FENTANYL IMMUNOASSAY UPDATES: ASSAYS AVAILABLE

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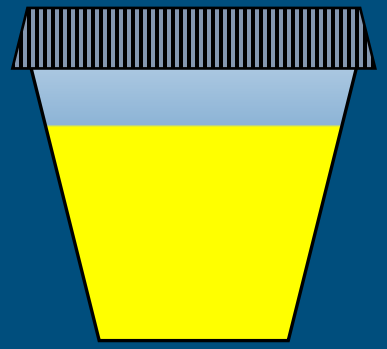
HOMOGENOUS IMMUNOASSAYS FOR FENTANYL IN URINE



IA:S FOR URINE

ASSAYS TARGETING FENTANYL

Manufacturer	Name	Cutoff ng/mL	Cross-react. Norfentanyl	QC	Status
ARK Diagnostics	**ARK Fentanyl II**	**1**	**7%**	**±50%**	**510k**
ARK Diagnostics	ARK Fentanyl II 0.5	0.5	8%	±50%	E&I
Immunalysis	**SEFRIA Fentanyl**	**1**	**0%**	**±50%**	**510k**
Immunalysis	HEIA Fentanyl	2	0%	-50%, +100%	?
Thermo Scientific	DRI Fentanyl	2	0%	±50%	?

ASSAYS TARGETING NORFENTANYL

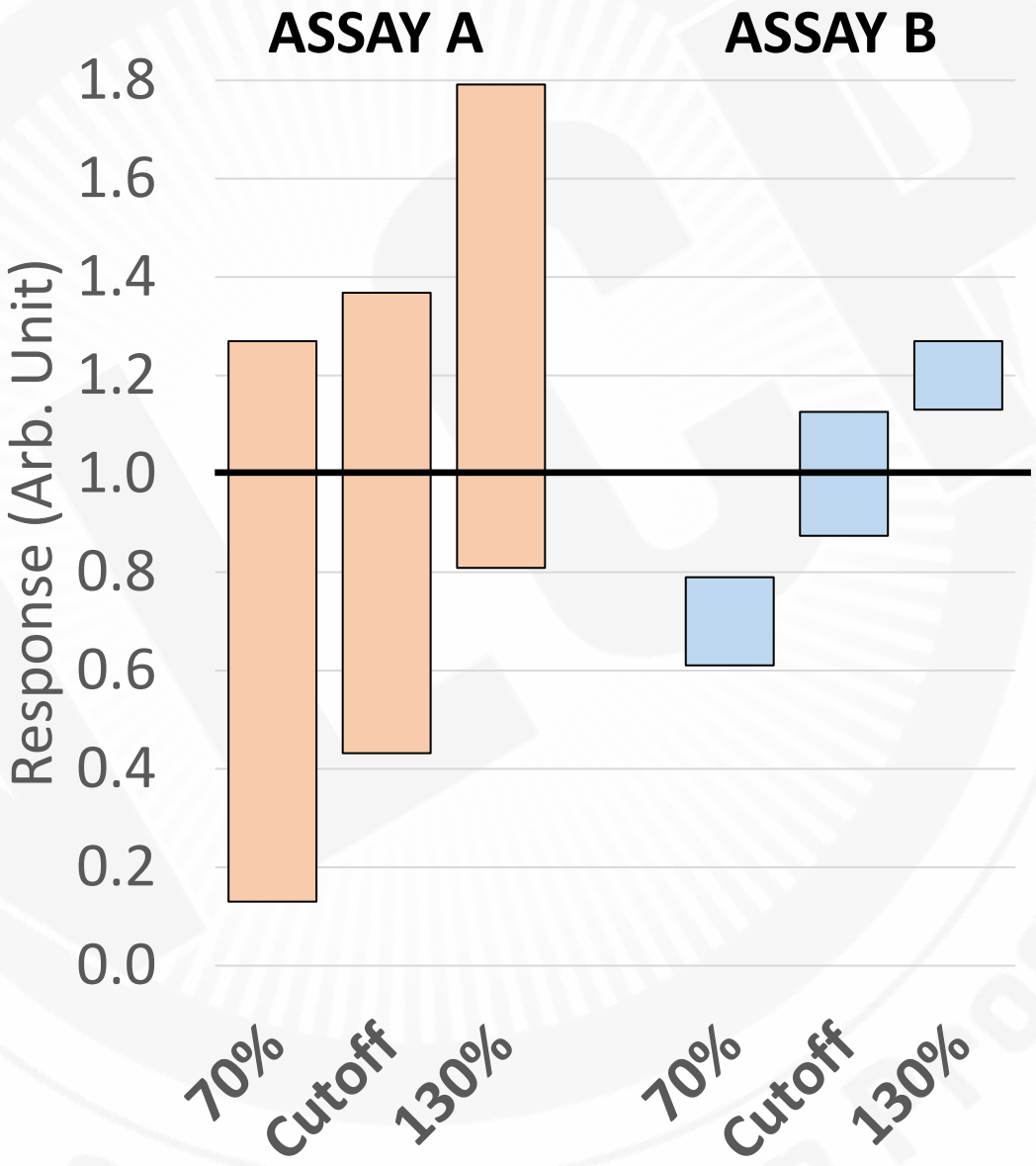
Manufacturer	Name	Cutoff ng/mL	Cross-react. Fentanyl	QC	Status
Lin-Zhi	LZI Fentanyl	5	156%	±25%	?
Lin-Zhi	LZI Fentanyl II	5	132%	±25%	?

3

MORE THAN CUTOFFS

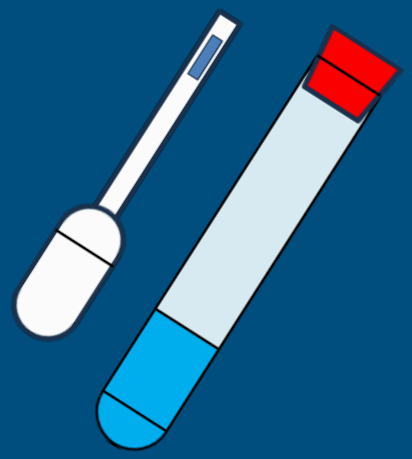
- Two Assays with 1 ng/mL fentanyl cutoff.
- QC 70% and 130% of cutoff
- Inter-run (n=8), Mean ±2SD

- Assay B show much better performance

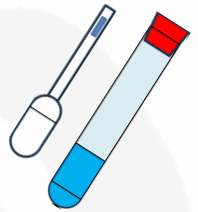


Budelier et al (2020) JALM, 1277

FENTANYL CONCENTRATIONS IN ORAL FLUID



FENTANYL IN ORAL FLUID (OF)



- Ion trapping produce higher concentrations of Fentanyl in OF vs blood
  - Fentanyl – basic drug pKa 8.4
  - Typically more ionized in OF (pH 6.2-7.4) than blood (pH 7.4)

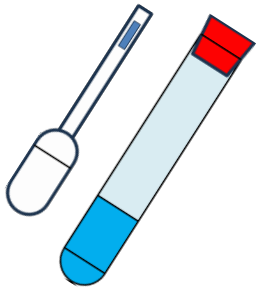
- Verified by previous research
  - Heiskanen et al – mean OF/plasma ratio 3.0 (n=54)
  - Harper et al – 59% of specimens >20 ng/mL in OF, only 8.7% in blood.

White & Moore (2018) Detection of Drugs and Their Metabolites in Oral Fluid, Elsevier; Heiskanen et al (2015) J Pain Sympt Man, 524; Harper et al (2023) JOFS, 1686.

FENTANYL CONCENTRATIONS IN OF (NG/ML)

Study	n	Population	Device	cutoff	Median (Q1-Q3)	Mean [range]
Heltsey 2012	10	Chronic pain	Quantisal	0.1	1.15	4.5 [0.1-26.7]
West 2018	146	MAT treatment, buprenorphine	Quantisal	0.2	1.3 (0.4-10.4)	
Bista 2015	163[a]	Cancer pain Fentanyl patch	Salivette	0.01	4.8-5.0	[0.012-38]
Heltsey 2011	424	Chronic pain	Quantisal	1	6.6	49.8 [0.2-5,300]
Mahowald 2021	46	Addiction medicine	Intercept	0.5	8.1	37.8 [0.5-519]
Harper 2023	129	DUID arrests	Quantisal	?	59% >20	

a Data in ng/mL collected from 56 participants.



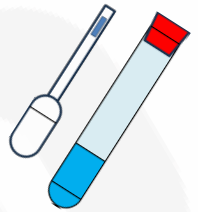
Fentanyl patches

High screening cutoff (1 ng/mL

Extreme population

Heltsey et al (2021) JAT, 3675; West et al (2018) Drug Alcohol Depend, 183; Bista et al (2015) Clin Therapeutics, 2468; Heltsey et al (2011) JAT, 529; Mahowald et al (2021) JALM, 1533; Harper et al (2023) JOFS, 1686.

ORAL FLUID VS URINE CONCENTRATIONS



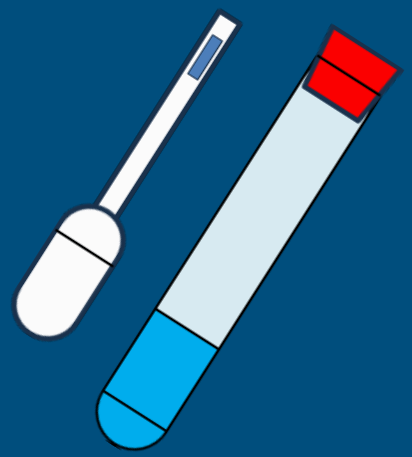
- Three studies measuring both urine and OF Fentanyl concentrations

Study	Urine median (ng/mL)	OF median (ng/mL)	Urine / OF
West 2018	5.9 ng/mL (n=103)	1.3 ng/mL (n=146)	4.5x
Mahowald 2021	33.6 ng/mL (n=44)	8.1 ng/mL (n=44)	4.1x
Heltsey 2012	13 ng/mL (n=11)	1.2 ng/mL (n=10)	11.3x

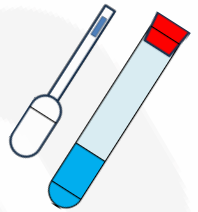
- Median OF concentrations 4.1-11.3x lower than urine
- To achieve similar sensitivity as urine, OF cutoff likely needs to be lower than in urine.

West et al (2018) Drug Alcohol Depend, 183; Mahowald et al (2021) JALM, 1533; Heltsey et al (2012) JAT, 75..

FENTANYL IA'S FOR ORAL FLUID



OF IMMUNOASSAYS FOR FENTANYL



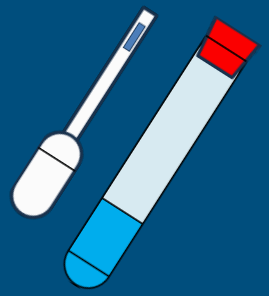
- One laboratory uses EIA to screen – 5 ng/mL cutoffs

- **ELISA**
  - Neogen
  - Immunalysis
  - Randox

- **Randox Biochip**
  - DoA Multistat Oral Fluid II – 1.5 ng/mL cutoff

TAKE HOME MESSAGES

- Immunoassays are available to measure fentanyl in urine.
  - Most target fentanyl with limited norfentanyl cross-reactivity.



- Fentanyl can be detected in oral fluid
  - Concentrations around 3x higher than in blood
  - Concentrations around 4-11x lower than in urine
- FDA cleared Immunoassays for fentanyl in oral fluid are lacking
- Some immunoassays are being used to screen for fentanyl in oral fluid as “lab-developed tests” after validation

Thank you

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