INDICAID™
FENTANYL DRUG DETECTION TEST
INSTRUCTIONS FOR USE

CLIA Waived
For *in vitro* diagnostic use only.
Medical and other professional *in vitro* diagnostic use labeling.

INTENDED USE
The INDICAID™ Fentanyl Drug Detection Test is a rapid, one-step immunoassay for the qualitative detection of fentanyl in human urine at the cutoff concentrations of 1 ng/mL.

This device provides only preliminary drug test results. To obtain a quantitative result or a confirmation of a presumptive positive result, a more specific alternative method must be used. GC/MS or LC/MS is the preferred confirmatory method.

Professional judgment should be applied to drug test results, particularly when preliminary positive results are indicated.

It is for *in vitro* diagnostic use only.

TECHNOLOGY AND EXPLANATION
Fentanyl is an extremely fast acting synthetic opioid related to the phenylpiperidiens. It has the brand names of Sublimaze, Actiq, Durogestic, Fentora and others. Fentanyl is approximately 100 times more potent than morphine, with 100 micrograms of fentanyl approximately equivalent to 10 mg of morphine or 75 mg of meperidine in analgesic activity (1.2). Fentanyl is a potent narcotic analgesic with rapid onset and short duration of action. Historically, it has been used to treat chronic breakthrough pain and is commonly used pre-procedures. Illicit use of pharmaceutical fentanyl first appeared in the mid-1970s. Because the effects of fentanyl last for only a very short time, it is even more addictive than heroin. The regular users may become addicted very quickly. Fentanyl is much more potent than heroin, and tends to produce significantly worse respiratory depression, making it somewhat more dangerous than heroin to users. The overdose of fentanyl has caused death. In humans, the drug appears to be metabolized primarily by oxidative N-dealkylation to Norfentanyl and other inactive metabolites that do not contribute materially to the observed activity of the drug. Within 72 hours of intravenous (IV) administration, approximately 75% of the dose is excreted in urine, mostly as metabolites with <10% representing unchanged drug (3,4).

Fentanyl is a controlled substance. As an analgesic, fentanyl can be used for cancer pain treatment. It can also be used to treat severe chronic pain that requires opioid analgesics. Fentanyl can also be abused in a manner similar to other opioid antagonists (legal or illicit).

TEST PRINCIPLE
The INDICAID™ Fentanyl Drug Detection Test is a rapid lateral fluid immunoassay utilizing specific antibodies to qualitatively detect fentanyl at the cutoff concentration of 1ng/mL in human urine. The assay is based on competitive immunoassay procedure in which the drug conjugates immobilized on nitrocellulose membrane compete with the drugs if present in specimen for the limited amount of antibody on colloidal gold conjugates. If there is no drug present or the drug concentration in the specimen is below cutoff level, the red colloidal gold conjugate will bind to the drug conjugate at the specific test region, to form a visible band which indicated a negative result. If there is drug present in the specimen at above cutoff level, the drug will bind to the limited antibodies on colloidal gold, leaving no antibody available for binding to the drug conjugates on membrane. Thus, the absences of a test line band present at specific test region indicates a presumptive positive result for that drug.

The INDICAID™ Fentanyl Drug Detection Test contains one membrane strip which consists of a membrane, a colloidal gold conjugate pad, a sample pad and an absorbent pad. Fentanyl protein conjugate is coated onto specific region on the membrane known as the "Test Region", and the colloidal gold conjugate pad contains anti-Fentanyl antibody colloidal gold conjugates coated onto a fibrous pad.

PRECAUTIONS
1. The test device is for single use and should remain in its original sealed pouch until ready for use.
2. Do not use after the expiration date indicated on the kit.
3. Handle all urine specimens as if potentially infectious. The used device should be discarded according federal, state and local regulation.
4. Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample.
5. The device is for prescription use.
6. The device is used for *in vitro* diagnostic use.

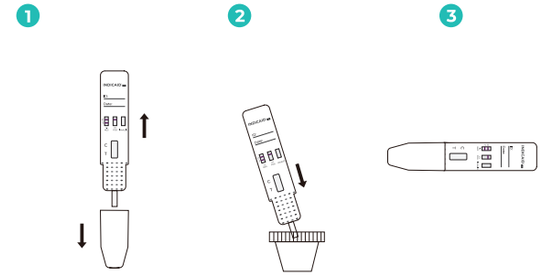
MATERIAL
Material Provided
· Test devices packaged individually in a foil pouch with desiccant.
· 1 Package Insert.

Material Required But Not Provided
· Watch, clock or timer
· Urine collection cup

Storage And Stability
1. Store at 2°C-30°C for 24 months. Do not open pouch until ready to perform the assay.
2. Keep away from direct sunlight moisture and heat.

SPECIMEN COLLECTION AND HANDLING
The INDICAID™ Fentanyl Drug Detection Test is designed for use with urine specimens. Urine sample should be tested immediately after collection.

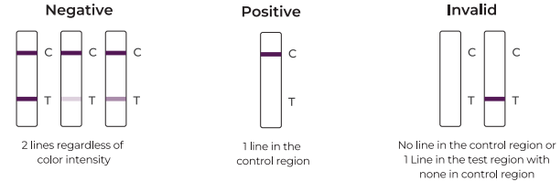
TEST PROCEDURE
IMPORTANT: Do not open pouch until ready to perform the assay.
1. Remove the test device from the sealed pouch and use the device as soon as possible.
2. Put urine specimen into a cup and fill (cup not included).
3. Pull the cap off gently by holding the sides to expose the pad. Hold the top portion of the device (above the testing window).
4. Dip the sample pad of the test device into the sample for at least 15 seconds. The maximum time for dipping is 30 seconds.
5. Place the cap onto the device, lay it on a flat surface.
6. Once the liquid moves to the test window, start the timer.
7. Read the test results at 5 minutes, do not read results after 10 minutes.



INTERPRETING TEST RESULTS
Negative Results
A red colored band should be observed in control region (C), and test region. The color and density of the test band may vary for control and drug test region.

Presumptive Positive Results
When the control band is visible in the control region (C) and no band appears at the test region, the result is a presumptive positive.

Invalid
When no band appears in the control (C) region, the test is invalid regardless of the results in the test region. If the test is invalid, check testing procedures. Repeat the test using a new device.



NOTE: Any Indication of a line in the test region (T) should be considered a line, And therefore, a negative result.

IMPORTANT: Do not compare color intensity of one test band to another. Read each test independently. Any dark or light red band is observed in the test region along with the presence of the control line (C), the sample should be considered negative. For confirmation of a presumptive positive result, a more specific quantitative method (GC/MS or LC/MS) must be used.

QUALITY CONTROL
The device has built-in control band in each window at the control regions (C) to indicate that the test has performed properly. If the control bands do not appear, the test device should be discarded. The use of external controls is strongly recommended as good laboratory testing practice to verify test performance. The same assay procedure should be followed with external control materials as with a urine specimen. When external controls do not produce the expected results, do not run test specimens.

Laboratories should comply with all federal, state, and local laws, guidelines and regulations.

LIMITATIONS
1. The assay is designed for human urine use only.
2. The test only provides a qualitative, preliminary results. Positive results only indicate the presumptive presence of drug and do not indicate or measure intoxication. A more specific alternative method must be used. GC/MS or LC/MS is the preferred confirmatory method.
3. Technical or procedural errors as well as substances in certain foods and certain medications may interfere with the test and cause false results.

PERFORMANCE CHARACTERISTICS
1. Precision / Cutoff
Precision studies were performed using CLSI EP05-A3 as a guideline. Drug-free, negative human urine was supplemented with fentanyl (±25%, ±50%, ±75%, cutoff, ±100%). Each level was assayed in triplicate, twice a day for 10 days · and three personnel tested three batches of products at three sites (N=180). Results are summarized in table below.

Relative % Cutoff	Concentration (ng/mL)	# of results	Results (Agreement)
- 100%	0.00	180-/0+	Negative100%
- 75%	0.25	180-/0+	Negative100%
-50%	0.50	180-/0+	Negative100%
-25%	0. 75	135-/45+	Negative75%
Cutoff	1.00	94-/86+	Negative52.2% Positive47.8%
+25%	1.25	180+/0-	Positive100%
+50%	1.50	180+/0-	Positive100%
+75%	1.75	180+/0-	Positive100%
+100%	2.00	180+/0-	Positive100%

2. Method Comparison
The accuracy of test was evaluated by testing with clinical urine samples which were previously analyzed by LC/MS method. 80 unaltered clinical urine specimens were tested. The results are summarized below:

INDICAID Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Lot 1	Positive	0	0	4	22	17
	Negative	10	17	9	1	0
Lot 2	Positive	0	0	6	21	17
	Negative	10	17	7	2	0
Lot 3	Positive	0	0	6	21	17
	Negative	10	17	7	2	0

% agreement is >90%

3. Specificity - Cross Reactivity

The specificity was evaluated by adding its structurally related compounds to negative urine sample. The results are expressed as the lowest concentration of the compound, in ng/mL, that produced a positive result.

Compound	Concentration ng/mL	% of cross reactivity
Norfentanyl	50	2%
Acetyl fentanyl	1	100%
Acrylfentanyl	10	10%
Isobutyryl fentanyl	2.5	40%
Ocfentanil	10	10%
Butyryl fentanyl	2.5	40%
Furanyl fentanyl	7.5	13.3%
Valeryl fentanyl	10	10%
(±) β-hydroxythiofentanyl	5	20%
Para-fluorobutyrylfentanyl (p-FBF)	10	10%
Para-fluoro fentanyl	1	100%
(±)-3-cis-methylfentanyl	10	10%
Carfentanil	10000	0.01%
Sufentanil	10000	0.01%
Norcarfentanil	100000	<0.001%
Acetyl norfentanyl	10	10%
Remifentanil	10000	0.01%
Alfentanil	10000	0.01%
ω-1-Hydroxyfentanyl	20000	0.005%
4-Fluoro-isobutyrylfentanyl	50	2%
Despropionyl fentanyl (4-ANPP)	2500	0.04%

The following opioids compounds were tested at a concentration of 100ug/mL. Negative results were obtained for all these compounds. There is no cross-reactivity for these compounds using the INDICAID™ Fentanyl Drug Detection Test.

6-Acetyl morphine	Naltrexone
Amphetamine	Norbuprenorphine
Buprenorphine	Norcodeine
Buprenorphineglucuronide	Norketamine
Codeine	Normeperidine
Dextromethorphan	Normorphine
Dihydrocodeine	Noroxycodone
EDDP	Oxycodone
EMDP	Oxymorphone
Fluoxetine	Pentazocine (Talwin)
Heroin	Pipamperone
Hydrocodone	Risperidone
Hydromorphone	Tapentadol
Ketamine	Thioridazine
Levorphanol	Tilidine
Meperidine	Tramadol
Methadone	Tramadol-O-Desmethyl
Morphine	Tramadol-N-Desmethyl
Morphine-3-glucuronide	Trazodone
Naloxone	

4. Specificity - Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drug fentanyl urine with concentrations at 50% below and 50% above Cut-Off levels. These urine samples were tested using three batches of each device. Compounds that showed no interference at a concentration of 100µg/mL or specified concentrations are summarized in the following tables.

Acetaminophen	Doxepin	Nortriptyline
Acetone (1000mg/dL)	Ecgonine methyl ester	Noscapine
Acetophenetidin	Ephedrine	O-Hydroxyhippuric acid
Acetylsalicylic acid	Erythromycin	Octopamine
Albumin (100mg/dL)	Ethanol (1%)	Oxalic acid (100 mg/dL)
Albuterol	Fenoprofen	Oxazepam
Aminopyrine	Fluphenazine	Oxolinic acid
Amitriptyline	Furosemide	Oxymetazoline
Amobarbital	Galactose (10mg/dL)	Papaverine
Amoxicillin	Gamma Globulin (500mg/dL)	Penicillin G
Ampicillin	Gentisic acid	Perphenazine
Apomorphine	Glucose (3000mg/dL)	Phencyclidine
Ascorbic acid	Hemoglobin	Phenelzine
Aspartame	Hydralazine	Phenobarbital
Atropine	Hydrochlorothiazide	Prednisone
Benzilic acid	Hydrocortisone	Propoxyphene (50ug/ml)
Benzoic acid	Hydroxytyramine	Propranolol
Benzoylecgonine	Ibuprofen	Pseudoephedrine
Bilirubin	Imipramine	Quinine
Boric Acid (1%)	Isoproterenol	Ranitidine
Bupropion	Isoxsuprine	Riboflavin (10mg/dL)
Caffeine	Ketamine	Salicylic acid
Carbamazepine	Ketoprofen	Secobarbital
Chloral hydrate	Labetalol	Serotonin (5-Hydroxytyramine)
Chloramphenicol	Lidocaine	Sulfamethazine
Chlorothiazide	Loperamide	Sulindac
Chlorpromazine	Maprotiline	Tetrahydrocortisone 3-(β-Dglucuronide)
Cholesterol	Meperidine	Tetrahydrocortisone 3-acetate
Clomipramine	Meprobamate	Tetrahydrozoline
Clonidine	Methapyrilene	Thiamine
Cortisone	Methaqualone	Thioridazine
Cotinine	Methoxyphenamine	Triamterene
Creatinine	Metronidazole (300ug/ml)	Trifluoperazine
Cyclobenzaprine	N-Acetylprocainamide	Trimethoprim
Deoxycorticosterone	NaCl (4000mg/dL)	Tyramine
Desipramine	Nalidixic acid	Urea (2000mg/dL)
Dextromethorphan	Naloxone	Uric acid
Diclofenac	Naltrexone	Valproic acid (250ug/ml)
Diflunisal	Naproxen	Venlafaxine
Digoxin	Niacinamide	Verapamil
Diphenhydramine	Nicotine	Zomepirac
DL-Tryptophan	Nifedipine	β-Estradiol
DL-Tyrosine	Norethindrone	

5. pH and Specific Gravity Interference

The pH and specific gravity of urine samples has no effect on the performance of the INDICAID™ Fentanyl Drug Detection Test when the pH ranges between 4.0-9.0, and SG1.000- 1.035.

BIBLIOGRAPHY OF SUGGESTED READING

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MEANING OF SYMBOLS ON PACKAGE


Consult instructions for use

In vitro diagnostic medical device


Manufacturer

Batch number


Caution, consult accompanying documents


Keep away from sunlight


Do not re-use

Store between 2°C-30°C


Expiration date


Production Date


Contains sufficient for <n>test

ASSISTANCE

If you have any questions regarding the use of this product, please call our Technical Support Number +1 877-625-1603 (9 a.m. to 5 p.m. CDT).

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