

Another tool to help combat the opioid crisis

Qualitative Detection of Norfentanyl and Fentanyl Metabolites

Fentanyl, a synthetic opioid analgesic, along with the semi-synthetic opioid Oxycodone, continue to be a key driver of the United States opioid epidemic. Due to its potency and ease of manufacture, fentanyl has become the most prevalent opioid being sold for illicit use in many communities, overtaking Heroin¹.

The true extent of Fentanyl abuse in the United States is hard to quantify, as it is often combined with other drugs in illicit opioid drug formulations.¹

DRITM Fentanyl II Assay EEE 10028972 Rx Only Reagent 1 Antibody/Substrate 1 x 115 mL Reagent 2 Enzyme 1 x 115 mL Reagent 2 Enzyme 1 x 115 mL Reagent 3 Antibody/Substrate 1 x 115 mL Reagent 4 Antibody/Substrate 1 x 115 mL Reagent 5 Antibody/Substrate 1 x 115 mL Reagent 6 To The Control of Control of

1. USA and Canada only. Cleveland NDEWS Hotspot Final Report 09 04 19584, pages425–429(2020)

The Thermo Scientific™ DRI™ Fentanyl II immunoassay offers:

- Specific detection of fentanyl and its major metabolite, norfentanyl
- High sensitivity assay with excellent precision around the 1 ng/mL cutoff
- Excellent correlation to LC-MS/MS
- Liquid, Ready-to-Use
- Low cross-reactivity to other non-fentanyl synthetic opioids and over-the-counter medication

Cross-Reactivity

The DRI Fentanyl II Assay exhibits exceptional specificity to Fentanyl (table 1), its primary metabolite Norfentanyl, and many important fentanyl analogs. The assay was tested for cross-reactivity to prevalent synthetic, semi-synthetic, and non-synthetic opioids (table 2) and demonstrates excellent robustness against other prevalent synthetic, semi-synthetic, and non-synthetic opioids.

Compound	Positive Concentration ng/mL	Percent Cross- Reactivity %
Norfenantyl	15	7
Acetyl Fentanyl	1.1	90.91
Isobutyryl fentanyl	1.1	90.91
Acrylfentanyl	1.3	76.92
Butyryl fentanyl	1.4	71.43
Furanyl fentanyl	1.5	66.67
Ocfentanil	1.6	62.5
Valeryl fentanyl	2.3	43.48
β-hydroxyfentanyl	9.5	10.53
Acetyl norfentanyl	12.1	8.26
(±) β-hydroxythiofentanyl	32.7	3.06
(±)-3-cis-methyl fentanyl	144.1	0.69
Carfentanil	448.2	0.22
Despropionyl fentanyl (4-ANPP)	471.8	0.21
Sufentanil	2,362	0.04
Norcarfentanil	>50,000	<0.002
Remifentanil	>10,000	<0.01
Alfentanil	>100,000	<0.001

Table 1

Compound	Concentration Tested (µg/mL)	Results
6-Acetyl morphine (Heroin metabolite)	100	Negative
Buprenorphine / Buprenorphine glucuronide	100	Negative
Hydrocodone / Hydromorphone	100	Negative
Methadone / EDDP	100	Negative
Morphine	100	Negative
Tramadol	100	Negative
Oxycodone / Oxymorphone	100	Negative
Naloxone / Naltrexone	100	Negative

Table 2

Accuracy

The DRI Fentanyl II assay provides results with exceptional concordance with LC-MS/MS methods in a low-cost, easy to use package. There were 147 patient samples tested for Fentanyl using the DRI Fentanyl II assay and an LC-MS/MS method. For samples positive for Fentanyl via LC-MS/MS, the DRI Fentanyl II assay exhibited 100% concordance.

	Low Negative <0.5 ng/mL	Near Cutoff Negative 0.5-0.9 ng/mL	Near Cutoff Positive 1.0-1.5 ng/mL	High Positive >1.5 ng/mL
Positive	1*	21*	11	62
Negative	50	2	0	0

* Out of a total of 74 samples containing less than 1 ng/mL according to LC-MS/MS, 22 samples recovered positive via the DRI Fentanyl II Assay. However, these samples contained significant concentrations of Norfentanyl. Details regarding these discordant samples can be found in the assay package insert.



See Package Insert for complete details.

In the United States and Canada:

Customer service USA: 1-800-232-3342

Customer service Canada: 1-800-282-4075 press 1 Order online: sales.diagnostics.fmt@thermofisher.com



Learn more at thermofisher.com/fentanyl-ii

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