

## Fentanyl (FTY) Test Dip Card 20(Colloidal Gold)

### FOR IN VITRO DIAGNOSTIC USE

#### PACKING SPECIFICATION

25 Tests/ Kit (SUPG266025)

#### INTENDED USE

This product is suitable for qualitative detection of Fentanyl (FTY) in human urine samples.

Fentanyl (FTY), a powerful narcotic analgesic, is a special opioid receptor stimulant. Fentanyl is one of the varieties regulated by the United Nations Single Convention on Narcotic Drugs of 1961. Among internationally controlled opiates, fentanyl is one of the most commonly used drugs to treat moderate to severe pain. After continuous fentanyl injections, patients will develop symptoms of opioid withdrawal syndrome, such as endocrine disorders, irritability, etc., and addiction after long-term fentanyl use.

The test results of this product are for clinical reference only, and cannot be used solely as the basis for confirming or excluding cases. For further confirmation and evaluation of urine samples, detection should be carried out using more sensitive and specific detection methods, such as Gas Chromatography-Mass Spectrometer (GC-MS), High Performance Liquid Chromatography (HPLC), etc.

#### PRINCIPLE OF THE PROCEDURE

This product adopts the principle of competitive inhibition and colloidal gold immunochromatography, using colloidal gold labeled monoclonal antibody as indicator marker, to qualitatively detect FTY in human urine samples.

The test card contains a FTY test strip. The nitrocellulose membrane test area (T) was coated with FTY-bovine serum albumin conjugate, and the quality control area (C) was coated with sheep anti-rabbit IgG polyclonal antibody. FTY monoclonal antibody and rabbit IgG polyclonal antibody were labeled with colloidal gold. When the FTY concentration of the sample is higher than or equal to the minimum detection limit of the product, the colloidal gold labeled monoclonal antibody will be competitively bound with the corresponding conjugate coated on the test area (T), and the color of the detection line is inhibited and the result is positive. When the sample does not contain FTY or its concentration is below the minimum detection limit of the product, the corresponding conjugate on the test line reacts with sufficient colloidal gold labeled monoclonal antibody, the test line will be colored, and the result is negative. The quality control area (C) will be colored regardless of whether the sample contains the corresponding substance to be tested, which is the criterion to judge whether the chromatography process is normal.

#### COMPONENT

1. Main components:

Specification		25 tests/kit
Ingredients		
Test Card with Desiccant in a Sealed Foil Pouch		25
Instruction for use		1

#### MATERIALS REQUIRED BUT NOT PROVIDED

- Urine cups or clean containers
- Timer

**Note:** Ingredients from different batches of the kit should not be mixed

#### STORAGE AND STABILITY

- Kits should be stored at 4°C~30°C in a cool, dark, dry place, valid for 24 months.
- The test card should be used as soon as possible within 1 hour after the aluminum foil pouch is unsealed.

- Do not freeze.
- MFD date and EXP date: marked on the label.

#### OPERATION STEPS

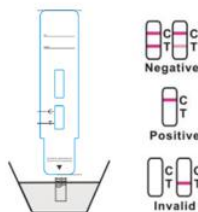
##### Sample Requirement

- Applicable sample type: urine.
- Urine samples must be collected using disposable urine cups or clean containers.
- Test with fresh urine at room temperature. If urine cannot be detected in time, it can be stored at 2°C to 8°C for 48 hours, and stored at -20°C or lower temperature for longer time. Samples should be restored to room temperature before detection, and repeated freeze-thaw should not be avoided.
- The test sample should be clarified. If the urine shows turbid precipitation, the supernatant should be taken for detection after centrifugation precipitation.
- Specimens shall be transported in ice boxes and ice or sealed in foam boxes and ice.
- Samples should be handled in accordance with local biosafety requirements

##### Test Procedure

Please read the instructions carefully before testing. The test should be carried out at room temperature (18°C~26°C). So as not to affect the accuracy of the experimental results.

- Remove the sample to be tested and the reagent required from the storage condition and balance to room temperature.
- Tear the aluminum foil bag along the incision, remove the test card and mark it.
- Remove the cap from the end of the test card and dip the test strip vertically into the urine specimen with the arrow pointing at the urine specimen. Note that the liquid level does not exceed the warning position line.
- After 10-15 seconds, the liquid runs past the top of the visual field window, remove the test card, place the card flat on the table, and start timing.
- The results should be observed within 5 minutes and showed no clinical significance after 10 minutes.



#### INTERPRETATION OF TEST RESULTS

Positive (+): only one purplish red band appears in the quality control area (C), and no purplish red band appears in the test area (T). The positive results showed that the drug concentration in urine was above its threshold.

Negative (-): two purplish red bands appear. One is located in the test area (T) and the other is located in the quality control area (C). The negative results showed that the drug concentration in urine was below its threshold.

Invalid: there is no purplish red strip in the control area (C). It indicates improper operation or the kit has failed. In this case, carefully read the instructions again and retest with a new reagent. If the problem persists, stop using this batch number of products immediately and contact the local supplier.

#### LIMITATIONS

- This product is only used for qualitative detection of FTY in urine samples. If you need to detect the specific content, please use relevant professional instruments, such as gas chromatography analysis.
- This method may lead to false negative results for the following reasons: the drug concentration in the sample is lower than the minimum detection limit of the detection reagent, and the low concentration sample cannot be detected; Improper

operation during test or other factors that may affect test, such as improper transportation and storage render reagents ineffective, etc.

- This method may lead to false positive results due to: such as the subject takes some relevant drugs or eats some relevant food.

#### QUALITY CONTROL

- Coincidence rate of positive quality control

The test results of 3 positive quality control P1 ~ P3 were all positive, and the positive coincidence rate was 3/3 (+/+).

- Coincidence rate of negative quality control

The test results of 7 negative quality control N1 ~ N7 were all negative, and the negative coincidence rate was 7/7 (-/-).

- Repeatability

The repeatability control R test was tested for 10 times, and the results were all positive and consistent.

- LOD (limit of detection)

The LOD control L1-L3 with different concentrations was tested. L1 was negative and L2-L3 was positive.

**Note:** P1 ~ P3, N1 ~ N7, R, L1~L3 are all samples of enterprise internal control.

#### PRODUCT PERFORMANCE INDEX

##### Sensitivity/minimum detection limit:

The Fentanyl (FTY) Test Dip Card 20(Colloidal Gold) is used for qualitative detection of FTY in human urine samples, and the threshold / minimum detection limit is 20 ng/ml.

##### Specificity:

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine with the concentration 50% below and above the minimum detection limit, respectively. All potential interfering substances were added at a concentration of 100µg/mL. The urine specimens were tested with the test device. None of the urine samples showed any deviation from the expected results.

Acetaminophen	Cotinine	Ketoprofen	Phenelzine
Acetophenetidin	Creatinine	Loperamide	D,L-Propranolol
N-Acetylprocainamide	Deoxycorticosterone	Maprotiline	D-Propoxyphene
Acetylsalicylic Acid	Dextromethorphan	Meprobamate	D-Pseudoephedrine
Aminopyrine	Diclofenac	Labetalol	Quinidine
Amoxicillin	Diffunisal	Meperidine	Quinine
Ampicillin	Digoxin	Meprobamate	Ranitidine
Ascorbic Acid	Diphenhydramine	Methylphenidate	Salicylic acid
Apomorphine	(-)-ψ-Ephedrine	Nalidixic Acid	Serotonin (5-Hydroxytyramine)
Aspartame	β-Estradiol Ethyl-p-aminobenzoate	Naloxone	Sulfamethazine
Atropine	Ethyl-p-aminobenzoate	Naltrexone	Sulindac
Benzilic Acid	Fenoprofen	Naproxen	Tetracycline
Benzoic Acid	Furosemide	Niacinamide	Tetrahydrocortisone, 3 Acetate

Benzphetamine	Gentisic Acid	Nifedipine	Thiamine
D,L-Brompheniramine	Hemoglobin	Norethindrone	Thioridazine
Caffeine	Hydralazine	D-Norpropoxyphene	D, L-Tyrosine
Chloralhydrate	Hydrochlorothiazide	Noscapine	Tolbutamide
Chloramphenicol	Hydrocortisone	D,L-Octopamine	Triamterene
Chlorothiazide	O-Hydroxyhippuric Acid	Oxalic Acid	Trifluoperazine
(±) Chlorpheniramine	p-Hydroxytyramine	Oxolinic Acid	Trimethoprim
Chlorpromazine	Ibuprofen	Oxymetazoline	D, L-Tryptophan
Chloroquine	Iproniazid	Papaverine	Tyramine
Cholesterol	Isoproterenol	Penicillin-G	Uric Acid
Clonidine	Isosuprine	Pentazocine	Verapamil
Cortisone	Ketamine	Perphenazine	Zomepirac







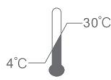









#### PRECAUTIONS

1. This product is a disposable in vitro diagnostic reagent, do not reuse, do not use expired products.
2. This product is suitable for testing human urine samples. Abnormal results may occur when testing with other samples or solutions.
3. The desiccant in the aluminum foil pouch should not be taken internally.
4. Dilution and unclean samples or improper handling may produce incorrect results. A new collection container should be used for each sample to avoid contamination of the sample.
5. Too early, too late or in the dark light interpretation of the results, can produce false results.
6. Due to the difference of samples, the color depth of test area (T) and quality control area (c) may be different during the test, but as long as it is visible, regardless of its color depth, it shall be regarded as occurring.
7. Urine samples, laboratory waste, disposable items, etc. should be disposed of as potential infectious substances.
8. Safety operation regulations should be observed during the test operation, and work clothes, gloves, etc. should be properly worn during the operation.
9. As with all diagnostic reagents, the final diagnosis should be made by a physician who considers all test indicators and clinical symptoms.

#### BIBLIOGRAPHY

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#### Key to symbols used:

	<b>In Vitro Diagnostic Medical Device</b>		<b>Materials Included</b>
	<b>Test Card with Desiccant in a Sealed Foil Pouch</b>		<b>Instruction for Use</b>
	<b>Consult Instructions For Use</b>		<b>Date of Manufacture</b>
	<b>Store at 4~30°C</b>		<b>Do Not Reuse</b>
	<b>Expiration Date</b>		<b>Catalogue Number</b>
	<b>Manufacturer</b>		<b>Keep away from Sunlight</b>
	<b>Lot Number</b>		<b>Tests per Kit</b>
	<b>Authorized Representative</b>		<b>Keep Dry</b>



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