

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

**A. 510(k) Number:**

**k041743**

**B. Purpose for Submission:**

New product

**C. Analyte:**

Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methylenedioxymethamphetamine (MDMA), Opiates, Oxycodone, Phencyclidine, Propoxyphene, and Tricyclic Antidepressants

**D. Type of Test:**

Qualitative lateral flow immunochromatographic test

**E. Applicant:**

ACON Laboratories, Inc.

**F. Proprietary and Established Names:**

ACON TRI-fect Drug Screen Test Device

**G. Regulatory Information:**

1. Regulation section:

21 CFR §862.3100: Test System, Amphetamine

21 CFR §862.3150: Test System, Barbiturate

21 CFR §862.3170: Enzyme Immunoassay, Benzodiazepine

21 CFR §862.3250: Enzyme Immunoassay, Cocaine and Cocaine Metabolites

21 CFR §862.3870: Enzyme Immunoassay, Cannabinoids

21 CFR §862.3610: Test System, Methamphetamine (MDMA)

21 CFR §862.3650: Enzyme Immunoassay, Opiates (Oxycodone)

Unclassified : Enzyme Immunoassay, Phencyclidine

21 CFR §862.3700: Enzyme Immunoassay, Propoxyphene

21 CFR §862.3910: Tricyclic Antidepressant Drugs Test System

2. Classification:

Class II

3. Product Code:

DKZ, DIS, JXM, DIO, LDJ, LAF, DJG, LCM, JXN, LFG

4. Panel:

Toxicology (91)

**H. Intended Use:**1. Intended use(s):

This device is used in the diagnosis and treatment of drug use or overdose.

2. Indication(s) for use:

“The ACON multi-CLIN Drug Screen Test Device is a rapid chromatographic immunoassay for the qualitative and simultaneous detection of Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methylenedioxymethamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, and Tricyclic Antidepressants in urine. The designated cut-off concentrations for these drugs are as follows: Amphetamine 1000 ng/mL, Barbiturates (Secobarbital) 300 ng/mL, Benzodiazepines (Oxazepam) 300 ng/mL, Cocaine 300 ng/mL, Marijuana 50 ng/mL, Methylenedioxymethamphetamine 500 ng/mL, Opiates (Morphine) 300 ng/mL, Oxycodone 100 ng/mL, Phencyclidine 25 ng/mL, Proxiphenone 300 ng/mL and Tricyclic Antidepressants (Nortriptyline) 1000 ng/mL. They are intended for healthcare professionals including professionals at point-of-care sites.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive test results are used.”

3. Special condition for use statement(s):

The ACON multi-CLIN Drug Screen Test provides only a preliminary analytical test result. A more specific alternative chemical method, such as GC/MS, must be used to obtain a confirmed analytical result. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

4. Special instrument Requirements:

Not applicable, as the device is a visually-read single-use device.

**I. Device Description:**

The device is a single-use visually read cassette device in a bi-fold plastic housing. It contains the test strips, up to four strips containing up to eleven tests with an internal control test on each strip, and a sample well for the urine for each strip. A plastic sample dispenser is also provided. Several drops of urine are added to start the test which employs traditional immunochromatographic technology. Each cassette housing can accommodate three identical panels; the test panel and an optional snap-on positive and negative external control panel.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
ACON One-Step Multi-drug Multi-line Screen Test: Amphetamines, Cocaine, Methamphetamine, Opiates, Marijuana, and PCP  
ACON One-Step Multi-drug Multi-line Screen Test: Barbiturates, Benzodiazepines, Methadone, MDMA, Opiates, and Tricyclic Antidepressants  
ACON OXY One-Step Oxycodone Test Device  
ACON One-Step Propoxyphene Test Device
2. Predicate K number(s):  
k020313, k023946, k033047, k040445
3. Comparison with predicate:  
The device is similar to or the same as to the previously cleared predicate(s) in the following ways: manufacturer, test principles, indication for use, cut-off concentration(s), used in a professional and point-of-care setting, sample matrix, endpoint, and test time.

The essential difference between the device and the predicate(s) is the test format; the new test contains up to 11 drug assays on up to four immunochromatographic strips in a new housing while the predicate(s) were individual tests on each strip or cartridge.

**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 antibody-coated particles in the device. The antibody-coated particles will then be captured by immobilized drug-specific conjugate and a colored line will appear in the test line region. A red line will not form if the sample contains drug in excess of the cutoff level because the drug will saturate all the binding sites of the drug-specific antibody. Each strip in the device contains a procedural control. Formation of a red line in control region indicates that the proper volume of urine has been added and membrane wicking has occurred. If a line does not form in the control region then the test is not valid and users are cautioned to repeat the test. A 'presumptive positive' is determined by the appearance of a procedural control line AND no line appearing next to a drug test region.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:
  - a. *Precision/Reproducibility:*

The sponsor tested the device to determine if its analytical specificity was at or around the same designated cut-off concentrations as those of the individual predicate strips. Cutoffs for amphetamines, cocaine, THC, opiates, and PCP are based on the recommendation of the Substance Abuse and Mental Health Services Administration (SAMHSA). Drug free urine and drug urine samples at -65% cut-off, -50% cutoff, -25% cut-off, +25% cut-off, and +50% cutoff were tested with three lots of ACON TRI-fect Drug Screen Test Device as well as three lots of ACON Single Drug Test Strips according to package inserts. Each lot was tested thirty times. The average percent correct read is described in the table below:

### Cut-Off Concentration Testing: Average Correct Result

| Drug Tested               | Drug-free Urine | -65% Cut-Off | -50% Cut-Off | -25% Cut-Off | +25% Cut-Off | +50% Cut-Off |
|---------------------------|-----------------|--------------|--------------|--------------|--------------|--------------|
| Amphetamines              | 100%            | 100%         | 100%         | 90.0         | 100          | 100%         |
| Barbiturates              | 100%            | 100%         | 100%         | 81.1         | 100          | 100%         |
| Benzodiazepines           | 100%            | 100%         | 100%         | 100          | 74.4         | 100%         |
| Cocaine/Metabolites       | 100%            | 100%         | 100%         | 100          | 100          | 100%         |
| Marijuana (THC)           | 100%            | 100%         | 100%         | 100          | 100          | 100%         |
| MDMA                      | 100%            | 100%         | 100%         | 81.1         | 100          | 100%         |
| Opiates                   | 100%            | 100%         | 100%         | 80.0         | 100          | 100%         |
| Oxycodone                 | 100%            | 100%         | 100%         | 84.4         | 100          | 100%         |
| Phencyclidine             | 100%            | 100%         | 100%         | 100          | 85.6         | 100%         |
| Propoxyphene              | 100%            | 100%         | 100%         | 78.9         | 100          | 100%         |
| Tricyclic Antidepressants | 100%            | 100%         | 100%         | 100          | 100          | 100%         |

**b. Linearity/assay reportable range:**

Not applicable. The assay is intended for qualitative use.

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

This device has internal process controls. A red line appearing in the negative control region confirms sufficient sample volume, adequate membrane wicking, and that the correct technique has been used. Users are informed not to interpret the test if a line forms in the positive control region or if no line forms in the negative control region.

Control standards are not supplied with this device but the manufacturer recommends the use of commercially available controls. It is good laboratory practice to confirm the test procedure and to verify proper test performance. Users should follow all applicable guidelines for testing QC materials.

**d. Detection limit:**

See the Precision/Reproducibility section above for performance around the stated cutoff concentration.

**e. Analytical specificity:**

The drugs tested for by this device, their known metabolites, and related compounds were spiked into drug-free urine at a concentration of 1000 ug/mL, then serially diluted and tested with the ACON multi-CLIN Drug Screen Test Device until the concentrations which yielded a negative result were obtained. The following table lists the lowest concentration which yields a positive result for the compound being tested when read at five minutes. Cross-reactivity was calculated by dividing the concentration at which the compound yielded a positive result by the designated cut-off concentration.

**ACON multi-CLIN Drug Test: Cross-reactivity of Compounds**

| Compound               | Conc (ng/mL) | % Cross Reactivity | Compound                                    | Conc (ng/mL) | % Cross Reactivity |
|------------------------|--------------|--------------------|---|--------------|--------------------|
| <b>AMPHETAMINES</b>    |              |                    | <b>METHYLENEDIOXYMETHAMPHETAMINE (MDMA)</b> |              |                    |
| d-Amphetamine          | 1,000        | 100                | 3,4-MDMA                                    | 500          | 100                |
| d,l-Amphetamine        | 3000         | 33                 | l-Methamphetamine                           | 100,000      | 0.5                |
| l-Amphetamine          | 50,000       | 2                  | 3,4-MDA                                     | 3000         | 17                 |
| p-OH-Amphetamine       | 3125         | 32                 | 3,4-MDMA                                    | 300          | 167                |
| 3,4-MDA                | 2000         | 50                 | <b>OPIATES</b>                              |              |                    |
| Phentermine            | 3000         | 33                 | Morphine                                    | 300          | 100                |
| <b>BARBITURATES</b>    |              |                    | Codeine                                     | 300          | 100                |
| Secobarbital           | 300          | 100                | Ethylmorphine                               | 6250         | 5                  |
| Amobarbital            | 300          | 100                | Hydrocodone                                 | 50,000       | 0.6                |
| Alphenal               | 150          | 200                | Hydromorphone                               | 3125         | 10                 |
| Aprobarbital           | 200          | 150                | Levorphanol                                 | 1500         | 20                 |
| Butobarbital           | 75           | 400                | 6-Monoacetylmorphine                        | 400          | 75                 |
| Butalbital             | 2500         | 12                 | Morphine-3- $\beta$ -d-glucuronide          | 1000         | 30                 |
| Butethanol             | 100          | 300                | Norcodeine                                  | 6250         | 5                  |
| Cyclobarbital          | 400          | 75                 | Normorphone                                 | 100,000      | 0.3                |
| Cyclopentobarbital     | 600          | 50                 | Oxycodone                                   | 30,000       | 1                  |
| Pentobarbital          | 300          | 100                | Oxymorphone                                 | 100,000      | 0.3                |
| Phenobarbital          | 100          | 300                | Thebaine                                    | 6250         | 5                  |
| <b>BENZODIAZEPINES</b> |              |                    | <b>OXYCODONE</b>                            |              |                    |
| Oxazepam               | 300          | 100                | Oxycodone                                   | 100          | 100                |
| Alprazolam             | 196          | 153                | 6-Acetylcodeine                             | 100,000      | 0.1                |
| Alprazolam, -OH        | 1262         | 24                 | Codeine                                     | 25,000       | 0.4                |
| Bromazepam             | 1562         | 19                 | Dihydrocodeine                              | 12,500       | 0.8                |
| Chlordiazepoxide       | 1562         | 19                 | Ethylmorphine                               | 25,000       | 0.4                |
| Clobazam               | 98           | 306                | Hydrocodone                                 | 6250         | 2                  |
| Clonazepam             | 781          | 38                 | Hydromorphone                               | 12,500       | 0.8                |

| Compound                       | Conc (ng/mL) | % Cross Reactivity | Compound                           | Conc (ng/mL) | % Cross Reactivity |
|--------------------------------|--------------|--------------------|------------------------------------|--------------|--------------------|
| Chlorazepate                   | 195          | 154                | Levorphanol                        | 100,000      | 0.1                |
| Delorazepam                    | 1562         | 19                 | 6-Monoacetylmorphine               | 100,000      | 0.1                |
| Desalkylflurazepam             | 390          | 77                 | Morphine                           | 100,000      | 0.1                |
| Diazepam                       | 195          | 154                | Morphine-3- $\beta$ -d-glucuronide | 100,000      | 0.1                |
| Estazolam                      | 2500         | 12                 | Norcodeine                         | 100,000      | 0.1                |
| Flunitrazepam                  | 390          | 77                 | Normorphone                        | 100,000      | 0.1                |
| ( $\pm$ ) Lorazepam            | 1562         | 19                 | Oxymorphone                        | 780          | 13                 |
| RS-Lorazepam glucuronide       | 156          | 192                | Procaine                           | 100,000      | 0.1                |
| Midazolam                      | 12,500       | 2                  | Thebaine                           | 25,000       | 0.4                |
| Nitrazepam                     | 98           | 306                | <b>PHENCYCLIDINE</b>               |              |                    |
| Norchlordiazepoxide            | 195          | 154                | Phencyclidine                      | 25           | 100                |
| Nordiazepam                    | 390          | 77                 | 4-Hydroxyphencyclidine             | 12,500       | 0.2                |
| Temazepam                      | 98           | 306                | <b>PROPOXYPHENE</b>                |              |                    |
| Triazolam                      | 2500         | 12                 | d-Propoxyphene                     | 300          | 100                |
| <b>COCAINE</b>                 |              |                    | Norpropoxyphene                    | 300          | 100                |
| Benzoyllecgonine               | 300          | 100                | <b>TRICYCLIC ANTIDEPRESSANTS</b>   |              |                    |
| Cocaine                        | 780          | 38                 | Nortriptyline                      | 1000         | 100                |
| Cocaethylene                   | 12,500       | 2                  | Amitriptyline                      | 1500         | 67                 |
| Ecgonine                       | 32,000       | 0.9                | Clomipramine                       | 12,500       | 8                  |
| <b>MARIJUANA</b>               |              |                    | Cyclobenzaprine                    | 6250         | 16                 |
| 11-nor- $\Delta^9$ -THC-9-COOH | 50           | 100                | Desipramine                        | 200          | 500                |
| Cannabinol                     | 20,000       | 0.25               | Imipramine                         | 400          | 250                |
| $\Delta^8$ -THC                | 15,000       | 0.33               | Maprotiline                        | 2000         | 50                 |
| $-\Delta^9$ -THC               | 15,000       | 0.33               | Nordoxepine                        | 1000         | 100                |
|                                |              |                    | Perphenazine                       | 50,000       | 2                  |
|                                |              |                    | Promazine                          | 1500         | 67                 |
|                                |              |                    | Promethazine                       | 25,000       | 4                  |
|                                |              |                    | Trimipramine maleate               | 3000         | 33                 |

Almost 200 compounds were tested for possible interference with the ACON TRI-fect Drug Screen Test in drug-free urine, in a urine pool spiked with -65% of the cutoff levels of the drugs of abuse, and in a urine pool spiked with +50% of the cutoff levels of the drugs of abuse. The compounds tested for possible interference are listed in the package insert; no compound caused an incorrect test result in any of the three urine pools when tested at 1000 ng/mL.

The pH of an aliquoted negative urine pool was adjusted to a range of 5 to 9 in 1 pH unit increments; four of the five aliquots were spiked with a drug to -65%, -50%, +25%, and +50% of the cutoff concentration. The spiked, pH-adjusted urine was tested in duplicate. Altering the pH of the urine sample did not affect the accuracy of any of the test results.

Fifteen (15) urine samples of specific gravity ranging from 1.004 to 1.034 were aliquoted into five samples each; one sample remained neat while the other four aliquots were spiked with each drug to the concentration of -65%, -50%, +25%, and +50% of the cutoff respectively. Each sample was tested in duplicate. Variations in specific gravity did not affect the accuracy of any of the test results.

*f. Assay cut-off:*

The identified cutoff concentrations for amphetamines, cocaine, THC, opiates, and PCP are those recommended by the Substance Abuse and Mental Health Services Administration (SAMHSA); these cutoffs are listed above. The test will yield a positive result when a given drug exceeds this concentration in the urine sample. Analytical performance of the device around the cutoff is described in SectionbM.1.a. above.

2. Comparison studies:

*a. Method comparison with predicate device:*

Urine samples were collected from presumed non-user volunteers and known positive specimens were obtained from several clinical laboratories. Drug positive samples were confirmed by GC/MS or HPLC. Specimens were coded, randomized, and blinded for side-by-side comparisons between ACON TRI-fect Drug Screen Test and ACON Single Drug Test Strips. The results are shown in the tables below:

**Comparison of ACON TRI-fect to ACON One Step Tests**

|                                   |          | ACON Single Test |     |     |     |     |      |     |      |
|-----------------------------------|----------|------------------|-----|-----|-----|-----|------|-----|------|
|                                   |          | AMP              |     | BAR |     | BZO |      | COC |      |
|                                   |          | pos              | neg | pos | neg | pos | neg  | pos | neg  |
| ACON TRI-fect                     | Positive | 140              | 0   | 103 | 0   | 122 | 1    | 132 | 4    |
|                                   | Negative | 3                | 307 | 0   | 307 | 0   | 302  | 0   | 308  |
|                                   | Total    | 143              | 307 | 103 | 307 | 122 | 303  | 132 | 312  |
| % Agreement with ACON Single Test |          | 98               | 100 | 100 | 100 | 100 | 99.7 | 100 | 98.7 |
| % Overall Agreement               |          | 99               |     | 100 |     | 99  |      | 99  |      |

|                                   |          | ACON Single Test |     |      |      |     |     |     |      |
|-----------------------------------|----------|------------------|-----|------|------|-----|-----|-----|------|
|                                   |          | THC              |     | MDMA |      | OPI |     | OXY |      |
|                                   |          | pos              | neg | pos  | neg  | pos | neg | pos | neg  |
| ACON TRI-fect                     | Positive | 132              | 0   | 91   | 1    | 149 | 0   | 141 | 2    |
|                                   | Negative | 9                | 307 | 0    | 301  | 0   | 300 | 0   | 307  |
| Total                             |          | 141              | 307 | 91   | 302  | 149 | 300 | 141 | 309  |
| % Agreement with ACON Single Test |          | 94               | 100 | 100  | 99.7 | 100 | 100 | 100 | 99.4 |
| % Overall Agreement               |          | 98               |     | 99   |      | 100 |     | 99  |      |

|                                   |          | ACON Single Test |     |     |     |     |     |
|-----------------------------------|----------|------------------|-----|-----|-----|-----|-----|
|                                   |          | PCP              |     | PPX |     | TCA |     |
|                                   |          | pos              | neg | pos | neg | pos | neg |
| ACON TRI-fect                     | Positive | 89               | 0   | 135 | 0   | 54  | 0   |
|                                   | Negative | 0                | 301 | 0   | 305 | 0   | 316 |
| Total                             |          | 89               | 301 | 135 | 305 | 54  | 316 |
| % Agreement with ACON Single Test |          | 100              | 100 | 100 | 100 | 100 | 100 |
| % Overall Agreement               |          | 100              |     | 100 |     | 100 |     |

Samples were analyzed by GC/MS and compared to the ACON TRI-fect test. Samples were considered positive if they were above the cutoff level listed in Section H.2. The percentage of samples  $\pm 25\%$  of the cutoff (as determined by GC/MS) varied by drug: AMP 7.6%, BAR 2.9%, BZO 2.6%, COC 7.7%, THC 5.1%, MDMA 2.8%, OPI 3.8%, OXY 2%, PCP 3.1%, PPX 1.6%, TCA 6.2%. Results are described in the tables below:

### Comparison of ACON TRI-fect to GC/MS

|                        |          | GC/MS |      |     |     |     |      |     |     |
|------------------------|----------|-------|------|-----|-----|-----|------|-----|-----|
|                        |          | AMP   |      | BAR |     | BZO |      | COC |     |
|                        |          | pos   | neg  | pos | neg | pos | neg  | pos | neg |
| ACON TRI-fect          | Positive | 134   | 6    | 99  | 4   | 135 | 2    | 119 | 17  |
|                        | Negative | 2     | 308  | 2   | 305 | 5   | 308  | 0   | 308 |
| Total                  |          | 136   | 314  | 101 | 309 | 140 | 310  | 119 | 325 |
| % Agreement with GC/MS |          | 98.5  | 98.1 | 98  | 99  | 96  | 99.4 | 100 | 95  |
| % Overall Agreement    |          | 98    |      | 99  |     | 99  |      | 96  |     |

|                        |          | GC/MS |      |      |      |     |      |      |     |
|------------------------|----------|-------|------|------|------|-----|------|------|-----|
|                        |          | THC   |      | MDMA |      | OPI |      | OXY  |     |
|                        |          | pos   | neg  | pos  | neg  | pos | neg  | pos  | neg |
| ACON TRI-fect          | Positive | 116   | 16   | 88   | 4    | 140 | 9    | 140  | 3   |
|                        | Negative | 5     | 311  | 0    | 301  | 0   | 300  | 1    | 306 |
| Total                  |          | 121   | 327  | 88   | 305  | 140 | 309  | 141  | 309 |
| % Agreement with GC/MS |          | 95.9  | 95.1 | 100  | 98.7 | 100 | 97.1 | 99.3 | 99  |
| % Overall Agreement    |          | 95    |      | 99   |      | 98  |      | 99   |     |

|                        |          | GC/MS |      |      |     |     |      |
|------------------------|----------|-------|------|------|-----|-----|------|
|                        |          | PCP   |      | PPX  |     | TCA |      |
|                        |          | pos   | neg  | pos  | neg | pos | neg  |
| ACON TRI-fect          | Positive | 85    | 4    | 145  | 0   | 32  | 22   |
|                        | Negative | 1     | 300  | 1    | 304 | 0   | 316  |
| Total                  |          | 86    | 304  | 146  | 304 | 32  | 338  |
| % Agreement with GC?MS |          | 98.8  | 98.7 | 99.3 | 100 | 100 | 93.5 |
| % Overall Agreement    |          | 99    |      | 99   |     | 94  |      |

**b. Matrix comparison:**

Not applicable; this test is for urine samples only.

**3. Clinical studies:**

**a. Clinical sensitivity:**

The device's reproducibility in the hands of professional users was demonstrated in studies conducted at three doctor's office sites. A registered medical assistant at each site tested urine that was spiked with multiple drugs at the following concentrations: 0, -50% of the stated cutoff concentration, -25% cutoff, +25% cutoff, and +50% cutoff. Ninety blinded and randomized specimens were tested at each site, which included 15 samples for each of the five drug levels and 15 samples that generated invalid results. Thus, a total of 60 samples were tested for each level of drug. All invalid tests were correctly interpreted; the results of the drug testing are presented in the table below:

**Reproducibility of ACON TRI-fect Test at Different Drug Levels**

| Test         | % Cut-Off | % Correct Read | Test      | % Cut-Off | % Correct Read |
|--------------|-----------|----------------|-----------|-----------|----------------|
| Amphetamines | 0         | 100            | Opiates   | 0         | 100            |
|              | -50%      | 100            |           | -50%      | 100            |
|              | -25%      | 84             |           | -25%      | 84             |
|              | +25%      | 100            |           | +25%      | 100            |
|              | +50%      | 100            |           | +50%      | 100            |
| Barbiturates | 0         | 100            | Oxycodone | 0         | 100            |
|              | -50%      | 100            |           | -50%      | 100            |

| Test                       | % Cut-Off | % Correct Read | Test                             | % Cut-Off | % Correct Read |
|----------------------------|-----------|----------------|----------------------------------|-----------|----------------|
|                            | -25%      | 84             |                                  | -25%      | 84             |
|                            | +25%      | 100            |                                  | +25%      | 100            |
|                            | +50%      | 100            |                                  | +50%      | 100            |
| <b>Benzodiazepines</b>     | 0         | 100            | <b>PCP</b>                       | 0         | 100            |
|                            | -50%      | 100            |                                  | -50%      | 100            |
|                            | -25%      | 84             |                                  | -25%      | 84             |
|                            | +25%      | 100            |                                  | +25%      | 100            |
|                            | +50%      | 100            |                                  | +50%      | 100            |
| <b>Cocaine Metabolites</b> | 0         | 100            | <b>Propoxyphene</b>              | 0         | 100            |
|                            | -50%      | 100            |                                  | -50%      | 100            |
|                            | -25%      | 84             |                                  | -25%      | 84             |
|                            | +25%      | 100            |                                  | +25%      | 100            |
|                            | +50%      | 100            |                                  | +50%      | 100            |
| <b>THC/Marijuana</b>       | 0         | 100            | <b>Tricyclic Antidepressants</b> | 0         | 100            |
|                            | -50%      | 100            |                                  | -50%      | 100            |
|                            | -25%      | 84             |                                  | -25%      | 84             |
|                            | +25%      | 100            |                                  | +25%      | 100            |
|                            | +50%      | 100            |                                  | +50%      | 100            |
| <b>MDMA</b>                | 0         | 100            | <b>Invalid Result Samples</b>    | 0         | 100            |
|                            | -50%      | 100            |                                  | -50%      | 100            |
|                            | -25%      | 84             |                                  | -25%      | 84             |
|                            | +25%      | 100            |                                  | +25%      | 100            |
|                            | +50%      | 100            |                                  | +50%      | 100            |

Overall agreement of TRI-fect with expected results in the hands of professional users at point-of-care sites: 2398/2475 = 97%

***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.