Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
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510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

k191638

B Applicant

MedTest Dx

C Proprietary and Established Names

Pointe scientific cocaine metabolite enzyme immunoassay

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
DIO	Class II	21 CFR 862.3250 - Cocaine And Cocaine Metabolite Test System	TX - Clinical Toxicology

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Benzoylecgonine

C Type of Test:

Immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

BS-480 Chemistry Analyzer
BA-800 Chemistry Analyzer

IV Device/System Characteristics:

A Device Description:

The Pointe Scientific 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 Pointe Scientific Cocaine Metabolite Enzyme Immunoassay has a cutoff of 150 ng/mL benzoylecgonine.

B Principle of Operation:

The Pointe Scientific Cocaine Metabolite Enzyme Immunoassay 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.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Cocaine Metabolite Enzyme Immunoassay

B Predicate 510(k) Number(s):
k113139

C Comparison with Predicate(s):

Device & Predicate Device(s):	k191638	k113139
Device Trade Name	**Pointe Scientific Cocaine Metabolite Enzyme Immunoassay**	**Cocaine Metabolite Enzyme Immunoassay**
General Device Characteristic Similarities		
Intended Use/Indications For Use	To be used for the determination of benzoylecgonine in human urine. 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.	Same
Contents	The assay consists of ready-to-use liquid reagents. Reagent 1 contains a mouse	Same

Device & Predicate Device(s):	k191638	k113139
	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	
Analyte	Benzoylecgonine	Same
Cutoff	150 ng/mL	Same
Matrix	Urine	Same
Controls	2 levels (112.5 ng/mL, 187.5 ng/mL)	Same
Storage	2-8°C until expiration date	Same
General Device Characteristic Differences		
Calibrators	2 Levels (0 ng/mL, 150 ng/mL)	5 Levels (0, 75, 150, 300, 1000 ng/mL)

VI Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

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 2 replicates, with two runs per day, for 20 days, on both the BS-480 Chemistry Analyzer and the BS-800M Chemistry Analyzer. The qualitative results are presented below as Positive/Negative.

BS-480 Chemistry Analyzer:

	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

BA-800M Chemistry Analyzer:

	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

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

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

Results were identical for both the BS-480 Chemistry Analyzer and the BS-800M Chemistry Analyzer.

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 with benzoylecgonine to 75% of the cutoff and 125% of the cutoff. No positive or negative interference due to pH was observed on either the BS-480 Chemistry Analyzer or the BS-800M Chemistry Analyzer.

To test for possible positive and/or negative interference from specific gravity, urine samples having specific gravity ranging from 1.009 g/mL to 1.031 g/mL were used. Each of these samples were divided into three aliquots and two were spiked with benzoylecgonine 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 on either the BS-480 Chemistry Analyzer or the BS-800M Chemistry Analyzer.

Cross Reactivity

Cross-reactivity was established by spiking various concentrations of structurally related and unrelated compounds into drug-free urine.

The following tables summarize approximate the 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:

Cross-reactant	Target Concentration (ng/mL)	% Cross Reactivity
Benzoylecgonine	150	100 %
Cocaethylene	4,000	4.58 %
Cocaine (BS-480)	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

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 %
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 %

4. Assay Reportable Range:

   Not applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Two levels of calibrators (0 and 150 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 that is traceable to NIST standard.

6. Detection Limit:

   Not applicable.

7. Assay Cut-Off:

   The Pointe Scientific Cocaine Metabolite Enzyme Immunoassay has a cutoff of 150 ng/mL benzoylecgonine.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Two methods comparison studies were conducted, one on the BS-480 Chemistry Analyzer and one on the BS-800M Chemistry Analyzer. 114 unaltered clinical urine remnant samples were evaluated over 3 nonconsecutive days by the Pointe Scientific Cocaine Metabolite Enzyme Immunoassay and compared to LC/MS. Results. The data is summarized below for each analyzer.

   BS-480 Chemistry Analyzer:

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

   BA-800M Chemistry Analyzer:

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

2. Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Not applicable.

VII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

VIII Conclusion:

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