# Rapid Fentanyl Urine Test

**For *in vitro* diagnostic use only.** ***CLIA WAIVED***

***Medical and other professional in vitro diagnostic use labeling.***

## INTENDED USE

The *EKLA Rapid Fentanyl Urine Test* is a rapid visual immunoassay for the qualitative, presumptive detection of Fentanyl in human urine specimens at a cut-off concentration of 1.0 ng/mL. It is for *in vitro* diagnostic use only.

The tests provide only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

## Contents of the kit

### Materials Provided

- Test devices
- Disposable pipettes
- Package insert

### Materials Required but Not provided

- Timer
- Specimen collection container

## PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package.
- Do not use the test if the foil pouch or canister is damaged.
- Do not reuse tests.
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Humidity and temperature can adversely affect results.

## STORAGE AND STABILITY

- The kit should be stored at 36-86℉(2-30°C) until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch or closed canister until use.
- Do not freeze.
- Kits should be kept out of direct sunlight.

## PROCEDURE

**Bring tests to room temperature (59-86℉(15-30°C)) before use.**

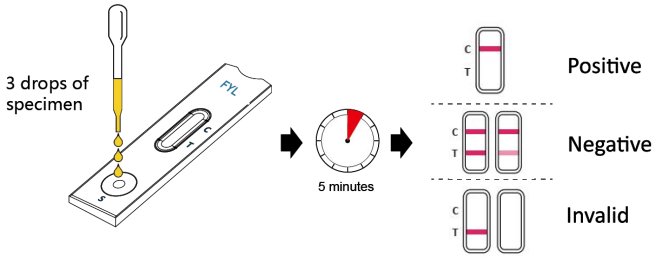
1. **Collect Urine Sample**

   Collect urine in a clean and dry container.

2. Remove the test from its sealed pouch, and place it on a clean, level surface.
3. Using the provided disposable pipette, transfer 3 drops of specimen to the specimen well (S) of the device and start the timer.

   **Do not add any solution to the result area.**

   As the test begins to work, color will migrate across the membrane.
4. Wait for the colored band(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.




## INTERPRETATION OF RESULTS

**POSITIVE: Only one colored band appears, in the control region (C).** No apparent colored band appears in the test region (T).

**NEGATIVE: Two colored bands appear on the membrane.** One band appears in the control region (C) and another band appears in the test region (T).

**INVALID: Control band fails to appear.** Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

**NOTE:**

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered negative. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

## LIMITATIONS

1. The *EKLA Rapid Fentanyl Urine Test* should be only used for the qualitative detection of Fentanyl.
2. This assay provides a preliminary analytical test result only.
3. There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results.
4. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. Therefore, please preclude the possibility of urine adulteration prior to testing.
5. A positive result indicates the presence of a Fentanyl only, and does not indicate or measure intoxication.
6. A negative result does not at any time rule out the presence of Fentanyl in urine, as they may be present below the minimum detection level of the test.
7. This test does not distinguish between Fentanyl and certain medications.

## QUALITY CONTROL

1. Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal procedural control, confirming sufficient specimen volume and correct procedural technique.
2. External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.
3. 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 and regulations.

## PERFORMANCE CHARACTERISTICS

### A. Accuracy

The accuracy of the test was confirmed by testing 82 clinical urine specimens in parallel with LC-MS. The results are shown below.

| Test | | 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 cutoff and +50%) | High Positive by LC/MS (greater than +50%) |
|---|---|---|---|---|---|---|
| Operator 1 | Positive | 0 | 0 | 2 | 16 | 22 |
| | Negative | 5 | 16 | 19 | 2 | 0 |
| Operator 2 | Positive | 0 | 0 | 2 | 16 | 22 |
| | Negative | 5 | 16 | 19 | 2 | 0 |
| Operator 3 | Positive | 0 | 0 | 3 | 17 | 22 |
| | Negative | 5 | 16 | 18 | 1 | 0 |

% agreement among positives is 95.8%
% agreement among negatives is 94.4%

### B. Specificity and Cross-reactivity

The minimum concentration required to obtain a positive result of the drug metabolites and other components for the test is listed below.

| Compounds | Minimum concentration required to obtain a positive result (ng/mL) | % Cross-Reactivity |
|---|---|---|
| Acetyl fentanyl | 5 | 20.00 |
| Acrylfentanyl | 5 | 20.00 |
| ω-1-Hydroxyfentanyl | 50000 | 0.002 |
| Isobutyryl fentanyl | 5 | 20.00 |
| Ocfentanil | 100 | 1.00 |
| Butyryl fentanyl | 25 | 4.00 |
| Furanyl fentanyl | 10 | 10.00 |
| Valeryl fentanyl | 50 | 2.00 |
| (±) β-hydroxythiofentanyl | 5 | 20.00 |
| 4-Fluoro-isobutyrylfentanyl | 50 | 2.00 |
| Para-fluorobutyryl fentanyl | 25 | 4.00 |

| | | |
|---|---|---|
| Para-fluoro fentanyl | 25 | 4.00 |
| (±)-3-cis-methyl fentanyl | 50 | 2.00 |
| Carfentanil | 10000 | 0.01 |
| Despropionyl fentanyl (4-ANPP) | 50000 | 0.002 |
| Sufentanil | >10000 | <0.01 |
| Alfentanil | >100000 | <0.001 |
| Remifentanil | >10000 | <0.01 |
| Norfentanyl | >100000 | <0.001 |
| Acetyl norfentanyl | >100000 | <0.001 |
| Norcarfentanil | >10000 | <0.01 |

The opioids compounds at the concentration listed below are verified to be no cross-reactivity for the test.

| Compounds | Concentration |
|---|---|
| 6-Acetyl morphine | 100 ug/mL |
| Amphetamine | 100 ug/mL |
| Buprenorphine | 100 ug/mL |
| Buprenorphineglucuronide | 100 ug/mL |
| Codeine | 100 ug/mL |
| Dextromethorphan | 100 ug/mL |
| Dihydrocodeine | 100 ug/mL |
| EDDP | 100 ug/mL |
| EMDP | 100 ug/mL |
| Fluoxetine | 100 ug/mL |
| Heroin | 100 ug/mL |
| Hydrocodone | 100 ug/mL |
| Hydromorphone | 100 ug/mL |
| Ketamine | 100 ug/mL |
| Levorphanol | 100 ug/mL |
| Meperidine | 100 ug/mL |
| Methadone | 100 ug/mL |
| Morphine | 100 ug/mL |
| Morphine-3-glucuronide | 100 ug/mL |
| Naloxone | 100 ug/mL |
| Naltrexone | 100 ug/mL |
| Norbuprenorphine | 100 ug/mL |
| Norcodeine | 100 ug/mL |
| Norketamine | 100 ug/mL |
| Normeperidine | 100 ug/mL |
| Normorphine | 100 ug/mL |
| Noroxycodone | 100 ug/mL |
| Oxycodone | 100 ug/mL |
| Oxymorphone | 100 ug/mL |
| Pentazocine (Talwin) | 100 ug/mL |
| Pipamperone | 100 ug/mL |
| Risperidone | 100 ug/mL |
| Tapentadol | 100 ug/mL |
| Thioridazine | 100 ug/mL |
| Tilidine | 100 ug/mL |
| Tramadol | 100 ug/mL |
| Tramadol-O-Desmethyl | 100 ug/mL |
| Tramadol-N-Desmethyl | 100 ug/mL |
| Trazodone | 100 ug/mL |

**C. Precision**

| Result / Drug Conc. % of cutoff | Lot 1 | Lot 2 | Lot 3 |
|---|---|---|---|
| -100% | 60(-)/ 0(+) | 60(-)/ 0(+) | 60(-)/ 0(+) |
| -75% | 60(-)/ 0(+) | 60(-)/ 0(+) | 60(-)/ 0(+) |
| -50% | 60(-)/ 0(+) | 60(-)/ 0(+) | 60(-)/ 0(+) |
| -25% | 58(-)/2(+) | 58(-)/2(+) | 57(-)/ 3(+) |
| cutoff | 35(+)/ 25(-) | 36(+)/24(-) | 35(+)/ 25(-) |
| +25% | 60(+)/0(-) | 60(+)/0(-) | 60(+)/0(-) |
| +50% | 60(+)/0(-) | 60(+)/0(-) | 60(+)/0(-) |
| +75% | 60(+)/0(-) | 60(+)/0(-) | 60(+)/0(-) |
| +100% | 60(+)/0(-) | 60(+)/0(-) | 60(+)/0(-) |

**D. Effect of Urine Density and pH**

Eight urine samples of different urine density were tested. The results showed that varying urine density did not affect the test results.

Six urine samples of different pH from acidic to basic were tested. The results showed that varying ranges of pH did not affect the test results.

**E. Interference**

The compounds listed below showed no interference.

| | | |
|---|---|---|
| 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 | Tetrahydrocortisone3-(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 | |

**Index of Symbols**

| | | | | | |
|---|---|---|---|---|---|
|  | Consult instructions for use or consult electronic instructions for use |  | Contains sufficient for <n> tests |  | Store between 35.6-86°F (2-30°C) |
|  | *In vitro* diagnostic medical device |  | Batch code |  | Catalogue number |
|  | Manufacturer |  | Use-by date |  | Do not re-use |
|  | Do not use if package is damaged and consult instructions for use |  | Unique device identifier | | |

## *CLIA WAIVED*

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