January 29, 2026

MEDTOX Diagnostics, Inc.
Elizabeth Brock
Regulatory Affairs Manager
1238 Anthony Road
Burlington, North Carolina 27215

Re: K252684
Trade/Device Name: Labcorp Fentanyl Urine Visual Test
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: DJG
Dated: August 22, 2025
Received: August 25, 2025

Dear Elizabeth Brock:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JOSEPH A. KOTAREK -S
Digitally signed by JOSEPH A. KOTAREK -S
Date: 2026.01.29 16:21:43 -05'00'

Joseph Kotarek
Toxicology Branch Chief
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252684

Device Name
Labcorp Fentanyl Urine Visual Test

Indications for Use *(Describe)*
The Labcorp Fentanyl Urine Visual Test is a lateral flow competitive immunoassay for the rapid qualitative detection of norfentanyl (fentanyl metabolite) in human urine at a cutoff of 5 ng/mL. It is intended for prescription use. For in vitro diagnostic use only.

This test provides only a preliminary result. Clinical consideration and professional judgment must be applied to any drug test result, particularly in evaluating a preliminary positive result. To confirm preliminary positive results, a more specific analytical method must be used. Gas Chromatography-Mass Spectrometry (GC-MS), Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS), and High Performance Liquid Chromatography (HPLC) are the preferred confirmatory methods.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

K252684 510(k) SUMMARY

[In accordance with 21 CFR 807.92]

Submitter

MEDTOX Diagnostics, Inc.
1238 Anthony Road
Burlington, North Carolina 27215

Phone: 336-226-6311
Facsimile: 336-229-4471

Contact Person: Elizabeth Brock
Regulatory Affairs Manager
Phone: 336-482-2862

Date Prepared: December 19, 2025

Trade or Proprietary Name of Device: Labcorp Fentanyl Urine Visual Test

Common or Usual Name: Drugs of Abuse Screen Urine Test

Regulatory Class: Class II

Regulatory information:

Product Code	Classification	Regulation Section	Panel
DJG	Class II	862.3650, Opiate Test System (Fentanyl)	Clinical Toxicology

Predicate Devices

Chemtron Biotech, Inc., Chemtrue® Drug Screen Fentanyl Test (K232736)

Reference Method: Fentanyl Liquid Chromatography / Mass Spectroscopy / Mass Spectroscopy (LC-MS/MS)

Device Description

The Labcorp Fentanyl Urine Visual Test (the "DEVICE") is a lateral flow competitive immunoassay for the rapid qualitative detection of Norfentanyl (nFEN), the primary urinary metabolite of Fentanyl, in human urine at concentrations above 5 ng/mL. It is intended for prescription use.

The single use, in vitro diagnostic DEVICE is available in a cassette format with a disposable dropper provided for sample transfer.

The DEVICE contains a test strip that gives a qualitative result for presence of Norfentanyl in human urine. The DEVICE is read visually and has labeling with instructions for interpreting test results.

Intended Use / Indications for Use

The Labcorp Fentanyl Urine Visual Test is a lateral flow competitive immunoassay for the rapid qualitative detection of norfentanyl (fentanyl metabolite) in human urine at a cutoff of 5 ng/mL. It is intended for prescription use. For in vitro diagnostic use only.

This test provides only a preliminary result. Clinical consideration and professional judgment must be applied to any drug test result, particularly in evaluating a preliminary positive result. To confirm preliminary positive results, a more specific analytical method must be used. Gas Chromatography-Mass Spectrometry (GC-MS), Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS), and High Performance Liquid Chromatography (HPLC) are the preferred confirmatory methods.

Summary of Technological Characteristics – comparison with predicate

The Labcorp Fentanyl Urine Visual Test (the "DEVICE") has the same technological characteristics as the predicate device. Both the subject DEVICE and the predicate device are in vitro diagnostic devices utilizing colloidal gold based lateral flow immunoassay technology to detect the presence of norfentanyl in human urine. Both devices have the same test procedure; a urine sample is added to the test device and allowed to react for a specified period of time, after which the user interprets the test results visually. Both devices are single-use devices.

The subject DEVICE differs from the predicate device in terms of test device format, and aspects such as packaging or labeling. The subject DEVICE is a cassette design with a dropper for sample transfer, whereas the predicate device comes in a dip card or cup format. These differences do not raise new questions of safety or effectiveness.

Overall characteristics of the subject DEVICE and the predicate device are summarized in Table 1 below:

Table 1. Comparison of Similarities/Differences for the DEVICE and Predicate Device.

Table 1 – Similarities/Differences		
Item	**Subject Device**	**Predicate K232736**
Device Trade Name	Labcorp Fentanyl Urine Visual Test	Chemtrue® Drug Screen Fentanyl Cup/Dip Card Tests
Intended Use/ Indications for Use	Same	Qualitative detection of drugs of abuse in human urine

Table 1 – Similarities/Differences		
Item	**Subject Device**	**Predicate K232736**
Device Type	Same	In vitro diagnostic
Analyte	Same	Norfentanyl
Cutoff	Same	5 ng/mL
Specimen Type	Same	Human Urine
Method	Same	Competitive lateral flow immunoassay
Test Device Format	Cassette	Cup/Dip Card
Test Procedure	Sample is added to a single use test cassette by disposable dropper. The test is then timed and interpreted visually.	Sample is added to a single use test cup or dip card. The test is then timed and interpreted visually.
Conditions for Use	Prescription use	OTC – Over The Counter

Principle of Operation

The DEVICE uses lateral flow competitive immunoassay technology in which a modified drug (drug-protein conjugate) competes with drug that may be present in the urine. The colorless drug-protein conjugate is applied to the membrane of the test strip at the test line position. The colored drug-specific antibody-colloidal gold is applied to the sample pad of the test strip. When urine is transferred onto the sample pad it dissolves and migrates the colored antibody-colloidal gold across the strip membrane. If drug is not present or is below the cutoff, the drug-specific antibodies will bind to the conjugate line on the membrane and the colloidal gold will form a visible line, which indicates a negative result. If drug is present in the urine, the drug-specific antibodies will bind to the drug in solution and bypass the conjugate on the membrane and no line will form, which indicates a preliminary positive result.

A visible control line should form in the control line position regardless of whether drug is present to indicate that the test has been performed properly.

Performance Characteristics

Performance data for the DEVICE are summarized and presented below.

A. Analytical Performance:

1. Precision/Reproducibility:

Precision/reproducibility studies were carried out for the DEVICE using urine samples containing Norfentanyl spiked into a drug-free urine pool with LC-MS/MS confirmed concentrations of 0%, 25%, 50%, 75%, 100%, 125%, 150%, and 200% of the test cutoff. These samples were prepared in a blind randomized panel in triplicate and evaluated by three (3) in-house operators over five (5) days using three (3) different lots. The results are summarized in Table 2 below.

Table 2. Sensitivity/Precision/Distribution of Random Error

% of Cutoff	1st Lot Neg/Pos	2nd Lot Neg/Pos	3rd Lot Neg/Pos	Total Neg/Pos
Neg	45/0	45/0	45/0	135/0
25%	45/0	45/0	45/0	135/0
50%	45/0	45/0	45/0	135/0
75%	40/5	35/10	31/14	106/29
100%	20/25	22/23	18/27	60/75
125%	3/42	8/37	3/42	14/121
150%	0/45	0/45	0/45	0/135
200%	0/45	0/45	0/45	0/135

2. Linearity:

Not applicable. These devices are intended for qualitative use only.

3. Analytical Specificity/Interference:

Analytical specificity (cross reactivity and interference) data are summarized below.

Related Compounds and Cross-Reactants

Structurally related and reacting compounds for Norfentanyl were evaluated on the DEVICE for cross reactivity by diluting reference standards in drug-free urine pool.

Results for related and reacting compounds shown in Table 3 below are expressed as follows:

- Reactive compound: approximate minimum concentration required to produce a positive result, listed first in the table
- Non-reactive compound: concentration where no interference was observed, listed last in the table (results negative at all concentrations)
- The "% Cross-Reactive" values were calculated from the cutoff level for the DEVICE divided by the minimum positive concentration as percentage.

Table 3. Related Compounds and Cross-reactants

Compound	Result	% Cross-Reactive
Norfentanyl (nFEN) *(Norfentanyl, 5 ng/mL)*		
Parent drug: Fentanyl	Positive at 7.5 ng/mL	67%
Fentanyl/Norfentanyl analog cross-reactants		
3-Methylfentanyl	Positive at 150 ng/mL	3%
4-Fluoro-Isobutyryl Fentanyl	Positive at 15 ng/mL	33%
4'-Methylacetyl Fentanyl (para-Methacetyl Fentanyl)	Positive at 750 ng/mL	1%
Acetyl Fentanyl	Positive at 5 ng/mL	100%
Acetyl Norfentanyl	Positive at 50 ng/mL	10%
Acryl Fentanyl	Positive at 10 ng/mL	50%

Compound	Result	% Cross-Reactive
Alfentanil	Positive at 2,500 ng/mL	< 1%
Butyryl Fentanyl	Positive at 10 ng/mL	50%
Cis-DL-3-Methylfentanyl	Positive at 100 ng/mL	5%
Cyclopropyl Fentanyl	Positive at 10 ng/mL	50%
Cyclopropyl Norfentanyl	Positive at 7.5 ng/mL	67%
Fluorocyclopropyl Fentanyl (para-Fluorocyclopropyl Fentanyl)	Positive at 15 ng/mL	33%
Furanyl Fentanyl	Positive at 25 ng/mL	20%
Furanyl Norfentanyl	Positive at 7.5 ng/mL	67%
(±) β-Hydroxythiofentanyl	Positive at 10 ng/mL	50%
Isobutyryl Fentanyl	Positive at 7.5 ng/mL	67%
Isobutyryl Norfentanyl	Positive at 5 ng/mL	100%
Methoxyacetylfentanyl (MAF)	Positive at 15 ng/mL	33%
N-Benzylfuranyl Norfentanyl	Positive at 50 ng/mL	10%
N-Benzyl-Para-Fluoro Norfentanyl	Positive at 25 ng/mL	20%
Octfentanil	Positive at 500 ng/mL	1%
Para-Fluoro-Butyryl Fentanyl (p-FBF)	Positive at 75 ng/mL	7%
Para-Fluorofentanyl	Positive at 10 ng/mL	50%
Phenylacetyl Fentanyl	Positive at 7.5 ng/mL	67%
Remifentanil	Positive at 100 ng/mL	5%
THF Fentanyl (THFF)	Positive at 35 ng/mL	14%
Thienyl Fentanyl	Positive at 15 ng/mL	33%
Trans-DL-3-Methylfentanyl	Positive at 10 ng/mL	50%
Valeryl Fentanyl	Positive at 50 ng/mL	10%
Non-Fentanyl cross-reactants		
Fluphenazine	Positive at 50,000 ng/mL	< 1%
Perphenazine	Positive at 75,000 ng/mL	< 1%
Quinidine	Positive at 25,000 ng/mL	< 1%
Quinine	Positive at 50,000 ng/mL	< 1%
Risperidone	Positive at 2,500 ng/mL	< 1%
Risperidone Metabolite: 9-Hydroxyrisperidone (Paliperidone)	Positive at 2,500 ng/mL	< 1%
Non-reactive Fentanyl/Norfentanyl analogs		
Carfentanil	Negative at 500 ng/mL	Non-reactive*
Despropionylfentanyl (4-ANPP)	Negative at 1,000 ng/mL	Non-reactive
MT-45	Negative at 3,500 ng/mL	Non-reactive*
4-Methoxybutyryl Fentanyl	Negative at 5,000 ng/mL	Non-reactive*
Norcarfentanil	Negative at 1,000 ng/mL	Non-reactive
Sufentanil	Negative at 1,000 ng/mL	Non-reactive
U-47700	Negative at 5,000 ng/mL	Non-reactive*

*These Non-reactive compounds produced negative interference with the test at higher concentrations, however this interference is not expected to impact test performance.

Interference Data

The DEVICE was evaluated for cross-reactivity by assaying each of the below compounds or conditions in a drug-free urine pool, and for interference by assaying each compound or condition in drug-free urine pool fortified with Norfentanyl at 50% of cutoff or 150% of cutoff separately. Per the Precision/Reproducibility data Norfentanyl at 50% of cutoff is the concentration where results for all lots were 95% negative or greater (C5), and Norfentanyl at 150% of cutoff is the concentration where results for all lots were 95% positive or greater (C95). Each compound or condition was assayed one at a time using five (5) replicates for each concentration of Norfentanyl and each result was visually interpreted. The compound concentrations and conditions below produced consistently negative results with the negative urine pool, and the 50% / 150% of cutoff urines gave the expected negative / positive results.

Non-cross-reactive Endogenous Compounds:

The DEVICE was evaluated for cross-reactivity and interference with endogenous compounds. None of these compounds demonstrated cross-reactivity or interference at the indicated concentration levels tested with the DEVICE. The endogenous compounds and their non-reactive concentration are summarized in Table 4 below.

Table 4. Non-reactive Endogenous Compounds

Endogenous Compound	Concentration (ng/mL)	Endogenous Compound	Concentration (ng/mL)
Acetone	10,000,000	Glucose	30,000,000
Albumin, Human	5,000,000	Hemoglobin, Human	3,000,000
Ascorbic Acid	5,000,000	Niacinamide	100,000
Atropine	100,000	Nicotinic Acid	100,000
Beta-Hydroxybutyric Acid	100,000	Octopamine	150,000
Bilirubin	20,000	Oxalic Acid	100,000
Biotin	100,000	Potassium Chloride	10,000,000
Calcium Chloride	3,000,000	Pyridoxine	90,000
Cholesterol	100,000	Quinolinic Acid	100,000
Creatine Hydrate	100,000	Riboflavin	75,000
Creatinine	5,000,000	Sodium Chloride	10,000,000
Deoxycorticosterone	100,000	Thiamine	100,000
Dopamine (3-Hydroxytyramine)	100,000	Tryptamine	100,000
Ethanol	10,000,000	Tyramine	100,000
Galactose	100,000	Urea	60,000,000
Gamma Globulin	5,000,000	Uric Acid	100,000

pH and Specific Gravity:

The DEVICE was evaluated for pH interference. Each negative and fortified urine control was adjusted by either 6N NaOH or 6N HCl to pH values across the normal range for human urine – 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, and 9.0. None of the pH conditions demonstrated cross-reactivity or interference with the DEVICE.

The DEVICE was evaluated for specific gravity interference by assaying negative and fortified urine samples that had specific gravity values across the normal range for human urine – 1.001, 1.004, 1.010, 1.014, 1.020, 1.025, and 1.030. None of the specific gravity conditions demonstrated cross-reactivity or interference with the DEVICE.

Common Drugs:

The DEVICE was evaluated for cross-reactivity and interference with commonly prescribed drugs, common over-the-counter drugs, and common drugs of abuse. Concentrations were used that were at or above a medically relevant concentration when feasible (concentrations in urine known/calculatable and compound availability). None of the compounds demonstrated cross-reactivity or interference at the indicated concentration levels tested with the DEVICE. The common drugs and their non-reactive concentration are summarized in Table 5 below.

Table 5. Non-reactive Common Drugs

Common Drug	Concentration (ng/mL)	Common Drug	Concentration (ng/mL)
1-(3-Trifluoromethylphenyl)-piperazine	100,000	Isotonitazene	10,000
11-Hydroxy- 9-THC	10,000	Ketamine	100,000
11-Nor-9-carboxy- 9-THC	10,000	Labetalol	1,800,000
4-Bromo-2,5, Dimethoxyphenethylamine	100,000	Lamotrigine	100,000
6-Acetylmorphine (6-MAM)	100,000	Lansoprazole	100,000
7-Aminoclonazepam	100,000	L-Cotinine	100,000
7-Aminoflunitrazepam	100,000	L-Erythromycin	100,000
7-Aminonitrazepam	10,000	Levonorgestrel	100,000
Acetaminophen	2,900,000	Levorphanol	100,000
Acetylsalicylic Acid	100,000	Levothyroxine (L-Thyroxine)	100,000
AH-7921 (Doxylam)	10,000	Lisinopril	100,000
AH-8529	100,000	L-Methamphetamine	100,000
AH-8533	100,000	Loperamide	100,000
Albuterol	100,000	Loratadine	100,000
Allopurinol	100,000	Lorazepam	100,000
Alprazolam	100,000	Losartan	100,000
Aminopyrine (4-Dimethylaminoantipyrine)	100,000	Lurasidone	10,000
Amlodipine Besylate	100,000	Lysergic Acid Diethylamide (LSD)	10,000
Amoxicillin	2,600,000	Maprotiline	100,000
Ampicillin	100,000	Meperidine	100,000
Apixaban	100,000	Meprobamate	100,000
Apomorphine	100,000	Metformin	2,900,000
Aspartame	100,000	Methadone	100,000
Atenolol	200,000	Methapyrilene	100,000
Atorvastatin	100,000	Methylphenidate	100,000
Baclofen	100,000	Metonitazene	10,000

Common Drug	Concentration (ng/mL)	Common Drug	Concentration (ng/mL)
Benzocaine	100,000	Metoprolol	550,000
Benzoic Acid	100,000	Mitragynine	100,000
Benzoylecgonine	100,000	Morphine	300,000
Benzylpiperiazine	10,000	Morphine-3-glucuronide	10,000
Brompheniramine	100,000	Nalidixic Acid	100,000
Buprenorphine	100,000	Naloxegol	100,000
Bupropion	100,000	Naloxone	100,000
Caffeine	1,200,000	Naltrexone	100,000
Cannabidiol	100,000	Naproxen	1,800,000
Carbamazepine	100,000	N-Desmethyltapentadol	10,000
Carisoprodol	100,000	Nifedipine	100,000
Carvedilol	100,000	Norbuprenorphine	100,000
Cetirizine	100,000	Norcodeine	100,000
Chloramphenicol	100,000	Nordiazepam	100,000
Chlorcyclizine	100,000	Norethindrone	100,000
Chlordiazepoxide	100,000	Norketamine	100,000
Chlorpheniramine	100,000	Normeperidine	100,000
Chlorpromazine	15,000	Normorphine	10,000
Cimetidine	1,800,000	Noroxycodone	100,000
Citalopram	100,000	Norpropoxyphene	100,000
Clofibrate	100,000	Norpseudoephedrine (Cathine)	100,000
Clomipramine	100,000	Noscapine	100,000
Clonazepam	100,000	Omeprazole	100,000
Clonidine	100,000	Oxazepam	100,000
Clopidogrel	200,000	Oxazepam Glucuronide	1,000
Codeine	120,000	Oxycodone	100,000
Cortisone	100,000	Oxymetazoline	100,000
Cyclobenzaprine	100,000	Oxymorphone	100,000
Cyclodextrin-r	100,000	Pantoprazole	100,000
Cyproheptadine	100,000	Papaverine	100,000
DL-Isoproterenol	100,000	Penicillin-G (Benzylpenicillin)	100,000
D-Amphetamine	350,000	Pentazocine	35,000
Demoxepam	100,000	Perospirone	10,000
Dextromethorphan	100,000	Phenelzine	100,000
Diclofenac	200,000	Pheniramine	100,000
Difunisal	100,000	Phentermine	100,000
Dihydrocodeine	100,000	Phenylephrine	100,000
Diphenhydramine	100,000	Phenylethylamine	100,000
Diphenylhydantoin (Phenytoin)	100,000	Pravastatin	100,000
D-Methamphetamine	100,000	Prednisone	100,000
Doxylamine	100,000	Promazine	100,000

Common Drug	Concentration (ng/mL)	Common Drug	Concentration (ng/mL)
D-Pseudoephedrine	250,000	Promethazine	100,000
Duloxetine	150,000	Propoxyphene	10,000
EDDP (Methadone metabolite)	100,000	Propranolol	700,000
Ephedrine	100,000	Propylhexedrine	50,000
Ergocalciferol	100,000	Pyrilamine	150,000
Escitalopram	100,000	Pyrogallol	100,000
Esomeprazole Mg hydrate	250,000	Ranitidine	150,000
Estrone	100,000	Rosuvastatin	100,000
Ethinyl Estradiol	100,000	Salicylic Acid	1,000,000
Famotidine	1,000,000	Sertindole	10,000
Fenfluramine	100,000	Sertraline	30,000
Fenofibrate	100,000	Simvastatin	100,000
Fexofenadine	75,000	Sodium Azide	100,000
Fluoxetine	100,000	Sulfamethazine	100,000
Fluticasone	100,000	Sulindac	100,000
Furosemide	500,000	Tamsulosin	100,000
Gabapentin	4,500,000	Temazepam	100,000
Gemfibrozil	100,000	Tetracycline	100,000
Gentisic Acid	100,000	Tetrahydrozoline	100,000
Glipizide	100,000	Thioridazine	100,000
Guaifenesin	100,000	Tianeptine	100,000
Heroin (Diacetylmorphine)	100,000	Tramadol	450,000
Hexobarbital	10,000	Trazodone	10,000
Hydralazine	100,000	Trifluoperazine	100,000
Hydrochlorothiazide	150,000	Venlafaxine	100,000
Hydrocodone	100,000	Xylazine	100,000
Hydrocortisone	100,000	Ziprasidone	100,000
Hydromorphone	100,000	Zolpidem	100,000
Ibuprofen	2,700,000	Zolpidem Tartrate	100,000
Insulin	100,000		

4. Assay Reportable Range:

Characterization of how the device performs around the claimed cutoff concentration appears in the precision study (section A.1 above). Higher concentrations perform equivalent to the highest concentration evaluated in the precision study. The DEVICE is a competitive test and there is no hook-effect at higher concentrations.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

All drug calibrators of the device are traceable to available commercial reference materials.

6. Detection Limit:

Characterization of how the device performs at low analyte concentrations appears in the precision study (section A.1 above).

7. Assay Cut-Off:

Characterization of how the device performs around the claimed cutoff concentration appears in the precision study (section A.1 above).

8. Stability:

To establish and support the shelf life and expiration date, stability studies were conducted under accelerated temperature (at 45°C), and real time (2°C to 30°C) with three (3) lots of the DEVICE. The accelerated stability study results support two (2) years shelf life of the products stored at 2°C to 30°C. Real-time stability studies are still on going.

9. Flex Testing:

To evaluate robustness of the DEVICE, flex testing studies were conducted after the devices were exposed to various sample volumes, common types of contamination or damage, non-urine specimen types, preservatives, and humidity and temperature conditions. The results support the robustness of the DEVICE.

B. Comparison Studies:

1. Method Comparison with Predicate Device:

The accuracy of the DEVICE was evaluated by a method comparison study comparing the performance of the DEVICE to the LC-MS/MS reference method. Clinical urine samples were assayed in a randomized panel of blind coded urine samples that were interpreted visually. The eighty-seven (87) unaltered clinical urine samples contained either no target drug/metabolite or varying concentrations of Norfentanyl as determined by LC-MS/MS results. Three (3) operators each tested the 87 samples on a different test lot. The results are summarized in Table 6 below.

Table 6. Accuracy with Clinical Samples Compared to LC-MS/MS

Fentanyl Test (nFEN) (5 ng/mL Cutoff)		Concentration by LC-MS/MS (ng/mL)				
		(-)			(+)	
		No Drug Present	Low Negative (<50% of cutoff)	Near Cutoff Negative (50% - 100% of cutoff)	Near Cutoff Positive (100% - 150% of cutoff)	True Positive (>150% of cutoff)
1st Lot	Positive (+)	0	0	3*	4	36
	Negative (-)	40	3	1	0	0
2nd Lot	Positive (+)	0	0	3*	4	36
	Negative (-)	40	3	1	0	0
3rd Lot	Positive (+)	0	0	3*	4	36
	Negative (-)	40	3	1	0	0

*Summary of concentrations for discordant samples (50-100% of cutoff)

Fentanyl Test (nFEN) Result	Norfentanyl by LC-MS/MS (ng/mL)
Positive (+)	4.76
Positive (+)	3.86
Positive (+)	3.34

The same 3 clinical samples produced positive results with all 3 lots tested.

2. Matrix Comparison:

Not applicable. These devices are for use with urine samples only.

C. Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

D. Clinical Cut-Off:

Not applicable.

E. Expected Values/Reference Range:

Not applicable.

Conclusions

The Labcorp Fentanyl Urine Visual Test (the “DEVICE”) is as safe, as effective, and performs as well as or better than the legally marketed predicate device. The DEVICE has the same intended use, technological characteristics, and principles of operation as its predicate device. The DEVICE indications for use fall within the use population of the predicate device, and the DEVICE format is a cassette design with a dropper for sample transfer while the predicate device is a dip card or cup format. Comparison of similarities and differences between the DEVICE and the predicate device raises no new issues of safety or effectiveness. Thus, the DEVICE is substantially equivalent to its predicate device.

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

References:

1. Disposition of Toxic Drugs and Chemicals in Man, 10th ed., R.C. Baselt. Biomedical Publications, Seal Beach (USA) (2014), pp. 846–849, ISBN: 978-0-9626523-9-4.
2. Silverstein JH, Rieders MF, McMullin M, Schulman S, Zahl K. An analysis of the duration of fentanyl and its metabolites in urine and saliva. *Anesth Analg*. 1993 Mar;76(3):618-21. DOI: 10.1213/00000539-199303000-00030. PMID: 8452277.