

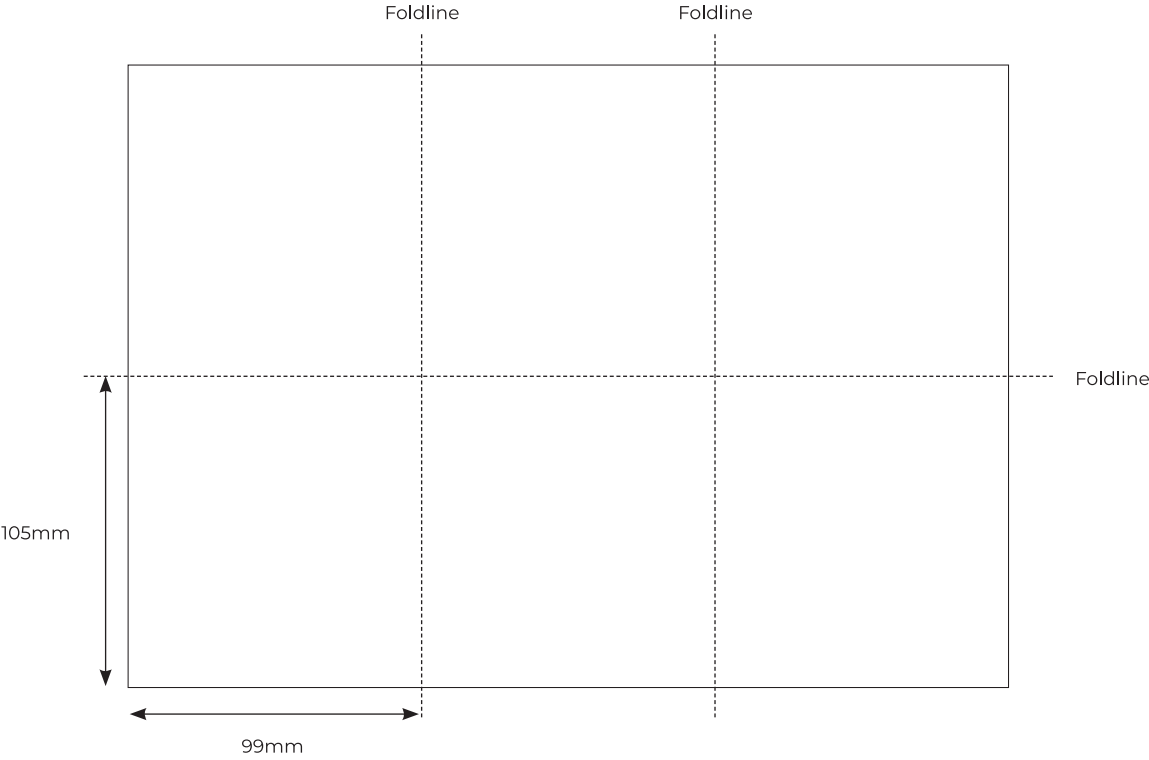


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USER INSTRUCTIONS

INDICAID™

Fentanyl Rapid Detection Test



A rapid test for the qualitative detection of fentanyl in powder.
For harm reduction use.

INTENDED USE

INDICAID™ FENTANYL RAPID DETECTION TEST is a rapid chromatographic immunoassay for the detection of fentanyl in powder at a cut-off concentration of 10 ng/mL.

This assay provides only a qualitative, preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

SUMMARY

Fentanyl belongs to powerful narcotics analgesics, and is a μ special opiates receptor stimulant. Fentanyl is one of the varieties listed in management of United Nations "Single Convention of narcotic drug in 1961". Among the opiates agents under international control, fentanyl is one of the most commonly used to cure moderate to severe pain.¹ After continuous injection of fentanyl, the sufferer will have the performance of protracted opioid abstinence syndrome, such as ataxia and irritability etc.,^{2,3} which leads to addiction after taking fentanyl over a long time. Compared with drug addicts of amphetamine, drug addicts who take fentanyl have a higher possibility of HIV infection rate, due to more dangerous injection behavior and more lifelong medication overdose.⁴

INDICAID™ FENTANYL RAPID DETECTION TEST is a rapid powder screening test that can be performed without the use of an instrument. The test utilizes the antibody to selectively detect elevated levels of fentanyl in powder. The INDICAID™ FENTANYL RAPID DETECTION TEST (Powder) yields a positive result when the fentanyl in powder exceed 10 ng/mL.

PRINCIPLE

INDICAID™ FENTANYL RAPID DETECTION TEST is an immunoassay based on the principle of competitive binding. Drugs which may be present in the powder specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a powder specimen migrates upward by capillary action. Fentanyl, if present in the powder specimen below 10 ng/mL, will not saturate the binding sites of the antibody in the test. The antibody coated particles will then be captured by immobilized fentanyl-protein 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 fentanyl level exceeds 10 ng/mL because it will saturate all the binding sites of anti-fentanyl antibody.

A drug-positive powder specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative powder specimen or a specimen containing a drug concentration less than the cut-off 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.

REAGENTS

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

PRECAUTIONS

- For harm reduction use.
- Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

STORAGE AND STABILITY

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

NOTE: Once the canister has been opened, the remaining test(s) are stable for 50 days only.

MATERIALS

Materials Provided

- Test dipsticks, package insert

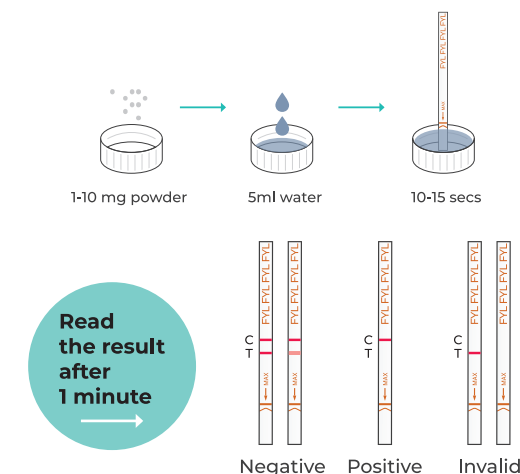
Materials Required but Not Provided

- Specimen collection container, timer, water

DIRECTIONS FOR USE

Allow the test, specimen, water to reach room temperature (15-30°C) prior to testing.

1. Prepare specimen collection containers and powder sample.
2. Pour powder sample into the specimen collection containers.
3. Dilute 1-10mg of powder with 5mL of water (1 mineral water bottle cap $\approx$ 5mL). Mix well.
4. Remove the test dipstick from the sealed pouch or closed canister and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
5. With the arrow pointing toward the water immerse the test dipstick vertically in the water specimen for at least 10 to 15 seconds. **Immerse the strip to at least the level of the wavy lines, but not above the arrow on the test dipstick.**
6. Start the timer and wait for lines to appear on the membrane. **Read the results after 1 minute** and do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE: Two colored lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T). This negative result indicates that the fentanyl concentration is below the detectable level (10 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 fentanyl concentration exceeds the detectable level (10 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 with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. INDICAID™ FENTANYL RAPID DETECTION TEST provides only a qualitative preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
2. It is possible that technical or procedural errors, as well as other interfering substances in the powder specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in powder specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another powder specimen.
4. A positive result indicates presence of the drug but does not indicate level of intoxication, administration route or concentration in powder.
5. A negative result may not necessarily indicate drug-free powder. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications. The test shall not encourage the use, supply, or production of illegal drugs or controlled substances in any way. The test is intended for harm reduction purposes. Follow the advice of your local harm reduction or public health agency.



PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

A drug-free pool was spiked with fentanyl at the following concentrations: 0 ng/mL, 5 ng/mL, 7.5 ng/mL, 10 ng/mL, 12.5 ng/mL, 15 ng/mL and 30 ng/mL. The results demonstrate >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Fentanyl Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0%	30	30	0
5	-50%	30	30	0
7.5	-25%	30	26	4
10	Cut-off	30	13	17
12.5	+25%	30	3	27
15	+50%	30	0	30
30	+300%	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected by the INDICAID™ FENTANYL RAPID DETECTION TEST at 5 minutes.

Compound	Conc. (ng/mL)	Compound	Conc. (ng/mL)
Fentanyl	10	Cyclopro Fentanyl	250
Norfentanyl	>100,000	(±)cis-3-Methylfentanyl	250
Butyl Fentanyl	150	Valeryl Fentanyl	100
Methoxyacetyl-fentanyl	20	Acetyl Fentanyl	20
Ocfentanil	100	para-Fluorobutaryl fentanil	100
4-Fluoro-isobutaryl Fentanyl	100	para-Fluorofentanil	50

Precision

A study was using three different lots of product to demonstrate the within run, between run and between operator precision. An identical dipstick of coded specimens containing, according to GC/MS, no fentanyl, 25% fentanyl above and below the cut-off, and 50% fentanyl above and below the 10 ng/mL cut-off was provided to each site. The following results were tabulated:

Fentanyl Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
5	10	10	0	10	0	10	0
7.5	10	8	2	7	3	8	2
12.5	10	2	8	2	8	1	9
15	10	0	10	0	10	0	10

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in drug-free pool. The following compounds show no cross-reactivity when tested with INDICAID™ FENTANYL RAPID DETECTION TEST at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol	Delorazepam	Lidocaine	Pyridoxine HCL
Acetaminophen	Disopyramide	Loperamide	Pyrogallol
Acamprosate	R (-)-Deprenyl	Lorazepam	Quetiapine Fumarate
Albumin	Desalkylflurazepam	Lormetazepam	Quinidine
Alprazolam	Desipramine	Levonorgestrel	Quinine
Amantadine	Tobramycin	Meperidine	Quinolinic Acid
Aifentanyl	Dexamethasone	Meprobamate	Ranitidine
Amikacin	Dextromethorphan	Methamphetamine	Riboflavin
7-Amino-clonazepam	Diazepam	D-Methamphetamine	Risperidone
7-Aminoflunitrazepam	Diclofenac Sodium	Methotrexate	(R)-Apomorphine
7-Aminonitrazepam	Dicumarol	Salbutamol	Salicylic Acid
Amitriptyline	Digoxin	Hexachloro-cyclohexane	Sufentanyl
Amlodipine Besylate	Dihydrocodeine	Methylone HCL	Remifentanyl
Amobarbital	Dimenhydrinate	Deoxycorticosterone	21 Super-Vita
MDMA	Ampicillin	Methylphenidate HCl	Sulfamethazine
Amoxicillin	Diphenhydramine	Mirtazapine	Sulfisoxazole
Acetylsalicylic acid	Diphenoxylate	Morphine	Sulindac
Calcium Carbonate	PMMA HCL	Nalidixic Acid	Tyramine
Sodium Oxalate	Doxepin	Naloxone	Thebaine
Clindamycin	Droperidol	Naltrexone	Temazepam
Atenolol	Duloxetine	Aspartame	Tetracycline
Atomoxetine HCL	EDDP	Niacinamide	Tetrahydrozoline
Baclofen	Emetine	Nifedipine	11-nor-Δ ⁸ -THC-9COOH
Barbital	Epinephrine	Nimesulide	11-nor-Δ ⁸ -THC-9COOH
Beclometasone dipropionate	Estazolam	Nitrazepam	R(-)-Selegiline
Benzilic Acid	Ketoprofen	Norcodeine	[(-)-Deprenyl]
Benzoic Acid	Ethylmorphine	Nordiazepam	Theophylline
Benzoyllecgonine	Ethylone HCL	Norfloxacin	Thioridazine
Bromazepam	PEG-400	Nortriptyline	I-Thyroxine
Brompheniramine	Etodolac	Ferrous sulfate	Tizanidine HCL
Buspirone	Fenofibrate	Pantoprazole Sodium	Valacyclovir
Butalbital	Fenoprofen	Orphenadrine	Tomoxetine
Caffeine	Flunitrazepam	Oxazepam	Topiramate
Guaiacol Glyceryl Ether carbamate	Fexofenadine hydrochloride	Oxymetazoline	Tramsdol Hydrochloride
Cannabidiol	Gemfibrozil	Oxymorphone	Trans-2-Phenylcyclopro
Carbamazepine	d (+) Glucose	Pantoprazole	4-Dimethylamino-antipyrine
Carisoprodol	D-Glucose	Phenobarbital	Triazolam
Cephalexin	Guaifenesin	Papaverine	Trifluoperazine
Chlordiazepoxide	Haloperidol	Paroxetine	Trimethobenzamide
Chloroquine	Hemoglobin	Ethyl-p-aminobenzoate	Trimethoprim
Chlorothiazide	Omeprazole	Pemoline	Trimipramine
			d,l-Tryptophan

Hydrochlorothiazide			
Carfentanyl	Hydroxyzine	Phenelzine	(+)- Chlorpheniramine
Chlorpropamide	Hydrocortisone	Pheniramine	Valsartan capsules
Chlorprothixene	Pseudoephedrine	Phenothiazine	Vancomycin
Cimetidine	Ibuprofen	5-Pentanoic Acid	Venlafaxine
Ciprofloxacin	Imipramine	Phentermine	Verapamil
Clomipramine	Isoxsuprine	2-Phenylethylamine	Zolpidem tartrate
Clonazepam	Itraconazole	Perphenazine	Zomepirac
Clorazepam dipotassium	Kanamycin	PMA HCL	(2-Hydroxypropyl)-β-
Cyclodextrin			
Cocaine	Prednisone	Pylamine	α -Naphthaleneacetic Acid
Codeine	Promazine	Procaine	α-Hydroxyalprazolam
Cortisone Acetate	Levetiracetam	o-Desmethyl-cis-tramadol	Ascorbic acid L-
Ascorbic Acid			
Creatinine	Labetalol	Promethazine	(S)-(+)-Methoxy-α-methyl-2-naphthaleneacetic
5,5-Diphenylhydantoin	Letrozol	Propranolol HCL	

EXPLANATION OF SYMBOLS

	Consult instructions for use		Do not reuse
	Manufacturer		Catalog number
	Temperature limit		Batch code
	Contains sufficient for <n> tests		Use-by date
	Do not use if package is damaged and consult instructions for use		

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