CLIA WAIVED

Accurate Rapid Fentanyl Test Strip (Urine)

Instructions For Use

A rapid test for the qualitative detection of FEN (Fentanyl) in human urine.

For in vitro diagnostic use only.

For medical and other professional in vitro diagnostic labeling.

INTENDED USE

The Healgen® Accurate Rapid Fentanyl Test Strip (Urine) is an immunoassay intended for the qualitative detection of fentanyl in human urine at a cutoff concentration of 1.0 ng/mL.

This test provides only a preliminary result. A more specific alternative chemical method must be used to obtain a confirmed presumptive positive result. Gas Chromatography-Mass Spectrometry (GC-MS), Liquid Chromatography-Mass Spectrometry (LC-MS), and their tandem mass-spectrometer versions are the preferred confirmatory methods. Careful consideration and judgment should be applied to any drugs of abuse screen test result, particularly when evaluating preliminary positive results.

SUMMARY

Fentanyl is a short-acting, synthetic narcotic analgesic that is 100 times stronger than morphine. The drug was developed in 1959 and was originally intended as an adjunct to anesthesia during surgery. For chronic pain management, the drug is also available as a transdermal patch, or in lollipop form. In the illicit drug market, diversion of these prescription versions of fentanyl has been displaced by clandestine fentanyl, which is often added to other street drugs without the knowledge of the user. As a result, fentanyl is a major contributor to fatal and nonfatal overdoses.[1, 2, 3] The need for a rapid, accurate method to determine potential fentanyl use is paramount to patient triage and treatment.
The Healgen® Accurate Rapid Fentanyl Test Strip (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The Healgen® Accurate Rapid Fentanyl Test Strip (Urine) yields a positive result when Fentanyl in urine exceeds 1.0 ng/mL.

PRINCIPLE

The Healgen® Accurate Rapid Fentanyl Test Strip (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.
During testing, a urine specimen migrates upward by capillary action. Fentanyl, if present in the urine specimen below 1.0 ng/mL, will not saturate the binding sites of antibody-coated particles in the test device. The antibody-coated particles will then be captured by immobilized FEN conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the FEN level exceeds 1.0 ng/mL because it will saturate all the binding sites of anti-FEN antibodies.
A drug-positive urine specimen will not generate a colored line in the test line region, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cutoff will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred. The test device contains mouse monoclonal antibody-conjugated particles and corresponding drug-protein conjugates. Goat antibodies are employed in the control line system.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only. Do not use after the expiration date.
2. The test is for single-use. Do not reuse it.
3. Do not touch the test zone of the Test Strip.
4. The test should remain in the sealed pouch until use.
5. Do not ingest the desiccant. The function of the desiccant is to keep the Test Strip dry.
6. Every specimen should be collected using a new container to avoid contamination.
7. All specimens should be considered potentially hazardous and handled accordingly.
8. Do not pass the maximum line (MAX) on the test strip when immersing the strip. If it passed, please retest with a new test strip.
9. The used test device should be discarded according to local regulations.
10. The user should not take any decision of medical relevance without first consulting his/her medical practitioner.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 36-86°F (2-30°C). The test is valid for 24 months and remains stable through the expiration date printed on the sealed pouch. The Test Strips must remain in the sealed pouch until use. **DO NOT FREEZE**. The lot and the expiration date are printed on the foil packaging and outer package (e.g. box/bag). Do not use beyond the expiration date.

MATERIALS

Materials Provided

- Test Strip
- Instructions For Use

Materials Required But Not Provided

- Timer, clock, or watch
- Specimen Collection Containers (and container lid, if applicable)

REAGENTS / REACTIVE INGREDIENTS

The Test Strip is packaged in sealed aluminum foil pouch with a desiccant. The test device contains mouse monoclonal antibody-conjugated particles and corresponding drug-protein conjugates. Goat antibodies are employed in the control line system.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used.

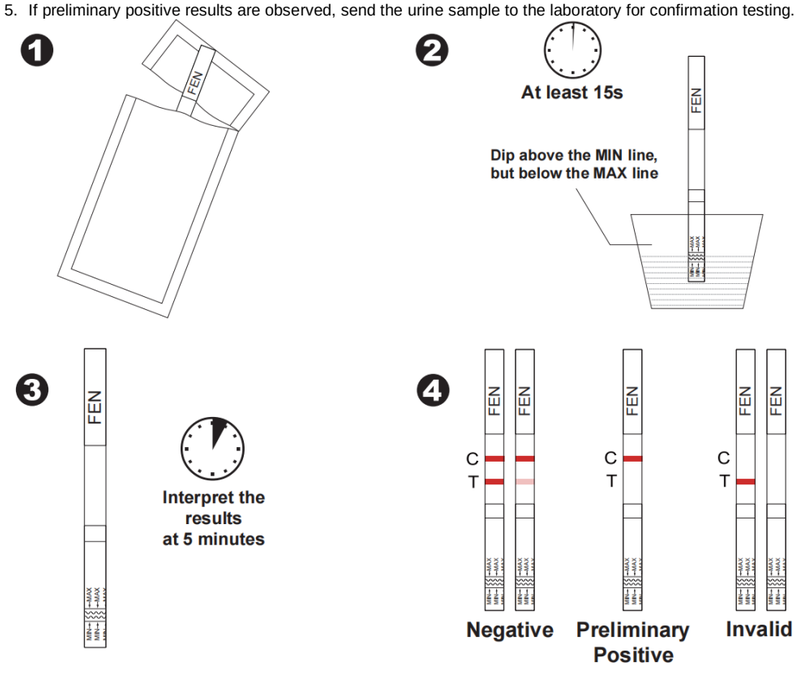
Specimen Storage

Urine specimens may be stored at 36-46°F (2-8°C) for up to 48 hours prior to testing. For long-term storage, specimens may be frozen and stored below -4°F (-20°C). Specimens can be frozen and thawed up to 3 times when stored at -4°F (-20°C).. Frozen specimens should be thawed and mixed before testing.

DIRECTIONS FOR USE

If refrigerated, allow the test, urine specimen and/or controls to reach room temperature [59-86° F (15-30° C)] prior to testing.

1. Remove the Test Strip from the sealed pouch and use within one hour.
2. With arrows pointing toward the urine specimen, immerse the Test Strip vertically in the urine specimen for at least 15 seconds. The urine level should be above the minimum line (MIN) on the test strip but below the maximum line (MAX). Both MIN and MAX are indicted on the test strip.
3. Set a timer for 5 minutes.
4. Place the Test Strip on a non-absorbent flat surface and wait for the colored line(s) to appear. Read the results at 5 minutes. Do not interpret the result before 5 minutes and after 10 minutes. See the illustration below.
5. If preliminary positive results are observed, send the urine sample to the laboratory for confirmation testing.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

This product can only perform qualitative analysis

NEGATIVE (-):* Two colored lines appear. One colored line should appear in the control line region (C) and another colored line should appear in the test line region (T). A negative result indicates t there is no Fentanyl in the specimen, or the concentration is below the detectable level (1.0 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). A positive result indicates that the Fentanyl concentration exceeds the detectable level (1.0 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 procedure using a new test. If the problem persists, discontinue using the lot immediately and contact your local supplier.

QUALITY CONTROL

A procedural control is included in the test. 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. The recommended quality control material available to users is Fentanyl Cerilliant F-013 at 1.0 mg/mL. Users 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 any other applicable guidelines and regulations.

LIMITATIONS

1. The Healgen® Accurate Rapid Fentanyl Test Strip (Urine) provides only a qualitative, preliminary result.
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. A confirmed positive result indicates presence of the drug 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 cutoff level of the test.
5. This test does not distinguish between drugs of abuse and prescription medications.

PERFORMANCE CHARACTERISTICS

Accuracy

80 clinical urine specimens previously quantitated by LC-MS were tested with the Healgen® Accurate Rapid Fentanyl Test Strip (Urine). Each test was performed by three operators. Results were as follows:

Operator	Healgen Result	LC-MS (ng/mL)	
		Above 1.0 ng/mL (Positive)	Below 1.0 ng/mL (Negative)
Operator 1	Positive	39	2
	Negative	1	38
	Accuracy	96.3%	
Operator 2	Positive	38	3
	Negative	2	37
	Accuracy	93.8%	
Operator 3	Positive	38	1
	Negative	2	39
	Accuracy	96.3%	

Analytical Specificity

The following table lists compounds that are positively detected in urine by the Healgen® Accurate Rapid Fentanyl Test Strip (Urine).

Fentanyl (cutoff=1.0 ng/mL)	Concentration (ng/mL)	Cross- Reactivity (%)
Fentanyl	1	100%
Norfentanyl	30,000	0.003%
Carfentanil	8,000	0.013%
Sufentanil	50,000	0.002%
Cyclopropyl fentanyl	1	100%
Furanyl Fentanyl	10	10%
Para-Fluorobutyryl fentanyl	10	10%
4-Fluoro-isobutyrylfentanyl	5	20%
O-Fluorofentanyl	10	10%
2'-Fluoro ortho-Fluorofenyanyl	10	10%
Valeryl Fentanyl	5	20%
(±) β-Hydroxythiofentanyl	3	33.33%
Tetrahydrofuranyl fentanyl	1.56	64.10%
2-Thiofuranyl fentanyl	5	20%
Methoxyacetyl fentanyl	1.56	64.10%
4-methoxybutyryl fentanyl (para)	20	5%
N-methyl norfentanyl	20,000	0.005%
3',4'-dimethoxy Fentanyl	125	0.8%
Acetyl-α-methyl fentanyl	62.5	1.6%
4'-methyl acetyl fentanyl	125	0.8%
Benzyl fentanyl	125	0.8%
Meta-methoxy Furanyl fentanyl	100	1%
α-methyl fentanyl	62.5	1.6%
Para-Fluoro fentanyl	1	100%
Ocfentanil	5	20%
Isobutyryl fentanyl	2.5	40%
Butyryl fentanyl	3	33.33%
Acetyl fentanyl	1	100%
Acrylfentanyl	0.9	111.11%
Risperidone	50,000	0.002%

9-Hydroxyrisperidone	10,000	0.01%
(±)-3-cis-methyl fentanyl	50	2%
Despropionyl fentanyl (4-ANPP)	7000	0.014%
ω-1-Hydroxyfentanyl	50,000	0.002%
Acetyl norfentanyl	>100 µg/mL	<0.001%
Norcarfentanil	>100 µg/mL	<0.001%
Remifentanil	>100 µg/mL	<0.001%
Alfentanil	>100 µg/mL	<0.001%

Non-Cross Reacting Compounds

The following opioid compounds were tested at a concentration of 100 µg/mL. A negative result was obtained for all these compounds. There is no cross-reactivity for these compounds using the Healgen® Accurate Rapid Fentanyl Test Strip (Urine).

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

Precision

This study was performed by three point of care (POC) personnel at each of 3 POC sites using masked samples. Three lots were run at each concentration for each lot per day. The results as follows:

Concentration	n	Lot 1		Lot 2		Lot 3	
		-	+	-	+	-	+
0 ng/mL	60	60	0	60	0	60	0
0.25 ng/mL	60	60	0	60	0	60	0
0.5 ng/mL	60	60	0	60	0	60	0
0.75 ng/mL	60	57	3	60	0	60	0
1 ng/mL	60	26	34	25	35	22	38
1.25 ng/mL	60	0	60	0	60	0	60
1.5 ng/mL	60	0	60	0	60	0	60
1.75 ng/mL	60	0	60	0	60	0	60
2 ng/mL	60	0	60	0	60	0	60

Interference

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

Non-Interfering Compounds

Acetaminophen	Creatinine	Ketamine	Perphenazine
Acetone (1000 mg/dL)	Cyclobenzaprine	Ketoprofen	Phencyclidine
Acetophenetidin	Deoxycorticosterone	Labetalol	Phenelzine
Acetylsalicylic acid	Desipramine	Lidocaine	Phenobarbital
Albumin (100mg/dL)	Dextromethorphan	Loperamide	Prednisone
Albuterol	Diclofenac	Maprotiline	Propoxyphene
Aminopyrine	Diflunisal	Meperidine	Propranolol
Amitriptyline	Digoxin	Meprobamate	Pseudoephedrine
Amobarbital	Diphenhydramine	Methapyrilene	Quinine
Amoxicillin	DL-Tryptophan	Methaqualone	Ranitidine
Ampicillin	DL-Tyrosine	Methoxyphenamine	Riboflavin

			(10mg/dL)
Apomorphine	Doxepin	Metronidazole (300µg/mL)	Salicylic acid
Ascorbic acid	Ecgonine methyl ester	N-Acetylprocainamide	Secobarbital
Aspartame	Ephedrine	NaCl (4000mg/dL)	Serotonin (5-Hydroxytyramine)
Atropine	Erythromycin	Nalidixic acid	Sulfamethazine
Benzilic acid	Ethanol (1%)	Naloxone	Sulindac
Benzoic acid	Fenoprofen	Naltrexone	Tetrahydrocortisone 3-(ahDglucuronide)
Benzoylecgonine	Fluphenazine	Naproxen	Tetrahydrocortisone 3-acetate
Bilirubin	Furosemide	Niacinamide	Tetrahydrozoline
Boric Acid (1%)	Galactose (10mg/dL)	Nicotine	Thiamine
Bupropion	Gamma Globulin (500mg/dL)	Nifedipine	Thioridazine
Caffeine	Gentisic acid	Norethindrone	Triamterene
Carbamazepine	Glucose (3000mg/dL)	Nortriptyline	Trifluoperazine
Chloral hydrate	Hemoglobin	Noscapine	Trimethoprim
Chloramphenicol	Hydralazine	O-Hydroxyhippuric acid	Tyramine
Chlorothiazide	Hydrochlorothiazide	Octopamine	Urea (2000mg/dL)
Chlorpromazine	Hydrocortisone	Oxalic acid (100mg/dL)	Uric acid
Cholesterol	Hydroxytyramine	Oxazepam	Valproic acid (250µg/mL)
Clomipramine	Ibuprofen	Oxolinic acid	Venlafaxine
Clonidine	Imipramine	Oxymetazoline	Verapamil
Cortisone	Isoproterenol	Papaverine	Zomepirac
Cotinine	Isoxsuprine	Penicillin G	β-Estradiol

Effect of Urinary Specific Gravity and pH

A total of 12 urine samples with specific gravities (SG) ranging from 1.000-1.035 were collected. Target drugs were spiked to these urine samples at +50% cutoff and -50% cutoff concentrations. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

The pH of an aliquoted negative urine pool was adjusted to a pH range of 4 to 9 in 1 pH unit increments and spiked with Fentanyl at +50% cutoff and -50% cutoff concentrations. The spiked, pH-adjusted urine was tested with the Healgen® Accurate Rapid Fentanyl Test Strip (Urine) in duplicate. The results demonstrated that varying ranges of pH do not interfere with the performance of the test.

BIBLIOGRAPHY AND SUGGESTED READING

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3. LI Ze-hua, WANG Kai, XU Bin, ZHUANG Xiao-mei, ZHAO Jin, GUO Lei, XIE Jian-wei. Advances in metabolic transformation of fentanyls. Chinese Journal of Pharmacology and Toxicology. 2021, 35(3): 223-234.
4. Baselt, Randall, Disposition of Toxic Drugs and Chemicals in Man. 12th edition.

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INDEX OF SYMBOLS

	Do not reuse		See Instruction for Use		Expiration Date
Σ	Tests per Kit	2°C 30°C	Store between 2-30°C(36-86°F)		Keep Dry
LOT	Batch Number	REF	Catalog#		Keep Away from Sunlight
UDI	Unique Device Identifier	IVD	For *in vitro* diagnostic use only		Manufacturer

ASSISTANCE

If you have any questions regarding the use of this product, please call our Technical Support Number 1-866-982-3818 (8:30 a.m. to 5 p.m. CDT).

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