

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

k050186

B. Purpose of the Submission:

New device

C. Analyte:

Amphetamines, Barbiturates, Benzodiazepines, Cannabinoids, Cocaine, Methadone, Methylenedioxyamphetamine (MDMA), Methamphetamine, Opiates (Morphine), Oxycodone, Phencyclidine and Tricyclic Antidepressants.

D. Type of Test:

Qualitative immunoassay

E. Applicant:

Ameditech, Inc.

F. Proprietary and Established Names:

Ameditech ImmuTest Multi-Drug Screen Panel III

G. Regulatory Information:

1. Regulation section:

862.3100, Enzyme Immunoassay, Amphetamine

862.3150, Enzyme Immunoassay, Barbiturate

862.3170, Enzyme Immunoassay, Benzodiazepine

862.3870, Enzyme Immunoassay, Cannabinoids

862.3250, Enzyme Immunoassay, Cocaine and Cocaine Metabolites

862.3620, Enzyme Immunoassay, Methadone

862.3610, Thin Layer Chromatography, Methamphetamine

862.3650, Enzyme Immunoassay, Opiates

862.3910 Thin Layer Chromatography, Tricyclic Antidepressants

Unclassified, Enzyme Immunoassay, Phencyclidine

2. Classification:

Class II

3. Product Code:

DKZ, DIS, JXM, LDJ, DIO, DJR, DJC, DJG, LFG, LCM, respectively

4. Panel:

Toxicology (91)

H. Intended Use:

1. Intended use(s):
Refer to Indications for use below.
2. Indication(s) for use:
The Ameditech ImmuTest Multi-Drug Screen Panel III is an In Vitro screen test device for the qualitative detection of multi-drugs in human urine. The cutoff concentrations for this panel test are as follows.

Test	Calibrator	Cutoff (ng/mL)
Cocaine Metabolite (COC)	Benzoylcegonine	300
Tetrahydrocannabinol (THC)	11-nor- Δ^9 -THC-9-COOH	50
Methamphetamine (MET1000)	Methamphetamine	1000
Opiates (OPI)	Morphine	2000
Phencyclidine (PCP)	Phencyclidine	25
Amphetamine (AMP)	Amphetamine	1000
Barbiturates (BAR)	Secobarbital	300
Benzodiazepines (BZO)	Oxazepam	300
Methadone (MTD)	Methadone	300
Tricyclic Antidepressants (TCA)	Nortriptyline	1000
Oxycodone (OXY)	Oxycodone	100
3,4 methylenedioxy-Methamphetamine (MDMA)	3,4 methylenedioxy-Methamphetamine	500

This test uses multiple test strips in card format (test strips are placed in a card strip holder), cassette format (test strips are placed in a cassette strip holder), and cup format (test strips are placed in a lid strip holder). This test is used to obtain a visual, qualitative result and is intended for professional use.

This assay provides only a preliminary result. Clinical consideration and professional judgment must be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectroscopy (GC/MS) is the preferred confirmation method.

3. Special condition for use statement(s):
See Indications for Use statement above.
4. Special instrument Requirements:
Not applicable. The device is a visually read single-use device.

I. Device Description:

The ImmuTest Multi-Drug Screen Panel III consists of six single-use drug test strips (2 drugs per strip) that are used in one of three formats: card, cassette and cup format.

The length of the test strips are 50 mm for the cup and 59 mm for the card and cassette format. Addition of urine initiates the test which employs traditional immunochromatographic technology.

J. Substantial Equivalence Information:

1. Predicate device name(s):
ImmuTest Multi-Drug Screen Panel, ImmuTest Multi-Drug Screen Panel II and InstaCheck Drug Screen Test TCA.
2. Predicate K number(s):
k040092, k042975 and k981605
3. Comparison with predicate:
The device is similar to or the same as the previously cleared predicate(s) in the following ways: test principles, indication for use, for use in a professional and point-of-care setting, read time and sample matrix. The candidate device and the predicates are both visually-read single use devices.

The essential difference between the device and the predicate devices are that this device allows for 12 drugs to be tested as opposed to 7 drugs with the predicate.

Differences		
Item	Device	Predicate
Opiate cutoff Conc.	2000 ng/mL	300 ng/mL
# of drugs testable	12 drugs	7 drugs

K. Standard/Guidance Document Referenced (if applicable):

The sponsor did not reference any standards in the submission.

L. Test Principle:

The device employs lateral flow immunochromatographic technology and is based on the principle of competitive binding. Drugs, if present in concentrations below the cutoff level, will not saturate the binding sites of the antibody coated particles on the drug specific test strips. The antibody-coated particles will then be captured by immobilized drug-specific conjugate and a colored line will appear in the control region and the test region. If the sample contains drugs above the cutoff level, a colored line will not appear in the strips test region. Binding of drug in the sample causes the absence of a line at the test area, i.e., a positive result. When drug is not present in the sample, the drug-labeled conjugate binds at the test line, resulting in formation of a line, i.e., a negative result. Formation of a colored line in the control region indicates that the proper volume of urine has been added. If a colored line does not appear in the controls region, the test result is inconclusive and should be repeated. The absence or presence of the line is determined visually by the operator.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision was assessed by conducting a lot-to-lot precision study and also by conducting precision studies at four sites. The lot-to-lot precision study used drug free urine and drug urine samples of -50% cutoff, -25% cutoff, the cutoff, +25% cutoff and +50% cutoff. The samples were tested with three lots of the ImmuTest Multi-Drug Screen Panel III device (card format) for 3 consecutive days. 10 samples for each of the 6 concentrations were tested daily for each lot. Testing one lot per day for 3 days produced a total of 540 results per drug. The results are summarized in the table below.

Specimen description: drug free urine spiked with the drugs listed below in the chart.

Number of days: three

Replicates per day: one

Runs per day: one

Lots of product used: three

Number of operators: one

Operator Education: B.S. degree in Chemistry

Testing Facility: Ameditech

Results of the studies are presented below-

Drug	Conc. (ng/mL)	Total # Tested	Lot 1 (+/-)	Lot 2 (+/-)	Lot 3 (+/-)
	0	90	0/30	0/30	0/30
	500	90	0/30	0/30	0/30
	750	90	6/24	8/22	9/21
AMP (Amphetamine)	1000	90	16/14	18/12	14/16
	1250	90	20/10	22/8	21/9
	1500	90	30/0	30/0	30/0
	0	90	0/30	0/30	0/30
	150	90	0/30	0/30	0/30
	225	90	8/22	10/20	6/24
BAR (Secobarbital)	300	90	19/11	15/15	17/13
	375	90	24/6	21/9	22/8
	450	90	0/30	0/30	0/30
	0	90	0/30	0/30	0/30
	150	90	0/30	0/30	0/30
	225	90	6/24	8/22	7/23
BZO (Oxazepam)	300	90	18/12	16/14	19/11
	375	90	25/5	24/6	22/8
	450	90	30/0	30/0	30/0
	0	90	0/30	0/30	0/30
	150	90	0/30	0/30	0/30
	225	90	5/25	8/22	6/24
COC (Benzoylecgonine)	300	90	13/17	12/18	16/14
	375	90	23/7	22/8	20/10
	450	90	30/0	30/0	30/0

	0	90	0/30	0/30	0/30
	250	90	0/30	0/30	0/30
	375	90	8/22	10/20	6/24
MDMA	500	90	14/16	19/11	17/13
(3,4-methylenedioxy-methamphetamine)	625	90	22/8	21/9	19/21
	750	90	30/0	30/0	30/0
	0	90	0/30	0/30	0/30
	500	90	0/30	0/30	0/30
	750	90	7/23	9/21	6/24
MET100 (Methamphetamine)	1000	90	17/13	16/14	13/17
	1250	90	24/6	22/8	20/10
	1500	90	30/0	30/0	30/0
	0	90	0/30	0/30	0/30
	150	90	0/30	0/30	0/30
	225	90	6/24	5/25	8/22
MTD (Methadone)	300	90	13/17	16/14	14/16
	375	90	21/9	19/11	22/8
	450	90	30/0	30/0	30/0
	0	90	0/30	0/30	0/30
	1000	90	0/30	0/30	0/30
	1500	90	6/24	9/21	7/23
OPI (Morphine)	2000	90	18/12	14/16	17/13
	2500	90	23/7	25/5	21/9
	3000	90	30/0	30/0	30/0
	0	90	0/30	0/30	0/30
	50	90	0/30	0/30	0/30
	75	90	12/18	10/20	13/17
OXY (Oxycodone)	100	90	18/12	21/9	20/10
	125	90	25/5	22/8	24/6
	150	90	30/0	30/0	30/0
	0	90	0/30	0/30	0/30
	12.5	90	0/30	0/30	0/30
	18.75	90	8/22	5/25	5/25
PCP (Phencyclidine)	25	90	14/16	16/14	12/18
	31.25	90	21/9	20/10	25/5
	37.5	90	30/0	30/0	30/0
	0	90	0/30	0/30	0/30
	500	90	0/30	0/30	0/30
	750	90	4/26	6/24	6/24
TCA (Nortriptyline)	1000	90	16/14	12/18	13/17
	1250	90	23/7	21/9	22/8
	1200	90	30/0	30/0	30/0
	0	90	0/30	0/30	0/30
	25	90	0/30	0/30	0/30
	37.5	90	6/24	5/25	7/23
THC (11-nor-Δ9-THC-9-COOH)	50	90	15/15	12/18	13/17
	62.5	90	18/12	19/11	21/9
	75	90	30/0	30/0	30/0

OXY (Oxycodone)	0	90	0/90	0/90	0/90	0/90	0/90	0/90
	50	90	0/90	0/90	0/90	0/90	0/90	0/90
	75	90	35/55	32/58	28/62	30/60	32/58	29/61
	100	90	59/31	58/32	56/34	54/36	55/35	57/33
	125	90	71/19	72/18	74/16	70/20	69/21	73/17
	150	90	90/0	90/0	90/0	90/0	90/0	90/0
MDMA	0	90	0/90	0/90	0/90	0/90	0/90	0/90
	250	90	0/90	0/90	0/90	0/90	0/90	0/90
	375	90	24/66	21/69	20/70	22/68	24/66	22/68
	500	90	50/40	49/41	52/38	51/39	54/36	52/38
	625	90	62/28	66/24	63/27	65/25	68/22	64/26
	750	90	90/0	90/0	90/0	90/0	90/0	90/0

The results demonstrated that the performance for the cup and cassette devices is the same as the card device.

The card format data from reader A in the above study represented the Ameditech site in a 4 site assay study. The other 3 external sites analyzed 5 sample cups per drug concentration listed below. The testing was conducted for 3 days and totaled 90 samples per drug.

Drug	Conc. (ng/mL)	#1 (+/-)	#2 (+/-)	#3 (+/-)	Ameditech (+/-)	Total (+/-)
	0	0/15	0/15	0/15	0/90	0/135
	500	0/15	0/15	0/15	0/90	0/135
	750	2/13	4/11	5/10	23/67	34/101
AMP (Amphetamine)	1000	8/7	9/6	10/5	48/42	75/60
	1250	14/1	12/3	11/4	63/27	110/25
	1500	15/0	15/0	15/0	90/0	135/0
	0	0/15	0/15	0/15	0/90	0/135
	150	0/15	0/15	0/15	0/90	0/135
	225	2/13	4/11	4/11	24/66	34/101
BAR (Secobarbital)	300	6/9	8/7	9/6	51/39	74/61
	375	11/4	10/5	14/1	67/23	102/33
	450	15/0	15/0	15/0	90/0	135/0
	0	0/15	0/15	0/15	0/90	0/135
	150	0/15	0/15	0/15	0/90	0/135
	225	3/12	2/13	4/11	21/69	30/105
BZO (Oxazepam)	300	7/8	6/9	9/6	53/37	75/60
	375	12/3	11/4	13/2	71/19	107/28
	450	15/0	15/0	15/0	90/0	135/0

	0	0/15	0/15	0/15	0/90	0/135
	150	0/15	0/15	0/15	0/90	0/135
	225	4/11	5/10	2/13	19/71	30/105
COC (Benzoyllecgonine)	300	8/7	9/6	7/9	41/49	65/70
	375	10/5	12/3	12/3	65/25	99/36
	450	15/0	15/0	15/0	90/0	135/0
	0	0/15	0/15	0/15	0/90	0/135
	250	0/15	0/15	0/15	0/90	0/135
	375	4/11	3/12	4/11	24/66	35/100
MDMA (3,4-methylenedioxy-methamphetamine)	500	8/7	8/7	9/6	50/40	75/60
	625	11/4	10/5	12/3	62/28	95/40
	750	15/0	15/0	15/0	90/0	135/0
	0	0/15	0/15	0/15	0/90	0/135
	500	0/15	0/15	0/15	0/90	0/135
	750	2/13	4/11	3/12	22/68	31/104
MET100 (Methamphetamine)	1000	11/4	9/6	8/7	49/41	77/58
	1250	14/1	12/3	11/4	61/29	98/37
	1500	15/0	15/0	15/0	90/0	135/0
	0	0/15	0/15	0/15	0/90	0/135
	150	0/15	0/15	0/15	0/90	0/135
	225	4/11	5/10	3/12	19/71	31/104
MTD (Methadone)	300	8/7	10/5	8/7	43/47	69/66
	375	12/3	11/4	10/5	62/28	95/40
	450	15/0	15/0	15/0	90/0	135/0
	0	0/15	0/15	0/15	0/90	0/135
	1000	0/15	0/15	0/15	0/90	0/135
	1500	4/11	3/12	4/11	27/63	38/97
OPI (Morphine)	2000	7/8	9/6	8/7	52/38	76/59
	2500	12/3	11/4	12/3	69/21	104/31
	450	15/0	15/0	15/0	90/0	135/0
	0	0/15	0/15	0/15	0/90	0/135
	50	0/15	0/15	0/15	0/90	0/135
	75	5/10	4/11	6/9	35/55	50/85
OXY (Oxycodone)	100	9/6	8/7	10/5	59/31	86/49
	125	14/1	13/2	13/2	71/19	111/24
	150	15/0	15/0	15/0	90/0	135/0
	0	0/15	0/15	0/15	0/90	0/135
	12.5	0/15	0/15	0/15	0/90	0/135
	18.75	3/12	4/11	1/14	18/72	26/109
PCP (Phencyclidine)	25	9/6	5/10	6/9	42/48	62/73
	31.25	12/3	11/4	10/5	66/24	9/36
	37.5	15/0	15/0	15/0	90/0	135/0

	0	0/15	0/15	0/15	0/90	0/135
	500	0/15	0/15	0/15	0/90	0/135
	750	3/12	4/11	2/13	16/74	25/110
TCA (Nortriptyline)	1000	6/9	7/8	6/9	41/49	60/75
	1250	10/5	12/3	11/3	66/24	99/36
	1500	15/0	15/0	15/0	90/0	135/0
	0	0/15	0/15	0/15	0/90	0/135
	25	0/15	0/15	0/15	0/90	0/135
	37.5	1/14	3/12	2/13	18/72	24/111
THC (11-nor-Δ^9-THC-9-COOH)	50	6/9	7/8	5/10	40/50	58/77
	62.5	10/5	12/3	11/4	58/32	91/44
	75	15/0	15/0	15/0	90/0	135/0

The precision results above identified samples that contained 0 ng/mL and 50% below the cut-off as negatives and identified samples that were 50% above the cut-off as positives.

b. Linearity/assay reportable range:

Not applicable. The assay is intended for qualitative use.

c. Traceability (controls, calibrators, or method):

Test results with this device were compared to GC/MS results. See method comparison below.

This device has internal process controls. A colored line appearing in the control region confirms that sufficient sample volume and that the correct technique has been used. Users are informed not to interpret the test if a colored line failed to appear in the control region. External controls are not supplied with this device.

d. Detection limit:

Sensitivity of this assay is characterized by validating performance around the claimed cutoff concentration of the assay, including a determination of the lowest concentration of drug that is capable of producing a positive result.

The sponsor tested the device to determine the analytical sensitivity at, above and below the designated cutoff concentrations. Drug free urine and drug urine samples of -50% cutoff, -25% cutoff, the cutoff, +25% cutoff and +50% cutoff were tested with three lots of the ImmuTest Multi-Drug Screen Panel III device (card format) for 3 consecutive days. Ten samples for each of the 6 concentrations were tested daily for each lot. 540 specimens were independently interpreted by 2 readers. The results are summarized in the table below.

Drug	Conc (ng/mL)	# Tested	# Positive	# Negative	% Positive
AMP (Amphetamine)	0	180	0	0	0%
	500	180	0	0	0%
	750	180	44	136	24%
	1000	180	97	83	54%
	1250	180	129	51	72%
	1500	180	180	0	100%
BAR (Secobarbital)	0	180	0	0	0%
	150	180	0	0	0%
	225	180	46	134	26%
	300	180	99	81	55%
	375	180	132	48	73%
	450	180	180	0	100%
BZO (Oxazepam)	0	180	0	0	0%
	150	180	0	0	0%
	225	180	44	136	24%
	300	180	105	75	58%
	375	180	140	40	78%
	450	180	180	0	100%
COC (Cocaine)	0	180	0	0	0%
	150	180	0	0	0%
	225	180	40	140	22%
	300	180	83	96	46%
	375	180	117	53	65%
	450	180	180	0	100%
MDMA (3,4-methylenedioxy-methamphetamine)	0	180	0	180	0%
	250	180	0	180	0%
	375	180	45	135	25%
	500	180	99	81	55%
	625	180	128	52	71%
	750	180	180	0	100%
MET100 (Methamphetamine)	0	180	0	180	0%
	500	180	0	180	0%
	750	180	42	138	23%
	1000	180	96	84	53%
	1250	180	124	56	69%
	1500	180	180	0	100%
MTD (Methadone)	0	180	0	180	0%
	150	180	0	180	0%
	225	180	40	140	22%
	300	180	84	96	47%
	375	180	123	57	68%
	450	180	180	0	100%
OPI (Morphine)	0	180	0	180	0%
	1000	180	0	180	0%
	1500	180	52	128	29%
	2000	180	103	77	57%
	2500	180	141	39	78%
	3000	180	180	0	100%

	0	180	0	180	0%
	50	180	0	180	0%
	75	180	67	113	37%
OXY (Oxycodone)	100	180	117	63	65%
	125	180	143	37	79%
	150	180	180	0	100%
	0	180	0	180	0%
	12.5	180	0	180	0%
	18.75	180	34	146	19%
PCP (Phencyclidine)	25	180	82	98	46%
	31.25	180	131	49	73%
	37.5	180	180	0	100%
	0	180	0	180	0%
	500	180	0	180	0%
	750	180	35	145	19%
TCA (Nortripyline)	1000	180	80	100	44%
	1250	180	133	47	74%
	1500	180	180	0	100%
	0	180	0	180	0%
	25	180	0	180	0%
	37.5	180	34	146	19%
THC (11-nor-Δ9-THC-9-COOH)	50	180	84	96	47%
	62.5	180	115	65	64%
	75	180	180	0	100%

e. Analytical specificity:

e.1 Cross Reactivity Study

Cross-reactivity was established by spiking various drugs, their metabolites and other compounds likely to be present in urine into drug-free urine. The concentration of the drug/drug metabolites, structure-related compounds standard solution was determined by GC/MS. These solutions were spiked into drug-free urine at a concentration of 100 $\mu\text{g/mL}$, then serially diluted and tested with the ImmuTest Multi-Drug Screen Panel III until the concentration yielded a negative result. Cross-reactivity was calculated by dividing the concentration at which the compound yielded a positive result by the designated cut-off concentration.

$$\text{Cross-Reactivity} = \frac{\text{Lowest concentration of the targeted drug that generates a positive result}}{\text{Lowest concentration of compound that generates a positive result}}$$

By analyzing various concentration of each compound the sponsor determined the concentration of the drug that produced a response approximately equivalent to the cutoff concentration of the assay. Results of those studies appear in the table(s) below:

Compound	Concentration (ng/mL)	% Cross-reactivity
Cocaine Metabolite		
Benzoyllecgonine	300	100
Cocaine	300	100
THC		
11-nor- Δ^9 -THC-9-carboxylic acid	50	100
11-hydroxy- Δ^9 -tetrahydrocannabinol	1,000	5
Δ^8 -tetrahydrocannabinol	5,000	1
Δ^9 -tetrahydrocannabinol	5,000	1
Cannabinol	10,000	0.5
Cannabidiol	>100,000	<0.05
Methamphetamine (1000 ng/mL)		
d-Methamphetamine	1000	100
d-Amphetamine	50,000	2
l-Amphetamine	>100,000	<1
(+/-)3,4-methylenedioxyethylamphetamine	50,000	2
(+/-)3,4-methylenedioxyamphetamine	100,000	1
3,4-methylenedioxymethylamphetamine	3,000	33
l-Methamphetamine	10,000	10
Ephedrine	>100,000	<1
Mephentermine	75,000	13
Opiates (2000 ng/mL)		
Morphine	2,000	100
Codeine	2,000	100
6-Monoacetylmorphine	3000	67
Ethylmorphine	5,000	40
Heroin	10,000	20
Hydrocodone	40,000	5
Hydromorphone	50,000	4
Morphine-3-glucuronide	5,000	40
Nalorphine	5,000	40

Compound	Concentration (ng/mL)	% Cross-reactivity
PCP		
Phencyclidine	25	100
Tenocyclidine	2,000	1.25
Amphetamine		
d-Amphetamine	1,000	100
dl-Amphetamine	2,500	40
(+/-)3,4-methylenedioxyamphetamine	1,250	80
d-Methamphetamine	50,000	2
(+/-)3,4-methylenedioxymethamphetamine	50,000	2
Benzodiazepines		
Oxazepam	300	100
Alprazolam	400	75
Bromazepam	250	120
Chlordiazepoxide	300	100
Clobazam	1000	30
Clonazepam	500	60
Clorazepate Dipotassium	150	200
Desalkylflurazepam	200	150
Diazepam	450	67
Estazolam	300	100
Flunitrazepam	300	100
Flurazepam	300	100
Lorazepam	500	60
Medazepam	300	100
Nitrazepam	250	120
Nordiazepam	150	200
Prazepam	500	60
Temazepam	200	150
Triazolam	450	67

Compound	Concentration (ng/mL)	% Cross-reactivity
Barbiturates		
Secobarbital	300	100
Allobarbital	600	50
Alphenal	200	150
Amobarbital	1500	20
Aprobarbital	300	100
Barbital	1500	20
Butabarbital	400	75
Butalbital	300	100
Butethal	450	67
Pentobarbital	400	75
Phenobarbital	450	67
Lorazepam	>100,000	<1
Methadone		
(+/-) Methadone	300	100
Methadol	1,500	20
Doxylamine	>100,000	<1
Tricyclic Antidepressant		
Nortriptyline	1,000	100
Nordoxepin	2,000	50
Trimipramine	2,000	50
Amitriptyline	1,500	67
Promazine	1,500	67
Desipramine	400	250
Doxepin	3,000	33
Maprotiline	2,000	50
Oxycodone		
Oxycodone	100	100
Hydrocodone	5,000	2
Hydromorphone	50,000	0.2
Morphine	>100,000	<0.1
Codeine	50,000	0.2
Heroin	>100,000	<0.1
MDMA		
3,4-methylenedioxymethamphetamine	500	100
3,4-methylenedioxyethylamphetamine	450	111
3,4-methylenedioxyamphetamine	4,000	12.5

4-Dimethylamino-antipyrine	+	+	+	+	+	+	+	+	+	+	+	+
Diphenhydramine	+	+	+	+	+	+	+	+	+	+	+	+
Dopamine	+	+	+	+	+	+	+	+	+	+	+	+
(+/-)-Ephedrine	+	+	+	+	+	+	+	+	+	+	+	+
Erythromycin	+	+	+	+	+	+	+	+	+	+	+	+
Ethanol	+	+	+	+	+	+	+	+	+	+	+	+
Furosemide	+	+	+	+	+	+	+	+	+	+	+	+
Glucose	+	+	+	+	+	+	+	+	+	+	+	+
Guaiacol Glyceryl Ether	+	+	+	+	+	+	+	+	+	+	+	+
Hemoglobin	+	+	+	+	+	+	+	+	+	+	+	+
Ibuprofen	+	+	+	+	+	+	+	+	+	+	+	+
(+/-)-Isoproterenol	+	+	+	+	+	+	+	+	+	+	+	+
Ketamine	+	+	+	+	+	+	+	+	+	+	+	+
Levorphanol	+	+	+	+	+	+	+	+	+	+	+	+
Lidocaine	+	+	+	+	+	+	+	+	+	+	+	+
(1R,2S)-(-)-N-Methyl-Ephedrine	+	+	+	+	+	+	+	+	+	+	+	+
(+)-Naproxen	+	+	+	+	+	+	+	+	+	+	+	+
Niacinamide	+	+	+	+	+	+	+	+	+	+	+	+
Nicotine	+	+	+	+	+	+	+	+	+	+	+	+
(+)-Norephedrine	+	+	+	+	+	+	+	+	+	+	+	+
Oxalic Acid	+	+	+	+	+	+	+	+	+	+	+	+
Penicillin- G	+	+	+	+	+	+	+	+	+	+	+	+
Pheniramine	+	+	+	+	+	+	+	+	+	+	+	+
Phenothiazine	+	+	+	+	+	+	+	+	+	+	+	+
1-Phenylephrine	+	+	+	+	+	+	+	+	+	+	+	+
β -Phenylethylamine	+	+	+	+	+	+	+	+	+	+	+	+
Procaine	+	+	+	+	+	+	+	+	+	+	+	+
Quinidine	+	+	+	+	+	+	+	+	+	+	+	+
Rantidine	+	+	+	+	+	+	+	+	+	+	+	+
Riboflavin	+	+	+	+	+	+	+	+	+	+	+	+
Sodium Chloride	+	+	+	+	+	+	+	+	+	+	+	+
Sulindac	+	+	+	+	+	+	+	+	+	+	+	+
Theophylline	+	+	+	+	+	+	+	+	+	+	+	+
Tyramine	+	+	+	+	+	+	+	+	+	+	+	+

The compounds listed above, when tested at a final concentration of 100 $\mu\text{g/mL}$, did not alter the expected negative or positive results of the ImmuTest Multi-Drug Screen Panel III Device. Therefore, at 100 $\mu\text{g/mL}$ concentration, all of these compounds listed will not interfere with the test results obtained by the ImmuTest Multi-Drug Screen Panel III Device.

e.3 Urinary pH

Sample solutions containing drug concentrations that were 50% above and 50% below the cutoff used in the sensitivity studies were adjusted between the range from 4 to 9 in 1.0 pH increments using either HCl or NaOH. The pH adjusted sample solutions were tested in triplicates with the ImmuTest Multi-Drug Screen Panel III. An unaltered sample was used as a control. The results are summarized in the table below.

Drug	Conc. (ng/mL)	Control (+/-)	pH 4 (+/-)	pH 5 (+/-)	pH 6 (+/-)	pH 7 (+/-)	pH 8 (+/-)	pH 9 (+/-)
COC	150	0/3	0/3	0/3	0/3	0/3	0/3	0/3
	450	3/0	3/0	3/0	3/0	3/0	3/0	3/0
THC	25	0/3	0/3	0/3	0/3	0/3	0/3	0/3
	75	3/0	3/0	3/0	3/0	3/0	3/0	3/0
MET	500	0/3	0/3	0/3	0/3	0/3	0/3	0/3
	1500	3/0	3/0	3/0	3/0	3/0	3/0	3/0
OPI	1000	0/3	0/3	0/3	0/3	0/3	0/3	0/3
	3000	3/0	3/0	3/0	3/0	3/0	3/0	3/0
PCP	12.5	0/3	0/3	0/3	0/3	0/3	0/3	0/3
	37.5	3/0	3/0	3/0	3/0	3/0	3/0	3/0
AMP	500	0/3	0/3	0/3	0/3	0/3	0/3	0/3
	1500	3/0	3/0	3/0	3/0	3/0	3/0	3/0
BZO	150	0/3	0/3	0/3	0/3	0/3	0/3	0/3
	450	3/0	3/0	3/0	3/0	3/0	3/0	3/0
BAR	150	0/3	0/3	0/3	0/3	0/3	0/3	0/3
	450	3/0	3/0	3/0	3/0	3/0	3/0	3/0
MTD	150	0/3	0/3	0/3	0/3	0/3	0/3	0/3
	450	3/0	3/0	3/0	3/0	3/0	3/0	3/0
TCA	500	0/3	0/3	0/3	0/3	0/3	0/3	0/3
	1500	3/0	3/0	3/0	3/0	3/0	3/0	3/0
OXY	50	0/3	0/3	0/3	0/3	0/3	0/3	0/3
	150	3/0	3/0	3/0	3/0	3/0	3/0	3/0
MDMA	250	0/3	0/3	0/3	0/3	0/3	0/3	0/3
	750	3/0	3/0	3/0	3/0	3/0	3/0	3/0

The urinary pH variations, when tested with urine samples from pH 4 to 9, did not affect the expected test results of the ImmuTest Multi-Drug Screen Panel III Device.

e.4 Urinary Specific Gravity

Sample solutions containing drug concentrations that were 50% above and 50% below the cutoff used in the sensitivity studies were adjusted to specific gravities that ranged from 1.003 to 1.04.

Specific gravity was determined by the weight of the sample solution divided by the volume (g/mL). The specific gravity adjusted samples were tested in triplicates with the ImmuTest Multi-Drug Screen Panel III. An unaltered sample was used as a control. The results are summarized in the table below.

Drug	Conc. (ng/mL)	Control SG 1.01 (+/-)	SG 1.003 (+/-)	SG 1.02 (+/-)	SG 1.03 (+/-)	SG 1.04 (+/-)
COC	150	0/3	0/3	0/3	0/3	0/3
	450	3/0	3/0	3/0	3/0	3/0
THC	25	0/3	0/3	0/3	0/3	0/3
	75	3/0	3/0	3/0	3/0	3/0
MET	500	0/3	0/3	0/3	0/3	0/3
	1500	3/0	3/0	3/0	3/0	3/0
OPI	1000	0/3	0/3	0/3	0/3	0/3
	3000	3/0	3/0	3/0	3/0	3/0
PCP	12.5	0/3	0/3	0/3	0/3	0/3
	37.5	3/0	3/0	3/0	3/0	3/0
AMP	500	0/3	0/3	0/3	0/3	0/3
	1500	3/0	3/0	3/0	3/0	3/0
BZO	150	0/3	0/3	0/3	0/3	0/3
	450	3/0	3/0	3/0	3/0	3/0
BAR	150	0/3	0/3	0/3	0/3	0/3
	450	3/0	3/0	3/0	3/0	3/0
MTD	150	0/3	0/3	0/3	0/3	0/3
	450	3/0	3/0	3/0	3/0	3/0
TCA	500	0/3	0/3	0/3	0/3	0/3
	1500	3/0	3/0	3/0	3/0	3/0
OXY	50	0/3	0/3	0/3	0/3	0/3
	150	3/0	3/0	3/0	3/0	3/0
MDMA	250	0/3	0/3	0/3	0/3	0/3
	750	3/0	3/0	3/0	3/0	3/0

Specific gravity

Specific gravity variations of the urine samples, when tested between 1.004 to 1.04, did not affect the accuracy of the test results obtained with the ImmuTest Multi-Drug Screen Panel III.

f. Assay cut-off:

The Substance Abuse and Mental Health Services Administration (SAMHSA) has not recommended a cutoff concentration for barbiturates, benzodiazepines, 3,4-methylenedioxymethamphetamine,

methadone, tricyclic antidepressants and oxycodone. The cutoffs for these drugs were chosen based on the levels used by predicate devices. SAMHSA has recommended a cutoff concentration for methamphetamine, opiates, PCP, cocaine metabolites, THC and amphetamines. The ImmuTest Multi-Drug Screen Panel III followed the SAMHSA recommendation for these drugs.

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision section, above.

2. Comparison studies:

a. *Method comparison with predicate device:*

The ImmuTest Multi-Drug Screen Panel III device was compared to the GC/MS values, ImmuTest Multi-Drug Screen Panel I, ImmuTest Multi-Drug II and the InstaCheck Drug Screen for TCA. Studies were conducted and results are presented in the 2 charts shown below.

Sample description: A total of 1641 samples were obtained from 3 clinical testing laboratories. 25 additional diluted samples were also included and were prepared by diluting positive samples with negative urine. This was done in order to obtain more samples near the cutoff concentrations. Sixty negative urine samples were collected from presumed non-users volunteers. 45 of the 60 samples were analyzed and were tested by the ImmuTest Multi-Drug Screen Panel III and with one of the predicate devices listed above. The remaining 15 samples were analyzed and found negative on the GC/MS.

Sample selection: The study included an adequate number of samples that contained drugs near to the cutoff concentration of the assay. Approximately 10% of the study samples are evenly distributed between plus and minus 50% of the claimed cutoff concentration.

Number of study sites: one

Type of study site(s): Manufacturer's facility

Operator description: Not specified.

Candidate Device Results vs. Predicate Device Results

Test			Predicate Devices		% Agreement with Predicate Devices
			Positive	Negative	
COC	ImmuTest	Positive	79	0	98.8
		Negative	1	83	100
THC	ImmuTest	Positive	55	2	100
		Negative	0	87	87.8
MET	ImmuTest	Positive	63	0	96.9
		Negative	2	72	100
OPI	ImmuTest	Positive	53	3	100
		Negative	0	66	95.7
PCP	ImmuTest	Positive	60	0	98.4
		Negative	1	80	100
AMP	ImmuTest	Positive	65	0	97.0
		Negative	2	83	100
BZO	ImmuTest	Positive	51	1	96.2
		Negative	2	79	98.8
BAR	ImmuTest	Positive	88	0	97.8
		Negative	2	68	100
MTD	ImmuTest	Positive	69	2	100
		Negative	0	66	97.1
TCA	ImmuTest	Positive	22	0	95.7
		Negative	1	93	100
OXY	ImmuTest	Positive	54	2	100
		Negative	0	65	97.0
MDMA	ImmuTest	Positive	42	2	100
		Negative	0	75	97.4

Candidate Device Results vs. stratified GC/MS Values

ImmuTest Multi-Drug Screen Panel III	GC/MS Negative	GC/MS Near Cutoff Negative (between -50% and Cutoff)	GC/MS Near Cutoff Positive (between Cutoff and +50%)	GC/MS Positive (greater than +50%)	Percent Agreement with GC/MS
COC	0	210-279 ng/mL	327-443 ng/mL	551-33,770 ng/mL	% Agreement
Positive	0	0	8	71	98.8
Negative	15	8	1	0	100
THC	0	35-48 ng/mL	51-72 ng/mL	80-507 ng/mL	% Agreement
Positive	0	1	24	32	100
Negative	15	12	0	0	96.4
MET	0	519-912 ng/mL	1,017-1,473 ng/mL	1,587-291,000 ng/mL	% Agreement
Positive	0	0	5	58	98.4
Negative	20	8	1	0	100
OPI	0	1,087-1969 ng/mL	2,073-3,011 ng/mL	3,092-230,140 ng/mL	% Agreement
Positive	0	2	9	45	100
Negative	15	6	0	0	91.3
PCP	0	14-24.5 ng/mL	28-38 ng/mL	40-36,210 ng/mL	% Agreement
Positive	0	0	4	56	96.8
Negative	15	4	2	0	100
AMP	0	567-934 ng/mL	1,043-1,449 ng/mL	1,600-98,700 ng/mL	% Agreement
Positive	0	0	10	55	98.5
Negative	15	9	1	0	100
BZO	<150 ng/mL	151-299 ng/mL	317-445 ng/mL	452-20,620 ng/mL	% Agreement
Positive	0	2	13	37	100
Negative	18	18	0	0	94.7
BAR	<150 ng/mL	228-284 ng/mL	338-449 ng/mL	525-29,920 ng/mL	% Agreement
Positive	0	1	5	83	97.8
Negative	15	7	2	0	95.7
MTD	<150 ng/mL	150-275 ng/mL	303-422 ng/mL	506-71,800 ng/mL	% Agreement

Positive	0	0	6	65	98.6
Negative	15	5	1	0	100
ImmuTest Multi-Drug Screen Panel III	GC/MS Negative	GC/MS Near Cutoff Negative (between -50% and Cutoff)	GC/MS Near Cutoff Positive (between Cutoff and +50%)	GC/MS Positive (greater than +50%)	Percent Agreement with GC/MS
TCA*	<378 ng/mL	504-960 ng/mL	1,010-1,326 ng/mL	1,600-4,958 ng/mL	% Agreement
Positive	0	1	12	9	100
Negative	23	11	0	0	97.1
OXY	<50 ng/mL	50-98 ng/mL	118-148ng/mL	201-9,455ng/mL	% Agreement
Positive	0	2	6	47	100
Negative	15	6	0	0	91.3
MDMA	<250 ng/mL	257-397 ng/mL	522-759 ng/mL	1,220-7,5000 ng/mL	% Agreement
Positive	0	1	6	37	100
Negative	24	6	0	0	96.8

* The concentrations of TCA samples were confirmed by HPLC.

GC/MS values used to categorize samples in this table are based on the sum of the concentrations of:

Barbiturates: Pentobarbital, Phenobarbital and Secobarbital.

Benzodiazepines: Alprazolam, Oxazolam and Temazepam.

Amphetamine: N/A

Cocaine: N/A

MDMA: N/A

Methamphetamine: N/A

Methadone: N/A

Opiates: Morphine and Codeine

Oxycodone: N/A

Phencyclidine: N/A

THC: N/A

TCA: Nortriptyline

b. Matrix comparison:

Not applicable. The assay is intended for only one sample matrix.

3. Clinical studies:
 - a. *Clinical sensitivity:*
Not applicable. Clinical studies are not typically submitted for this device type.
 - b. *Clinical specificity:*
Not applicable. Clinical studies are not typically submitted for this device type.
 - c. *Other clinical supportive data (when a and b are not applicable):*
4. Clinical cut-off:
Not applicable.
5. Expected values/Reference range:
Not applicable

N. Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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