March 12, 2020

MedTest Dx
William Cripps
Director, R&D, QA/RA
5449 Research Drive
Canton, MI 48188

Re: k191638
Trade/Device Name: Pointe Scientific Cocaine Metabolite Enzyme Immunoassay
Regulation Number: 21 CFR 862.3250
Regulation Name: Cocaine And Cocaine Metabolite Test System
Regulatory Class: Class II
Product Code: DIO
Dated: January 27, 2020
Received: January 28, 2020

Dear William Cripps:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

Please note that if you modify your IVD in the future to exceed any of the limitations to the exemption found in 21 CFR 862.9(c), your device will require a new 510(k) prior to marketing this device in the United States and will not be exempt from the premarket notification requirements so long as it exceeds the limitations to the exemption found in 21 CFR 862.9.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191638

Device Name
Pointe Scientific Cocaine Metabolite Enzyme Immunoassay

Indications for Use *(Describe)*
Indications For Use: The Pointe Scientific Cocaine Metabolite Enzyme Immunoassay is intended for the qualitative determination of benzoylecgonine (a cocaine metabolite) in human urine at a cutoff value of 150 ng/mL. Rx only.

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 or Liquid Chromatograph/Mass Spectrometry (GC/MS or LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of Safe Medical Device Act of 1990 and 21 CFR 807.92.

a. Device Information

Category	Comments
Sponsor	MedTest Dx 5449 Research Drive Canton, MI 48188 Phone: 734-487-8300 Fax: 734-483-1592
Correspondent Contact Information	William Cripps Director, R&D/RA/QA Email: wcripps@medtestdx.com Phone: 734-487-8300 ext. 120 Fax: 734-483-1592
Device 510(k) Number	K191638
Device Common Name	Cocaine Metabolite Enzyme Immunoassay
Trade or Proprietary Name	Pointe Scientific Cocaine Metabolite Enzyme Immunoassay
Candidate Device Product Code, Classification, Classification Name & Panel	DIO, Class II, 21 CFR 862. 3250 – Cocaine Metabolite Test System, 91 – Toxicology

Predicate Device Information

Predicate Device	Cocaine Metabolite Enzyme Immunoassay
Predicate Device Manufacturer	Lin-Zhi International, Inc.
Predicate Device Premarket Notification #:	K113139

b. Date Summary Prepared

June 17, 2019
Updated January 27, 2020
Updated February 3, 2020
Updated February 26, 2020

c. Description of Device

The Cocaine Metabolite Enzyme Immunoassay consists of ready-to-use liquid reagents:

- Reagent 1 contains a mouse monoclonal anti-benzoylecgonine antibody, glucose-6-phosphate (G6P) nicotinamide adenine dinucleotide (NAD), stabilizers and sodium azide (0.09%) as a preservative.

- Reagent 2 contains glucose-6-phosphate dehydrogenase (G6PDH) labeled with benzoylecgonine in buffer with sodium azide (0.09%) as a preservative.

The 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. Enzyme activity decreases upon binding to the antibody, and the drug concentration in the sample is measured in terms of enzyme activity. In the absence of drug in the sample, benzoylecgonine-labeled G6PDH conjugate is bound to antibody, and the enzyme activity is inhibited. On the other hand, when drug is present in the sample, antibody binds to the free drug; the unbound benzoylecgonine-labeled G6PDH then exhibits its maximal enzyme activity. Active enzyme converts nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that can be measured spectrophotometrically at a 340 nm primary wavelength.

The assay has a cutoff of 150 ng/mL benzoylecgonine.

d. Intended Use

The Pointe Scientific Cocaine Metabolite Enzyme Immunoassay is intended for the qualitative determination of benzoylecgonine (a cocaine metabolite) in human urine at a cutoff value of 150 ng/mL. Rx only.

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 or Liquid Chromatograph/Mass Spectrometry (GC/MS or LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

e. Comparison to Predicate Device

The chart below illustrates the similarities between the Pointe Scientific Cocaine Metabolite Enzyme Immunoassay and the predicate, Lin-Zhi International (LZI) Cocaine Metabolite Enzyme Immunoassay.

Characteristics	Cocaine Metabolite Enzyme Immunoassay (Proposed Device)	Lin-Zhi International (LZI) K113139 (Predicate Device)
Intended Use	The Pointe Scientific Cocaine Metabolite Enzyme Immunoassay is intended for the qualitative determination of benzoylecgonine (a cocaine metabolite) in human urine at a cutoff value of 150 ng/mL. Rx only. 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 or Liquid Chromatograph/Mass Spectrometry (GC/MS or LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.	To be used for the qualitative and semi-quantitative determination of benzoylecgonine in human urine, at a cutoff value of 150 ng/mL. This assay is designed for prescription use with a number of clinical chemistry analyzers. 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 or Liquid Chromatograph/Mass Spectrometry (GC/MS or LC/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.
Contents	The assay consists of ready-to-use liquid reagents. Reagent 1 contains a mouse monoclonal anti-benzoylecgonine antibody, glucose-6-phosphate (G6P) nicotinamide adenine dinucleotide (NAD), stabilizers and sodium azide (0.09%) as a preservative. Reagent 2 contains glucose-6-phosphate dehydrogenase (G6PDH) labeled with benzoylecgonine in buffer with sodium azide (0.09%) as a preservative	Same
Analyte	Benzoylecgonine	Same
Cutoff	150 ng/mL	Same
Matrix	Urine	Same
Calibrators	2 Levels (0 ng/mL, 150 ng/mL)	5 Levels (0, 75, 150, 300, 1000 ng/mL)
Controls	2 levels (112.5 ng/mL, 187.5 ng/mL)	Same
Storage	2-8°C until expiration date	Same

f. Performance Data

Performance was evaluated at the MedTest Dx site on both the Mindray BS-480 and the Mindray BA-800M clinical chemistry analyzers.

Method Comparison Studies

Method comparison studies were performed following CLSI EP-12A2, using remnant urine samples obtained from a third-party biorepository. Results obtained through the Pointe Scientific Cocaine Metabolite Enzyme Immunoassay were compared against results obtained from a fully validated and qualified Agilent 6460 LC/MS. Included below is the precision and accuracy data for the analytical reference method on the Agilent 6460 LC/MS.

When analyzing Benzoylecgonine reference materials from Cerilliant with the reference LC/MS method, the following results were obtained.

Precision

Benzoylecgonine Std	Mean (ng/mL)	%CV
Level 1	19.13	5.3
Level 2	25.81	6.5
Level 3	136.13	5.3

Accuracy

Reference Level	Assigned Value	Recovered Value	% Recovery
Level 1	10 ng/mL	10.70 ng/mL	107.0
Level 2	18.75 ng/mL	20.11 ng/mL	107.2
Level 3	25 ng/mL	25.80 ng/mL	103.2
Level 4	75 ng/mL	69.89 ng/mL	93.2
Level 5	150 ng/mL	149.89 ng/mL	99.9
Level 6	250 ng/mL	274.49 ng/mL	109.7

Traceability

All standards used in the LC/MS methods are certified reference materials obtained from Cerilliant.

BS-480:

114 unaltered clinical urine remnant samples were evaluated on 3 nonconsecutive days by the Pointe Scientific Cocaine Metabolite Enzyme Immunoassay and compared to LC/MS. Results from the qualitative study are presented below.

Candidate Device Results	Negative	< 75 ng/mL by LC/MS	75-150 ng/mL by LC/MS	150-225 ng/mL by LC/MS	>225 ng/mL by LC/MS
Positive	0	0	1	4	36
Negative	56	8	4	5	0

% Agreement among positives is 88.9% (40/45)
% Agreement among negatives is 98.6% (68/69)

Discordant Results

Cutoff Value	Pointe Scientific Cocaine Metabolite Enzyme Immunoassay Result	Drug Metabolite LC/MS Value Result
150 ng/mL	Positive	Negative (102 ng/mL)
150 ng/mL	Negative	Positive (222 ng/mL)
150 ng/mL	Negative	Positive (214 ng/mL)
150 ng/mL	Negative	Positive (156 ng/mL)
150 ng/mL	Negative	Positive (165 ng/mL)
150 ng/mL	Negative	Positive (164 ng/mL)

BA-800M

114 unaltered clinical urine remnant samples were evaluated on 3 nonconsecutive days by the Pointe Scientific Cocaine Metabolite Enzyme Immunoassay and compared to LC/MS. Results from the qualitative study are presented below.

Candidate Device Results	Negative	< 75 ng/mL by LC/MS	75-150 ng/mL by LC/MS	150-225 ng/mL by LC/MS	>225 ng/mL by LC/MS
Positive	0	0	1	6	36
Negative	56	8	4	3	0

% Agreement among positives is 93.3% (42/45)
% Agreement among negatives is 98.6% (68/69)

Discordant Results

Cutoff Value	Pointe Scientific Cocaine Metabolite Enzyme Immunoassay Result	Drug Metabolite LC/MS Value Result
150 ng/mL	Positive	Negative (102 ng/mL)
150 ng/mL	Negative	Positive (214 ng/mL)
150 ng/mL	Negative	Positive (156 ng/mL)
150 ng/mL	Negative	Positive (164 ng/mL)

Precision Studies

Precision studies were conducted in accordance with CLSI EP05-A3. Precision was determined by spiking benzoylecgonine into drug free urine at various concentrations (zero, -75%, -50%, -25%, at the cutoff, 125%, 150%, 175% and 200% of the cutoff). Concentrations were confirmed by LC/MS. Testing for both the with-in run and between-run studies were performed by testing each sample in replicate, with two runs per day, for 20 days. The qualitative results are presented below as Positive/Negative.

BS-480 Qualitative Results (Pos/Neg):

	Within Run		Between Run	
Sample concentration (ng/mL)	**No. Observations**	**# Neg/#Pos**	**No. Observations**	**# Neg/#Pos**
0 (negative)	20	20/0	80	80/0
37.5 (-75% c/o)	20	20/0	80	80/0
75 (-50% c/o)	20	20/0	80	80/0
112.5 (-25% c/o)	20	20/0	80	80/0
150 (cutoff)	20	19/1	80	68/12
187.5 (+25% c/o)	20	0/20	80	0/80
225 (+50% c/o)	20	0/20	80	0/80
262.5 (+75% c/o)	20	0/20	80	0/80
300 (+100% c/o)	20	0/20	80	0/80

These results indicate that the Pointe Scientific Cocaine Metabolite Enzyme Immunoassay has acceptable precision on the BS-480.

BA-800M Qualitative Results (Pos/Neg):

	Within Run		Between Run	
Sample concentration (ng/mL)	**No. Observations**	**# Neg/#Pos**	**No. Observations**	**# Neg/#Pos**
0 (negative)	20	20/0	80	80/0
37.5 (-75% c/o)	20	20/0	80	80/0
75 (-50% c/o)	20	20/0	80	80/0
112.5 (-25% c/o)	20	20/0	80	80/0
150 (cutoff)	20	7/13	80	41/39
187.5 (+25% c/o)	20	0/20	80	0/80
225 (+50% c/o)	20	0/20	80	0/80
262.5 (+75% c/o)	20	0/20	80	0/80
300 (+100% c/o)	20	0/20	80	0/80

These results indicate that the Pointe Scientific Cocaine Metabolite Enzyme Immunoassay has acceptable precision on the BA-800M.

Interference (Endogenous Substances) Study

Interference studies were conducted following a modification to CLSI EP07.

The following endogenous compounds were added into drug-free urine, urine sample spiked to 75% of benzoylecgonine and urine spiked to 125% of benzoylecgonine at various concentrations. The substances listed in the table below were determined not to interfere at the concentration shown.

To test for possible positive and/or negative interference from pH, urine samples having pH from 3, 4, 5, 6, 7, 8, 9, 10 and 11 were used. Each of these samples were divided into two aliquots for each drug and spiked to 75% of the cutoff and 125% of the cutoff. No positive or negative interference due to pH was observed.

Qualitative results were identical for the BS-480 and BA-800M analyzers.

BS-480 and BA-800M Interference

Interfering Substances	Spiked [ ] (mg/dL)	Qualitative Result		
		0 ng/mL (Pos/Neg)	112.5 ng/mL Control (Pos/Neg)	187.5 ng/mL Control (Pos/Neg)
Acetaminophen	10	Neg	Neg	Pos
Acetone	1000	Neg	Neg	Pos
Ascorbic Acid	400	Neg	Neg	Pos
Aspirin	10	Neg	Neg	Pos
Caffeine	10	Neg	Neg	Pos
Creatinine	500	Neg	Neg	Pos
Ethanol	1000	Neg	Neg	Pos
Galactose	10	Neg	Neg	Pos
r-Globulin	500	Neg	Neg	Pos
Glucose	1500	Neg	Neg	Pos
Hemoglobin	300	Neg	Neg	Pos
Human Serum Albumin	500	Neg	Neg	Pos
Ibuprofen	10	Neg	Neg	Pos
Oxalic Acid	100	Neg	Neg	Pos
Riboflavin	7.5	Neg	Neg	Pos
Sodium Chloride	3000	Neg	Neg	Pos
Urea	2000	Neg	Neg	Pos

To test for possible positive and/or negative interference from pH, urine samples having pH from 3, 4, 5, 6, 7, 8, 9, 10 and 11 were used. Each of these samples were divided into two aliquots for each drug and spiked to 75% of the cutoff and 125% of the cutoff. No positive or negative interference due to pH was observed.

Interfering pH	Spiked [ ] (mg/dL)	Qualitative Result		
		0 ng/mL (Pos/Neg)	112.5 ng/mL Control (Pos/Neg)	187.5 ng/mL Control (Pos/Neg)
pH 3	---	Neg	Neg	Pos
pH 4	---	Neg	Neg	Pos
pH 5	---	Neg	Neg	Pos
pH 6	---	Neg	Neg	Pos

Interfering pH	Spiked [ ] (mg/dL)	Qualitative Result		
		0 ng/mL (Pos/Neg)	112.5 ng/mL Control (Pos/Neg)	187.5 ng/mL Control (Pos/Neg)
pH 7	---	Neg	Neg	Pos
pH 8	---	Neg	Neg	Pos
pH 9	---	Neg	Neg	Pos
pH 10	---	Neg	Neg	Pos
pH 11	---	Neg	Neg	Pos

To test for possible positive and/or negative interference from specific gravity, urine samples having specific gravity ranging from 1.000 g/mL to 1.031 g/mL were used. Each of these samples were divided into three aliquots and two were spiked to 75% of the cutoff and 125% of the cutoff, the third was not spiked. No positive or negative interference due to specific gravity was observed.

BS-480 Specific Gravity Interference

Specific Gravity of Specimen (g/mL)	Qualitative Result		
	0 ng/mL (Pos/Neg)	112.5 ng/mL Control (Pos/Neg)	187.5 ng/mL Control (Pos/Neg)
1.000	Neg	Neg	Pos
1.000	Neg	Neg	Pos
1.004	Neg	Neg	Pos
1.010	Neg	Neg	Pos
1.013	Neg	Neg	Pos
1.017	Neg	Neg	Pos
1.018	Neg	Neg	Pos
1.020	Neg	Neg	Pos
1.021	Neg	Neg	Pos
1.021	Neg	Neg	Pos
1.025	Neg	Neg	Pos
1.031	Neg	Neg	Pos

BA-800M Specific Gravity Interference

Specific Gravity of Specimen	Qualitative Result		
	0 ng/mL (Pos/Neg)	112.5 ng/mL Control (Pos/Neg)	187.5 ng/mL Control (Pos/Neg)
1.009	Neg	Neg	Pos
1.012	Neg	Neg	Pos
1.017	Neg	Neg	Pos
1.018	Neg	Neg	Pos
1.020	Neg	Neg	Pos
1.020	Neg	Neg	Pos
1.024	Neg	Neg	Pos
1.026	Neg	Neg	Pos
1.029	Neg	Neg	Pos

Cross Reactivity

Cross-reactivity was established by spiking various concentrations of structurally related and unrelated compounds into drug-free urine. Following a “least burdensome approach”, manufacturer studies performed on another analyzer have been referenced after completing proof of principle testing on a subset of structurally and non-structurally related compounds. Right to Reference Letter is located in Appendix F.

Proof of Principle Testing performed on Mindray BA-800M and Mindray BS-480:

BA-800M Structurally Related Compounds

Cross Reactant	Target Concentration (ng/mL)	%Cross Reactivity Calculated based on Analyzer Recovered Concentration	%Cross Reactivity Calculated based on Cutoff Concentration
Benzoylecgonine	150	113.43%	100.00 %
Cocaine	10,000	1.52%	1.50 %

BA-800M Structurally Unrelated Pharmacological Compounds:

Cross-reactant	Target Concentration (ng/mL)	% Cross Reactivity
Meperidine	500,000	0.00 %

BS-480 Structurally Related Compounds

Cross Reactant	Target Concentration (ng/mL)	%Cross Reactivity Calculated based on Analyzer Recovered Concentration	%Cross Reactivity Calculated based on Cutoff Concentration
Benzoylecgonine	150	105.37%	100.00 %
Cocaine	10,000	1.62%	1.50 %

BS-480 Structurally Unrelated Pharmacological Compounds:

Cross-reactant	Target Concentration (ng/mL)	% Cross Reactivity
Meperidine	500,000	0.00 %

Referenced Cross Reactivity Testing on Hitachi 717:

The following tables summarizes the approximate quantity of each compound that is equivalent in assay reactivity to the 150 ng/mL benzoylecgonine cutoff. 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 or the maximal concentration of the compound tested that gave a response with cross-reactivity below the cutoff calibrator. The percent cross-reactivity of those compounds are presented below.

Structurally Related Cocaine Compound (as found in Appendix F):

Cross-reactant	Target Concentration (ng/mL)	% Cross Reactivity
Benzoylecgonine	150	96.03 %
Benzoylecgonine	300	102.10 %
Cocaethylene	4,000	4.58 %
Cocaine	25,000	0.62%
Ecgonine	400,000	0.03 %
Ecgonine, Methyl Ester	500,000	0.00 %
Norcocaine	30,000	0.68 %
Atropine	500,000	0.00 %

Structurally Unrelated Pharmacological Compounds (as found in Appendix F):

Cross-reactant	Target Concentration (ng/mL)	% Cross Reactivity
Acetaminophen	500,000	0.00 %
Acetylsalicylic Acid	500,000	0.00 %
Amobarbital	500,000	0.00 %
Amoxicillin	500,000	0.00 %
Amphetamine	500,000	0.00 %
Bupropion	500,000	0.00 %
Captopril	500,000	0.00 %
Caffeine	500,000	0.00 %
Chlordiazepoxide	500,000	0.00 %
Chlorpheniramine	500,000	0.00 %
Chlorpomazine	500,000	0.00 %
Codeine	500,000	0.00 %
Dextromethorphan	500,000	0.00 %
Diazepam	500,000	0.00 %
Digoxin	500,000	0.00 %
Enalapril	500,000	0.00 %
Fluoxetine	100,000	0.01 %
Glyburide	500,000	0.00 %
Ibuprofen	500,000	0.00 %
Lidocaine	500,000	0.00 %
Meperidine	500,000	0.00 %
Methadone	100,000	0.01 %
Methamphetamine	500,000	0.00 %
Methaqualone	500,000	0.00 %
Morphine	500,000	0.00 %
Nicodine	500,000	0.00 %
Nifedipine	100,000	0.00 %
Oxazepam	100,000	0.00 %
Phencyclidine	500,000	0.00 %
Phenobarbital	500,000	0.00 %

Cross-reactant	Target Concentration (ng/mL)	% Cross Reactivity
Propoxyphene	100,000	0.00 %
Ranitidine	500,000	0.00 %
Salicyluric acid	500,000	0.00 %
Secobarbital	500,000	0.00 %
11-nor- THC-COOH	500,000	0.00 %
Valproic Acid	500,000	0.00 %
Verapamil	500,000	0.00 %

Traceability

Two levels of calibrators (0 and 150 ng/mL) and two levels of control material (112.5 ng/mL, 187.5 ng/mL) are available for use with the Pointe Scientific Cocaine Metabolite Enzyme Immunoassay. A commercially available benzoylecgonine standard solution from Cerilliant Analytical Reference Standards is used and traceable to NIST standard. This standard solution is made into a secondary (lower concentration) stock solution. The secondary stock solution is then spiked into the calibrators and controls to the desired concentration. The concentrations are confirmed by GC/MS.

Conclusion

We feel that the enclosed data supports a determination that the Pointe Scientific Cocaine Metabolite Enzyme Immunoassay is substantially equivalent in terms of composition and performance to the product marketed by Lin-Zhi International.