# InstaStrip Fentanyl Rapid Test (Urine)

## Package Insert

***CLIA waived***

*A dipstick test for the qualitative detection of Fentanyl in human urine.*
*For medical and other professional in vitro diagnostic labeling.*

**【INTENDED USE】**

The InstaStrip Fentanyl Rapid Test (Urine) is intended for the qualitative detection of fentanyl in human urine at the cutoff value of 1.0 ng/mL.
The assay provides only a preliminary analytical result. A more specific alternative chemical method (e.g., gas or liquid chromatography and mass spectrometry) must be used in order to obtain a confirmed analytical result. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.

**【SUMMARY】**

Fentanyl is the leading cause of overdose deaths in the United States, clearly establishing its use as a life-threatening condition. From 2015 to 2021, a 7.5-fold increase in fentanyl-involving deaths was reported by the National Institute for Drug Abuse (NIDA) [1]. A report published in 2023 by National Vital Statistics System shows that every day, approximately 150 individuals die as a result of overdoses caused by synthetic opioids such as fentanyl [2]. Most fentanyl-related overdoses are caused by illicit fentanyl and/or fentanyl analogs, either alone or in combination with other narcotics [3]. Quick identification of fentanyl as the contributing drug and administration of naloxone is essential for saving an overdosed patient's life [4]. Even in the case of adulteration of fentanyl into other opioids, the detection of fentanyl is important for determining appropriate naloxone dosage and frequency [4].

**【PRINCIPLE】**

The InstaStrip Fentanyl Rapid Test (Urine) is an immunoassay technique that is based on competitive lateral flow immunoassay to detect the presence of fentanyl in human urine samples. The urine sample is added to a provided test tube containing dried rabbit monoclonal antibody-gold nanoparticle (Ab-AuNP) conjugates. This mixture is applied to the InstaStrip Fentanyl test strip. The pre-immobilized fentanyl-BSA on the test line competes with fentanyl in the urine sample for binding to the Ab-AuNPs. The device is designed so that when the fentanyl concentration in the urine sample exceeds 1 ng/mL, the test line is no longer visible. The control line is always visible due to the binding of the Ab-AuNPs to the control line.

**【COMPONENTS】**

- Urine collection cup ×1
- Test tube ×1
- Test strip in sealed pouch x1
- Dropper ×1

**【WARNINGS AND PRECAUTIONS】**

- For *in vitro* diagnostic use only (not for internal use).
- Be careful when handling urine because it may contain infectious agents. Always wear gloves and wash hands with soap and water after handling urine.
- To ensure that the test will work properly the testing instructions must be followed. Failure to do so may result in inaccurate results.
- Avoid exposure of your skin and eyes to the solution in the extraction tube. The reagent solution in the tube contains a harmful chemical (see table below). If the solution contacts the skin or eyes, flush with large amounts of water. If irritation persists, seek medical advice. https://www.poisonhelp.org or 1-800-222-1222

| Hazardous Ingredients for the Reagent Solution | | |
|---|---|---|
| Chemical Name | Harms (GHS) code for each ingredient | Concentration |
| Sodium Azide | H314 Causes severe skin burns and eye damage<br>H318 Causes serious eye damage | 0.1% |

- IF ON SKIN: Gently wash with plenty of soap and water. Immediately call a POISON CENTER or doctor/ physician.
- If EYE Contact: Immediately flush eyes with plenty of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Get medical attention immediately.
- Get medical advice/attention if you feel unwell.

**【STORAGE AND STABILITY】**

Store ALL test components at room temperature 59°F to 86°F (15–30 °C) until the expiration date on the label. Do not freeze. When stored and handled as directed, unopened reagents are stable until the expiration date on the label. Do not open pouch until ready to perform the assay. Improper storage of reagents can affect assay performance.

**【SPECIMEN COLLECTION AND PREPARATION】**

The InstaStrip Fentanyl Rapid Test (Urine) is formulated for use with urine specimens. Do not centrifuge or add preservatives to urine. Urine samples should be collected so that testing may be performed as soon as possible, preferably during the same day. Specimens that have been refrigerated must be brought to room temperature prior to testing. Previously frozen specimens must be thawed, brought to room temperature, and mixed thoroughly prior to testing. Note: All materials coming in contact with urine specimens should be handled and disposed of as if potentially infectious. Avoid contact and follow good laboratory practice.

**[REAGENT HANDLING]**

The reagent and test strip are provided ready to use.
Do not use kits or components after the expiration date given on the label.
Do not mix reagents from different kit lots.

**[MATERIALS]**

**Materials Provided**

Urine collection cup, test tube, test strip, dropper

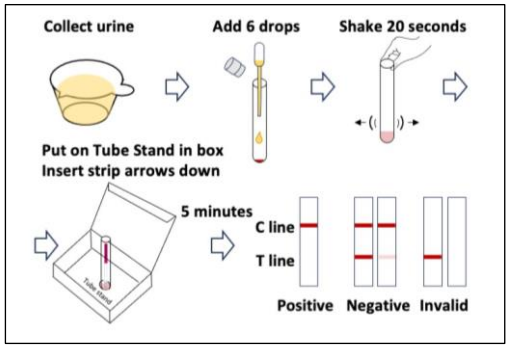
**Materials Required But Not Provided**

Timer

**[DIRECTIONS FOR USE]**

Refer to the illustration below.

1. Collect urine in the provided urine collection cup.
2. Pull off the test tube cap, use the provided dropper to transfer 6 drops of urine (approximately 150 μL) to the test tube bottom, discard the dropper.
3. Gently shake the test tube for 20 seconds, until the red pellet at the bottom disappears. Sample turns pink.
4. Place the test tube on the tube stand in the box.
5. Remove the test strip from the sealed pouch and insert into the test tube, arrows facing down. Recap the test tube.
6. Start the timer for 5 minutes.
7. At the end of 5 minutes, place the test tube against the result read chart to read your result. Do not interpret the result after 20 min.
8. If preliminary positive results are observed, send the urine sample to the laboratory for confirmation.




**【INTERPRETATION OF RESULTS】**

Refer to the illustration above.
**NEGATIVE:* Two colored lines appear.** One colored line should be in the control line region (C line) and another colored line should be in the test line region (T line). A negative result indicates that the Fentanyl concentration is below the detectable level (1 ng/mL).
***NOTE:** A faint colored line at T line should be read as negative.
**POSITIVE: One colored line appears in the control line region (C).** No line appears in the test line region (T). A positive result indicates that the Fentanyl concentration exceeds the detectable level (1 ng/mL).
**INVALID: Control line fails to appear.** Incorrect test procedures are the most likely reasons for invalid results. Review the procedure and repeat the test using a new test. If the problem persists, discontinue using the lot immediately and contact your local distributor.

**【QUALITY CONTROL】**

An internal procedural control has been built into the test to ensure that the test performs properly. The appearance of a line in the control region (C line) serves as the internal procedural control to verify that the reagents in the test are still working, and that the test is valid.
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. Such controls can be made by spiking a fentanyl standard (eg. Cerilliant catalog number F-013) into drug free human urine at ±50% of the cutoff concentration. User should follow federal, state and local guidelines for testing quality control materials. Laboratories should comply with all federal state, and local laws, as well as all guidelines.

**[LIMITATIONS]**

- Use the test with human urine only.
- The test is for one time use only; it is not reusable.
- This test provides only a preliminary result. A more specific alternative method must be used to obtain a confirmed analytical result. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive. Gas or liquid chromatography/mass spectrometry is the preferred confirmatory method.
- A contaminated or tainted urine sample may give false results.

**【PERFORMANCE CHARACTERISTICS】**

**Accuracy**

Eighty-five unaltered clinical urine samples with fentanyl concentrations measured by an LC-MS/MS method in a CLIA laboratory were tested using the InstaStrip Fentanyl Rapid Test (Urine). Each sample was tested by three operators blinded to the LC-MS/MS results. The results are listed below.

| | | LC-MS/MS Result | | | | |
|---|---|---|---|---|---|---|
| **Operator** | **InstaStrip Result** | **Negative** | **Low Negative by LC/MS (less than -50%)** | **Near Cutoff Negative by LC/MS (Between -50% and cutoff)** | **Near Cutoff Positive by LC/MS (Between the cutoff and +50%)** | **High Positive by LC/MS (greater than +50%)** |
| Operator 1 | Positive | 0 | 0 | 1 | 7 | 36 |
| | Negative | 11 | 21 | 9 | 0 | 0 |
| Operator 2 | Positive | 0 | 0 | 0 | 7 | 36 |
| | Negative | 11 | 21 | 10 | 0 | 0 |
| Operator 3 | Positive | 0 | 0 | 0 | 6 | 36 |
| | Negative | 11 | 21 | 10 | 1 | 0 |

**Analytical Specificity**

The cross reactivity of the InstaStrip Fentanyl Rapid Test (Urine) to the fentanyl analogs tested in urine is listed below.

| **Compounds for cross reactivity** | **Concentration Approximately Equivalent to the Cutoff(ng/mL)** | **Percent (%) cross reactivity** |
|---|---|---|

| | | |
|---|---|---|
| Acetyl fentanyl | 1 | 100 |
| Acetyl norfentanyl | >10000 | <0.01 |
| Acrylfentanyl | 1.8 | 56 |
| Alfentanil | >10000 | <0.01 |
| Benzodioxole fentanyl | 4.8 | 21 |
| Butyryl fentanyl | 1 | 100 |
| Carfentanil | >10000 | <0.01 |
| Crotonyl fentanyl | 1 | 100 |
| Despopionyl 2' fluoro-ortho-fluorofentanyl | >10000 | <0.01 |
| Despropionyl fentanyl (4-ANPP) | 10000 | 0.01 |
| Furanyl fentanyl | 1.9 | 53 |
| (±) β-hydroxythiofentanyl | 7.5 | 13 |
| Isobutyryl fentanyl | 1.7 | 59 |
| N-benzyl furanyl norfentanyl | >10000 | <0.01 |
| N-benzyl parafluoro cyclopropyl norfentanyl | >10000 | <0.01 |
| (±)-3-cis-methyl fentanyl | 9.2 | 11 |
| Norcarfentanil | >10000 | <0.01 |
| Norfentanyl | >10000 | <0.01 |
| o-Fluorofentanyl | 1 | 100 |
| 4-Fluoro-isobutyryl fentanyl | 1 | 100 |
| Ocfentanil | 2.2 | 45 |
| Para-chloroisobutyrul fentanyl | 1.8 | 56 |
| Para-fluoro fentanyl | 2.8 | 36 |
| Para-fluorobutyryl fentanyl (p-FBF) | 2.5 | 40 |
| Remifentanil | >10000 | <0.01 |
| Sufentanil | >10000 | <0.01 |
| Tetrahydrofyranyl fentanyl | 2.3 | 43 |
| Valeryl fentanyl | 2.9 | 34 |
| β-hydroxyfentanyl | 7.5 | 13 |
| ω-1-Hydroxyfentanyl | 7.5 | 13 |

The following structurally related compounds were tested at 100 µg/mL in urine. Negative results were obtained for all compounds. There is no cross-reactivity for these compounds using the InstaStrip Fentanyl Rapid Test (Urine).

| | | |
|---|---|---|
| 6-Acetyl morphine | Hydrocodone | Ofloxacin |
| Amphetamine | Hydromorphone | Oxycodone |
| Buprenorphine | Ketamine | Oxymorphone |
| Buprenorphine glucuronide | Levorphanol | Pentazocine (Talwin) |
| Ceftriaxone | MDMA | Pipamperone |
| M-Chlorophenylpiperazine | Meperidine | 1-(3-chlorophenyl) Piperazine (hydrochloride) |
| Ciprofloxacin | Methadone | Quinidine |
| Cocaine | Methamphetamine | Risperidone |
| Codeine | Morphine | Tapentadol |
| Dextromethorphan | Morphine-3-glucuronide | Thioridazine |
| Dihydrocodeine | Naloxone | Tilidine |
| Diphehydramine | Naltrexone | Tramadol |
| Duloxetine | Norbuprenorphine | Tramadol-O- Desmethyl |
| EDDP | Norcodeine | Tramadol-N- Desmethyl |
| EMDP | Norketamine | Trazodone |
| Fluoxetine | Normeperidine | |
| Haloperidol | Normorphine | |
| Heroin | Noroxycodone | |

**Precision**

Precision studies were carried out for samples with concentrations of -100% cut off, -75% cut off, -50% cut off, -25% cut off, cut off, +25% cut off, +50% cut off, +75% cut off and +100% cut off. These samples were prepared by spiking fentanyl in negative samples. Each fentanyl concentration was confirmed by LC/MS. All sample aliquots were blindly labeled by the person who prepared the samples and didn't take part in the sample testing. For each concentration, tests were performed six tests per day for 10 days per device lot in a randomized order.

| Concentration (ng/mL) | n | Lot 1 | | Lot 2 | | Lot 3 | |
|---|---|---|---|---|---|---|---|
| | | + | - | + | - | + | - |
| 0 | 60 | 0 | 60 | 0 | 60 | 0 | 60 |
| 0.25 | 60 | 0 | 60 | 0 | 60 | 0 | 60 |
| 0.5 | 60 | 0 | 60 | 0 | 60 | 0 | 60 |
| 0.75 | 60 | 6 | 54 | 5 | 55 | 5 | 55 |
| 1 | 60 | 32 | 28 | 30 | 30 | 34 | 26 |
| 1.25 | 60 | 60 | 0 | 60 | 0 | 60 | 0 |
| 1.5 | 60 | 60 | 0 | 60 | 0 | 60 | 0 |
| 1.75 | 60 | 60 | 0 | 60 | 0 | 60 | 0 |
| 2 | 60 | 60 | 0 | 60 | 0 | 60 | 0 |

**Effect of Urinary pH and Specific Gravity**

To investigate the effect of urine specific gravity and urine pH, urine samples, with 1.000 to 1.035 specific gravity or urine samples with pH 4 to 9 were spiked with target fentanyl at 50% below and 50% above Cut-Off levels. These samples were tested using three lots of device. Results were all positive for samples at and above +50% Cut-Off and all negative for samples at and below -50% Cut-Off.

**Interference-Structurally Unrelated Compounds**

Structurally unrelated and potentially interfering compounds found in human urine of physiological or pathological conditions were added to drug-free urine. These samples were spiked with fentanyl to 0.5 ng/mL and 1.5 ng/mL. The urine samples were tested using three batches of InstaStrip Fentanyl Rapid Test (Urine). No interference was observed for the following compounds at 100 µg/mL or specified concentrations.

| | | | |
|---|---|---|---|
| Acetaminophen (500 µg/mL) | Cyclobenzaprine | Labetalol (15 µg/mL) | Phencyclidine |
| Acetone (1000 mg/dL) | Deoxycorticosterone | Lidocaine | Phenelzine |
| Acetophenetidin | Desipramine | Loperamide | Phenobarbital |
| Acetylsalicylic acid | Dextromethorphan | Maprotiline | Prednisone |
| Albumin (500 mg/dL) | Diclofenac | Meperidine | Propoxyphene |
| Albuterol | Diflunisal | Meprobamate | Propranolol |
| Aminopyrine | Digoxin | Methapyrilene | Pseudoephedrine |
| Amitriptyline | Diphenhydramine | Methaqualone | Quinine (15 µg/mL) |
| Amobarbital | DL-Tryptophan | Methoxyphenamine | Ranitidine |
| Amoxicillin | DL-Tyrosine | Metronidazole (300 µg/mL) | Riboflavin (10 mg/dL) |
| Ampicillin | Doxepin | N-Acetylprocainamide | Salicylic acid |
| Apomorphine | Ecgonine methyl ester | NaCl (4000 mg/dL) | Secobarbital |
| Ascorbic Acid (560 mg/dL) | Ephedrine | Nalidixic acid | Serotonin (5-hydroxytyramine) |
| Aspartame | Erythromycin | Naloxone | Sulfamethazine |
| Atropine | Ethanol (1%) | Naltrexone | Sulindac |
| Benzilic acid | Fenoprofen | Naproxen | Tetrahydrocortisone 3-(β-D-glucuronide) |
| Benzoic acid | Fluphenazine | Niacinamide | Tetrahydrocortisone 3-acetate |
| Benzoylecgonine | Furosemide | Nicotine | Tetrahydrozoline |
| Bilirubin | Galactose (10 mg/dL) | Nifedipine | Thiamine |
| Boric acid (1% w/v) | Gamma globulin (500 mg/dL) | Norethindrone | Thioridazine |
| Bupropion | Gentisic acid | | Triamterene |
| Caffeine | Glucose (3000 mg/dL) | Nortriptyline | Trifluoperazine |
| Carbamazepine | Hemoglobin (500 mg/dL) | Noscapine | Trimethoprim |
| Chloral hydrate | Hydralazine | Octopamine | Tyramine |
| Chloramphenicol | Hydrochlorothiazide | O-Hydroxyhippuric acid | Urea (2000 mg/dL) |
| Chlorothiazide | Hydrocortisone | Oxalic acid (100 mg/dL) | Uric acid |
| Chlorpromazine | Hydroxytyramine | Oxazepam | Valproic acid (250 µg/mL) |
| Cholesterol | Ibuprofen (500 µg/mL) | Oxolinic acid | Venlafaxine |
| Clomipramine | Imipramine | Oxymetazoline | Verapamil (20 µg/mL) |
| Clonidine | Isoproterenol | Papaverine | Zomepirac |
| Cortisone | Isoxsuprine (20 µg/mL) | Penicillin G | β-Estradiol |
| Cotinine | Ketamine | Perphenazine | |
| Creatinine (500 mg/dL) | Ketoprofen | | |

**[BIBLIOGRAPHY]**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| Symbol | Meaning |
|---|---|
| | Consult instruction for use |
| IVD | In-Vitro Diagnostic Medical Device |
| | Manufacturer |
| LOT | Batch code |
| REF | Product Information |
| | Do not reuse |
| | Temperature Limitation |
| | Use by date |
| Σ | Contains sufficient for <n>test |
| | Do not use if package is damaged and consult instructions for use |


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