DTAB Board Discussion

U.S. Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
Division of Workplace Programs

Mr. Ron Flegel, Division Director

Ms. Lisa Davis, Senior Toxicologist Policy Advisor

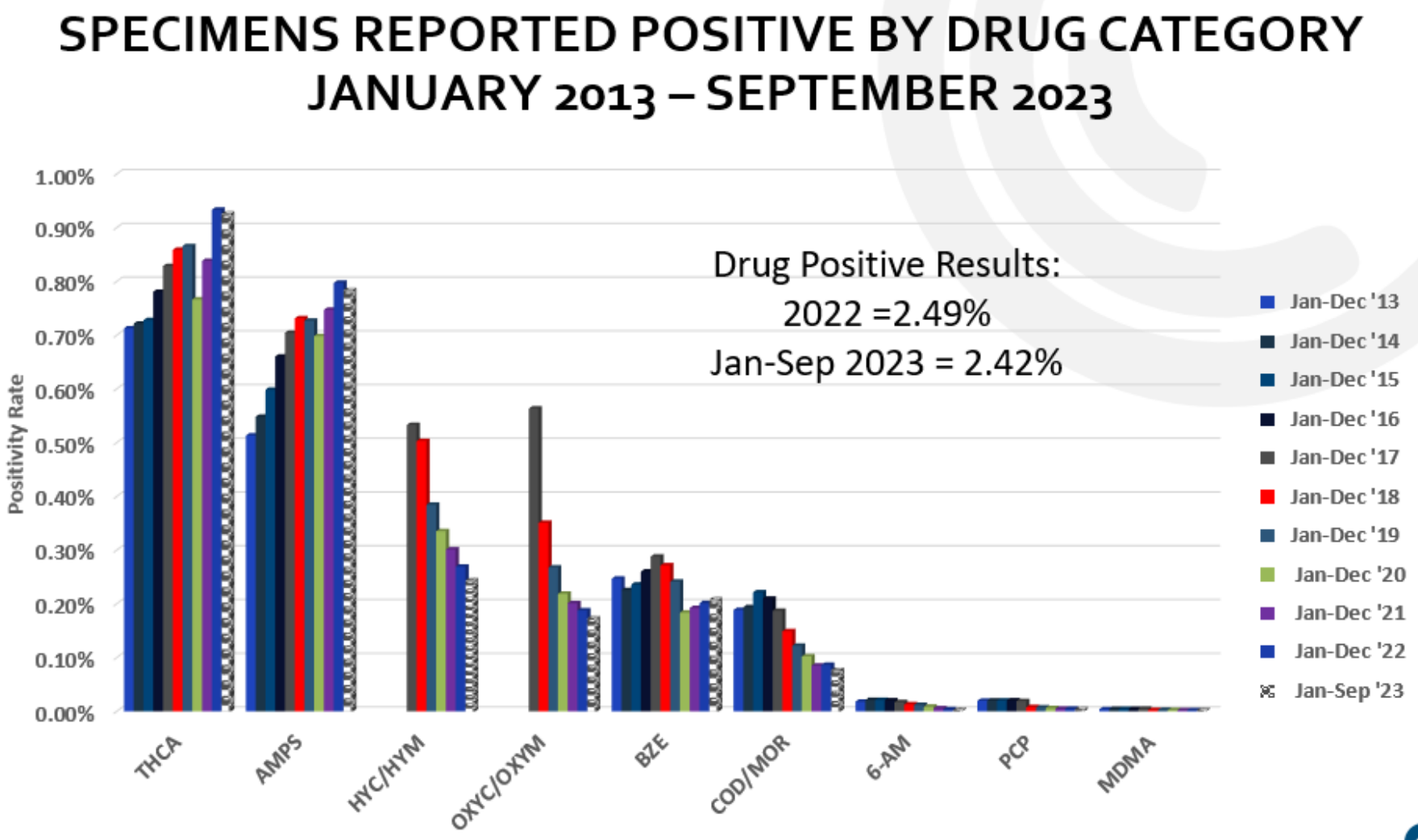
DTAB Open Session

December 5, 2023

DTAB Members Discussion

SAMHSA
Substance Abuse and Mental Health Services Administration

Drug Positivity Rates: Blind QC Included



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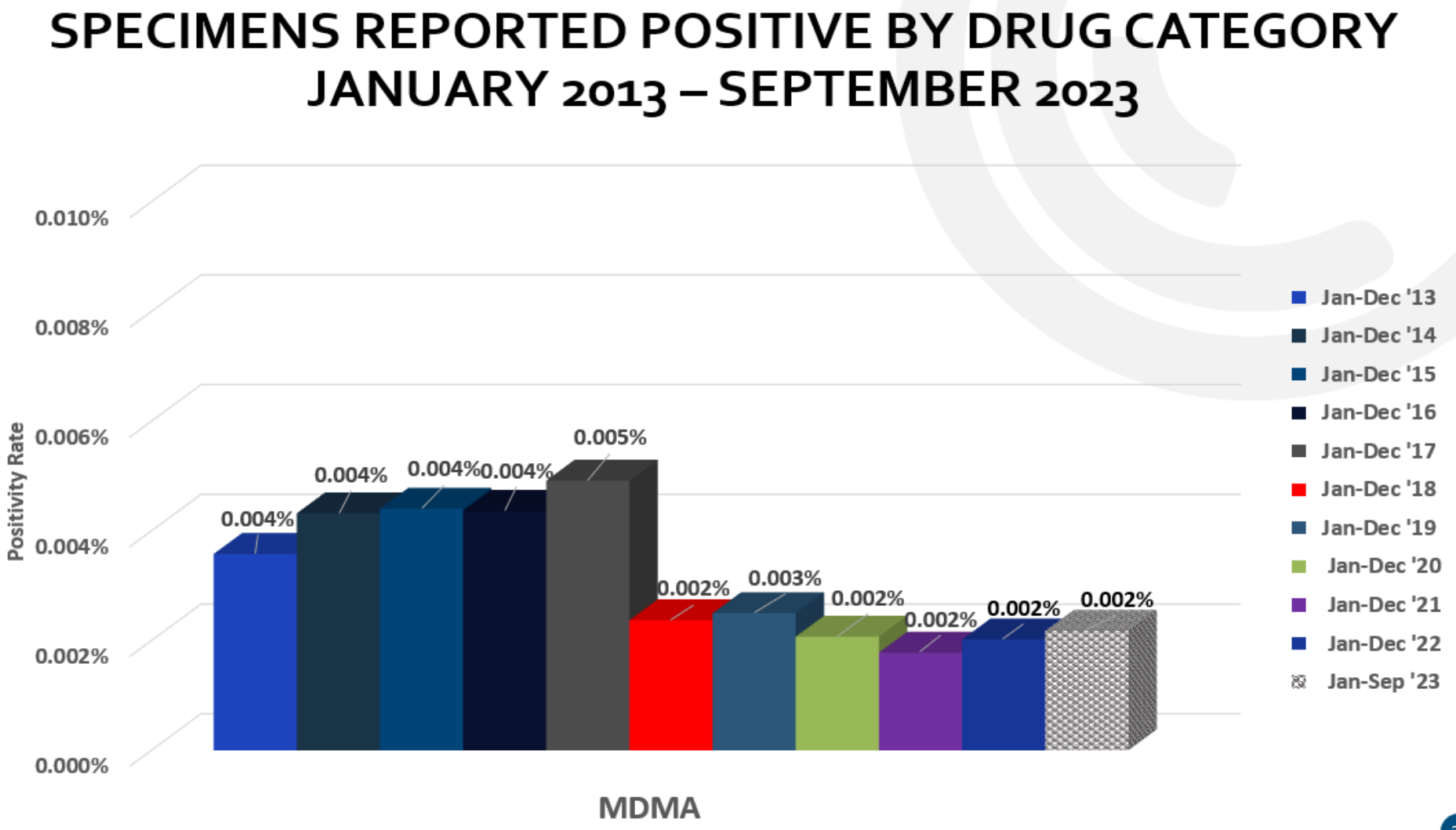
MDMA Positivity Rates: Blind QC Included



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Analyte Table Update

Written comments regarding the addition of Fentanyl to the analyte table and the removal of MDA and MDMA from the analyte table will be accepted for review for an additional 30 days no later than January 4th, 2024

Urine Analyte	Initial Test Cutoff	Confirmation Cutoff
Fentanyl	1 ng/mL	0.5 ng/mL
Norfentanyl	1 ng/mL	0.5 ng/mL

Oral Fluid Analyte	Initial Test Cutoff	Confirmation Cutoff
Fentanyl	1 ng/mL	0.5 ng/mL

Please submit those comments to: DFWP@samhsa.hhs.gov

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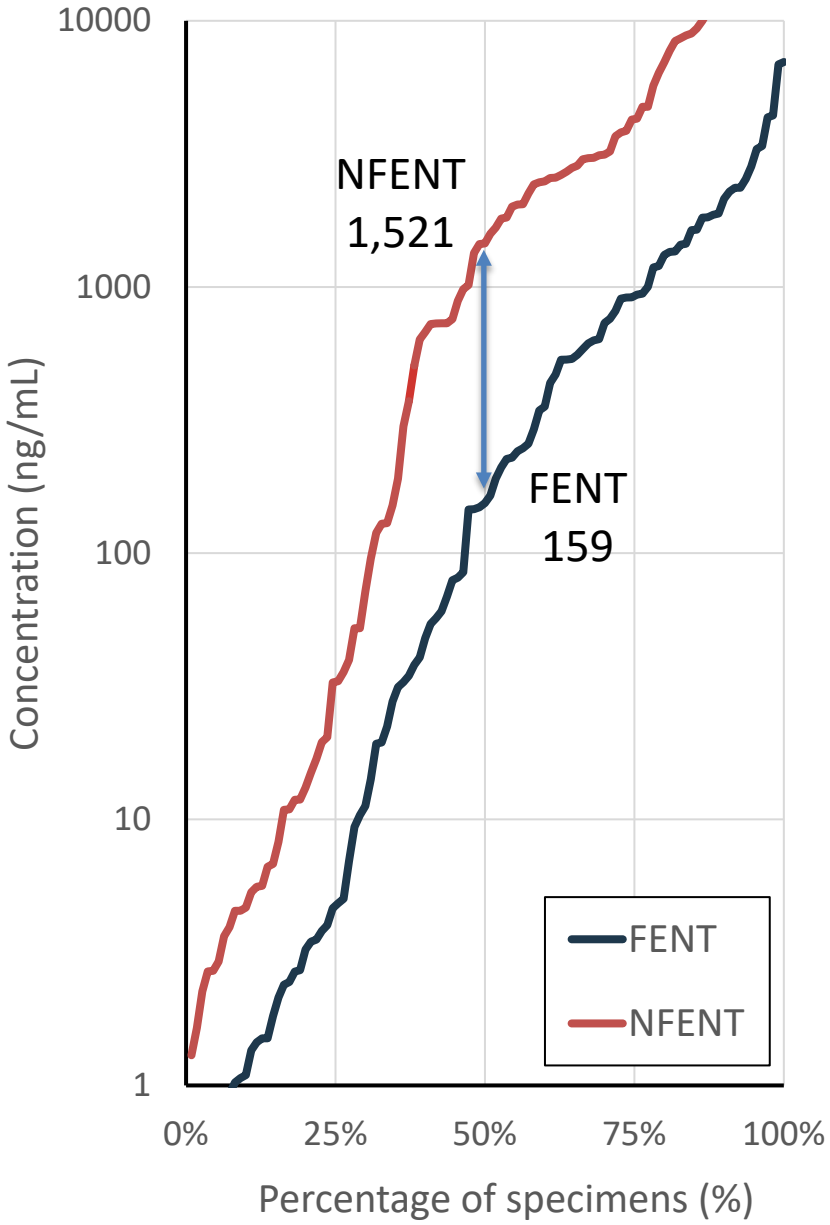
Fentanyl/norfentanyl concentrations (2022 Pulse testing study)



Analyte	n (%pos)	10%	Q1	Median	Q3	90%	Max
Fentanyl	110 (100%)	1.1	4.8	159	937	2,268	7,004
Norfentanyl	110 (100%)	4.7	32.9	1,521	4,408	14,941	34,623

METHOD

- Inclusion – IA Opiate (>2,000 ng/mL morphine)
- Inclusion – IA Fentanyl (>1 ng/mL, 7% cross-reactivity for norfentanyl)
- Sensitive LC-MS/MS quantification (0.05 ng/mL cutoff)

RESULTS

- Observed concentrations limited by fentanyl IA
  - Likely more specimens with <1 ng/mL

DEPRIEST ET AL 2010*

- 314 FENT/NFENT pos specimens from pain clinics (LOQ 0.5 ng/mL)
- **30% positive only for NFENT**
- FENT (n=221) Mean 59 ng/mL Median 22 ng/mL Range 0.5-596 ng/mL
- NFENT (n=191) Mean 134 ng/mL Median 25 ng/mL Range 0.5-1772 ng/mL

**Depriest A, Heltsley R, et al (2010) JAT 34(8), 444-449.*

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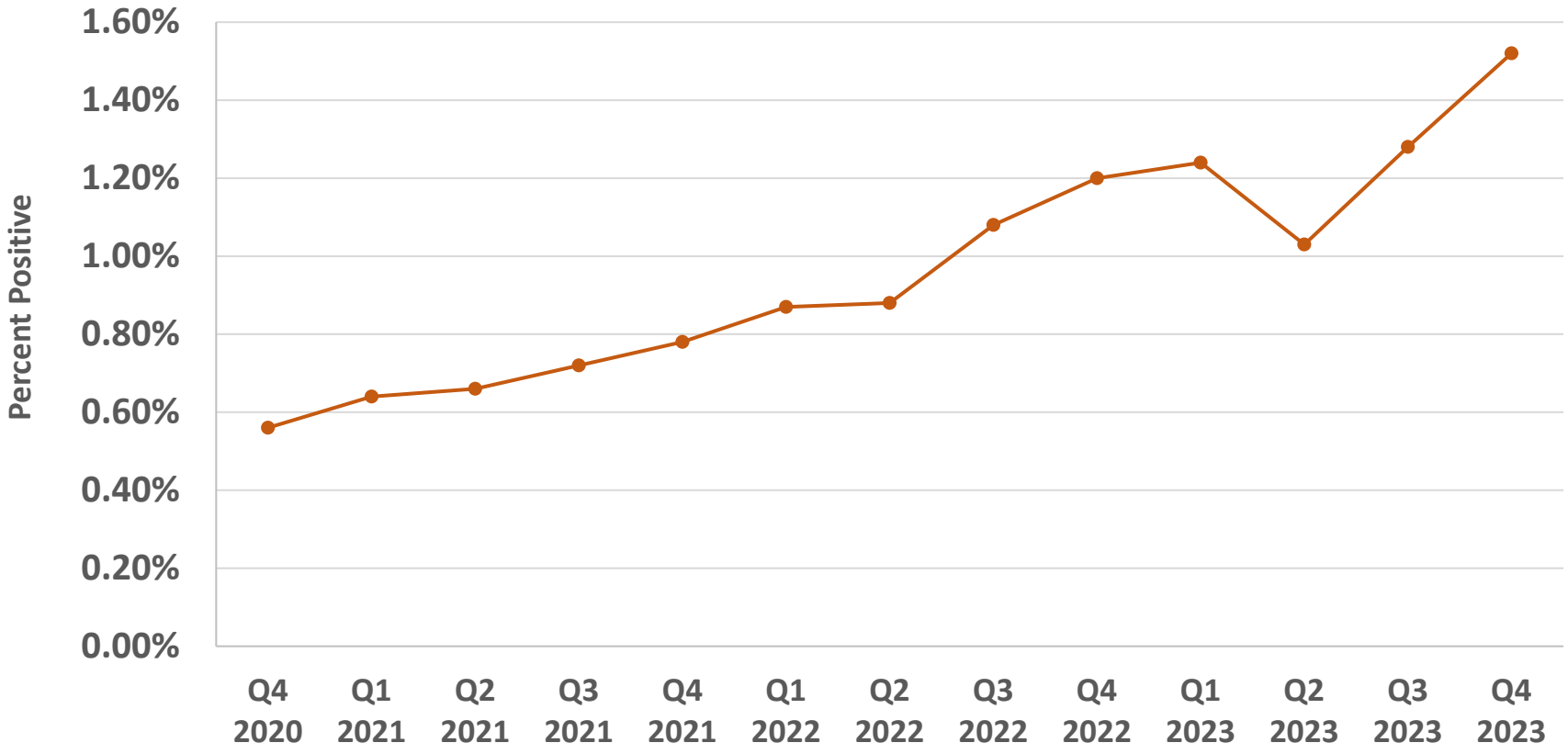
Workplace Fentanyl Confirmation Positivity Rate in Urine



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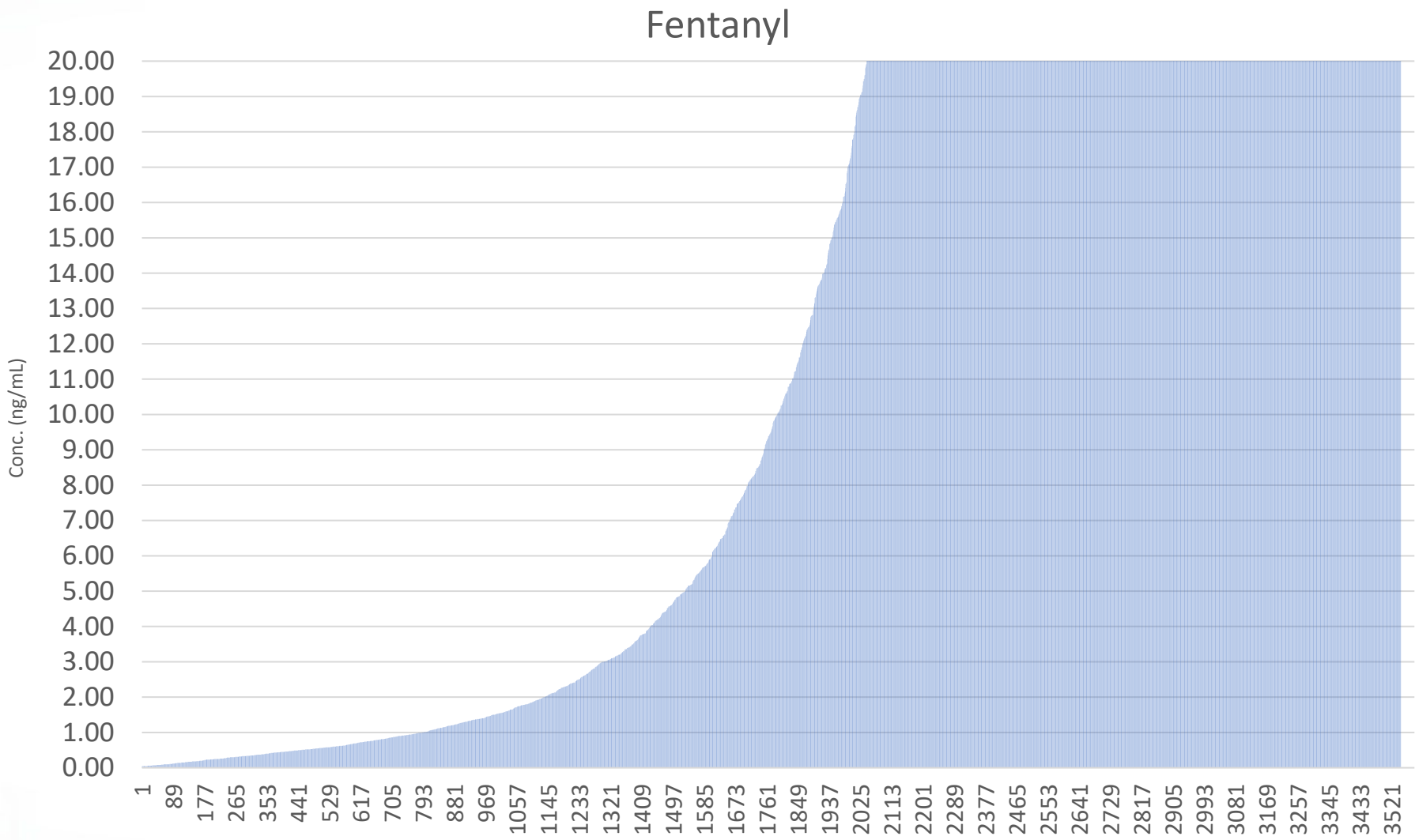

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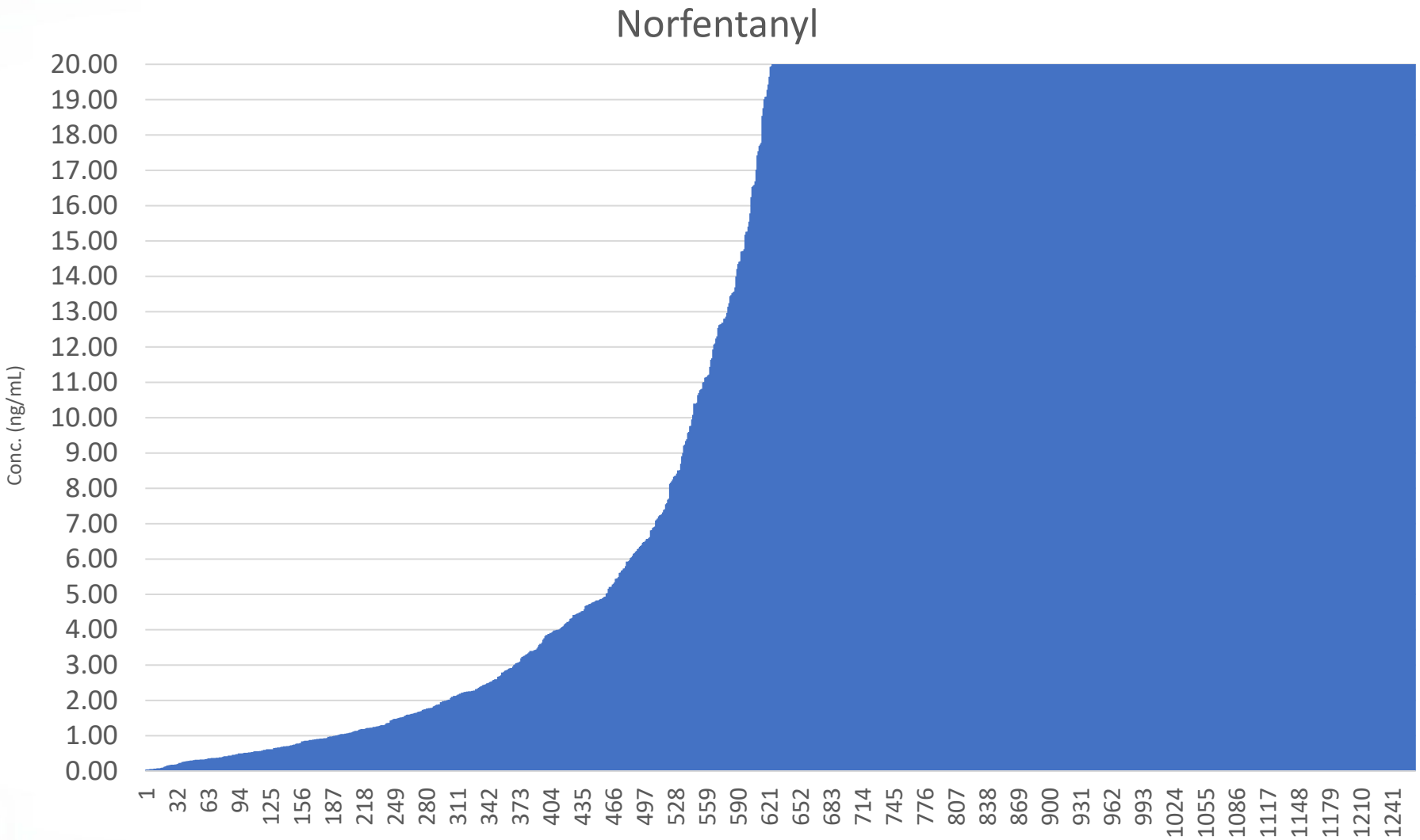

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Commercial Immunoassay kits for fentanyl

Specifications		Cross reactivity		Cutoffs		Pos spec (%)	
Fentanyl v. Norfentanyl		FENT	NFENT	FENT	NFENT	FENT	NFENT
Proposed		**100%**	**100%**	**1**	**1**	**102 (93%)**	**110 (100%)**
A kit 1	Norfentanyl	156%	100%	3.2	5	89 (81%)	99 (90%)
A kit 2	Norfentanyl	132%	100%	3.8	5	86 (78%)	99 (90%)
B kit 2	Fentanyl	100%	6.7%	1	15	102 (93%)	87 (79%)
C kit 2	Fentanyl	100%	6.7%	1	15	102 (93%)	87 (79%)
B kit 1	Fentanyl	100%	3.3%	1	30	102 (93%)	84 (76%)
D kit 1	Fentanyl	100%	<0.1%	1	>1,000	102 (93%)	NA
C kit 1	Fentanyl	100%	0.0%	2	10,000	94 (85%)	0 (0%)

NOTE: Missed specimens due to higher cutoffs for norfentanyl likely underestimated as specimens were included based on IA with 1 and 15 ng/mL cutoffs for FENT and NFENT, respectively

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