

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

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

K101160

**B. Purpose for Submission:**

New device

**C. Measurand:**

Benzoyllecgonine

**D. Type of Test:**

Qualitative and semi-quantitative immunoassay

**E. Applicant:**

Roche Diagnostics

**F. Proprietary and Established Names:**

Roche Oral Fluid Cocaine

**G. Regulatory Information:**

1. Regulation section:

21 CFR § 862.3250, Cocaine and Cocaine Metabolite Test System

2. Classification:

Class II

3. Product code:

DIO, enzyme immunoassay, cocaine and cocaine metabolites

4. Panel:

91 (Toxicology)

## H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

DAT Oral Fluid Cocaine (OFCOC) is an in vitro diagnostic test for the qualitative and semiquantitative detection of cocaine metabolite in human oral fluid when calibrated with benzoylecgonine on automated clinical chemistry analyzers at a cutoff concentration of 9 ng/mL in neat oral fluid. Samples must be exclusively collected with the Intercept<sup>®</sup> Oral Specimen Collection Device. Semiquantitative test results may be obtained that permit laboratories to assess assay performance as part of a quality control program and to estimate a dilution of the specimen for confirmation by a confirmatory method such as LC/MS/MS.

DAT Oral Fluid Cocaine provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Chromatography/mass spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

3. Special conditions for use statement(s):

For prescription use

The assay is not designated for use in point-of-care settings.

4. Special instrument requirements:

Roche/Hitachi Modular P analyzer

## I. Device Description:

The Oral Fluid Cocaine assay consists of two ready for use reagent solutions.

Reagent 1 (R1) contains Conjugated benzoylecgonine derivative in buffer with bovine serum albumin (BSA) and 0.09 % sodium azide

Reagent 2 (R2) Microparticles attached to benzoylecgonine antibody (mouse monoclonal) in buffer with bovine serum albumin (BSA) and 0.09 % sodium azide

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Cocaine Metabolite Intercept® MICRO-PLATE EIA

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

K001197

3. Comparison with predicate:

<b>Similarities</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Indications for Use	Same	For use in the detection of cocaine metabolite in human oral fluid collected with the Intercept Oral Specimen Collection Device.
Methodology	Same	Immunoassay

<b>Differences</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Cutoff	9 ng/mL in neat oral fluid	5 ng/mL when oral fluid collected with the Oral Specimen Collection Device
Platform	Roche Modular P analyzer	Microplate
Control concentrations	Synthetic oral fluid matrix: Zero, Negative (.5X), and Positive (1.5X)	Negative (.5X) and Positive (2X)
Calibrator concentrations	Zero, .5X, Cutoff, 2X, 4X, and 8X	Zero, Cutoff
Measurement mode	Qualitative and semi-quantitative measurements	Qualitative measurements only

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

The sponsor referenced the following standard in their submission:

- CLSI EP5-A2 Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline - 2<sup>nd</sup> edition

The sponsor referenced the following guidance document in their submission:

- Premarket Submission and Labeling Recommendations for Drugs of Abuse Screening Tests - Draft Guidance for Industry and FDA Staff

**L. Test Principle:**

The DAT oral fluids assays are based on the kinetic interaction of microparticles in a solution (KIMS) technology. The DAT oral fluids assays are qualitative and semi-quantitative. In the absence of sample drug, soluble drug conjugates bind to antibody-bound microparticles, causing formation of particle aggregates. As the aggregation reaction proceeds in the absence of sample drug, the absorbance increases. When an oral fluid sample contains the drug in question, this drug competes with the drug derivative conjugate for microparticle-bound antibody. Antibody bound to sample drug is no longer available to promote particle aggregation, and subsequent particle lattice formation is inhibited. The presence of sample drug diminishes the increasing absorbance in proportion to the concentration of drug in the sample. Sample drug content is determined relative to the value obtained for a known cutoff concentration of drug.

The Intercept® Oral Specimen Collection Device contains a preservative buffer that dilutes the neat oral fluid sample. The calibrator and control levels are set at diluted levels so that sample absorbance values can be compared directly to the absorbance values of the calibration curve. The assay result is reported as a positive or negative result relative to the neat oral fluid cutoff of 9 ng/mL.

NOTE: To correlate a semi-quantitative result from the assay or the associated LC/MS/MS confirmation result to a neat oral fluid value, the result from the assay or the associated LC/MS/MS confirmation test should be multiplied by a factor of 3.

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

1. Analytical performance:

All analytical performance data was collected on human oral fluid samples collected with the Intercept Oral Specimen Collection Device and analyzed on the Roche MODULAR P analyzer. The Intercept collection device includes a diluent that results in a dilution of approximately 1/3. The assay cannot be used to

measure undiluted (neat) samples. Analyte concentrations refer to the neat oral fluid concentration, unless otherwise noted.

*a. Precision/Reproducibility:*

Two studies were performed with the assay to evaluate precision.

In the first study, a benzoylecognine solution was added to each of 9 samples which were obtained from a human oral fluid pool of samples collected with the Intercept® Oral Specimen Collection Device. The resulting concentrations were approximately -100 %, -75 %, -50 %, -25 %, 0 %, +25 %, +50 %, +75 %, and +100 % of the cutoff calibrator value. The samples were tested in qualitative and semiquantitative modes. Following a CLSI (EP5-A2) precision protocol, samples were tested in 2 replicates per run, 2 runs per day for 21 days, total n = 84. One lot each of reagent, calibrator, and control were used and there were ten calibrations performed during the study.

**Qualitative Mode**

Note: this study was performed on samples already collected with the Intercept collection device. Therefore the data in the table below do not reflect any imprecision inherent in the collection process itself. Results were as follows:

<b>Drug</b>	<b>Concentration of Sample, ng/mL</b>	<b>Number of Determinations</b>	<b>Results #Neg / #Pos</b>
COC	zero drug	84	84 Neg / 0 Pos
COC	-75%	84	84 Neg / 0 Pos
COC	-50%	84	84 Neg / 0 Pos
COC	-25%	84	84 Neg / 0 Pos
COC	cutoff	84	58 Neg / 26 Pos
COC	+25%	84	0 Neg / 84 Pos
COC	+50%	84	0 Neg / 84 Pos
COC	+75%	84	0 Neg / 84 Pos
COC	+100%	84	0 Neg / 84 Pos

### Semiquantitative Mode

Note: this study was performed on samples already collected with the Intercept collection device. Therefore the data in the table below do not reflect any imprecision inherent in the collection process itself. Results were as follows:

Drug	Conc. of Sample, ng/mL	Results #Neg / #Pos	Within-run Precision		Total Precision	
			SD ng/mL	CV %	SD ng/mL	CV %
COC	zero drug	84 Neg / 0 Pos	0.10	N/A	0.12	N/A
COC	-75%	84 Neg / 0 Pos	0.14	16.2	0.17	19.1
COC	-50%	84 Neg / 0 Pos	0.17	11.8	0.18	12.7
COC	-25%	84 Neg / 0 Pos	0.19	9.3	0.21	10.8
COC	cutoff	49 Neg / 35Pos	0.17	5.9	0.20	6.8
COC	+25%	0 Neg / 84 Pos	0.19	5.1	0.22	5.8
COC	+50%	0 Neg / 84 Pos	0.16	3.5	0.20	4.4
COC	+75%	0 Neg / 84 Pos	0.16	3.2	0.23	4.6
COC	+100%	0 Neg / 84 Pos	0.17	3.0	0.23	4.1

In the second study, a benzoylceognine solution was added to neat human oral fluid sample pools at concentrations of 4.5, 6.75, 11.25, and 13.5 ng/mL. Each sample was then processed through each of 21 of the Intercept® Oral Specimen Collection Devices to achieve final concentrations at approximately -50 %, -25 %, +25 %, and +50 %, of the cutoff calibrator value. The intra-assay precision of the samples, including the processing of the samples through the collection device, was then tested in qualitative and

semiquantitative modes with the Oral Fluid Cocaine assay.

**Qualitative Mode**

Note: The values obtained in this study were collected from samples spiked with Cocaine prior to the collection step. Therefore the data in the table below reflects the performance of the entire system including the collection step.

Drug	Concentration of Sample	Number of Determinations	Results #Neg / #Pos
COC	-50%	21	21 Neg / 0 Pos
COC	-25%	21	21 Neg / 0 Pos
COC	+25%	21	0 Neg / 21 Pos
COC	+50%	21	0 Neg / 21 Pos

**Semiquantitative Mode**

Note: The values obtained in this study were collected from samples spiked with Cocaine prior to the collection step. Therefore the data in the table below reflects the performance of the entire system including the collection step.

Drug	Conc. of Sample	Results #Neg / #Pos	Precision	
			SD ng/mL	CV %
COC	-50%	21 Neg / 0 Pos	0.21	14.4
COC	-25%	21 Neg / 0 Pos	0.18	7.9
COC	+25%	0 Neg / 21 Pos	0.26	6.6
COC	+50%	0 Neg / 21 Pos	0.29	6.0

*b. Linearity/assay reportable range:*

Linearity studies were performed by spiking benzoylecgonine to a concentration above the highest calibrator (24 ng/mL) into a negative pool of human oral fluid collected with the Intercept® Oral Fluid Specimen Collection Device. The samples were then diluted serially with the negative pool and tested with the assay (n=3). Linearity was evaluated by comparing the measured value to the theoretical value generated from the serial dilutions. The results are summarized below.

<b>Low end linearity</b>	
<b>theoretical neat value (ng/mL)</b>	<b>recovery %</b>
0	0
1.24	139.2
2.4	98.2
3.63	110.2
4.83	101.3
6.01	98.5
7.23	104
8.43	91.3
9.66	97
10.86	100
12.06	105.9

<b>High end linearity</b>	
<b>theoretical neat value (ng/mL)</b>	<b>recovery %</b>
0	0
9.15	104.6
18.3	100.9
27.45	101.3
36.6	98.9
45.78	100.4
54.9	99.6
64.08	98.7
73.23	98.9
82.38	99.2
91.53	96.4

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

Calibrators and Controls were cleared in k093867

d. *Detection limit:*

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

e. *Analytical specificity:*

Cross-reactivity to structurally related compounds is determined by spiking related compounds into a negative pool of human oral fluid collected with the Intercept® Oral Fluid Specimen Collection Device. 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 below:

<b>COMPOUND</b>	<b>Approximate Cross Reactivity</b>
Cocaethylene	0.15%
Cocaine	0.70%
Ecgonine	0.09%
Ecgonine methyl ester	0.00%
Norcocaine	0.01%

Potential interference from structurally unrelated compounds were tested in both semi-quantitative and qualitative mode by spiking the potentially interfering compound into pools of human oral fluid collected with the Intercept® Oral Fluid Specimen Collection Device that contain both a low positive concentration (+50% of the cutoff) and a high negative concentration (-50% of the cutoff) of benzoylecgonine. The interfering compounds were tested initially at a concentration of 10,000 ng/mL. If cross-overs of the cutoff occurred at this 10,000 ng/mL, the concentration of the cross-reactant was reduced to determine the drug level at which the compounds does not cause cross-overs of the cutoff.

<b>Generic Name</b>	<b>Tested Concentration (ng/mL)</b>	<b>Approximate Neat Concentration (ng/mL)</b>	<b>Semi-Quantitative</b>		<b>Qualitative</b>	
			<b>Low Control</b>	<b>High Control</b>	<b>Low Control</b>	<b>High Control</b>
4-Aminophenyl sulfone	10,000	30,000	NEG	POS	NEG	POS
Acetaminophen	10,000	30,000	NEG	POS	NEG	POS
Acetylsalicylic acid	10,000	30,000	NEG	POS	NEG	POS
Alprazolam	10,000	30,000	NEG	POS	NEG	POS
Amitryptiline	10,000	30,000	NEG	POS	NEG	POS
Amobarbital	10,000	30,000	NEG	POS	NEG	POS
d-Amphetamine	10,000	30,000	NEG	POS	NEG	POS
l-Amphetamine	10,000	30,000	NEG	POS	NEG	POS
Ampicillin	10,000	30,000	NEG	POS	NEG	POS
Aspartame	10,000	30,000	NEG	POS	NEG	POS

Atropine	10,000	30,000	NEG	POS	NEG	POS
Benzococaine	10,000	30,000	NEG	POS	NEG	POS
Buprenorphine	10,000	30,000	NEG	POS	NEG	POS
Butabarbital	10,000	30,000	NEG	POS	NEG	POS
Caffeine	10,000	30,000	NEG	POS	NEG	POS
Chlordiazepoxide	10,000	30,000	NEG	POS	NEG	POS
Cotinine	10,000	30,000	NEG	POS	NEG	POS
Cyclizine	10,000	30,000	NEG	POS	NEG	POS
Desipramine	10,000	30,000	NEG	POS	NEG	POS
Dextromethorphan	10,000	30,000	NEG	POS	NEG	POS
Diazepam	10,000	30,000	NEG	POS	NEG	POS
Diphenhydramine	10,000	30,000	NEG	POS	NEG	POS
Doxepin	10,000	30,000	NEG	POS	NEG	POS
d-ephedrine	10,000	30,000	NEG	POS	NEG	POS
l-ephedrine	10,000	30,000	NEG	POS	NEG	POS
d,l-ephedrine	10,000	30,000	NEG	POS	NEG	POS
Fenopropfen	10,000	30,000	NEG	POS	NEG	POS
Fluoxetine	10,000	30,000	NEG	POS	NEG	POS
Gentisic acid	10,000	30,000	NEG	POS	NEG	POS
Glipizide	10,000	30,000	NEG	POS	NEG	POS
Ibuprofen	10,000	30,000	NEG	POS	NEG	POS
Imipramine	10,000	30,000	NEG	POS	NEG	POS
Ketamine	10,000	30,000	NEG	POS	NEG	POS
Loperamide	10,000	30,000	NEG	POS	NEG	POS
LSD	10,000	30,000	NEG	POS	NEG	POS
MDMA	10,000	30,000	NEG	POS	NEG	POS
Meperidine	10,000	30,000	NEG	POS	NEG	POS
Methadone	10,000	30,000	NEG	POS	NEG	POS
d-methamphetamine	10,000	30,000	NEG	POS	NEG	POS
l-methamphetamine	10,000	30,000	NEG	POS	NEG	POS
Methaqualone	10,000	30,000	NEG	POS	NEG	POS
Morphine	10,000	30,000	NEG	POS	NEG	POS
Naloxone	10,000	30,000	NEG	POS	NEG	POS
Naltrexone	10,000	30,000	NEG	POS	NEG	POS
Naproxen	10,000	30,000	NEG	POS	NEG	POS
Niacinamide	10,000	30,000	NEG	POS	NEG	POS
Nicotine	10,000	30,000	NEG	POS	NEG	POS
Nordiazepam	10,000	30,000	NEG	POS	NEG	POS
Oxazepam	10,000	30,000	NEG	POS	NEG	POS
Oxycodone	10,000	30,000	NEG	POS	NEG	POS
Pantoprazole	10,000	30,000	NEG	POS	NEG	POS
Penicillin G	10,000	30,000	NEG	POS	NEG	POS
Pentazocine	10,000	30,000	NEG	POS	NEG	POS
Pentobarbital	10,000	30,000	NEG	POS	NEG	POS
Phencyclidine	10,000	30,000	NEG	POS	NEG	POS
Phenobarbital	10,000	30,000	NEG	POS	NEG	POS
Phenylephrine	10,000	30,000	NEG	POS	NEG	POS
Phenylpropanolamine	10,000	30,000	NEG	POS	NEG	POS
Procainamide	10,000	30,000	NEG	POS	NEG	POS
Procaine	10,000	30,000	NEG	POS	NEG	POS

Promethazine	10,000	30,000	NEG	POS	NEG	POS
pseudoephedrine	10,000	30,000	NEG	POS	NEG	POS
Quetiapine	10,000	30,000	NEG	POS	NEG	POS
Quinidine	10,000	30,000	NEG	POS	NEG	POS
Ranitidine	10,000	30,000	NEG	POS	NEG	POS
Rifampin	10,000	30,000	NEG	POS	NEG	POS
Secobarbital	10,000	30,000	NEG	POS	NEG	POS
Δ9-THC	10,000	30,000	NEG	POS	NEG	POS
Tramadol	10,000	30,000	NEG	POS	NEG	POS
Trifluoroperazine	10,000	30,000	NEG	POS	NEG	POS
Trimipramine	10,000	30,000	NEG	POS	NEG	POS
Venlafaxine	10,000	30,000	NEG	POS	NEG	POS
Zomepirac	10,000	30,000	NEG	POS	NEG	POS

Potential interference from substances endogenous to oral fluid were tested in both semi-quantitative and qualitative mode by spiking the potentially interfering substance into pools of human oral fluid collected with the Intercept® Oral Fluid Specimen Collection Device that contain both a low positive concentration (+50% of the cutoff) and a high negative concentration (-50% of the cutoff) of benzoylecgonine. The interfering substances were tested at a concentrations equivalent to either  $\geq$  the highest concentration observed in diseased populations or, in cases where such data is unavailable, at  $\geq 10$ -times the mean concentration reported in healthy subjects. The results are summarized below.

Compound	Tested Cmpd. Conc.	Approx. Equiv. Neat saliva Conc.	Semi-quantitative		Qualitative	
			Neg Level	Pos Level	Neg Level	Pos Level
Albumin	5 mg/mL	15 mg/mL	NEG	POS	NEG	POS
Salivary $\alpha$ -Amylase	833 U/mL	2500 U/mL	NEG	POS	NEG	POS
Ascorbic Acid	10 mg/mL	30 mg/mL	NEG	POS	NEG	POS
Bilirubin	50 $\mu$ g/mL	150 $\mu$ g/mL	NEG	POS	NEG	POS
Hemoglobin	1 mg/mL	3 mg/mL	NEG	POS	NEG	POS
IgA	0.33 mg/mL	1 mg/mL	NEG	POS	NEG	POS
IgG	0.17 mg/mL	0.5 mg/mL	NEG	POS	NEG	POS
IgM	0.033 mg/mL	0.1 mg/mL	NEG	POS	NEG	POS

Potential interference from food and dental products were tested in both semi-quantitative and qualitative mode by spiking the potentially interfering substance into pools of human oral fluid collected with the Intercept® Oral Fluid Specimen Collection Device that contained both a low positive concentration (+50% of the cutoff) and a high negative concentration (-50% of the cutoff) of benzoylecgonine. The following products were tested by spiking into samples:

Alcohol (ethanol), Antiseptic Mouthwash, Baking soda, Whole blood, Cola, Cough Syrup, Cranberry juice, Hemoglobin, Hydrogen peroxide, Sodium chloride, Sugar, Toothpaste, Water

Additionally, the following substances were evaluated by volunteers:

Antacid, Chewing tobacco, Cigarettes, Hard candy, Milk, Orange juice, Tooth whitening strips

These substances were utilized by each of 10 volunteers. The Intercept® package insert recommends : “Wait at least 10 minutes after ingesting any food, drink, or drugs before collecting a sample” in the Directions for Use.

The volunteer-tested substances were evaluated by consuming/using the listed substance. Samples were collected after 2, 6, and 10-minute wait periods. The oral fluid samples were then spiked with benzoylecgonine at both a low positive concentration (+50% of the cutoff) and a high negative concentration (-50% of the cutoff). Samples were tested in triplicate, and the median value is reported.

<b>Compound</b>	<i>Semi-quantitative</i>		<i>Qualitative</i>	
	<b>Neg Level</b>	<b>Pos Level</b>	<b>Neg Level</b>	<b>Pos Level</b>
Alcohol (ethanol)	NEG	POS	NEG	POS
Antiseptic mouth wash	NEG	POS	NEG	POS
Baking soda	NEG	POS	NEG	POS
Whole blood	NEG	POS	NEG	POS
Cola	NEG	POS	NEG	POS
Cough Syrup	NEG	POS	NEG	POS
Cranberry juice	NEG	POS	NEG	POS
Hemoglobin	NEG	POS	NEG	POS
Hydrogen peroxide	NEG	POS	NEG	POS
Sodium chloride	NEG	POS	NEG	POS
Sugar	NEG	POS	NEG	POS
Toothpaste	NEG	POS	NEG	POS
Water	NEG	POS	NEG	POS

All of the volunteer tested interferents evaluated showed no interference after 10 minutes, which is the waiting time indicated in the instructions for use. The sponsor defined no interference as the negative control sample recovering less than the cutoff and the positive sample control recovering greater than the cutoff. Tums, teeth whitening strips, and orange juice each caused negative controls to recover above the cutoff in some of the volunteers after 2 minutes and 6 minutes. These samples had correct recoveries below the cutoff after 10 minutes.

Potential interference from pH was tested in both semi-quantitative and qualitative mode by spiking the potentially interfering substance into pools of human oral fluid collected with the Intercept® Oral Fluid Specimen Collection Device that contain both a low positive concentration (+50% of the cutoff) and a high negative concentration (-50% of the cutoff) of benzoylecgonine. The pH of the samples were adjusted to various pH levels ranging from 2.0-8.5. The normal range of saliva pH is 5.6-7.8. All of the 0.5 x cutoff samples read negative and all of the 1.5 x cutoff samples read positive with samples of pH 2 and 8.5.

*f. Assay cut-off:*

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision above.

2. Comparison studies:

*a. Method comparison with predicate device:*

Two method comparison studies were performed. In the first study, unaltered neat oral fluid samples containing cocaine were collected by expectoration and analyzed by LC/MS/MS. The samples were then processed through the Intercept® Oral Specimen Collection Device and were subsequently evaluated with both LC/MS/MS and with the OFCOC assay. Unaltered near cutoff samples were included in the sample set. Results were obtained from LC/MS/MS of the neat oral fluid sample, from LC/MS/MS of the diluted Intercept® sample, and from the OFCOC assay with the diluted Intercept® sample. The following results were obtained with the OFCOC assay on the Roche/Hitachi MODULAR P analyzer relative to the LC/MS/MS values.

Note: The values obtained in this study were collected from samples spiked with COC prior to the collection step. Therefore the results reflect the performance of the entire system including the collection step.

Qualitative, 9 ng/mL neat LC/MS/MS cutoff				
Low Neg by LC/MS/MS (less than - 50%)	Near Cutoff Negative by LC/MS/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS/MS (Between cutoff and +50%)	High Positive by LC/MS/MS (greater than +50%)	Percent Agreement with LC/MS/MS

Positive	1	2	3	45	100%
Negative	46	4	0	0	94%

Semi-quantitative, 9 ng/mL neat LC/MS/MS cutoff					
	Low Neg by LC/MS/MS (less than - 50%)	Near Cutoff Negative by LC/MS/MS (Between - 50% and cutoff)	Near Cutoff Positive by LC/MS/MS (Between cutoff and +50%)	High Positive by LC/MS/MS (greater than +50%)	Percent Agreement with LC/MS/MS
Positive	0	2	3	45	100%
Negative	45	5	0	0	100%

#### Discordant results

Roche COC OF Result		Benzoylcegonine Neat LC/MS/MS (ng/mL)	Cocaine Reference Neat LC/MS/MS (ng/mL)
Semi-Quant	Qual		
POS	POS	7.50	8.94
POS	POS	8.78	2.46
NEG	POS	4.02	9.90

In the second study, 40 oral fluid samples collected with the Intercept® Oral Specimen Collection Device that were previously screened negative using the Cocaine metabolite Intercept MICRO-PLATE EIA assay, were evaluated with the Oral Fluid Cocaine assay. Forty samples that were screened positive with the Cocaine metabolite Intercept MICRO-PLATE EIA were obtained from a clinical laboratory and were subsequently confirmed by LC/MS/MS to contain COC, were evaluated with the OFCOC. In addition, unaltered near cutoff samples were analyzed. These samples fell in the near cutoff negative range (between - 50 % and cutoff) and the near cutoff positive range (between cutoff and + 50 %) as measured by LC/MS/MS Four negative near cutoff samples and four positive near cutoff samples were assayed.

Note: this study was performed on samples already collected with the Intercept collection device. When the LC/MS/MS values of the diluted samples were compared to the immunoassay values, the following results were obtained. Therefore the results below do not reflect any inaccuracy inherent in the collection process itself.

	Semi-quantitative				Percent Agreement with LC/MS/MS
	Low Neg by LC/MS/MS (less than -50%)	Near Cutoff Negative by LC/MS/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS/MS (Between cutoff and +50%)	High Positive by LC/MS/MS (greater than +50%)	
Positive	0	1	4	36	97.5%
Negative	36	3	0	0	100%

	Semi-quantitative				Percent Agreement with LC/MS/MS
	Low Neg by LC/MS/MS (less than -50%)	Near Cutoff Negative by LC/MS/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS/MS (Between cutoff and +50%)	High Positive by LC/MS/MS (greater than +50%)	
Positive	0	1	4	36	97.5%
Negative	36	3	0	0	100%

Discordant Results

Roche COC OF Result		Benzoyllecgonine Reference Method (ng/mL)	Cocaine Reference Method (ng/mL)
Semi-Quant (ng/mL)	Qual		
POS	POS	6.678	10.824

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):

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.