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Emit® II Plus Cocaine Metabolite Assay

See shaded sections:
Updated information from 2019-03 version.

10871524_H

Cocaine Metabolite Assay

1 Intended Use

The Emit® II Plus Cocaine Metabolite Assay is a homogeneous enzyme immunoassay with a 150 ng/mL or 300 ng/mL cutoff. The assay is intended for use in the qualitative and semiquantitative analyses of benzoylecgonine (cocaine metabolite) in human urine. Emit® II Plus assays are designed for use with a number of chemistry analyzers.

The Emit® II Plus Cocaine Metabolite Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[1] Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.

2 Summary and Explanation of the Test

Cocaine is a central nervous system stimulant that is extracted from the coca plant. As a drug of abuse, cocaine is self-administered in a variety of ways, including inhalation and intravenous injection. Cocaine base can be smoked in a form that is commonly known as "crack." Cocaine is rapidly absorbed, especially when smoked. While all forms are potentially addicting, "crack" is especially likely to lead to dependence because of its more rapid and heightened effect on the abuser.[1]

Excretion rate patterns vary with the mode of administration and from individual to individual. Cocaine is almost completely metabolized, primarily in the liver, with only about one percent excreted in the urine unchanged. Most cocaine is eliminated as benzoylecgonine, the major metabolite of cocaine. Cocaine is also excreted in relatively lesser amounts as ecgonine methyl ester and ecgonine. Cocaine metabolites may be detected in urine for up to a couple of days after cocaine is used. Benzoylecgonine can be detected in urine within four hours after cocaine inhalation and remain detectable in concentrations greater than 1000 ng/mL for as long as 48 hours.[2–5]

The Emit® II Plus Cocaine Metabolite Assay tests for benzoylecgonine, the major metabolite of cocaine, in human urine. Positive results for specimens containing other compounds structurally unrelated to benzoylecgonine have not been observed.

Methods historically used for detecting benzoylecgonine in biological fluids include high-performance liquid chromatography, gas-liquid chromatography, and enzyme immunoassay.[6–8]

While confirmation techniques other than GC/MS may be adequate for some drugs of abuse, GC/MS is generally accepted as a vigorous confirmation technique for all drugs, since it provides the best level of confidence in the result.

3 Principle

The Emit® II Plus Cocaine Metabolite Assay is a homogeneous enzyme immunoassay technique used for the analysis of benzoylecgonine in human urine.[9] The assay is based on competition between drug in the specimen and drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for antibody binding sites. Enzyme activity decreases upon binding to the antibody, so the drug concentration in the specimen can be measured in terms of enzyme activity. Active enzyme converts nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that is measured spectrophotometrically. Endogenous serum G6PDH does not interfere because the coenzyme NAD functions only with the bacterial *(Leuconostoc mesenteroides)* enzyme employed in the assay.

4 Reagents

REF	Product Description	Volume
9H039UL/	**Emit® II Plus Cocaine Metabolite Assay**	28 mL/
9H029UL/	**Antibody/Substrate Reagent 1**	115 mL/
9H129UL	Sheep polyclonal antibodies* to benzoylecgonine (2.2 µg/mL), bovine serum albumin, G6P (15 mM), NAD (12 mM), preservatives, and stabilizers	1000 mL
	Enzyme Reagent 2	12 mL/
	Benzoylecgonine labeled with bacterial G6PDH (0.46 U/mL),* HEPES buffer, bovine serum albumin, preservatives, and stabilizers	50 mL/ 435 mL

****The antibody titer and enzyme conjugate activity may vary from lot to lot.***

Note: Reagents 1 and 2 are provided as a matched set. They should not be interchanged with components of kits with different lot numbers.

Precautions:

- Reagent 1 contains nonsterile sheep antibodies.
- Reagent 2 contains nonsterile mouse monoclonal antibodies.
- Reagents 1 and 2 contain nonsterile bovine serum albumin.

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

For *in vitro* diagnostic use.

Reagents:

The Emit® II Plus Cocaine Metabolite Assay reagents are provided liquid, ready to use and may be used directly from the refrigerator. Close the reagent bottles when not in use.

Note: Caps must always be replaced on the original containers.

When not in use, reagents must be stored at 2–8°C (36–46°F), upright and with screw caps tightly closed. If stored as directed, reagents are stable until the expiration date printed on the label. Refer to the application sheet for on instrument stability information. Do not freeze reagents. Avoid prolonged exposure to temperatures above 32°C. **Improper storage of reagents can affect assay performance.**

5 Specimen Collection and Preparation

- Urine specimens may be collected in plastic (i.e., polypropylene, polycarbonate, polyethylene) or glass containers. Some plastics can adsorb certain drugs.
- If not analyzed immediately, specimens may be stored unrefrigerated for up to 7 days. Specimens may be stored refrigerated (2–8°C) for 30 days before analysis. After 7 days unrefrigerated or 30 days refrigerated, samples should be stored frozen (-20°C) for up to 3 years.[10]
- Frozen specimens must be thawed and mixed thoroughly prior to analysis.
- Specimens with high turbidity should be centrifuged before analysis.
- Urine specimens within the pH range of 3.0 to 11.0 do not require prior adjustment of pH. However, benzoylecgonine in specimens can degrade upon prolonged exposure to pH levels greater than 9.0.
- Adulteration of the urine specimen may cause erroneous results. If adulteration is suspected, obtain another specimen.
- Human urine specimens should be handled and treated as if they are potentially infectious.

6 Procedure

Materials Provided

Emit® II Plus Cocaine Metabolite Assay
Antibody/Substrate Reagent 1
Enzyme Reagent 2

Materials Required But Not Provided

9A509UL Emit® Calibrator/Control Level 0
9A549UL Emit® Calibrator/Control Level 2
9A569UL Emit® Calibrator/Control Level 3
9A589UL Emit® Calibrator/Control Level 4
9A609UL Emit® Calibrator/Control Level 5

Commercial controls (see Quality Control, Semiquantitative Analysis)

Instruments

Siemens Healthcare Diagnostics provides instructions for using this assay on a number of chemistry analyzers. Contact the Technical Assistance Center in the USA or your local Siemens representative for application sheets.

Analyzers must be capable of maintaining a constant reaction temperature, pipetting specimens/reagents and measuring enzyme rates precisely, timing the reaction accurately, and mixing reagents thoroughly.

Assay Sequence

To run the assay, see the instrument operator's manual and the application sheets available from Siemens.

Calibration

Note: These reagents are qualified for use with these calibrators only. However, other control material may be used for quality control purposes.

Table 1 — Emit® Calibrators/Controls for use in Qualitative or Semi-quantitative Analysis

Desired Cutoff Level (ng/mL)	Additional Recommended Calibrators/Controls for Qualitative Analysis (ng/mL)	Required Calibrators/Controls for Semiquantitative Analysis (ng/mL)
150	Level 0 (0)	Level 0 (0)
(Level 2)	Level 5 (1000)	Level 2 (150)
		Level 3 (300)
300	Level 0 (0)	Level 4 (500)
(Level 3)	Level 5 (1000)	Level 5 (1000)

Note: For any individual cutoff level, a calibrator/control is used as either a calibrator or as a control when the assay is used for qualitative analysis. When a calibrator/control is used as a calibrator for an individual cutoff level, the other level calibrators/controls (above or below it, as listed above) are used as controls.

Qualitative Analysis

Calibrate by running the appropriate Emit® Calibrator/Control Level for the desired cutoff listed in Table 1 in duplicate. Validate the calibration by running controls (see Quality Control). Refer to the Emit® Calibrators/Controls instructions for use and the application sheet for additional information and instrument settings. Recalibrate as indicated by control results.

Semiquantitative Analysis

Prepare a calibration curve by running the appropriate Emit® Calibrators/Controls listed in Table 1. Validate the calibration by running controls (see Quality Control). Refer to the Emit® Calibrators/Controls instructions for use and the application sheet for additional information and instrument settings. Recalibrate as indicated by control results.

Quality Control

Qualitative Analysis

Validate the calibration by assaying controls. Ensure that the result from Emit® Calibrator/Control Level 0 (0 ng/mL) or Emit® Calibrator/Control Level 5 (1000 ng/mL) relates appropriately to the result from the cutoff calibrator chosen from column 1 in Table 1. That is,

- If Emit® Calibrator/Control Level 0 (0 ng/mL) was run, ensure that the result is negative relative to the selected cutoff calibrator level.
- If Emit® Calibrator/Control Level 5 (1000 ng/mL) was run, ensure that the result is positive relative to the selected cutoff calibrator level.

Once the calibration is validated, run urine specimens.

Semiquantitative Analysis

Validate the calibration curve by assaying commercial controls. Ensure that control results fall within acceptable limits as defined by your laboratory.

Once the calibration curve is validated, run urine specimens.

Qualitative and Semiquantitative Analysis

1. Follow government regulations or accreditation requirements for quality control frequency. At least once each day of use, analyze two levels of Quality Control (QC) material with known benzoylecgonine concentrations. Follow your laboratory internal QC procedures if the results obtained are outside acceptable limits.
2. Refer to the instrument operator's manual for appropriate instrument checks.

7 Results

Qualitative Analysis

Refer to Table 1 for the appropriate cutoff Emit® Calibrator/Control. Table 1 contains the concentration of benzoylecgonine present in the selected Emit® Calibrator/Control selected as a cutoff for distinguishing "positive" from "negative" specimens.

Positive Results. A specimen that gives a change in rate value greater than or equal to the Emit® Calibrator/Control cutoff rate value is interpreted as positive.

Negative Results. A specimen that gives a change in rate value less than the Emit® Calibrator/Control cutoff rate value is interpreted as negative: Either the specimen does not contain cocaine metabolites or cocaine metabolites are present in concentrations below the cutoff level for this assay.

Semiquantitative Analysis

The semiquantitation of positive results enables the laboratory to determine an appropriate dilution of the specimen for confirmation by GC/MS. Semiquantitation also permits the laboratory to establish quality control procedures and assess control performance. Refer to the Analytical Recovery section for the semiquantitative range.

Using the Emit® II Plus Cocaine Metabolite Assay, it is possible to make semiquantitative determinations of benzoylecgonine. An estimate of relative total drug concentrations may be obtained by running the appropriate Emit® Calibrators/Controls: Levels 0 (0 ng/mL), 2 (150 ng/mL), 3 (300 ng/mL), 4 (500 ng/mL), 5 (1000 ng/mL). Refer to the application sheet for instructions.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

Siemens has validated use of these reagents on various analyzers to optimize product performance and meet product specifications. User defined modifications are not supported by Siemens as they may affect performance of the system and assay results. It is the responsibility of the user to validate modifications to these instructions or use of the reagents on analyzers other than those included in Siemens Application Sheets or these instructions for use.

8 Limitations

- The assay is designed for use with human urine only.
- A positive result from the assay indicates the presence of cocaine metabolites but does not indicate or measure intoxication.
- Boric acid is not recommended as a preservative for urine.
- There is a possibility that substances and/or factors not listed (e.g., technical or procedural errors) may interfere with the test and cause false results.
- Interpretation of results must take into account that urine concentrations can vary extensively with fluid intake and other biological variables.
- Immunoassays that produce a single result in the presence of a drug and its metabolites cannot fully quantitate the concentration of individual components.
- The Emit® II Plus Cocaine Metabolite Assay cross reacts with Benzoylecgonine-glucuronide. If the confirmatory method used does not quantify this metabolite (or employ glucuronidase during sample preparation), then you may not be able to accurately confirm results from the Emit® II Plus Cocaine Metabolite Assay.

9 Expected Values

When the Emit® II Plus Cocaine Metabolite Assay is used as a qualitative assay, the amount of drugs and metabolites detected by the assay in any given specimen cannot be estimated. The assay results distinguish between positive and negative specimens—positive indicating specimens that contain cocaine metabolites.

When used semiquantitatively, the assay yields approximate, cumulative concentrations of the metabolites detected by the assay (see Section 7, Results).

10 Specific Performance Characteristics

The data that appear in this section were collected from the Beckman Coulter DxC 700 AU® Chemistry Analyzer using the Emit® II Plus Cocaine Metabolite Assay.

Method Comparison

Qualitative and Semiquantitative Accuracy Summary

150 ng/mL CUTOFF

A total of one-hundred two (102) unaltered samples were analyzed using the Emit® II Plus Cocaine Metabolite Assay and the reference method Gas Chromatography/Mass Spectrometry (GC/MS). Both methods used a 150 ng/mL cutoff. Twenty-one (21) samples were within ± 50% of the cutoff by GC/MS.

Sixty-one (61) samples showed positive results by both methods, while thirty-two (32) showed negative results by both methods. Nine (9) specimens showed negative results by GC/MS but positive by Emit® II Plus Cocaine Metabolite Assay.

The total agreement is 91%.

	GC/MS				
	Negative (<75 ng/mL)	Negative Within 50% below the cutoff (75–149 ng/mL)	Positive Within 50% above the cutoff (150–225 ng/mL)	Positive (>225 ng/mL)	% Agreement
Qualitative					
DxC 700 AU Positive	2	7	10	51	87
DxC 700 AU Negative	28	4	0	0	100
Semiquantitative					
DxC 700 AU Positive	2	7	10	51	87
DxC 700 AU Negative	28	4	0	0	100

Summary of Discordant Results, 150 ng/mL Cutoff, Qualitative

Emit® II Plus Cocaine Metabolite Assay (pos/neg)	GC/MS (ng/mL)	Major Drug Present by GC/MS
Positive	124	Benzoylecgonine
Positive	34	Benzoylecgonine
Positive	73	Benzoylecgonine
Positive	83	Benzoylecgonine
Positive	102	Benzoylecgonine
Positive	80	Benzoylecgonine
Positive	105	Benzoylecgonine
Positive	101	Benzoylecgonine
Positive	75	Benzoylecgonine

Summary of Discordant Results, 150 ng/mL Cutoff, Semi-Quantitative

Emit® II Plus Cocaine Metabolite Assay (pos/neg)	GC/MS (ng/mL)	Major Drug Present by GC/MS
Positive	124	Benzoylecgonine
Positive	34	Benzoylecgonine
Positive	73	Benzoylecgonine
Positive	83	Benzoylecgonine
Positive	102	Benzoylecgonine
Positive	80	Benzoylecgonine
Positive	105	Benzoylecgonine
Positive	101	Benzoylecgonine
Positive	75	Benzoylecgonine

300 ng/mL CUTOFF

A total of ninety-five (95) unaltered samples were analyzed using the Emit® II Plus Cocaine Metabolite Assay and the reference method Gas Chromatography/Mass Spectrometry (GC/MS). Both methods used a 300 ng/mL cutoff. Twenty-nine (29) samples were within ± 50% of the cutoff by GC/MS.

Forty-three (43) samples showed positive results by both methods, while forty-one (41) showed negative results by both methods. Eleven (11) specimens showed negative results by GC/MS but positive by Emit® II Plus Cocaine Metabolite Assay.

The total agreement is 88%.

	GC/MS				
	Negative (<150 ng/mL)	Negative Within 50% below the cutoff (150–299 ng/mL)	Positive Within 50% above the cutoff (300–450 ng/mL)	Positive (>450 ng/mL)	% Agreement
Qualitative					
DxC 700 AU Positive	1	10	18	25	80
DxC 700 AU Negative	40	1	0	0	100
Semiquantitative					
DxC 700 AU Positive	1	10	18	25	80
DxC 700 AU Negative	40	1	0	0	100

Summary of Discordant Results, 300 ng/mL Cutoff, Qualitative

Emit® II Plus Cocaine Metabolite Assay (pos/neg)	GC/MS (ng/mL)	Major Drug Present by GC/MS
Positive	217	Benzoylecgonine
Positive	240	Benzoylecgonine
Positive	173	Benzoylecgonine
Positive	207	Benzoylecgonine
Positive	233	Benzoylecgonine
Positive	143	Benzoylecgonine
Positive	217	Benzoylecgonine
Positive	173	Benzoylecgonine
Positive	232	Benzoylecgonine
Positive	157	Benzoylecgonine
Positive	234	Benzoylecgonine

Summary of Discordant Results, 300 ng/mL Cutoff, Semi-Quantitative

Emit® II Plus Cocaine Metabolite Assay (pos/neg)	GC/MS (ng/mL)	Major Drug Present by GC/MS
Positive	217	Benzoylecgonine
Positive	240	Benzoylecgonine
Positive	173	Benzoylecgonine
Positive	207	Benzoylecgonine
Positive	233	Benzoylecgonine
Positive	143	Benzoylecgonine
Positive	217	Benzoylecgonine
Positive	173	Benzoylecgonine
Positive	232	Benzoylecgonine
Positive	157	Benzoylecgonine
Positive	234	Benzoylecgonine

Analytical Recovery

Benzoylecgonine recovery samples were prepared by spiking known levels of benzoylecgonine into a negative urine pool. Each spiked sample was analyzed in replicates of five using the Emit® II Plus Cocaine Metabolite Assay. Results are shown in Table 2.

Table 2 — Results of Recovery

Expected Concentration (ng/mL)	Mean Benzoylecgonine Concentration by Emit® II Plus Cocaine Metabolite Assay (ng/mL)	% Recovery
0	6	N/A
50	53	106
100	103	103
150	150	100
225	235	104
300	298	99
375	380	101
500	543	109
750	792	106
900	906	101
1000	1029	103

Precision

The testing sequence for each level consisted of two replicates, twice a day, for twenty days (n = 80). Precision data were calculated according to the Clinical and Laboratory Standards Institute (CLSI) Guideline EP5-A2.

Repeatability and within lab precision for 150 ng/mL cutoff was determined by assaying urine pools spiked with benzoylecgonine at seven different levels and two commercial controls. Results are summarized in Tables 3 and 4.

Table 3 — 150 ng/mL Precision: Qualitative Analysis

Concentration (ng/mL)	% of cutoff	# of determinations	Repeatability Result	Within Lab Result
0	-100	80	80 Negative	80 Negative
38	-75	80	80 Negative	80 Negative
75	-50	80	80 Negative	80 Negative
113	-25	80	80 Negative	80 Negative
			9 Negative	9 Negative
150	Cutoff	80	71 Positive	71 Positive
188	+25	80	80 Positive	80 Positive
225	+50	80	80 Positive	80 Positive
263	+75	80	80 Positive	80 Positive
300	+100	80	80 Positive	80 Positive

Table 4 — 150 ng/mL Precision: Semi-Quantitative Analysis

Concentration (ng/mL)	% of cutoff	# of determinations	Repeatability Result	Within Lab Result
0	-100	80	80 Negative	80 Negative
38	-75	80	80 Negative	80 Negative
75	-50	80	80 Negative	80 Negative
113	-25	80	80 Negative	80 Negative
			9 Negative	9 Negative
150	Cutoff	80	71 Positive	71 Positive
188	+25	80	80 Positive	80 Positive
225	+50	80	80 Positive	80 Positive
263	+75	80	80 Positive	80 Positive
300	+100	80	80 Positive	80 Positive

Repeatability and within lab precision for 300 ng/mL cutoff was determined by assaying urine pools spiked with benzoylecgonine at seven different levels and two commercial controls. Results are summarized in Tables 5 and 6.

Table 5 — 300 ng/mL Precision: Qualtiative Analysis

Concentration (ng/mL)	% of cutoff	# of determinations	Repeatability Result	With-in Lab Result
0	-100	80	80 Negative	80 Negative
75	-75	80	80 Negative	80 Negative
150	-50	80	80 Negative	80 Negative
225	-25	80	80 Negative	80 Negative
			54 Negative	54 Negative
300	Cutoff	80	26 Positive	26 Positive
375	+25	80	80 Positive	80 Positive
450	+50	80	80 Negative	80 Negative
525	+75	80	80 Positive	80 Positive
600	+100	80	80 Positive	80 Positive

Table 6 — 300 ng/mL Precision: Semi-Quantitative Analysis

Concentration (ng/mL)	% of cutoff	# of determinations	Repeatability Result	Within Lab Result
0	-100	80	80 Negative	80 Negative
75	-75	80	80 Negative	80 Negative
150	-50	80	80 Negative	80 Negative
225	-25	80	80 Negative	80 Negative
300	Cutoff	80	54 Negative 26 Positive	54 Negative 26 Positive
375	+25	80	80 Positive	80 Positive
450	+50	80	80 Negative	80 Negative
525	+75	80	80 Positive	80 Positive
600	+100	80	80 Positive	80 Positive

Specificity

The Emit® II Plus Cocaine Metabolite Assay detects benzoylecgonine, the major metabolite of cocaine, in human urine. The tables below list the cross-reactivity for structurally related compounds. Data presented are representative of typical performance of this assay.

Structurally Related Compounds, 150 ng/mL, cutoff

Compound	Concentration Tested (ng/mL)	% Cross-Reactivity
Ecgonine*	24,000	0.6%
Cocaine*	29,000	0.5%
Norcocaine	2,091,000	<0.01%
Cocaethylene*	380,000	0.04%
Ecgonine Methyl Ester*	629,000	0.02%

Structurally Related Compounds, 300 ng/mL, cutoff

Compound	Concentration Tested (ng/mL)	% Cross-Reactivity
Ecgonine*	102,000	0.3%
Cocaine*	61,000	0.5%
Norcocaine	2,091,000	<0.01%
Cocaethylene*	1,092,000	0.03%
Ecgonine Methyl Ester*	1,961,000	0.02%

* Ecgonine, Cocaine, Cocaethylene, and Ecgonine Methyl Ester tested at the concentrations above produced a result approximately equivalent to the cutoff.

Table 7 lists the compounds that produce a negative result by the Emit® II Plus Cocaine Metabolite Assay. Specificity testing was performed at the 150 ng/mL cutoff, which represents the greatest potential for cross-reactivity. Positive results for compounds structurally unrelated to cocaine metabolite have not been observed.

Table 7 — Concentrations of Compounds Showing a Negative Response

Compound	Concentration Tested (µg/mL) at 150 ng/mL (0.15 µg/mL) Cutoff
Acetaminophen	1000
α-Acetyl *N*, *N* dinormethadol (dinor LAAM)	25
L-α-Acetylmethadol (LAAM)	25
N-Acetylprocainamide (NAPA)	400
Acetylsalicylic Acid	1000
Amitriptyline	1000
Buprenorphine	1000
Caffeine	1000
Cimetidine	1000
Clomipramine	2.5
Clonidine	1000
Codeine	500
Cotinine	100
Cyclobenzaprine	1000
Desipramine	800
Dextromethorphan	1000
Diphenhydramine	1000
Doxepin	1000
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	1000
Fluoxetine	1000
Glutethimide	500
Ibuprofen	1000
Ketamine	100
Ketorolac Tromethamine	1000
Lormetazepam	1
LSD	0.01
Meperidine	1000
Methadone	1000
Methaqualone	1500
Morphine	1000
Naproxen	1000
Nortriptyline	1000
Oxazepam	300
Phencyclidine	1000
Phenytoin	1000
Promethazine	1000
Propoxyphene	1000
Ranitidine	1000
Scopolamine	500
Secobarbital	1000
11-nor-Δ^9-THC-9-COOH	100
Thioridazine	100
Tramadol	1000
Tyramine	100
Zidovudine (AZT)	2000
Zolpidem	100

Non-Interfering Substances

Each of the following compounds when added to urine at ± 25% concentration of the cutoff do not yield a false response relative to either 150 or 300 ng/mL cutoff:

Table 8 — Non-Interfering Substances

Compound	Concentration
Acetone	0.5 g/dL
Ascorbic Acid	1.5 g/dL
Bilirubin	0.25 mg/dL
Creatinine	0.5 g/dL
Ethanol	0.5 g/dL
Gamma Globulin	0.5 g/dL
Glucose	2.0 g/dL
Hemoglobin	115 mg/dL
Human Serum Albumin	0.5 g/dL
Oxalic Acid	0.1 g/dL
Riboflavin	7.5 mg/dL
Sodium Chloride	6.0 g/dL
Urea	6.0 g/dL

Drug free urine pools with specific gravity values ranging from 1.000–1.030 and pH values ranging from 3.0–11.0 were split and spiked to final concentrations of 113 ng/mL, 188 ng/mL, 225 ng/mL and 375 ng/mL benzoylecgonine. These samples were then evaluated in qualitative and semi-quantitative modes. No interference was observed.

Analytical Sensitivity

The sensitivity level of the Emit® II Plus Cocaine Metabolite Assay is less than 35 ng/mL. This level represents the lowest concentration of benzoylecgonine that can be distinguished from 0 ng/mL with a confidence level of 95%.

11 Risk and Safety

H317
P280, P272, P302 + P352, P333 + P313, P501
Warning!
May cause an allergic skin reaction.

Wear protective gloves/protective clothing/eye protection/face protection. Contaminated work clothing should not be allowed out of the workplace. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Dispose of contents and container in accordance with all local, regional, and national regulations.
Contains: 5-chloro-2-methyl-3(2h)-isothiazolone mixture with 2-methyl-3(2h)-isothiazolone.

Safety data sheets (MSDS/SDS) available on siemens.com/healthcare

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13 Symbols Key

For technical assistance, call Siemens Healthcare Diagnostics:
1-800-227-8994 in the USA
1-800-264-0083 in Canada
Outside the USA and Canada, call your local Siemens representative.

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