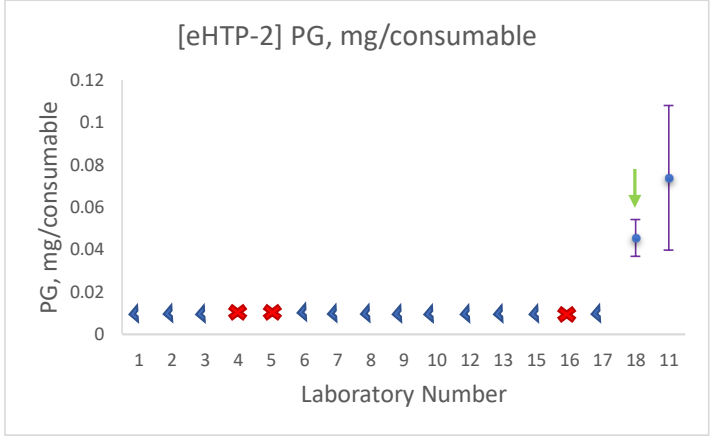
Analytes	Trapping	Extraction	Separation / Detection
PG, Gly, Nicotine	CFP	Isopropanol	GC-FID
CO	Gas bags	---	NDIR
NO & NOx	Gas bags or online	---	Chemiluminescence

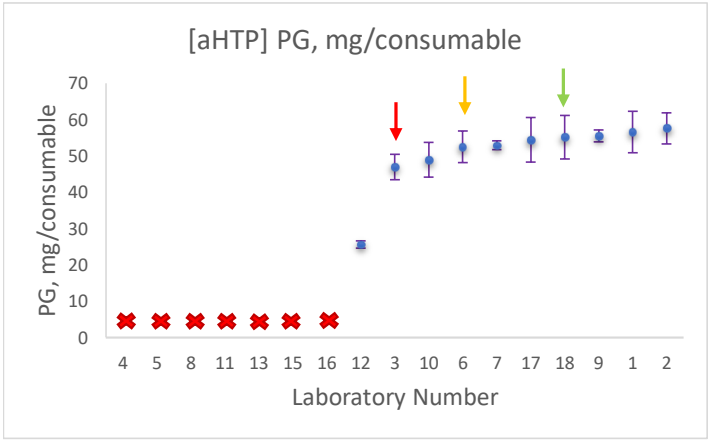
Proposal from CORESTA HTP TF to WG 22

- **Collaboration between CORESTA and ISO**
  - **Discussion at WG 22 to be based on the outcomes from this proficiency study**
    - Most widely used method among labs can be the candidate for the basis of CRMs and **ISO methods** for propylene glycol, glycerin, **nicotine**, **nitrogen oxide**, **nitrogen oxides**, **carbon monoxide**, **aerosol collected mass** and device mass loss when applicable.

Thank you very much!







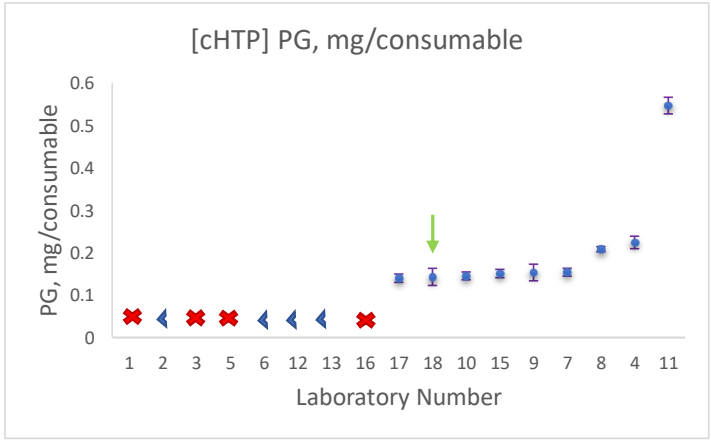


Figure 1. Propylene glycol results. Symbols indicate (red X) did not return data, (blue "less than" sign) analyte below method LOQ or LOD, (green arrow) use of mass spectrometry vs FID for detection, (red arrow) use of methanol vs isopropanol for extraction, (orange arrow) use of isopropanol/octadecane/ethanol vs isopropanol for extraction.

(4.2 Data plots)

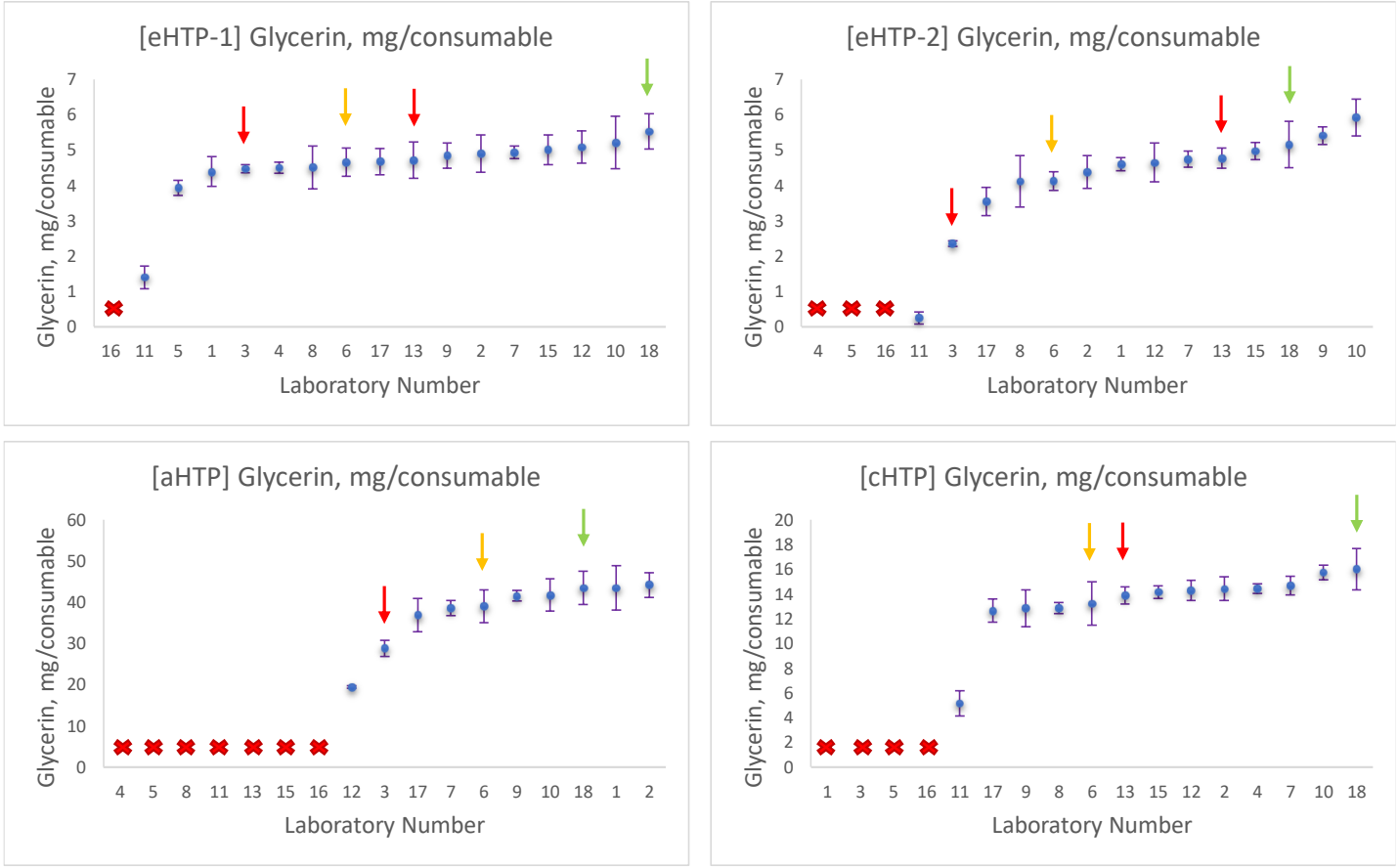


Figure 2. Glycerin results. Symbols indicate (red X) did not return data, (green arrow) use of mass spectrometry vs FID for detection, (red arrow) use of methanol vs isopropanol for extraction, (orange arrow) use of isopropanol/octadecane/ethanol vs isopropanol for extraction.

(4.2 Data plots)

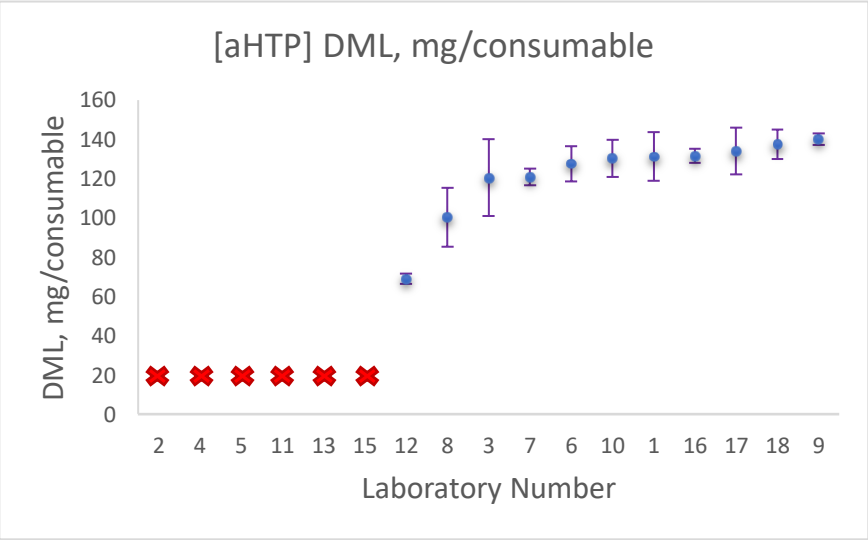


Figure 8. Device mass loss results. Symbols indicate: (red X) did not return data.

(4.2 Data plots)

r & R Results for PG and Gly

(4.3.2 Calculation of r&R)

Table 9. Estimates of test sample mean, standard deviations and repeatability and reproducibility for propylene glycol.

Analyte	Product	N° of Labs*	Mean mg/consumable	r	% r	R	% R	rSD (σ_r)	RSD (σ_R)
PG	eHTP-1	11	0,45	0,070	15,6	0,213	47,2	0,025	0,076
PG	eHTP-2	1*	-	-	-	-	-	-	-
PG	aHTP	6	54,30	12,30	22,7	14,03	25,8	4,393	5,011
PG	cHTP	7	0,17	0,034	20,0	0,099	58,8	0,012	0,035

*: The (-) symbol indicates r & R are not recommended due to only one laboratory.

Table 11. Estimates of test sample mean, standard deviations and repeatability and reproducibility for glycerin.

Analyte	Product	N° of Labs*	Mean mg/consumable	r	% r	R	% R	rSD (σ_r)	RSD (σ_R)
Glycerin	eHTP-1	11	4,73	1,229	26,0	1,517	32,1	0,439	0,542
Glycerin	eHTP-2	9	4,71	1,208	25,7	2,230	47,4	0,431	0,797
Glycerin	aHTP	7	37,96	9,086	23,9	25,37	66,8	3,245	9,061
Glycerin	cHTP	9	14,00	2,319	16,6	3,545	25,3	0,828	1,266

Labs 3, 6, 13, 18 Excluded

r & R Results for DML

(4.3.2 Calculation of r&R)

Table 16. Estimates of test sample mean, standard deviations and repeatability and reproducibility for device mass loss.

Analyte	Product	N° of Labs*	Mean mg/consumable	r	% r	R	% R	rSD (σ_r)	RSD (σ_R)
DML	aHTP	10	127,68	30,26	23,8	41,96	32,9	10,81	14,99

Z-Scores

- **Statistical analysis does not include data for labs which were below analytical limits**
- **Interpretation of Z Scores:**
  - **A result of $|z| \leq 2$ is considered to be acceptable**
  - **A result of $2 < |z| < 3$ is considered to give a warning**
  - **A result of $|z| \geq 3$ is considered to be unacceptable**

(4.3.4 Z-scores)

Z-Score Results for eHTP-1

Table 18: Z-Scores Results for eHTP-1.

Lab No.	PG	Nicotine	Glycerin	CO	NO	NOx	ACM	DML
1	-0,32	-1,30	-0,35	0,47	0,19	-0,28	-0,54	
2	0,44	-0,12	0,20	NA[1]	0,67	0,19	0,22	
3	-0,40	0,85	-0,26	-2,58	NA	NA	-0,47	
4	0,67	0,37	-0,24	-1,26	0,48	0,46	-0,16	
5	-0,22	1,60	-0,86	0,11	-1,30	-0,76	0,46	
6	2,74	-0,73	-0,06	0,09	NA	NA	0,05	
7	-0,86	1,03	0,24	-0,16	-2,43	-1,22	-0,87	
8	0,20	0,48	-0,22	0,82	0,84	1,91	-0,35	
9	0,58	-0,47	0,14	NA	-0,40	-0,57	0,20	
10	-0,14	-1,24	0,54	-0,11	0,20	0,01	-0,09	
11	1,43	0,52	-3,61	NA	NA	NA	-1,20	
12	NA	-0,81	0,41	-1,06	NA	NA	1,56	
13	-1,32	-0,99	0,00	-0,28	NA	NA	-0,18	
15	-0,01	1,99	0,32	1,41	NA	NA	0,03	
16	NA	NA	NA	0,30	0,00	-0,54	-2,29	
17	-0,80	-0,61	-0,04	0,61	0,91	1,84	1,57	
18	-0,40	-0,21	0,88	0,47	-0,28	-0,16	1,64	

1: NA indicates lab data is not available.

(4.3.4 Z-scores)

Z-Score Results for eHTP-2

Table 19: Z-Scores Results for eHTP-2.

Lab No.	PG	Nicotine	Glycerin	CO	NO	NOx	ACM	DML
1	NA[1]	0,11	0,10	0,10	-0,42	-1,05	-0,41	
2	NA	-0,31	-0,05	NA	1,99	1,73	-0,71	
3	NA	-2,00	-1,47	2,52	NA	NA	-1,04	
4	NA	NA	NA	NA	NA	NA	NA	
5	NA	NA	NA	NA	NA	NA	NA	
6	NA	-0,74	-0,24	NA	NA	NA	-0,49	
7	NA	1,54	0,20	-0,69	-1,23	0,12	0,45	
8	NA	0,47	-0,24	-0,44	0,21	0,53	-0,72	
9	NA	0,70	0,67	NA	-0,54	-0,73	0,55	
10	NA	0,16	1,03	NA	0,68	0,61	0,77	
11	0,71	-0,84	-2,95	NA	NA	NA	-1,81	
12	NA	-0,13	0,13	-1,19	NA	NA	1,70	
13	NA	-0,18	0,22	0,77	NA	NA	-0,06	
15	NA	1,93	0,36	0,31	NA	NA	0,56	
16	NA	NA	NA	-0,11	-0,73	-1,14	-1,11	
17	NA	-0,87	-0,65	-0,15	0,93	0,83	0,73	
18	-0,71	0,22	0,49	0,22	-0,42	-0,85	1,47	

1: NA indicates lab data is not available.

(4.3.4 Z-scores)

Z-Score Results for aHTP

Table 20: Z-Scores Results for aHTP.

Lab No.	PG	Nicotine	Glycerin	CO	NO	NOx	ACM	DML
1	0,42	-0,56	0,59	NA[1]	-1,05	-0,80	0,28	0,24
2	0,53	-0,75	0,68	NA	NA	NA	0,13	NA
3	-0,60	0,62	-1,28	NA	NA	NA	-0,11	-0,27
4	NA	NA	NA	NA	NA	NA	NA	NA
5	NA	NA	NA	NA	NA	NA	NA	NA
6	-0,02	0,60	0,02	NA	NA	NA	-0,04	0,06
7	0,03	-0,43	-0,03	-0,15	0,94	-0,32	-0,20	-0,26
8	NA	NA	NA	NA	0,11	1,12	-1,72	-1,26
9	0,31	0,25	0,34	NA	NA	NA	0,62	0,67
10	-0,39	-0,08	0,37	NA	NA	NA	0,07	0,20
11	NA	NA	NA	NA	NA	NA	NA	NA
12	-2,88	-2,44	-2,47	NA	NA	NA	-2,88	-2,77
13	NA	NA	NA	NA	NA	NA	NA	NA
15	NA	NA	NA	NA	NA	NA	NA	NA
16	NA	NA	NA	NA	NA	NA	0,03	0,26
17	0,19	0,98	-0,26	-0,38	NA	NA	0,09	0,38
18	0,27	0,60	0,58	0,53	NA	NA	0,38	0,54

1: NA indicates lab data is not available.

(4.3.4 Z-scores)

Z-Score Results for cHTP

Table 21: Z-Scores Results for cHTP.

Lab No.	PG	Nicotine	Glycerin	CO	NO	NOx	ACM	DML
1	NA[1]	NA	NA	NA	NA	NA	NA	
2	NA	-0,90	0,18	0,35	1,54	1,06	0,73	
3	NA	NA	NA	NA	NA	NA	NA	
4	0,39	0,06	0,19	0,45	-0,27	-0,55	0,09	
5	NA	NA	NA	NA	NA	NA	NA	
6	NA	-0,69	-0,26	0,30	NA	NA	-0,07	
7	-0,15	1,80	0,28	-2,99	-0,81	-0,48	1,22	
8	0,27	1,28	-0,40	0,17	0,71	-0,11	-0,89	
9	-0,15	-1,07	-0,40	0,16	NA	NA	0,18	
10	-0,21	-0,38	0,68	0,82	-0,21	-0,35	-0,20	
11	2,86	0,71	-3,26	NA	NA	NA	-2,98	
12	NA	-0,25	0,13	-0,78	-1,15	1,63	-0,13	
13	NA	-1,40	-0,02	-0,62	NA	NA	-0,35	
15	-0,17	1,18	0,08	0,43	NA	NA	-0,73	
16	NA	NA	NA	-0,28	1,10	0,35	0,20	
17	-0,25	-0,64	-0,47	-0,06	-0,90	-1,56	0,46	
18	-0,23	0,44	0,77	NA	NA	NA	0,71	

1: NA indicates lab data is not available.

(4.3.4 Z-scores)

Shipping: Overview

Origin of Test Products:

➢ eTHP Consumables	Switzerland, UK
➢ eTHP Devices	Switzerland, UK
➢ aTHP Consumables	Japan
➢ aTHP Devices	Japan
➢ cTHP Consumable	USA

Laboratories:

➢ Japan, USA, Germany, Italy, Switzerland, France, China, UK, Austria, Korea, Uruguay, Russia

Shipping:
Minimum Shipping Requirements

Shipment of consumables

- Quantity
- Value (for customs purposes only)
- Commodity / HS (Harmonised System) Code
- Shipper and receiver information and addresses
- Free of Charge invoice that states samples are for testing only, and have no commercial value. Not for re-sale

If consumables contain e-liquid

- Safety Data Sheet (SDS) for the liquid

Shipment of devices

All information in the list for consumables, plus the following:

- SDS for the battery contained in the device(s) showing the battery model number
- Battery Test summary report – UN 38.3

Both above documents must include the same battery model number

Other requirements – to be confirmed for each country

- Countries outside of the EU require a packing list
- A phytosanitary certificate may be required for some countries when shipping tobacco products

Shipping: Actions

- **Each laboratory needs to provide the following:**
  - **Provide a key contact for shipping, who is aware of customs and shipping procedures for the laboratory**
  - **Confirm shipping instructions for shipments into their country**
  - **Confirm if a customs broker will be used**
  - **Confirm if the laboratory is authorised to receive excisable tobacco products**