510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K234006

B Applicant

AllSource Screening Solutions

C Proprietary and Established Names

AllSource Drug Detector FenTest; AllSource Drug Detector Fentanyl Test

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NGL	Class II	21 CFR 862.3650 - Opiate Test System	TX - Clinical Toxicology

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Fentanyl

C Type of Test:

Qualitative lateral flow immunochromatographic assay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

AllSource Drug Detector FenTest is competitive binding, lateral flow immunochromatographic assay for qualitative detection of Fentanyl in human urine at the cutoff concentrations of 1 ng/mL.

The test provides 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.

For in vitro diagnostic use only.

The AllSource Drug Detector Fentanyl Test is a rapid, one-step immunoassay for the qualitative detection of fentanyl in human urine at the cutoff concentrations of 1 ng/mL.

This device provides only preliminary drug test results. To obtain a quantitative result or a confirmation of a presumptive positive result, a more specific alternative method must be used. GC/MS or LC/MS is the preferred confirmatory method.

Professional judgment should be applied to drug test results, particularly when preliminary positive results are indicated.

It is for in vitro diagnostic use only.

C Special Conditions for Use Statement(s):

OTC – Over The Counter

D Special Instrument Requirements:

None

IV Device/System Characteristics:

A Device Description:

AllSource Drug Detector Fentanyl Test is an immunoassay intended for the qualitative detection of fentanyl in human urine. Each AllSource Drug Detector Fentanyl Test device consists of a Test Dip Card and a package insert. Each Test Dip Card is sealed with sachets of desiccant in an aluminum pouch.

B Principle of Operation:

AllSource Drug Detector Fentanyl Test is a competitive and immunochromatography assay, and uses monoclonal antibody as the indicator marker to qualitatively detect fentanyl in human urine. The test cassette contains fentanyl test strip. The nitrocellulose membrane test area (T) of the test strip is correspondingly coated with fentanyl-bovine serum albumin conjugate, and the quality control area (C) is coated with goat anti-rabbit IgG polyclonal antibody. When the concentration

of fentanyl in the sample is higher than or equal to the cut-off of the product, it will compete with the corresponding conjugate coated on the test area (T) to bind to the monoclonal antibody, the test line is inhibited and the result is positive; while when the sample does not contain fentanyl or its concentration is lower than the cut-off of the product, the corresponding conjugate on the test line reacts with sufficient monoclonal antibodies; the test line will be visible and the result is negative. If there is no control line, it is an invalid result.

V Substantial Equivalence Information:

A Predicate Device Name(s):

AllTest Fentanyl Urine Test Cassette

B Predicate 510(k) Number(s):

K233417

C Comparison with Predicate(s):

Device & Predicate Device(s):	K234006	K233417
Device Trade Name	AllSource Drug Detector Fentanyl Test	AllTest Fentanyl Urine Test Cassette
General Device Characteristic Similarities		
Intended Use/Indications For Use	For the qualitative determination of fentanyl in human urine.	Same
Specimen	Human urine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assay based on antigen-antibody reaction	Same
Cut-off	1 ng/ml	Same
General Device Characteristic Differences		
Configuration	Dip Card	Cassette

VI Standards/Guidance Documents Referenced:

CLSI Guideline EP5-A3: Evaluation of Precision Performance of Quantitative Measurement Methods.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

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

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	60-/0+	60-/0+	60-/0+	46-/14+	28+/32-	60+/0-	60+/0-	60+/0-	60+/0-
Lot 2	60-/0+	60-/0+	60-/0+	44-/16+	28+/32-	60+/0-	60+/0-	60+/0-	60+/0-
Lot 3	60-/0+	60-/0+	60-/0+	45-/15+	30+/30-	60+/0-	60+/0-	60+/0-	60+/0-

2. Linearity:

Not Applicable.

3. Analytical Specificity/Interference:

Cross-Reactivity:
To test cross-reactivity, drug metabolites and other structurally related compounds that are likely to cross-react in urine samples were spiked into negative urine and were tested using three device lots. The lowest concentration that caused a positive result for each compound is listed below (if no cross reactivity was observed the highest concentration tested is shown):

Cross Reactant	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Norfentanyl	50	2%
Acetyl fentanyl	1	100%
Acrylfentanyl	10	10%
Isobutyryl fentanyl	2.5	40%
Ocfentanil	10	10%
Butyryl fentanyl	2.5	40%
Furanyl fentanyl	7.5	13.3%
Valeryl fentanyl	10	10%
(±) β-hydroxythiofentanyl	5	20%
Para-fluorobutyrylfentanyl (p-FBF)	10	10%

Para-fluoro fentanyl	1	100%
(±)-3-cis-methylfentanyl	10	10%
Carfentanil	10000	0.01%
Sufentanil	10000	0.01%
Norcarfentanil	100000	<0.001%
Acetyl norfentanyl	10	10%
Remifentanil	10000	0.01%
Alfentanil	10000	0.01%
ω-1-Hydroxyfentanyl	20000	0.005%
4-Fluoro-isobutyrylfentanyl	50	2%
Despropionyl fentanyl (4-ANPP)	2500	0.04%

The following opioids compounds were tested at a concentration of 100µg/mL. Negative results were obtained for all these compounds.

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

Interfering substances:
To evaluate potential interference, non-structurally related compounds were added to drug-free urine and target drug fentanyl urine with concentrations at 50% below and 50% above the cutoff. Compounds that show no interference at a concentration of 100µg/mL are summarized in the following table.

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 (50µg/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	Tetrahydrocortisone 3-(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 (250µg/ml)
Diflunisal	Naproxen	Venlafaxine
Digoxin	Niacinamide	Verapamil
Diphenhydramine	Nicotine	Zomepirac
DL-Tryptophan	Nifedipine	β-Estradiol
DL-Tyrosine	Norethindrone	

Effect of Urinary Specific Gravity and pH:
To investigate the effect of urine specific gravity and urine pH, urine samples, with specific gravity ranging from 1.000 to 1.035 or urine samples with pH ranging from 4 to 9 were spiked with the target drugs to concentrations at 50% below and 50% above Cutoff levels. These samples were tested using three lots of device. The results demonstrated that pH levels of 4 to 9 and specific gravity levels of 1.000 to 1.035 do not affect the results of the assays.

4. Assay Reportable Range:

   Not Applicable

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   The device is traceable to commercially available materials.

6. Detection Limit:

   Not applicable.

7. Assay Cut-Off:

   Refer to Section VII.A.1

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Method comparison studies for the AllSource Drug Detector Fentanyl Test were performed at three point-of-care test sites. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were blind labeled and compared to LC/MS results. The results are presented in the tables below.

		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%)
Site 1	Positive	0	0	4	22	17
	Negative	10	17	9	1	0
Site 2	Positive	0	0	6	21	17
	Negative	10	17	7	2	0
Site 3	Positive	0	0	6	21	17
	Negative	10	17	7	2	0

Discordant Results:

Site	Sample Number	LC/MS Result (ng/mL)	AllSource Result
Site 1	CP167	0.835	Positive
Site 1	CP322	0.937	Positive

Site 1	CP298	0.941	Positive
Site 1	CP127	0.967	Positive
Site 1	CP365	1.059	Negative
Site 2	CP352	0.792	Positive
Site 2	CP167	0.835	Positive
Site 2	CP322	0.937	Positive
Site 2	CP318	0.957	Positive
Site 2	CP127	0.967	Positive
Site 2	CP191	0.98	Positive
Site 2	CP365	1.059	Negative
Site 2	CP279	1.036	Negative
Site 3	CP308	0.818	Positive
Site 3	CP294	0.838	Positive
Site 3	CP298	0.941	Positive
Site 3	CP318	0.957	Positive
Site 3	CP127	0.967	Positive
Site 3	CP191	0.98	Positive
Site 3	CP253	1.099	Negative
Site 3	CP365	1.059	Negative

2. Lay user study:
A lay user study was performed at three intended user sites with 140 lay persons. They had diverse educational and professional backgrounds and ranged in age from 18 to >50 years. Urine samples were prepared at the following concentrations: -100%, +/-75%, +/-50%, +/-25% of the cut-off by spiking fentanyl into drug free-pooled urine specimens. The concentrations of the samples were confirmed by LC/MS. Each sample was aliquoted into individual containers, blind-labeled and randomized. Each participant was provided with the package insert, 1 blind labeled sample and a device. The results are summarized below:

% Cutoff	Number of samples	Fentanyl Concentration (ng/mL)	Results		Correct results (%)
			Number of Positive	Number of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	0.31	0	20	100
-50% Cutoff	20	0.48	0	20	100
-25% Cutoff	20	0.77	5	15	75
+25% Cutoff	20	1.22	20	0	100
+50% Cutoff	20	1.42	20	0	100
+75% Cutoff	20	1.78	20	0	100

3. Matrix Comparison:

Not applicable.

C Clinical Studies:

Not applicable.

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Not applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.