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

A. 510(k) Number:
K042975

B. Purpose of the Submission:
New 510(k)

C. Analyte:
Barbiturates, Benzodiazepines, Methadone, Methylenedioxymethamphetamine (MDMA), Methamphetamine, Opiates (Morphine) and Oxycodone.

D. Type of Test:
Qualitative Lateral Flow Immunochromatographic Test

E. Applicant:
Ameditech, Inc.

F. Proprietary and Established Names: ImmuTest Multi-Drug Screen Panel II

G. Regulatory Information:

1. Regulation section:
   862.3150, Enzyme Immunoassay, Barbiturate
   862.3170, Enzyme Immunoassay, Benzodiazepine
   862.3620, Enzyme Immunoassay, Methadone
   862.3610, Thin Layer Chromatography, Methamphetamine
   862.3650, Enzyme Immunoassay, Opiates
2. Classification:
   II
3. Product Code:
   DIS, JXM, DJR, LAF, DJG
4. Panel:
   Toxicology (91)

H. Intended Use:

1. Intended use(s):
   Refer to Indications for use.

2. Indication(s) for use:

The Ameditech ImmuTest Multi-Drug Screen Panel II 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)
Barbiturates (BAR)	Secobarbital	300
Benzodiazepines (BZO)	Oxazepam	300
3,4methylenedioxymethamphetamine (MDMA)	3,4methylenedioxymethamphetamine	500
Methamphetamine (MET1000)	d-Methamphetamine	1000
Methadone (MTD)	Methadone	300
Opiates (OPI300)	Morphine	300
Oxycodone (OXY)	Oxycodone	100

This test has three types of test format: 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, as the device is a visually read single-use device.

I. Device Description:

The ImmuTest Multi-Drug Screen Panel II consists of several single-use drug test strips that are used in one of three formats: card, cassette and cup format. The strips differ for the cup (50 mm) format and the card and cassette (59 mm) format. Addition of urine initiates the test which employs traditional immunochromatographic technology.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   InstaCheck Drug Screen Test BAR, Instacheck Drug Screen Test BZO, InstaCheck Drug Screen Test MDMA, QuickScreen Methamphetamine Test, QuickScreen Opiates Test, QuickScreen One Step Methadone Screening Test and RapidOne OXY.
2. Predicate K number(s):
   K990107, K990099, K011133, K000447, K972619, K982938 and K014101.
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, cut-off

concentrations(s), used in a professional and point-of-care setting 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 multiple drugs to be tested at once and the test time is shorter.

Differences		
Item	Device	Predicate
Read Time	5 minutes	8 minutes
# of drugs testable	7 drugs	1 drug

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

The sponsor did not reference any standards in their 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 a four site precision study. The lot-to-lot precision study used drug free urine and urine samples containing drug at the cutoff, 50% below the cutoff, 25% below the cutoff, 25% above the cutoff and 50% above the cutoff. The samples were tested with three lots of the ImmuTest Multi-Drug Screen Panel II device (card format) for 3 consecutive days. 10 samples for each of the 6 concentrations were tested daily for each lot. One lot per day for 3 days produced a total of 540 specimens 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
	150	90	0/30	0/30	0/30
	225	90	7/23	9/21	6/24
BAR (Secobarbital)	**300**	90	17/13	16/14	13/17
	375	90	24/6	22/8	10/20
	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	5/25	8/22	7/23
BZO (Oxazepam)	**300**	90	16/14	18/12	14/16
	375	90	22/8	20/10	21/9
	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	6/24	9/21	5/25
MDMA	**500**	90	18/12	19/11	16/14
(3,4-methylenedioxy-methamphetamine)	625	90	21/9	21/7	22/8
	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	8/22	7/23	7/23
MET100 (Methamphetamine)	**1000**	90	14/16	17/13	19/11
	1250	90	20/10	18/12	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	6/24	8/22	7/23
MTD (Methadone)	**300**	90	13/17	16/14	17/13
	375	90	22/8	21/9	23/7
	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	7/23	10/20	8/22
OPI300 (Morphine)	**300**	90	15/15	16/14	18/12
	375	90	21/9	22/8	19/11
	450	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	9/21	6/24	8/22
OXY (Oxycodone)	**100**	90	17/13	18/12	16/14
	125	90	19/11	23/7	21/9
	150	90	30/0	30/0	30/0

In order to show that all three formats of the devices (card, cup and cassette) are equivalent in readability, an additional study was conducted in conjunction with the above precision study. The data showed that all samples with drug concentration of 50% below cut-off were identified as negatives with card, cassette, and cup test formats. All samples with drug concentration of 50% above cut-off were identified as positives with all three formats. The chart below incorporates all three formats with the results of both readers.

Drug	Conc. (ng/ml)	# Tested	Card Format*		Cassette Format		Cup Format	
			A (+/-)	B (+/-)	A (+/-)	B (+/-)	A (+/-)	B (+/-)
BAR (Secobarbital)	0	90	0/90	0/90	0/90	0/90	0/90	0/90
	150	90	0/90	0/90	0/90	0/90	0/90	0/90
	225	90	22/68	26/64	23/67	25/65	24/66	27/63
	300	90	46/44	48/42	47/43	44/46	47/43	50/40
	375	90	66/24	65/25	65/25	67/23	70/20	69/21
	450	90	90/0	90/0	90/0	90/0	90/0	90/0
BZO (Oxazepam)	0	90	0/90	0/90	0/90	0/90	0/90	0/90
	150	90	0/90	0/90	0/90	0/90	0/90	0/90
	225	90	20/70	23/67	24/66	21/69	26/64	23/67
	300	90	48/42	47/43	45/45	47/43	49/41	51/39
	375	90	63/27	61/29	59/31	60/30	65/25	62/28
	450	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	20/70	22/68	19/71	22/68	23/67	26/64
	500	90	53/37	49/41	50/40	49/41	54/36	51/39
	625	90	66/24	65/25	65/25	67/23	70/20	68/22
	750	90	90/0	90/0	90/0	90/0	90/0	90/0

MET1000 (Methamphetamine)	0	90	0/90	0/90	0/90	0/90	0/90	0/90
	500	90	0/90	0/90	0/90	0/90	0/90	0/90
	750	90	22/68	21/69	23/67	25/65	26/64	25/65
	1000	90	50/40	48/42	46/44	44/46	50/40	49/41
	1250	90	59/31	66/24	65/25	62/28	69/21	71/19
	1500	90	90/0	90/0	90/0	90/0	90/0	90/0
MTD (Methadone)	0	90	0/90	0/90	0/90	0/90	0/90	0/90
	150	90	0/90	0/90	0/90	0/90	0/90	0/90
	225	90	21/69	24/66	19/71	22/68	25/65	23/67
	300	90	46/44	43/47	44/46	42/48	47/43	48/42
	375	90	66/24	67/23	65/25	62/28	68/22	70/20
	450	90	90/0	90/0	90/0	90/0	90/0	90/0
OPI300 (Morphine)	0	90	0/90	0/90	0/90	0/90	0/90	0/90
	150	90	0/90	0/90	0/90	0/90	0/90	0/90
	225	90	25/65	27/63	22/68	24/66	28/62	26/64
	300	90	49/41	47/43	49/41	50/40	50/40	52/38
	375	90	62/28	61/29	60/30	63/27	61/29	64/26
	450	90	90/0	90/0	90/0	90/0	90/0	90/0
OXY (Oyxcodone)	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	23/67	22/68	24/66	22/68	25/65	24/66
	100	90	51/39	48/42	50/40	51/39	53/37	55/45
	125	90	63/27	64/26	66/24	65/25	70/20	67/23
	150	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 were same as that for card device.

This card format data from reader A that is in the above study was also included in a 4 site assay study and represented the Ameditech site portion study. The other 3 sites are Vtias Healthcare(VH), Paradise Valley Hospital (PVH), and Scripps Mercy (SM). The additional 3 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)	VH (+/-)	PVH (+/-)	SM (+/-)	Ameditech (+/-)	Total (+/-)
	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	2/13	22/68	30/105
BAR (Secobarbital)	**300**	6/9	9/6	8/7	46/44	69/66

	375	10/5	12/3	10/5	66/24	98/37
	450	15/0	15/0	15/0	90/0	135/0
	0	90	0/15	0/15	0/90	0/135
	150	0/15	0/15	0/15	0/90	0/135
	225	4/11	2/13	5/10	20/70	31/104
BZO (Oxazepam)	**300**	10/5	7/8	9/6	48/42	74/61
	375	14/1	12/3	11/4	63/27	100/35
	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	3/12	3/12	1/14	20/70	27/108
MDMA (3,4-methylenedioxy-methamphetamine	**500**	5/10	8/7	6/9	53/37	72/63
	625	12/3	12/3	11/4	66/24	101/34
	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	4/11	2/13	2/13	22/68	30/105
MET100 (Methamphetamine)	**1000**	9/6	7/8	8/7	50/40	74/61
	1250	13/2	12/3	11/3	59/31	96/69
	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	5/10	21/69	32/103
MTD (Methadone)	**300**	9/6	8/7	10/5	46/44	73/62
	375	12/3	11/4	13/2	66/24	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	4/11	2/13	2/13	25/65	33/102
OPI300 (Morphine)	**300**	8/7	6/9	7/8	49/41	70/65
	375	11/4	10/5	12/3	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
	50	0/15	0/15	0/15	0/90	0/135
	75	1/14	2/13	3/12	23/67	29/106
OXY (Oxycodone)	**100**	7/8	7/8	6/9	51/39	71/64
	125	11/4	13/2	12/3	63/27	99/36
	150	15/0	15/0	15/0	90/0	135/0

The precision result revealed that the samples that contained 0 ng/mL, or were 50% below the cut-off were identified at negatives and the samples

that were 50% above the cut-off were all identified at positives at study sites and with all lots.

b. *Linearity/assay reportable range:*
Not applicable. The assay is intended for qualitative use.

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

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.
Controls are not supplied with this device. The presence of the control line serves as a built-in control, which demonstrates that the test is performing properly.

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 sensititivity at and around the designated cutoff concentrations. Drug free urine and urine samples containing drug at the cutoff, 50% below the cutoff, 25% below the cutoff, 25% above the cutoff and 50% above the cutoff were tested with three lots of the ImmuTest Multi-Drug Screen Panel II device (card format) for 3 consecutive days. 10 samples for each of the 6 concentrations were tested daily for each lot. The 1080 specimens per drug were independently interpreted by 2 readers (540 per reader). The results are summarized in the table below:

Drug	Conc (ng/mL)	# Tested	# Positive	# Negative	% Positive
	0	180	0	0	0%
	150	180	0	0	0%
	225	180	48	132	27%
BAR (Secobarbital)	**300**	180	94	86	52%
	375	180	131	49	73%
	450	180	180	0	100%
	0	180	0	0	0%
	150	180	0	0	0%
	225	180	43	137	24%
BZO (Oxazepam)	**300**	180	95	85	53%
	375	180	124	56	69%
	450	180	180	0	100%
	0	180	0	0	0%
	250	180	0	0	0%
	375	180	42	138	23%
MDMA (3,4-methylenedioxy-methamphetamine	**500**	180	102	78	57%
	625	180	131	49	73%
	750	180	180	0	100%
	0	180	0	180	0%
	500	180	0	180	0%
	750	180	43	137	24%
MET100 (Methamphetamine)	**1000**	180	98	82	54%
	1250	180	125	55	69%
	1500	180	180	0	100%
	0	180	0	180	0%
	150	180	0	180	0%
	225	180	45	135	25%
MTD (Methadone)	**300**	180	89	91	49%
	375	180	133	47	74%
	450	180	180	0	100%
	0	180	0	180	0%
	150	180	0	180	0%
	225	180	52	128	29%
OPI300 (Morphine)	**300**	180	96	84	53%
	375	180	123	57	68%
	450	180	180	0	100%
	0	180	0	180	0%
	50	180	0	180	0%
	75	180	45	135	25%
OXY (Oxycodone)	**100**	180	99	81	55%
	125	180	127	53	71%
	150	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 □g/mL, then serially diluted and tested with the ImmuTest Multi-Drug Screen Panel II 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 concentrations 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:

Methamphetamine

Drug Compound	Response equivalent to cutoff in ng/mL	% Cross-Reactivity
d-amphetamine	50,000	100
l-amphetamine	>100,000	<1
d-methamphetamine	1,000	2
l-methamphetamine	10,000	10
(-/+) 3,4-Methylenedioxyethylamphetamine(MDEA)	50,000	2
3,4-Methylenedioxymethamphetamine (MDMA)	3,000	33
(-/+) 3,4-Methylenedioxyamphetamine (MDA)	100,000	1
Ephedrine	>100,000	<1
Mephentermine	75,000	13

Opiates

Drug compound	Response equivalent to cutoff in ng/mL	% Cross-Reactivity
6-Monoacetylmorphine	350	86
Codeine	250	120
Heroin	750	40

Hydrocodone	500	60
Hydromorphone	500	60
Morphine	300	100
Morphine-3-β-glucuronide	300	100
Ethylmorphine	300	100
Nalorphine	5,000	6

Barbiturates

Compound	Response equivalent to cutoff in ng/mL	% Cross-Reactivity
Secobarbital	300	100
Allobarbital	600	50
Alphenal	200	150
Amobarbital	1500	20
Aprobarbital	300	100
Barbital	1500	20
Butabarbital	400	75
Butabital	300	100
Butethal	450	67
Pentobarbital	400	75
Phenobarbital	450	67

Benzodiazepines

Compound	Response equivalent to cutoff in ng/mL	% Cross-Reactivity
Oxazepam	300	100
Alprazolam	400	75
Bromazepam	250	120
Chlordiaepoxide	300	100
Clobazam	1000	30
Clonazepam	500	60
Clonazepate 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
Temezepam	200	150

Triazolam	450	67

Methadone

Compound	Response equivalent to cutoff in ng/mL	% Cross-Reactivity
(+/-) Methadone	300	100
Methadol	1,500	20

3,4- Methylenedioxymethamphetamine

Compound	Response equivalent to cutoff in ng/mL	% Cross-Reactivity
3,4-Methylenedioxymethamphetamine	500	100
3,4-Methylenedioxyethylamphetamine	450	111
3,4-methylenedioxyamphetamine	4,000	12.5

Oxycodone

Compound	Response equivalent to cutoff in ng/mL	% Cross-Reactivity
Oxycodone	100	100
Hydrocodone	5000	2
Hydromorphone	50000	0.2
Morphine	>100,000	<0.1
Codeine	50,000	0.2
Heroin	>100,000	<0.1

e.2 Interference Studies

The following compounds were evaluated for potential positive and negative interference with the assay. To evaluate potential interference, the sponsor prepared two urine pools that consisted of drug-free urine spiked with each of the 7 drugs to 50% below and 50% above cutoff concentrations. To aliquots of these pools, the sponsor added the potential interferent at a concentration of 100 □g/mL.

Results of the positive interference study are presented below:

Compound	BAR	BZO	MDMA	MET	MTD	OPI	OXY
Control	-	-	-	-	-	-	-
Acetaminophen	-	-	-	-	-	-	-
Acetone	-	-	-	-	-	-	-

Albumin	-	-	-	-	-	-	-
Amitriptyline	-	-	-	-	-	-	-
Ampicillin	-	-	-	-	-	-	-
Ascorbic Acid	-	-	-	-	-	-	-
Aspartame	-	-	-	-	-	-	-
Aspirin	-	-	-	-	-	-	-
Atropine	-	-	-	-	-	-	-
Benzocaine	-	-	-	-	-	-	-
Bilirubin	-	-	-	-	-	-	-
Caffeine	-	-	-	-	-	-	-
Chloroquine	-	-	-	-	-	-	-
(+)-Chlorpheniramine	-	-	-	-	-	-	-
(+/-) Chlorpheniramine	-	-	-	-	-	-	-
Creatine	-	-	-	-	-	-	-
Dexbrompheniramine	-	-	-	-	-	-	-
4-Dimethylaminoantipyrine	-	-	-	-	-	-	-
Diphenhydramine	-	-	-	-	-	-	-
Dopamine	-	-	-	-	-	-	-
(+/-)-Ephedrine	-	-	-	-	-	-	-
Erythromycin	-	-	-	-	-	-	-
Ethanol	-	-	-	-	-	-	-
Furosemide	-	-	-	-	-	-	-
Glucose	-	-	-	-	-	-	-
Guaiacol Glyceryl Ether	-	-	-	-	-	-	-
Hemoglobin	-	-	-	-	-	-	-
Ibuprofen	-	-	-	-	-	-	-
Imipramine	-	-	-	-	-	-	-
(+/-)-Isoproterenol	-	-	-	-	-	-	-
Ketamine	-	-	-	-	-	-	-
Levorphanol	-	-	-	-	-	-	-
Lidocaine	-	-	-	-	-	-	-
Maprotiline	-	-	-	-	-	-	-
(1R,2S)-(-)-N-Methyl-Ephedrine	-	-	-	-	-	-	-
(+)-Norephedrine	-	-	-	-	-	-	-
Oxalic Acid	-	-	-	-	-	-	-
Penicillin- G	-	-	-	-	-	-	-
Pheniramine	-	-	-	-	-	-	-
Phenothiazine	-	-	-	-	-	-	-
1-Phenylephrine	-	-	-	-	-	-	-
□-Phenylethylamine	-	-	-	-	-	-	-
Procaine	-	-	-	-	-	-	-
Quinidine	-	-	-	-	-	-	-
Rantidine	-	-	-	-	-	-	-
Riboflavin	-	-	-	-	-	-	-

Sodium Chloride	-	-	-	-	-	-	-
Sulindac	-	-	-	-	-	-	-
Theophylline	-	-	-	-	-	-	-
Trimipramine	-	-	-	-	-	-	-
Tyramine	-	-	-	-	-	-	-

The results of the negative interference study are presented below.

Compound	BAR	BZO	MDMA	MET	MTD	OPI	OXY
Control	+	+	+	+	+	+	+
Acetaminophen	+	+	+	+	+	+	+
Acetone	+	+	+	+	+	+	+
Albumin	+	+	+	+	+	+	+
Amitriptyline	+	+	+	+	+	+	+
Ampicillin	+	+	+	+	+	+	+
Ascorbic Acid	+	+	+	+	+	+	+
Aspartame	+	+	+	+	+	+	+
Aspirin	+	+	+	+	+	+	+
Atropine	+	+	+	+	+	+	+
Benzocaine	+	+	+	+	+	+	+
Bilirubin	+	+	+	+	+	+	+
Caffeine	+	+	+	+	+	+	+
Chloroquine	+	+	+	+	+	+	+
(+)-Chlorpheniramine	+	+	+	+	+	+	+
(+/-) Chlorpheniramine	+	+	+	+	+	+	+
Creatine	+	+	+	+	+	+	+
Dexbrompheniramine	+	+	+	+	+	+	+
4-Dimethylaminoantipyrine	+	+	+	+	+	+	+
Diphenhydramine	+	+	+	+	+	+	+
Dopamine	+	+	+	+	+	+	+
(+/-)-Ephedrine	+	+	+	+	+	+	+
Erythromycin	+	+	+	+	+	+	+
Ethanol	+	+	+	+	+	+	+
Furosemide	+	+	+	+	+	+	+
Glucose	+	+	+	+	+	+	+
Guaiacol Glyceryl Ether	+	+	+	+	+	+	+
Hemoglobin	+	+	+	+	+	+	+
Ibuprofen	+	+	+	+	+	+	+
Imipramine	+	+	+	+	+	+	+
(+/-)-Isoproterenol	+	+	+	+	+	+	+
Ketamine	+	+	+	+	+	+	+
Levorphanol	+	+	+	+	+	+	+
Lidocaine	+	+	+	+	+	+	+

Maprotiline	+	+	+	+	+	+	+
(1R,2S)-(-)-N-Methyl-Ephedrine	+	+	+	+	+	+	+
(+)-Norephedrine	+	+	+	+	+	+	+
Oxalic Acid	+	+	+	+	+	+	+
Penicillin- G	+	+	+	+	+	+	+
Pheniramine	+	+	+	+	+	+	+
Phenothiazine	+	+	+	+	+	+	+
1-Phenylephrine	+	+	+	+	+	+	+
□-Phenylethylamine	+	+	+	+	+	+	+
Procaine	+	+	+	+	+	+	+
Quinidine	+	+	+	+	+	+	+
Rantidine	+	+	+	+	+	+	+
Riboflavin	+	+	+	+	+	+	+
Sodium Chloride	+	+	+	+	+	+	+
Sulindac	+	+	+	+	+	+	+
Theophylline	+	+	+	+	+	+	+
Trimipramine	+	+	+	+	+	+	+
Tyramine	+	+	+	+	+	+	+

The compounds listed above, when tested at a final concentration of 100 □g/mL, did not alter the expected negative or positive results of the ImmuTest Multi-Drug Screen Panel II Device. Therefore, at 100 □g/mL concentration, all of these compounds listed will not interfere with the test results obtained by the ImmuTest Multi-Drug Screen Panel II 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 for pH between the range of 4 to 9 in 1.0 increments using either HCl or NaOH. The pH adjusted sample solutions were tested in triplicate with the ImmuTest Multi-Drug Screen Panel II. An unaltered sample was used as a control. The results are summarized in the table below:

Drug	Conc. (ng/mL)	Control pH 6.9 (+/-)	pH 4 (+/-)	pH 5 (+/-)	pH 6 (+/-)	pH 7 (+/-)	pH 8 (+/-)	pH 9 (+/-)
BAR	150 450	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0
BZO	150 450	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0

MDMA	250 750	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0
MET100	500 1500	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0
MTD	150 450	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0
OPI300	150 450	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 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 II 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 triplicate with the ImmuTest Multi-Drug Screen Panel II. 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 (+/-)
BAR	150 450	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0
BZO	150 450	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0
MDMA	250 750	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0
MET100	500 1500	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0
MTD	150 450	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0
OPI300	150 450	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0
OXY	50 150	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0	0/3 3/0

Specific gravity

Specific Gravity variations between 1.004 to 1.04, did not affect the accuracy of the test results obtained with the ImmuTest Multi0Drug Screen Panel II.

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 and oxycodone. The cutoff for those drugs and for opiates were chosen based on the levels used by predicate devices. SAMHSA has recommended a cutoff concentration for methamphetamine and the ImmuTest Multi-Drug Screen Panel II followed that recommendation.

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 Mutli-Drug Screen Panel II device was compared to the GC/MS, Applied Biotech/ Forefront Instacheck Drug Screen

Test-BAR/BZO/MDMA, Pharmatech Quickscreen Methamphetamine, Methadone, Opiates, American Bio Medica RapidOne Oxy devices and to GC/MS values. Studies were conducted and compiled into the 2 charts shown below.

Sample description: A total of 642 samples were obtained from 2 clinical testing laboratories. An additional 25 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-user volunteers. Forty five of the sixty samples were analyzed and were tested by the ImmuTest Multi-Drug Screen Panel II 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 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

			Predicate Devices		**% Agreement with Predicate Devices**
Test			**Positive**	**Negative**	
BAR	**ImmuTest**	Positive	87	1	97.5
		Negative	2	68	98.6
BZO	**ImmuTest**	Positive	50	2	96.2
		Negative	2	79	97.5
MDMA	**ImmuTest**	Positive	42	2	100
		Negative	0	75	97.4
MET1000	**ImmuTest**	Positive	65	0	97.0
		Negative	2	70	100
MTD	**ImmuTest**	Positive	69	2	100
		Negative	0	66	97.1
OPI300	**ImmuTest**	Positive	82	3	100
		Negative	0	67	95.7
OXY	**ImmuTest**	Positive	54	2	97.0

		Negative	0	65	100

Candidate Device Results vs. stratified GC/MS Values

ImmuTest Multi-Drug Screen Panel II	**Negative** by the predicate device or less than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)	**Percent Agreement with GC/MS**
BAR	<150 ng/mL	228-284 ng/mL	338-449 ng/mL	525-29,920 ng/mL	% Agreement
Positive	0	1	4	83	96.7
Negative	15	7	3	0	95.7
BZO	<150 ng/mL	151-299 ng/mL	317-445 ng/mL	452-20,620 ng/mL	% Agreement
Positive	0	3	12	37	98.0
Negative	18	17	1	0	92.1
MDMA	<250 ng/mL	257-397 ng/mL	522-759 ng/mL	1220-7,500 ng/mL	% Agreement
Positive	0	1	6	37	100
Negative	24	6	0	0	96.8
MET1000	<500 ng/mL	519-912 ng/mL	1,017-1,473 ng/mL	1,587-291,000 ng/mL	% Agreement
Positive	0	1	6	58	100
Negative	20	7	0	0	96.4
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
OPI300	<150 ng/mL	150-280 ng/mL	337-450 ng/mL	502-230,140 ng/mL	% Agreement
Positive	0	1	6	78	100
Negative	16	6	0	0	95.7
OXY	<50 ng/mL	50-98 ng/mL	118-148 ng/mL	201-9,455 ng/mL	% Agreement
Positive	0	1	6	47	100
Negative	15	7	0	0	95.7

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: Alpabenzodiazepine, Oxabenzodiazepine and Temabenzodiazepines.
MDMA: N/A
Methamphetamine: N/A

Methadone: N/A
Opiates: Morphine and Codeine
Oxycodone: N/A

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. Conclusion:

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