



# COMMENTS RECEIVED REGARDING ANALYTE TABLE CHANGES

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DTAB  
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# PUBLIC COMMENTS ON ANALYTE TABLE CHANGES

- Public comment period open from October 17, 2023 to January 4, 2024
  - 118 commenters
  - 176 comments received

# ADDITION OF FENTANYL AND NORFENTANYL

- 115 commenters agreed with the addition of fentanyl
  - Opioid epidemic
  - Number of overdose deaths
  - Safety sensitive positions and public health crisis
  - Ease of availability
- 20 commenters support the addition of norfentanyl
- 3 commenters disagreed with the addition of fentanyl
  - Expensive
  - Short window of detection
  - Time consuming for process of rule making
  - Truck driver shortages

# PROPOSED CUTOFFS FOR FENTANYL AND NORFENTANYL

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

# INITIAL TEST CUTOFFS FOR FENTANYL AND NORFENTANYL IN URINE

- Multiple commenters agreed with the proposed 1.0 ng/mL initial cutoff for Fentanyl
  - FDA-compliant screening reagents are already capable of meeting this cutoff
  - Urine is well established and a less-complex matrix
- Multiple commenters disagreed with the proposed 1.0 ng/mL initial cutoff for fentanyl and norfentanyl
  - A lower cutoff (0.75 ng/mL) was suggested
  - Screening assays at 1 ng/mL will push limits of traditional immunoassay technologies
  - Lack of availability of immunoassay kit with sufficient cross-reactivity to norfentanyl and fentanyl
  - No commercially available kit that targets norfentanyl; added cost/burden on laboratories
  - Suggested to not screen for norfentanyl – not pharmacologically active; a precursor to fentanyl

# URINE CONFIRMATORY TEST CUTOFFS FOR FENTANYL AND NORFENTANYL

- One commenter agreed with proposed confirmatory cutoff for Fentanyl and Norfentanyl at 0.5 ng/mL
- Several commenters disagreed with the proposed confirmatory cutoffs
  - Provided data from non-regulated testing from 2022-2023; 1.6% had a result <1.0 ng/mL; more than 50% of testing pool had results >100 ng/mL for fentanyl and >1000 ng/mL for norfentanyl
  - Provided data from SOFT presentation that showed extended elimination after fentanyl use; initial results of 410 ng/mL fentanyl; 1100 ng/mL norfentanyl. One month later fentanyl was 3.6 ng/mL and norfentanyl 8.2 ng/mL

# ORAL FLUID INITIAL TEST CUTOFF FOR FENTANYL

- Numerous commenters disagreed with the proposed 1.0 ng/mL initial cutoff for Fentanyl
  - Lack of FDA-approved immunoassay kit; too early to set cutoff at this target without approved kit
  - Use of alternate MS screening tool would be an added cost to labs
  - Less adoption of OF as an alternate matrix due to added costs
  - Oral fluid devices containing a buffer would dilute the specimen vs a neat device; reduce concentration three-fold or four-fold
  - Inability to meet stringent QC criteria ( $\pm 25\%$  QC; LOD at 40%)
- One commenter suggested a cutoff of 2-4 ng/mL
- One commenter suggested a 5 ng/mL cutoff
- One commenter requested research to support proposed cutoff

# ORAL FLUID CONFIRMATORY TEST CUTOFF FOR FENTANYL

- Multiple commenters disagreed with the proposed 0.5 ng/mL confirmatory cutoff for Fentanyl
- Laboratory challenges in achieving and maintaining robust assays that support this cutoff
  - Cited analytical difficulties when OF sample is in buffered solution; might not yield quality chromatography at concentrations of 0.05 ng/mL and lower when using diluted oral fluid
  - Possibility from carryover at low concentrations
- One commenter suggested a confirmatory cutoff of 1.0 ng/mL



# REMOVAL OF MDMA AND MDA

- Several commenters support the removal of MDMA and MDA from the panel
  - Effective date of removal is same as DOT's 49 CFR Part 40
  - Lowest positivity rate in any group
  - Removal from testing panel will not adversely affect workplace and public safety
- One commenter suggested that if MDMA were to be retained, it could be grouped with current amphetamines IA; >70% cross-reactivity currently

# REMOVAL OF MDMA AND MDA

- Several commenters disagree with the removal of MDMA and MDA from the panel
  - Challenges posed if DOT does not decide to adopt removal, additional challenges the laboratory faces
  - Laboratory challenges with LIMS if DOT does not adopt
  - Argued that even though it has the lowest positivity rate, not testing for it could lead to higher abuse
  - Removing these analytes would not result in cost savings for laboratories
  - Clinical research for use of MDMA for PTSD treatment may lead to higher use
  - Rarity of MDMA/MDA positives could be evidence testing deters use



**THANK YOU**

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