

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

A. 510(k) Number:

k092266

B. Purpose for Submission:

New device

C. Measurand:

Methamphetamine

D. Type of Test:

Qualitative and semi-quantitative enzyme immunoassay

E. Applicant:

Randox Laboratories

F. Proprietary and Established Names:

Randox Methamphetamine Assay
Randox Multi Drug Calibrator Set
Randox Multi Drug Control Level I and II

G. Regulatory Information:

| Product Code | Classification | Regulation Section | Panel |
|--------------|----------------|---|----------------|
| LAF | II | 862.3619- Methamphetamine test system | 91-Toxicology |
| DKB | II | 862.3200– Clinical toxicology calibrator | 91- Toxicology |
| DIF | I, reserved | 862.3280–Clinical toxicology control material | 91- Toxicology |

H. Intended Use:

1. Intended use(s):

See indications for use below

2. Indication(s) for use:

Randox Methamphetamine Assay

The Randox Laboratories Ltd. Methamphetamine Assay is an in vitro diagnostic test for the qualitative and semi-quantitative analysis of Methamphetamine in human urine at the cutoff of 1000 ng/mL. The assay is calibrated against methamphetamine. Qualitative and semi-quantitative results can be utilized in the diagnosis and treatment of Methamphetamine use or overdose. The Randox Methamphetamine Assay has been developed for use on the RXseries analyzers, which includes the Rx Daytona and the Rx Imola analyzers. This in vitro diagnostic device is intended for prescription use only.

The semi-quantitative mode is for purposes of

- (1) enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GCMS
- or
- (2) permitting laboratories to establish quality control procedures.

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatograph/Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Randox Multidrug Calibrator Set

The Randox Multidrug Calibrator Set consists of liquid calibrators containing Methamphetamine, Oxazepam and Methadone. There are 5 levels of calibrator. They have been developed for use in the calibration of Methamphetamine Benzodiazepines and Methadone assays for use on the RXseries analyzers, which includes the RX Daytona and the RX Imola analyzers. This in vitro diagnostic device is intended for prescription use only.

Randox Multidrug Controls, Level 1 & 2

The Randox Multidrug Controls level 1 and 2 are liquid controls containing Methamphetamine, Oxazepam and Methadone. There are 2 levels of controls. They have been developed for use in the quality control of Methamphetamines, Benzodiazepines and Methadone assays for use on the RXseries analyzers, which includes the RX Daytona and the RX Imola analyzers. This in vitro diagnostic device is intended for prescription use only.

3. Special conditions for use statement(s):

Prescription use only

4. Special instrument requirements:

The studies were performed on the X Daytona and the X Imola analyzers.

I. Device Description:

The assay consists of ready-to-use liquid reagents. Reagent 1 contains mouse monoclonal methamphetamine antibodies, glucose-6-phosphate (G6P), nicotinamide adenine dinucleotide (NAD), stabilizers and sodium azide <0.1% w/v. Reagent 2 contains amphetamine- labeled glucose-6-phosphate dehydrogenase (G6PDH) in buffer and sodium azide <0.1% w/v. The calibrators and controls are ready to use human urine-based liquid. The calibrators and controls are sold separately and previously cleared for benzodiazepine and methadone.

J. Substantial Equivalence Information:

1. Predicate device name(s):

DRI Multi-Drug Calibrators and Controls, Microgenics Corporation

2. Predicate 510(k) number(s):

k040758

3. Comparison with predicate:

| Similarities/Differences | | |
|--------------------------|--|--------------------------|
| Item | Device | Predicate |
| Intended Use | Qualitative and semi-quantitative analysis of methamphetamine in human urine | Same |
| Test Principle | A competitive enzyme immunoassay based on competition between drug in the sample and drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for a fixed amount of antibody in the reagent. In the absence of drug in the sample the drug-labeled G6PDH conjugate is bound to antibody and enzyme activity is inhibited. When free drug is present in the sample, antibody binds to the free drug and the unbound drug-labeled G6PDH exhibits its maximum enzyme activity. Active enzyme converts NAD to NADH resulting in an absorbance change measured spectrophotometrically at 340nm. | Same |
| Cutoff | 1000 ng/mL | 500 ng/mL and 1000 ng/mL |

| Similarities/Differences | | |
|--------------------------|--|--|
| Item | Device | Predicate |
| Matrix | Human Urine | Human Urine |
| Type of reagent | Liquid Ready to use, two reagent assay | Same |
| Calibrators | Liquid Ready to use (0, 300, 500, 1000, 2000 ng/mL) | Liquid ready to use (500, 1000, 1500, 2000 ng/mL) |
| Controls | Liquid ready to use (+/- 25% from cutoffs) | Same |

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

None were referenced

L. Test Principle:

The Randox Methamphetamine assay is based on competition between drug in the sample and drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for a fixed amount of antibody in the reagent. In the absence of drug in the sample, the drug-labeled G6PDH conjugate is bound to antibody, thus the enzyme activity is inhibited. When free drug is present in the sample, the antibody will bind to the free drug and the unbound amphetamine-labeled G6PDH exhibits its maximal enzyme activity. The G6PDH activity is measured spectrophotometrically at 340 nm because of conversion of NAD to NADH.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision studies were performed by spiking a d-methamphetamine into negative urine at various concentrations (-75%, -50%, -25%, +25% and 50%, 75% and 200% of the cutoff and negative). Concentrations were confirmed by GC-MS. Studies were performed on 2 RX Daytona systems and 2 RX Imola systems. Testing was performed twice a day for 20 non-consecutive days for all concentrations.

During the study, a calibration was performed twice on each of 4 analyzers and there were two operators. The results are presented in the table below:

| Qualitative Methamphetamine | | RX Daytona | RX Imola |
|------------------------------------|---------------------|------------|------------|
| Sample concentration (ng/mL) | No. Observations | | |
| | | # Neg/#Pos | # Neg/#Pos |
| 0 (negative) | 80 | 80/0 | 80/0 |
| 250 (-75% c/o) | 80 | 80/0 | 80/0 |
| 500 (-50% c/o) | 80 | 80/0 | 80/0 |
| 750 (-25% c/o) | 80 | 80/0 | 80/0 |
| 1250 (+25% c/o) | 80 | 0/80 | 0/80 |
| 1500 (+50% c/o) | 80 | 0/80 | 0/80 |
| 1750 (+75% c/o) | 80 | 0/80 | 0/80 |
| 2000 (+100% c/o) | 80 | 0/80 | 0/80 |

| Semi-quantitative Methamphetamine | | RX Daytona | RX Imola |
|--|---------------------|------------|------------|
| Sample concentration (ng/mL) | No. Observations | | |
| | | # Neg/#Pos | # Neg/#Pos |
| 0 (negative) | 80 | 80/0 | 80/0 |
| 250 (-75% c/o) | 80 | 80/0 | 80/0 |
| 500 (-50% c/o) | 80 | 80/0 | 80/0 |
| 750 (-25% c/o) | 80 | 80/0 | 80/0 |
| 1250 (+25% c/o) | 80 | 0/80 | 0/80 |
| 1500 (+50% c/o) | 80 | 0/80 | 0/80 |
| 1750 (+75% c/o) | 80 | 0/80 | 0/80 |
| 2000 (+100% c/o) | 80 | 0/80 | 0/80 |

b. Linearity/assay reportable range:

Linearity across the range was confirmed by spiking a drug free urine pool with drug and serially diluting the sample into 20 additional concentrations. Each sample was assayed on both the Daytona and Imola analyzers in the semi-quantitative mode. The dilutions were assayed in triplicate then averaged and compared to the expected result and the percent recovery was calculated. Results are presented in the table below:

| Methamphetamine | Daytona Analyzer | | Imola Analyzer | |
|-----------------|------------------|----------|----------------|----------|
| | Expected | Observed | % Recovery | Observed |
| 0 | 6 | n/a | 0 | n/a |
| 20 | 14.1 | 70.32 | 7.76 | 38.78 |
| 40 | 12.4 | 30.91 | 18.49 | 46.23 |
| 60 | 0 | 0.00 | 86.59 | 144.32 |
| 80 | 26.12 | 32.65 | 86.59 | 108.24 |
| 100 | 84.2 | 84.17 | 133.07 | 133.07 |
| 120 | 86.9 | 72.45 | 176.23 | 146.86 |
| 140 | 55.8 | 39.86 | 107.47 | 76.77 |
| 160 | 114.97 | 71.86 | 191.03 | 119.40 |
| 180 | 170.69 | 94.83 | 201.79 | 112.11 |
| 200 | 178.37 | 89.19 | 192.68 | 96.34 |
| 400 | 417.50 | 104.37 | 430.76 | 107.69 |
| 600 | 581.39 | 96.90 | 638.26 | 106.38 |
| 800 | 758.99 | 94.87 | 906.14 | 113.27 |
| 1000 | 936.01 | 93.60 | 1002.05 | 100.21 |
| 1200 | 1024.22 | 85.35 | 1166.54 | 97.21 |
| 1400 | 1256.26 | 89.73 | 1506.47 | 107.61 |
| 1600 | 1506.05 | 94.13 | 1499.85 | 93.74 |
| 1800 | 1834.94 | 101.94 | 1836.57 | 102.03 |
| 2000 | 2247.40 | 112.37 | 2159.67 | 107.98 |

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

Calibrators and controls for are traceable to Cerilliant Reference Standards and confirmed by GC/MS.

An intermediate concentration of calibrators (designated as master calibrator) was made by adding Methamphetamine Standard to buffered human urine matrix. This master calibrator was value-assigned by GC/MS. The master calibrators are then gravimetrically diluted using synthetic urine to various concentration levels. The concentration values of diluted calibrators/controls are assigned using GC/MS. These calibrators/controls become internal reference standards. These internal reference standards are aliquoted and stored at below -80°C environments and are used only for testing working calibrators (i.e. calibrators used to produce products). The production protocol for internal reference standards and working calibrators are identical except that the working calibrators are tested against the internal reference standards.

Stability: Shelf-life and open-vial stability studies were performed for the calibrators and controls using both accelerated and on-going real-time studies. The protocols were found to be adequate. The Randox Methamphetamine assay reagents, controls and calibrators are stable for 18 months when stored unopened at +2 to 8°C and for 28 days once opened and stored at +2 to 8°C.

Calibrators and controls are sold separately. In the labeling the sponsor recommends that users follow federal, state and local guidelines for testing external quality control materials.

d. Detection limit:

Performance at low drug concentrations in the semi-quantitative assay was characterized by the determination of recovery (see section b above).

e. Analytical specificity:

Cross-reactivity was established by spiking various concentrations of structurally related into drug-free urine. Results are expressed as a minimum concentration of metabolite or compound required to produce a response approximately equivalent to the cutoff concentration of the assay. The percent cross-reactivity of those compounds are presented below:

Structurally related:

| Daytona Compound | Qualitative | | Semi-quantitative | |
|----------------------------|-----------------------------|-----------------------|-----------------------------|-----------------------|
| | Equivalent to 1000 ng/mL | % Cross reactivity | Equivalent to 1000 ng/mL | % Cross reactivity |
| l-amphetamine | 58,650 | 1.17 | 53,059 | 1.88 |
| l-methamphetamine | 10,272 | 9.74 | 15,799 | 6.33 |
| d,l-methamphetamine | 2,170 | 46.08 | 1,987 | 50.34 |
| (+/-)-amphetamine | 1,512 | 66.13 | 1,550 | 64.53 |
| d-methamphetamine | 1,000 | 100 | 1,000 | 100 |
| d-amphetamine | 909 | 110.05 | 843 | 118.6 |
| MDA | 2,252 | 44.41 | 1,950 | 51.3 |
| MDMA | 4,131 | 24.21 | 2,519 | 39.7 |
| MDEA | 54,161 | 1.85 | 44,479 | 2.25 |
| MBDB | 4,356 | 22.96 | 4,056 | 24.66 |
| BDB | 7,631 | 13.1 | 7,520 | 13.3 |
| B-phenylethylamine | 56,133 | 1.78 | 54,329 | 1.84 |
| Tyramine | 100,000 | 0.27 | 100,000 | 0.27 |
| Phentermine | 36,740 | 2.72 | 31,822 | 3.14 |
| Phenylpropanolamine | 100,000 | 0.29 | 100,000 | 0.29 |
| Chlorpheniramine | 100,000 | 0 | 100,000 | 0 |

| Imola Compound | Qualitative | | Semi-quantitative | |
|---------------------|-----------------------------|-----------------------|-----------------------------|-----------------------|
| | Equivalent to 1000 ng/mL | % Cross reactivity | Equivalent to 1000 ng/mL | % Cross reactivity |
| l-amphetamine | 34,273 | 2.92 | 51,967 | 1.92 |
| l-methamphetamine | 13,942 | 7.17 | 14,676 | 6.81 |
| d,l-methamphetamine | 2,119 | 47.20 | 2,844 | 35.16 |
| (+/-)-amphetamine | 1,169 | 85.53 | 1,495 | 66.91 |
| d-methamphetamine | 1,000 | 100 | 1,000 | 100 |
| d-amphetamine | 698 | 143.26 | 905 | 110.47 |
| MDA | 1,412 | 70.82 | 1,944 | 51.45 |
| MDMA | 2,189 | 45.88 | 3,547 | 39.27 |
| MDEA | 28,283 | 3.54 | 53,076 | 1.88 |
| MBDB | 3,665 | 27.29 | 3,481 | 28.73 |
| BDB | 7,035 | 14.22 | 8,178 | 12.23 |
| B-phenylethylamine | 24,085 | 2.93 | 60,528 | 1.65 |
| Tyramine | 100,000 | 0.27 | 100,000 | 0.27 |
| Phentermine | 18,306 | 5.46 | 24,516 | 4.08 |
| Phenylpropanolamine | 100,000 | 0.29 | 100,000 | 0.29 |
| Chlorpheniramine | 100,000 | 0 | 100,000 | 0 |

Structurally un-related

This study was performed by spiking structurally unrelated compounds into urine samples containing d-methamphetamine. The concentration of drug in the urine sample were +25% and -25% of the cut-off concentration of 1000 ng/mL. The results are presented below:

| Compound | Conc. ng/mL | Daytona | | | |
|--------------------------------|----------------|--|-------------|--|-------------|
| | | -25% of 1000 ng/mL d-methamphetamine cutoff | | +25% of 1000 ng/mL d-methamphetamine cutoff | |
| | | Qualitative | Semi-quant. | Qualitative | Semi-quant. |
| 11-nor9-carboxy- delta9-THC | 100,000 | NEG | NEG | POS | POS |
| 11-hydroxy-delta9- THC | 100,000 | NEG | NEG | POS | POS |
| 6 Acetyl morphine | 100,000 | NEG | NEG | POS | POS |
| Amitriptyline | 100,000 | NEG | NEG | POS | POS |
| Amobarbital | 100,000 | NEG | NEG | POS | POS |
| Ascorbic acid | 100,000 | NEG | NEG | POS | POS |
| Aspirin | 100,000 | NEG | NEG | POS | POS |
| Benzoyllecgonine | 100,000 | NEG | NEG | POS | POS |
| Caffeine | 100,000 | NEG | NEG | POS | POS |
| Cannabidiol | 100,000 | NEG | NEG | POS | POS |
| Cocaethylene | 100,000 | NEG | NEG | POS | POS |

| | | Daytona | | | |
|----------------------------|----------------|--|--------|--|-----|
| Compound | Conc. ng/mL | -25% of 1000 ng/mL d-methamphetamine cutoff | | +25% of 1000 ng/mL d-methamphetamine cutoff | |
| | | Cocaine | 70,000 | NEG | NEG |
| Codeine | 70,000 | NEG | NEG | POS | POS |
| Cotinine | 100,000 | NEG | NEG | POS | POS |
| delta9-THC | 70,000 | NEG | NEG | POS | POS |
| d-Ephedrine | 100,000 | NEG | NEG | POS | POS |
| Diazepam | 100,000 | NEG | NEG | POS | POS |
| Dihydrocodeine | 100,000 | NEG | NEG | POS | POS |
| d,l-ephedrine | 100,000 | NEG | NEG | POS | POS |
| Ecgonine methyl ester | 100,000 | NEG | NEG | POS | POS |
| EDDP | 100,000 | NEG | NEG | POS | POS |
| EMDP | 100,000 | NEG | NEG | POS | POS |
| Heroin | 40,000 | NEG | NEG | POS | POS |
| Ibuprofen | 100,000 | NEG | NEG | POS | POS |
| l-ephedrine | 10,000 | NEG | NEG | POS | POS |
| LAAM | 100,000 | NEG | NEG | POS | POS |
| Methadone | 100,000 | NEG | NEG | POS | POS |
| Morphine | 100,000 | NEG | NEG | POS | POS |
| Oxycodone | 100,000 | NEG | NEG | POS | POS |
| Paracetamol | 100,000 | NEG | NEG | POS | POS |
| Phendimetrazine | 25,000 | NEG | NEG | POS | POS |
| R,R (-) Pseudoephedrine | 100,000 | NEG | NEG | POS | POS |
| S,S (+) Pseudoephedrine | 8,000 | NEG | NEG | POS | POS |
| Temazepam | 100,000 | NEG | NEG | POS | POS |

| | | Imola | | | |
|--------------------------------|----------------|--|-------------|--|-------------|
| Compound | Conc. ng/mL | -25% of 1000 ng/mL d-methamphetamine cutoff | | +25% of 1000 ng/mL d-methamphetamine cutoff | |
| | | Qualitative | Semi-quant. | Qualitative | Semi-quant. |
| 11-nor9-carboxy- delta9-THC | 100,000 | NEG | NEG | POS | POS |
| 11-hydroxy-delta9- THC | 100,000 | NEG | NEG | POS | POS |
| 6 Acetyl morphine | 100,000 | NEG | NEG | POS | POS |
| Amitriptyline | 100,000 | NEG | NEG | POS | POS |
| Amobarbital | 100,000 | NEG | NEG | POS | POS |
| Ascorbic acid | 100,000 | NEG | NEG | POS | POS |
| Aspirin | 100,000 | NEG | NEG | POS | POS |
| Benzoyllecgonine | 100,000 | NEG | NEG | POS | POS |

| Compound | Conc. ng/mL | Imola | | | |
|----------------------------|----------------|--|-----|--|-----|
| | | -25% of 1000 ng/mL d-methamphetamine cutoff | | +25% of 1000 ng/mL d-methamphetamine cutoff | |
| Caffeine | 100,000 | NEG | NEG | POS | POS |
| Cannabidiol | 100,000 | NEG | NEG | POS | POS |
| Cocaethylene | 100,000 | NEG | NEG | POS | POS |
| Cocaine | 70,000 | NEG | NEG | POS | POS |
| Codeine | 70,000 | NEG | NEG | POS | POS |
| Cotinine | 100,000 | NEG | NEG | POS | POS |
| delta9-THC | 70,000 | NEG | NEG | POS | POS |
| d-Ephedrine | 100,000 | NEG | NEG | POS | POS |
| Diazepam | 100,000 | NEG | NEG | POS | POS |
| Dihydrocodeine | 100,000 | NEG | NEG | POS | POS |
| d,l-ephedrine | 100,000 | NEG | NEG | POS | POS |
| Ecgonine methyl ester | 100,000 | NEG | NEG | POS | POS |
| EDDP | 100,000 | NEG | NEG | POS | POS |
| EMDP | 100,000 | NEG | NEG | POS | POS |
| Heroin | 40,000 | NEG | NEG | POS | POS |
| Ibuprofen | 100,000 | NEG | NEG | POS | POS |
| l-ephedrine | 5,000 | NEG | NEG | POS | POS |
| LAAM | 100,000 | NEG | NEG | POS | POS |
| Methadone | 100,000 | NEG | NEG | POS | POS |
| Morphine | 100,000 | NEG | NEG | POS | POS |
| Oxycodone | 100,000 | NEG | NEG | POS | POS |
| Paracetamol | 100,000 | NEG | NEG | POS | POS |
| Phendimetrazine | 25,000 | NEG | NEG | POS | POS |
| R,R (-) Pseudoephedrine | 100,000 | NEG | NEG | POS | POS |
| S,S (+) Pseudoephedrine | 5,000 | NEG | NEG | POS | POS |
| Temazepam | 100,000 | NEG | NEG | POS | POS |

Endogenous Compounds:

The sponsor prepared urine-free samples spiked with d-methamphetamine at concentration levels ($\pm 25\%$ of the cutoff) and evaluated the possible interference the following endogenous compounds; Total Bilirubin, Direct Bilirubin, Creatinine, Urea, Glucose, H.S.A., Ethanol, Acetone, Gamma globulin, Oxalic acid, Riboflavin, sodium Chloride, Boric acid, Sodium azide, Sodium fluoride. No positive or negative interference was seen.

To test for possible positive and/or negative interference from specific gravity, the sponsor prepared samples containing d-methamphetamine at concentration levels ($\pm 25\%$ of the cutoff) with specific gravities ranging from 1.000 to

1.030. No positive or negative interference due to specific gravity was observed.

To test for potential positive or negative interference from pH the sponsor prepared samples containing d-methamphetamine at concentration levels ($\pm 25\%$ of the cutoff) with pH values of 3, 4.5, 5, 6, 7, 8 and 11. No negative or positive interference due to pH was observed.

f. Assay cut-off:

Analytical performance of the device around the claimed cutoff is described in the precision section (1 a.) above.

2. Comparison studies:

a. Method comparison with predicate device:

The sponsor conducted a method comparison study to evaluate the performance of the device for detection of methamphetamine. In, the method comparison study, 91 unaltered clinical samples (45 negative and 46 positive) were tested with the Randox Methamphetamine assay and compared against the results obtained with GC/MS. The results of the studies are presented below:

Qualitative Methamphetamine

| | | Negative | Low Negative by GC/MS (less than - 50%) | Near Cutoff Negative by GC/MS (Between - 50% and cutoff) | Near Cutoff Positive by GC/MS (Between the cutoff and +50%) | High Positive by GC/MS (greater than +50%) | % Agreement |
|------------|----------|----------|---|--|---|--|-------------|
| RX Daytona | Positive | 0 | 0 | 1 | 16 | 30 | 100% |
| | Negative | 25 | 9 | 10 | 0 | 0 | 97.8% |
| RX Imola | Positive | 0 | 0 | 1 | 16 | 30 | 100% |
| | Negative | 25 | 9 | 10 | 0 | 0 | 97.8% |

Semi-quantitative Methamphetamine

| | | Negative | Low Negative by GC/MS (less than - 50%) | Near Cutoff Negative by GC/MS (Between - 50% and cutoff) | Near Cutoff Positive by GC/MS (Between the cutoff and +50%) | High Positive by GC/MS (greater than +50%) | % Agreement |
|------------|----------|----------|---|--|---|--|-------------|
| RX Daytona | Positive | 0 | 0 | 1 | 16 | 30 | 100% |
| | Negative | 25 | 9 | 10 | 0 | 0 | 97.8% |
| RX Imola | Positive | 0 | 0 | 1 | 15 | 30 | 97.8% |
| | Negative | 25 | 9 | 10 | 1 | 0 | 97.8% |

Discordant

| RX Daytona | | |
|----------------------|--|-------------------------------------|
| Cutoff Value (ng/mL) | Randox Methamphetamine Assay (POS/NEG) | Drug/Metabolite GC/MS value (ng/mL) |
| Qualitative | | |
| 1000 | POS | 904 Methamphetamine |
| Semi-quantitative | | |
| 1000 | POS | 904 Methamphetamine |

Discordant

| RX Imola | | |
|----------------------|--|-------------------------------------|
| Cutoff Value (ng/mL) | Randox Methamphetamine Assay (POS/NEG) | Drug/Metabolite GC/MS value (ng/mL) |
| Qualitative | | |
| 1000 | POS | 904 Methamphetamine |
| Semi-quantitative | | |
| 1000 | POS | 904 Methamphetamine |
| 1000 | NEG | 1138 Methamphetamine |

b. Matrix comparison:

Not applicable. The test is only for urine specimens.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Not applicable

N. Proposed 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.