Substance Abuse and Mental Health Services Administration

SAMHSA

www.samhsa.gov • 1-877-SAMHSA-7 (1-877-726-4727)

Behavioral Health is Essential To Health

Prevention Works

Treatment is Effective

People Recover

Substance Abuse and Mental Health Services Administration
SAMHSA
www.samhsa.gov • 1-877-SAMHSA-7 (1-877-726-4727)

ORAL FLUID PILOT PT PROGRAM: Lessons Learned

Dale Hart

RTI International

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

Oral Fluid Pilot PT Program History

- Program was started in April 2000
- Conducted 21 Occasions (Rounds) through 2007 (01-21)
- Program was suspended 2007-2011
- Conducted 24 Occasions 2011-2017 (22-45)

Oral Fluid Pilot PT Program

- Voluntary
  - NLCP open invitation
  - To join: submit Letter of Commitment and information on test methods
- Most Recent Occasion: 45
- Only aggregate data returned to participants
- Not graded

Oral Fluid Pilot PT - Process

- Develop sample scheme based on previous experience and NLCP needs
- Formulate samples per Occasion finalized scheme
  - Prepare 1-2 days prior to shipping
  - Freeze or refrigerate prepared samples
- Ship overnight: refrigerated
- Email Excel reporting form same day as shipping
  - Results due within 2 weeks of receipt

Oral Fluid Pilot PT – Process (cont'd)

- Reduce data (laboratory- reported results)
- Develop and present webinar
  - Prior to shipment of next Occasion
- Transmit aggregate data to Participants.

Oral Fluid Pilot PT Program Occasion 45

- Evaluate laboratory performance at low concentrations of analytes (40% of Confirmation Cutoff)
- Evaluate the effects of interfering compounds
- Compare laboratory results for “paired” samples prepared in human and synthetic oral fluid

Substance Abuse and Mental Health Services Administration
SAMHSA
www.samhsa.gov • 1-877-SAMHSA-7 (1-877-726-4727)

ORAL FLUID PILOT PT PROGRAM 2017

Occasion 45

February 15, 2017

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

Participating Laboratories Occasion 45

- Total of 15 participating labs
  - 13 Initial and Confirmatory Testing
  - 1 Initial Test Only
  - 1 Confirmatory Test Only
- Total of 3 manufacturing labs

Sample Scheme - Occasion 45

(Synthetic Oral Fluid Base Unless Otherwise Stated)

Sample	Challenge	Analytes
01	CT	THC/THCA, 40/0.50 ng/mL
02	CT	Cocaine/Benzoylecgonine/PCP, 3.2/3.2/4 ng/mL
03	CT	D,L-Amphetamine/D,L-Methamphetamine, 20/20 ng/mL
04	CT	MDMA/MDA/Oxymorphone, 25/25/15 ng/mL, Human Base
05	CT	6-Acetylmorphine/Morphine, 0.8/300 ng/mL
06	CT	Cocaine/Benzoylecgonine/PCP, 8/8/10 ng/mL
07	CT	MDMA/MDA/Oxymorphone, 25/25/15 ng/mL
08	CT	Oxycodone/Oxymorphone/Morphine, 6/6/300 ng/mL

Sample Scheme - Occasion 45

(Synthetic Oral Fluid Base Unless Otherwise Stated)

Sample	Challenge	Analytes
09	CT	Codeine/Morphine/Oxycodone, 6/6/300 ng/mL
10	CT	Hydrocodone/Hydromorphone/Morphine, 6/6/300 ng/mL
11	CT	Codeine/Morphine/Hydromorphone/Hydrocodone/Noroxycodone/Norcodeine, 6/6/6/300/45/45 ng/mL
12	CT	THC/THCA (glucuronide), 60/0.075 ng/mL
13	CT	THC/THCA, 0.8/0 ng/mL, Acceptable for IgG but unacceptable for albumin.
14	CT	D,L-Methamphetamine/D,L-Amphetamine, 20/20 ng/mL, Human Base
15	CT	6-Acetylmorphine/Hydrocodone/Hydromorphone, 2/45/45 ng/mL,

Initial Testing (Not Required)

Confirmatory Testing

- 13 LC-MS/MS (Includes 2 PCP by GC-MS and 1 THCA by GC-MS/MS)
- 1 GC-MS

PT Summary

Sample ID	Analyte	Target	Mean	Std Dev	n	%CV	Range**	#Outliers*	Comments
		ng/mL	ng/mL						
13	THC	0.80	0.88	0.14	9	16%	0.72 - 2.13	1	
01	THC	40.0	44.2	7.72	13	17%	36.1 - 61.6	0	
12	THC	60.0	66.5	8.48	13	13%	54.3 - 87.7	0	
01	THCA	0.50	0.50		2			0	
12	THCA-Glucuronide	0.075	0.070		2			0	
	(as Free THCA)								
02	Cocaine	3.20	2.99	0.70	11	23%	2 - 4.2	0	
06	Cocaine	8.00	7.54	1.14	12	15%	6 - 9.3	0	
02	Benzoylecgonine	3.20	3.19	0.46	13	14%	2.2 - 4.25	0	
06	Benzoylecgonine	8.00	7.80	0.93	14	12%	6.1 - 10	0	
03	Methamphetamine	20.0	21.7	2.32	13	11%	18 - 24.75	0	50% d-Methamphetamine
14 (H)	Methamphetamine	20.0	21.0	2.45	13	12%	18 - 23.9	0	50% d-Methamphetamine
03	Amphetamine	20.0	21.5	3.38	13	16%	14 - 26.1	0	50% d-Amphetamine
14 (H)	Amphetamine	20.0	20.9	3.08	12	15%	15.2 - 25.7	0	50% d-Amphetamine
04 (H)	MDMA	25.0	23.6	4.18	13	18%	16.4 - 30.6	0	
07	MDMA	25.0	23.9	3.28	13	14%	16.8 - 29.7	0	
04 (H)	MDA	25.0	24.7	3.44	13	14%	18.8 - 31.7	0	
07	MDA	25.0	24.6	3.57	13	15%	18.8 - 32.3	0	

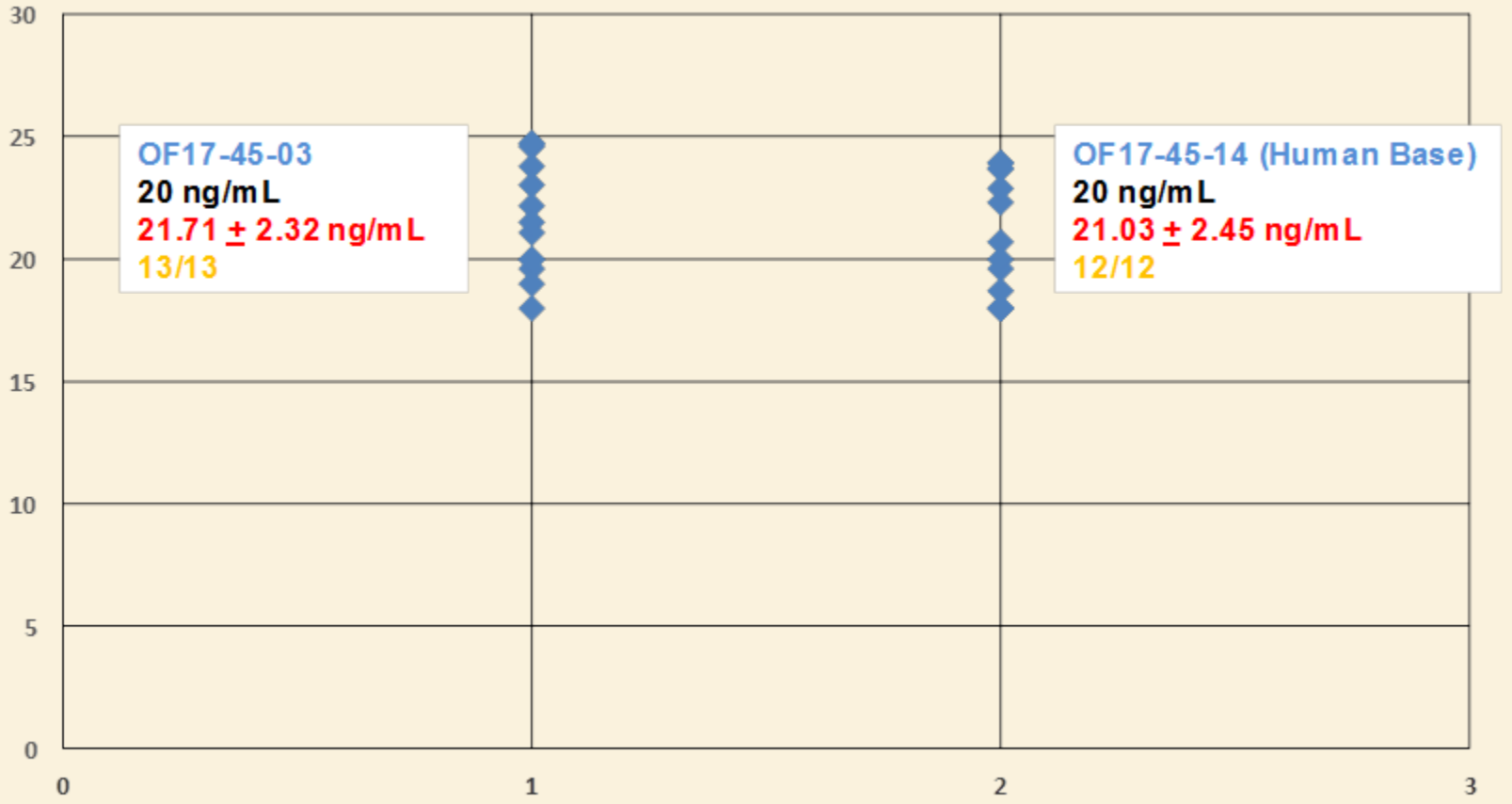
* Results with > 50% deviations removed from Mean, Std Dev, n and %CV

** Range includes all values (including outliers)

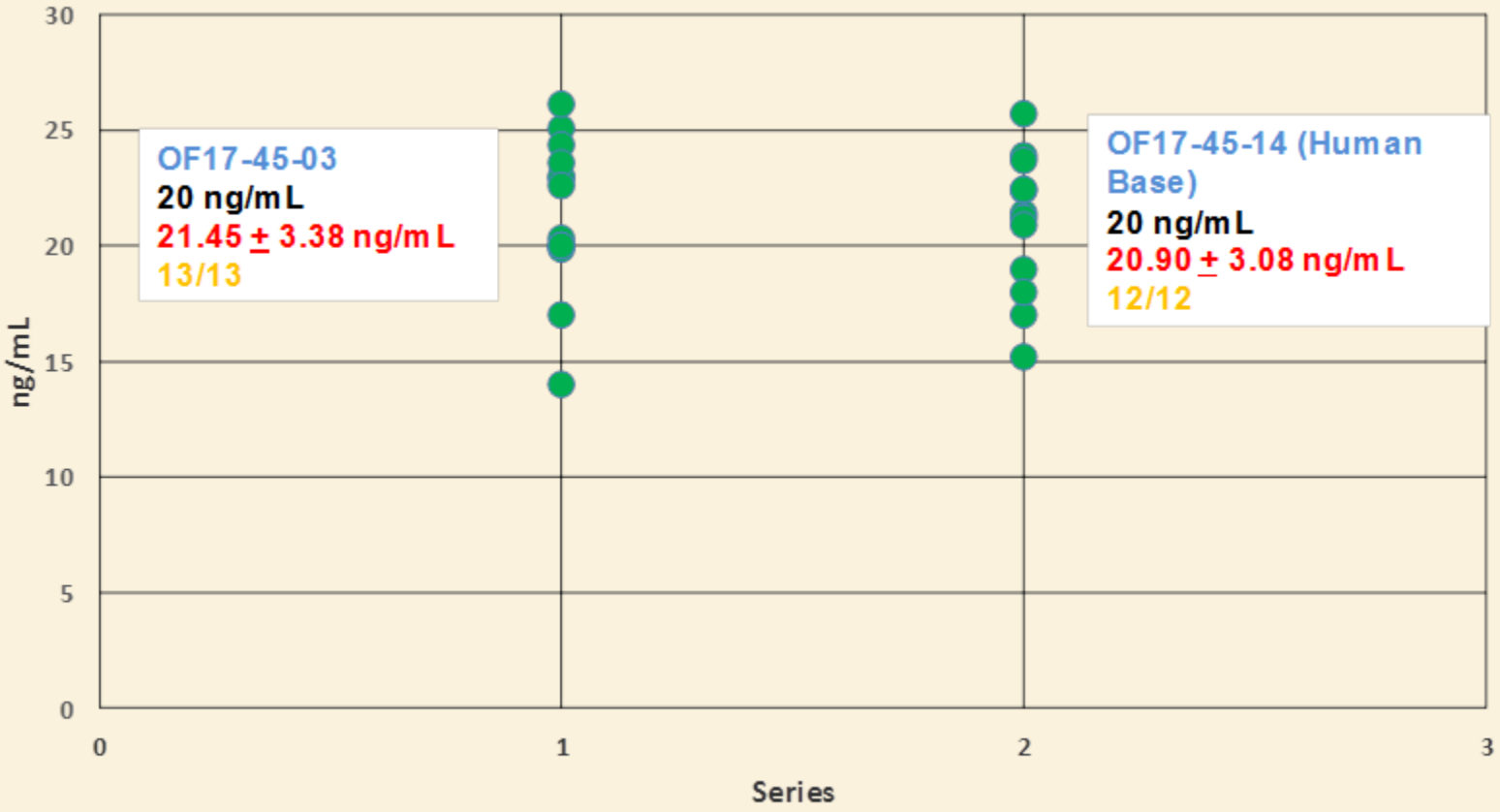
THCA (pg/mL)

Reports	Sample		
	01 (500 pg/mL)	12 (glucuronide, 75 pg/mL equivalent)	13 (0 pg/mL)
Lab A	422	28.1	<LOQ
Lab B	583	103	0

Methamphetamine(Cutoff = 25 ng/mL)



Amphetamine (Cutoff = 25 ng/mL)

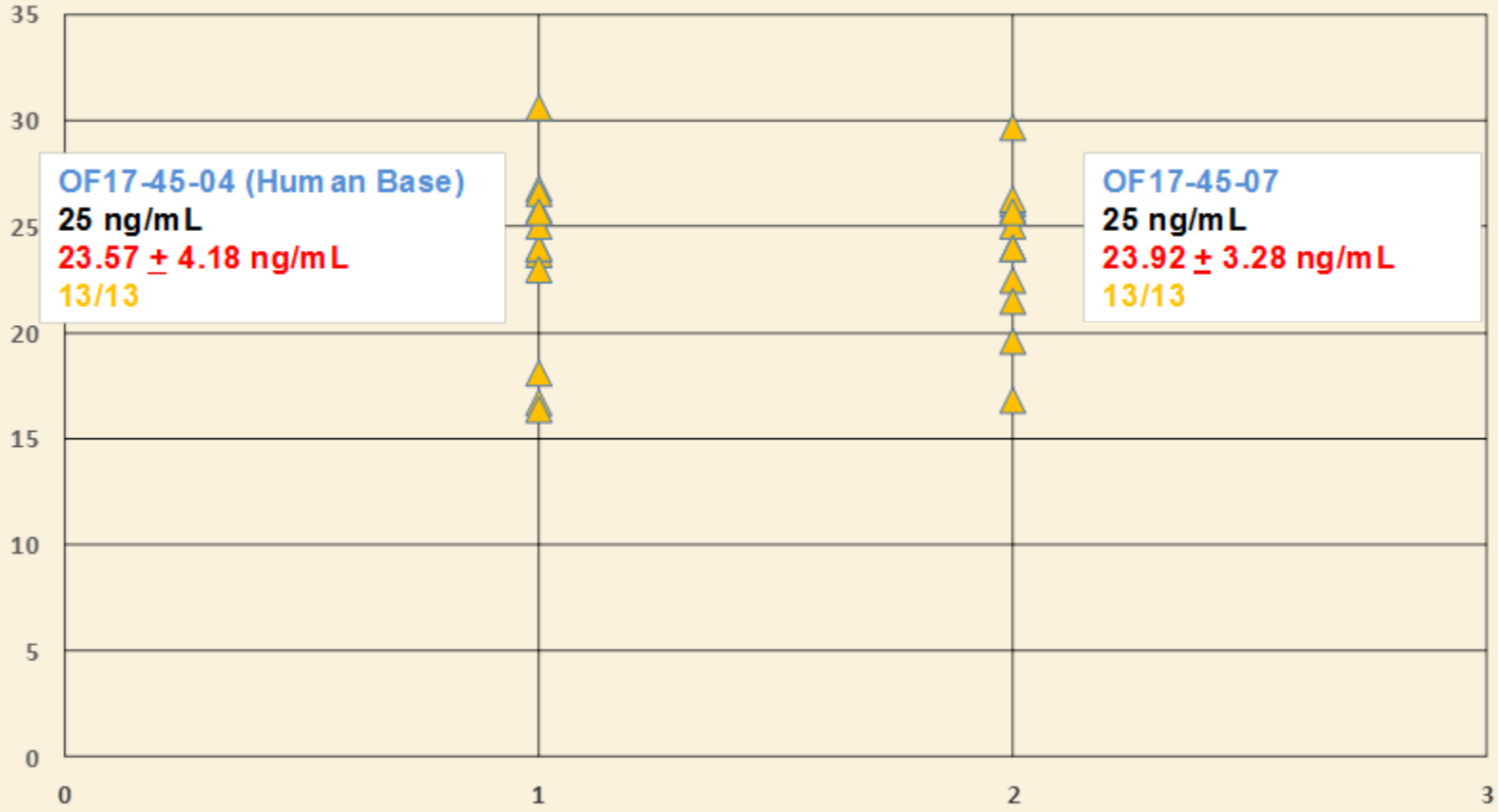


Substance Abuse and Mental Health Services Administration SAMHSA

Methamphetamine and Amphetamine Stereoisomers

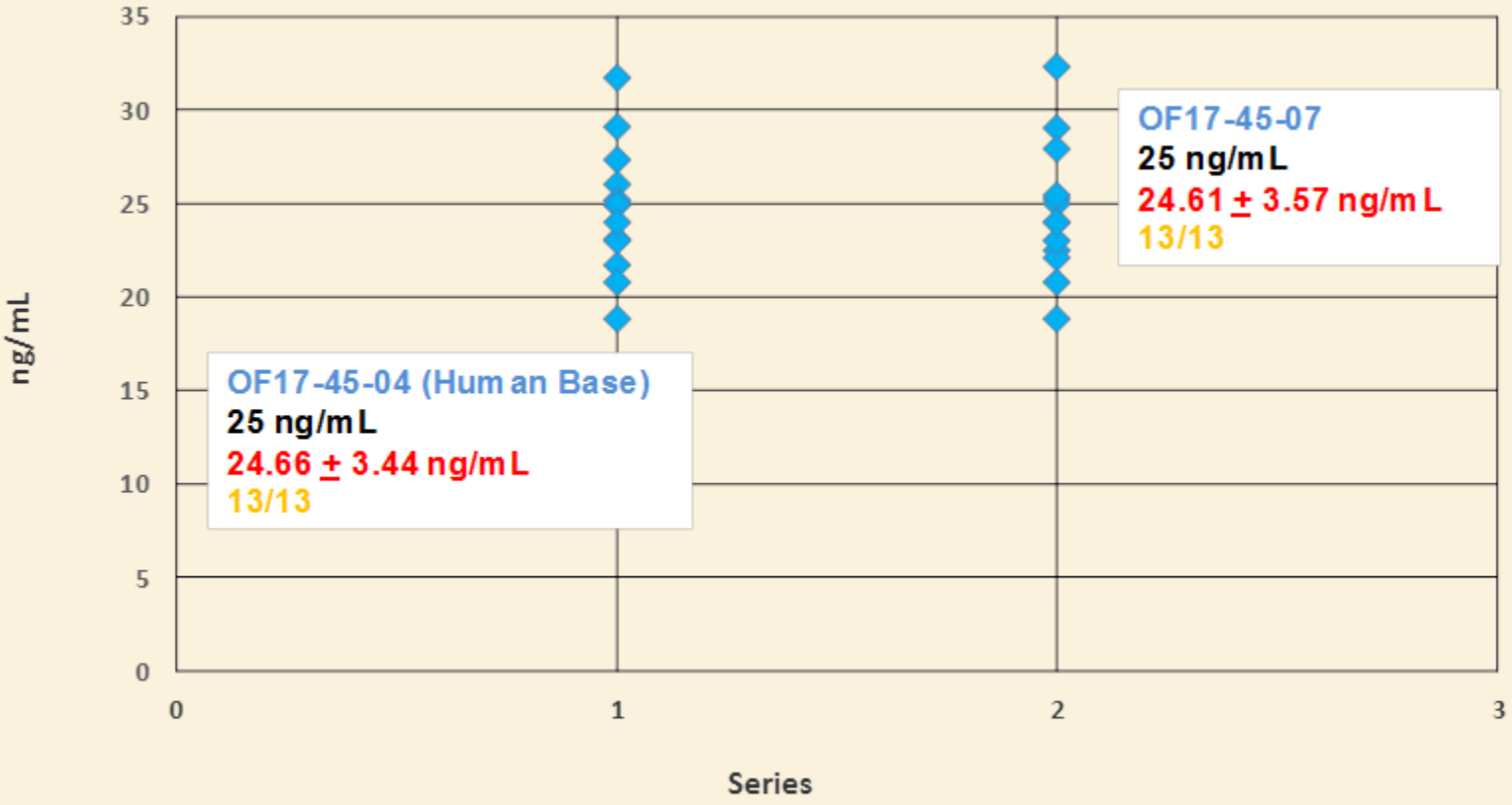
Sample	D-MAMP (%)	L-MAMP (%)	D-AMP (%)	L-AMP (%)	Methodology
OF17-45-03	49.7	50.3	-----	-----	Direct LC-MS/MS
	-----	50	-----	50	Marfey's Reagent
	49	-----	-----	-----	Direct LC-MS/MS
OF17-45-14	51.6	48.4	-----	-----	Direct LC-MS/MS
	-----	50	-----	50	Marfey's Reagent
	49	-----	-----	-----	Direct LC-MS/MS

MDMA (Cutoff = 25 ng/mL)



Substance Abuse and Mental Health Services Administration
SAMHSA

MDA (Cutoff = 25 ng/mL)



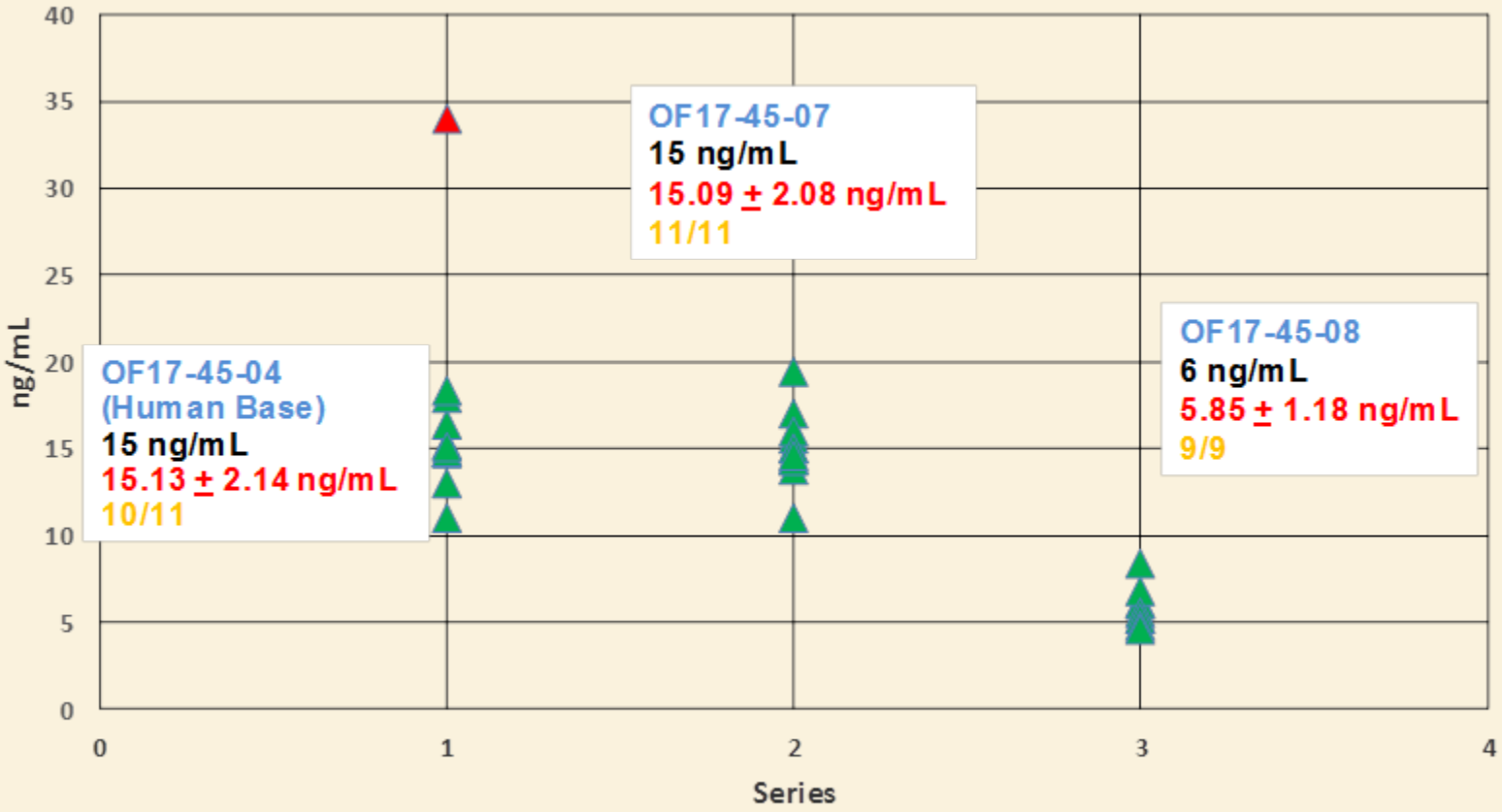
Substance Abuse and Mental Health Services Administration SAMHSA

PT Summary (cont'd)

Sample ID	Analyte	Target ng/mL	Mean ng/mL	Std Dev	n	%CV	Range**	#Outliers*	Comments
09	Codeine	6.00	6.05	1.25	11	21%	4 - 7.25	0	OXC - 300
11	Codeine	6.00	6.78	1.12	12	17%	5.2 - 15	1	NOXC - 45, NCOD - 45, HYC - 300
09	Morphine	6.00	5.89	0.65	10	11%	5 - 15.2	1	OXC - 300
11	Morphine	6.00	6.12	0.77	10	13%	5.2 - 15.2	1	NOXC - 45, NCOD - 45, HYC - 300
05	Morphine	300	286	42.6	14	15%	173.2 - 362	0	
08	Morphine	300	287	44.5	14	15%	174 - 346	0	
10	Morphine	300	282	42.4	14	15%	178.8 - 334	0	
05	6-Acetylmorphine	0.80	0.89	0.16	7	18%	0.35 - 1.2	1	MOR - 300
15	6-Acetylmorphine	2.00	1.93	0.34	12	18%	1.3 - 2.6	0	HYC - 45, HYM - 45
10	Hydrocodone	6.00	6.24	0.93	12	15%	5 - 8.1	0	MOR - 300
15	Hydrocodone	45.0	48.6	7.94	14	16%	38.8 - 72.2	0	
11	Hydrocodone	300	310	53.8	14	17%	234 - 438.1	0	
10	Hydromorphone	6.00	6.08	1.04	10	17%	4.3 - 12.7	1	MOR - 300
11	Hydromorphone	6.00	6.25	0.87	11	14%	5.2 - 8	0	NOXC - 45, NCOD - 45, HYC - 300
15	Hydromorphone	45.0	47.3	6.42	13	14%	38.8 - 60.18	0	
08	Oxycodone	6.00	5.92	1.20	12	20%	3 - 7.23	0	MOR - 300
09	Oxycodone	300	306	48.0	13	16%	220.4 - 404	0	
08	Oxymorphone	6.00	5.85	1.18	9	20%	4.6 - 8.4	0	MOR - 300
04 (H)	Oxymorphone	15.0	15.1	2.14	10	14%	11 - 34	1	
07	Oxymorphone	15.0	15.1	2.08	11	14%	11 - 19.4	0	
02	PCP	4.00	4.04	0.59	13	15%	2.7 - 5	0	
06	PCP	10.0	9.22	0.97	14	11%	7.3 - 10.8	0	
* Results with > 50% deviations removed from Mean, Std Dev, n and %CV									
** Range includes all values (including outliers)									

SAMHSA

Oxymorphone (Cutoff = 15 ng/mL)



Substance Abuse and Mental Health Services Administration
SAMHSA

Overall Trends

- In general, laboratory performance is good overall, with most laboratories reporting results for most of the samples (including samples at low concentrations).
- Nominal increases in C.V.s were observed for opiates/opiods in the presence of interfering compounds.
- Results for paired human and synthetic oral fluid samples were not statistically different.

Conclusions

At least among the laboratories surveyed, there still appears to exist a core of 7-8 laboratories capable of testing oral fluid and obtaining the correct results down to the levels required in the 2015 Proposed Guidelines.

Thank you. Questions? Comments?