

**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, Methylenedioxymethamphetamine (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) | Benzoyllecgonine | 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 |

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 reader A & B.

| Drug | Conc. (ng/mL) | # Tested | Cassette Format * | | Card Format | | Cup Format | |
|---|------------------|----------|-------------------|------------|-------------|------------|------------|------------|
| | | | A (+/-) | B (+/-) | A (+/-) | B (+/-) | A (+/-) | B (+/-) |
| COC (Benzoylcegonine) | 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 | 19/71 | 21/69 | 24/66 | 20/70 | 23/67 | 25/65 |
| | 300 | 90 | 41/49 | 42/48 | 44/46 | 43/47 | 46/44 | 47/43 |
| | 375 | 90 | 65/25 | 62/28 | 68/22 | 66/24 | 70/20 | 66/24 |
| | 450 | 90 | 90/0 | 90/0 | 90/0 | 90/0 | 90/0 | 90/0 |
| THC (11-nor- Δ^9 -THC-9-COOH) | 0 | 90 | 0/90 | 0/90 | 0/90 | 0/90 | 0/90 | 0/90 |
| | 25 | 90 | 0/90 | 0/90 | 0/90 | 0/90 | 0/90 | 0/90 |
| | 37.5 | 90 | 18/72 | 16/74 | 22/68 | 24/66 | 25/65 | 27/63 |
| | 50 | 90 | 40/50 | 44/46 | 47/43 | 49/41 | 44/46 | 46/44 |
| | 62.5 | 90 | 58/32 | 57/33 | 58/32 | 56/34 | 59/31 | 60/30 |
| | 75 | 90 | 90/0 | 90/0 | 90/0 | 90/0 | 90/0 | 90/0 |
| MET (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 | 20/70 | 23/67 | 19/71 | 21/69 | 25/65 |
| | 1000 | 90 | 49/41 | 47/43 | 47/43 | 48/42 | 50/40 | 49/41 |
| | 1250 | 90 | 61/29 | 63/27 | 66/24 | 62/28 | 65/25 | 68/22 |
| | 1500 | 90 | 90/0 | 90/0 | 90/0 | 90/0 | 90/0 | 90/0 |
| OPI (Morphine) | 0 | 90 | 0/90 | 0/90 | 0/90 | 0/90 | 0/90 | 0/90 |
| | 1000 | 90 | 0/90 | 0/90 | 0/90 | 0/90 | 0/90 | 0/90 |
| | 1500 | 90 | 27/63 | 25/65 | 28/62 | 25/65 | 25/65 | 26/64 |
| | 2000 | 90 | 52/38 | 51/39 | 50/40 | 48/42 | 46/44 | 49/41 |
| | 2500 | 90 | 69/21 | 72/18 | 68/22 | 66/24 | 71/19 | 69/21 |
| | 3000 | 90 | 90/0 | 90/0 | 90/0 | 90/0 | 90/0 | 90/0 |

| | | | | | | | | |
|------------------------|-------|----|-------|-------|-------|-------|-------|-------|
| PCP (Phencyclidine) | 0 | 90 | 0/90 | 0/90 | 0/90 | 0/90 | 0/90 | 0/90 |
| | 12.5 | 90 | 0/90 | 0/90 | 0/90 | 0/90 | 0/90 | 0/90 |
| | 18.75 | 90 | 18/72 | 16/74 | 20/70 | 23/67 | 21/69 | 19/71 |
| | 25 | 90 | 42/48 | 40/50 | 41/49 | 44/46 | 42/48 | 40/50 |
| | 31.25 | 90 | 66/24 | 65/25 | 62/28 | 64/26 | 66/24 | 69/21 |
| | 37.5 | 90 | 90/0 | 90/0 | 90/0 | 90/0 | 90/0 | 90/0 |
| AMP (Amphetamine) | 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 | 23/67 | 21/69 | 20/70 | 24/66 | 25/65 | 22/68 |
| | 1000 | 90 | 48/42 | 49/41 | 50/40 | 52/38 | 47/43 | 48/42 |
| | 1250 | 90 | 63/27 | 66/24 | 67/23 | 64/26 | 61/29 | 62/28 |
| | 1500 | 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 | 21/69 | 23/67 | 27/63 | 25/65 | 22/68 | 24/66 |
| | 300 | 90 | 53/37 | 52/38 | 49/41 | 50/40 | 51/39 | 52/38 |
| | 375 | 90 | 71/19 | 69/21 | 68/22 | 67/23 | 69/21 | 72/18 |
| | 450 | 90 | 90/0 | 90/0 | 90/0 | 90/0 | 90/0 | 90/0 |
| 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 | 24/66 | 22/68 | 20/70 | 21/69 | 23/67 | 26/64 |
| | 300 | 90 | 51/39 | 48/42 | 47/43 | 49/41 | 52/38 | 50/40 |
| | 375 | 90 | 67/23 | 65/25 | 63/27 | 60/30 | 62/28 | 64/26 |
| | 450 | 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 | 19/71 | 21/69 | 20/70 | 22/68 | 25/65 | 21/69 |
| | 300 | 90 | 43/47 | 41/49 | 43/47 | 45/45 | 48/42 | 46/44 |
| | 375 | 90 | 62/28 | 61/29 | 64/26 | 62/28 | 67/23 | 65/25 |
| | 450 | 90 | 90/0 | 90/0 | 90/0 | 90/0 | 90/0 | 90/0 |
| TCA (Nortriptyline) | 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 | 16/74 | 19/71 | 18/72 | 20/70 | 22/68 | 19/71 |
| | 1000 | 90 | 41/49 | 39/51 | 40/50 | 42/48 | 43/47 | 43/47 |
| | 1250 | 90 | 66/24 | 67/23 | 64/26 | 66/24 | 64/26 | 68/22 |
| | 1500 | 90 | 90/0 | 90/0 | 90/0 | 90/0 | 90/0 | 90/0 |

| | | | | | | | | |
|--------------------|-----|----|-------|-------|-------|-------|-------|-------|
| 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 (Benzoylecgonine) | 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% |

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

e.2 Interference Studies

The following compounds were evaluated for potential positive and negative interference with the assay. To evaluate for interference the sponsor prepared two urine pools that consisted of drug-free urine spiked with each of the 12 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 µg/mL.

Results of the positive interference study are presented below:

[illegible]

[illegible]

The results of the negative interference study are presented below.

[illegible]

| | | | | | | | | | | | | |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|
| 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 µg/mL, did not alter the expected negative or positive results of the ImmuTest Multi-Drug Screen Panel III Device. Therefore, at 100 µg/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 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

| | | | Predicate Devices | | % Agreement with Predicate Devices |
|------|----------|----------|-------------------|----------|------------------------------------|
| Test | | | 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.