Instant Drug Test II Fentanyl (norfentanyl) Urine Drug Screen Package Insert

A screen for the qualitative detection of fentanyl metabolite (norfentanyl) in human urine
For Research Use Only.

INTENDED USE

The Instant Drug Test II Fentanyl is a lateral flow immunochromatographic assay for the qualitative detection of Fentanyl metabolite (norfentanyl) in human urine at a cutoff level of 20 ng/mL.

The test provides a preliminary result only; preliminary positive results should be confirmed using an alternate chemical methodology (GC/MS, GC/MS/MS, LC/MS or LC/MS/MS) if the donor does not admit to use, if the attending medical professional advises or anytime test policies require. The IDT II test will detect Fentanyl metabolite only; it does not detect fentanyl analogs such as carfentanil, alfentanil or sufentanil.

SUMMARY

The United States is plagued with an opioid misuse, abuse and overdose epidemic[1]. The specific chemistry of the innumerable opioids available in the US can confound treatment practitioners, first-responders, and other professionals who dedicate themselves to helping people fight their addictions. At present, there is an alarming trend of heroin and other street drugs that have been contaminated with fentanyl. We are also seeing street drugs mislabeled as oxycodone or hydrocodone that are fentanyl. Dose for dose, fentanyl is 50 to 100 times for powerful than morphine[2]. The consumption of fentanyl that is mistakenly identified as a lower potency opiate can lead to overdose. There are no FDA cleared near-donor tests for the sensitive and selective detection of fentanyl in donors. The use of urine for the detection of drugs is long-established and is widely considered the gold-standard testing matrix and the primary urinary metabolite is norfentanyl. The window of detection for norfentanyl in human urine is 1-3 days after use.

TEST PRINCIPLE

The lateral flow tests are based on the principle of competitive-binding, antibody and antigen chemistry. The IDT II Fentanyl assay utilizes an anti-target antibody selected to specifically detect norfentanyl in human urine at a cutoff level of 20 ng/mL.

A urine specimen showing presumptive positive results for norfentanyl will not generate a colored line in the designated test (T) region of the lateral flow strip. Urine specimens bearing no norfentanyl or an insufficient concentration of norfentanyl relative to the 20 ng/mL cutoff level will generate a visible, colored line in the test (T) region of the lateral flow strip. A control line with a different antigen/antibody reaction is included on the lateral flow strip in the control (C) region. This control band must appear regardless of the presence or absence of norfentanyl for the strip to be considered valid. Preliminary positive results should be confirmed by gold-standard methodologies GC/MS, GC/MS/MS, LC/MS or LC/MS/MS using the same specimen as stated in the intended use.

REAGENTS

The test contains mouse monoclonal anti-norfentanyl antibody-coupled particles and norfentanyl-protein conjugate. A goat antibody is employed in the control line system.

PRECAUTION

- Do not use after the expiration date printed on the pouch.
- The test should remain in the sealed pouch until ready for use. Device must be used within 1 hour after pouch opening.
- Specimens should be considered potentially hazardous, although not classified as such.
- The used test should be discarded according to local regulations.

STORAGE AND STABILITY

- Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed. **DO NOT FREEZE**.
- Do not use the test after the expiration date printed on the pouch.

SPECIMEN COLLECTION AND PREPARATION

- The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.

Specimen Storage

- Urine specimens may be stored at room temperature for up to 72 hours prior to testing. For long-term storage, specimens should be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS

Materials Provided

- Dip Cards
- Package insert

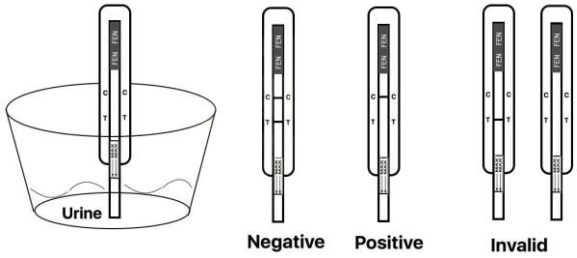
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

If refrigerated, allow the test, urine specimen, and/or controls to reach room temperature (15-30ºC) prior to testing.

1. Remove the test card from the sealed pouch and use it within one hour of opening.
2. With arrows pointing toward the urine specimen, **immerse the dip card vertically in the urine specimen for at least 20 seconds**. Replace the cap back onto the dip card and place the dip card on a non-absorbent flat surface, start the timer and wait for results. **Alternatively, the dip card can remain in the specimen throughout the testing process.**
3. Negative results can be interpreted as soon as they are apparent. Read positive results at 5 minutes. All results remain stable for 60 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* Two lines appear. One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the norfentanyl concentration in the urine is below the detection level (20 ng/mL).

***NOTE:** The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This positive result indicates that the norfentanyl concentration meets or exceeds the detection level (20 ng/mL).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test. If the problem persists, contact CLIAwaived toll free at 888-882-7739.

A procedural control is included in the device. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Controls are available through CLIAwaived, Inc.

LIMITATIONS

The Instant Drug Test II provides only a preliminary analytical test result. A more specific alternate chemical method should used in order to obtain a confirmed presumptive positive analytical result. Mass spectrometry-based instruments (GC/MS, GC/MS/MS, LC/MS or LC/MS/MS) are the preferred confirmation methods.

1. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
2. Adulterants in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the specimen should be recollected.
3. A positive result indicates the presumptive presence of norfentanyl but does not indicate level of intoxication, administration route or concentration in urine.
4. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.

PERFORMANCE CHARACTERISTICS

Accuracy

Blind testing was conducted using IDT II Fentanyl Urine Drug Screen and clinical specimens with confirmed levels of norfentanyl by LC-MS/MS. The results are shown below:

IDT II Fen Test Result	Range of LC-MS/MS Data (relative to 20 ng/mL norfentanyl test cutoff)						
	Drug-free	-50% to -25%	-25% to cutoff	Cutoff to +25%	+25% to +50%	>+50% of cutoff	Agreement
Negative	100	3	2	0	0	0	99.06%
Positive	0	0	1	3	3	46	100%

Analytical Sensitivity

A drug-free urine pool was spiked with norfentanyl at the following concentrations: 0 ng/mL, 10 ng/mL, 30 ng/mL and 40 ng/mL. The results demonstrate >99% correlation for drug-free, +/- 50% and +100% of the 20 ng/mL cut-off concentration. The data are below:

Norfentanyl Concentration (ng/mL)	Percent of Cutoff	n	Visual Result	
			Negative	Positive
0	0	30	30	0
10	-50%	30	30	0
20	+50%	30	0	30
40	+100%	30	0	30

Analytical Specificity

The following table lists compounds that are related to fentanyl that were tested on the Instant Drug Test II Fentanyl Urine Drug Screen.

Compound	Concentration (ng/mL)
Norfentanyl (calibrator)	20
Fentanyl (parent drug)	1,000
Alfentanil	>100,000
Sufentanil	>10,000
Carfentanil	>10,000

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or norfentanyl positive urine. The following compounds show no cross-reactivity when tested with the IDT II Fentanyl Urine Drug Screen at a concentration of 100 μg/mL.

Acetaminophen	4-Dimethylaminoantipyrine	Niacinamide
Acetone	Diphenhydramine	(+/-)-Norephedrine
Albumin	Dopamine	Oxalic acid
Ampicillin	(+/-)-Isoproterenol	Penicillin-G
Ascorbic acid	1R,2S(+)-Ephedrine	Pheniramine
Aspartame	Erythromycin	Phenothiazine
Aspirin	Ethanol	L-Phenylephrine
Atropine	Furosemide	B-Phenylethylamine
Benzocaine	Glucose	Procaine
Bilirubin	Guaiacol glyceryl ether	Quinidine
Caffeine	Hemoglobin	Ranitidine
Chloroquine	Ibuprofen	Riboflavin
(+)-Chlorpheniramine	(+/-)-Isoproterenol	Sodium chloride
(+/-)-Chlorpheniramine	Levorphanol	Sulindac
Creatine	Lidocaine	Theophylline
Dexbrompheniramine	(1R,2S)-(-)-n-Methylephedrine	Tyramine
Dextromethorphan	(+)-Naproxen	

BIBLIOGRAPHY AND SUGGESTED READING

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