SIEMENS Healthineers

Cocaine Metabolite (Coc)

Current Revision and Date[a]	Rev. 03, 2019-10	
Product Name	Atellica CH Cocaine Metabolite (Coc)	REF 11097504 (1520 tests)
Abbreviated Product Name	Atellica CH Coc	
Test Name/ID	Coc150 Coc300	
Systems	Atellica CH Analyzer	
Materials Required but Not Provided	Emit Calibrator/Control Level 0	REF 10445406 (9A509UL)
	Emit Calibrator/Control Level 2	REF 10445408 (9A549UL)
	Emit Calibrator/Control Level 3	REF 10445409 (9A569UL)
	Emit Calibrator/Control Level 4	REF 10445410 (9A589UL)
	Emit Calibrator/Control Level 5	REF 10445411 (9A609UL)
Specimen Types	Urine	
Sample Volume	25 µL	
Measuring Interval	Coc150 Cutoff: 150 ng/mL Coc300 Cutoff: 300 ng/mL Coc150 Semiquantitative Interval: 36–900 ng/mL Coc300 Semiquantitative Interval: 36–900 ng/mL	

[a] A vertical bar in the page margin indicates technical content that differs from the previous version.

CE

Intended Use

The Atellica® CH Cocaine Metabolite (Coc) assay is a homogeneous enzyme immunoassay with a 150 ng/mL (SAMHSA initial test cutoff level) or 300 ng/mL cutoff. The Coc assay is for *in vitro* diagnostic use in the qualitative or semiquantitative analyses of benzoylecgonine (cocaine metabolite) in human urine using the Atellica® CH Analyzer. The Coc 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. 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.[1]

Summary and Explanation

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 (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.[2]

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.[3-6]

The Atellica CH Coc 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.[7-9]

While confirmation techniques other than GC/MS may be adequate for some drugs of abuse, GC/MS is generally accepted as a rigorous confirmation technique for all drugs, since it provides the best level of confidence in the result.[2]

Principles of the Procedure

The Atellica CH Coc assay is a homogeneous enzyme immunoassay technique used for the analysis of specific compounds in human urine.[10] The Atellica CH Coc assay uses the Syva® *Emit® II Plus* Cocaine reagents filled into Atellica CH containers.

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 G6PDH does not interfere because the coenzyme NAD functions only with the bacterial (*Leuconostoc mesenteroides*) enzyme employed in the assay.

Reagents

Material Description	Storage	Stability[a]
Atellica CH Coc **Pack 1 (P1)**	Unopened at 2–8°C	Until expiration date on product
Well 1 (W1) Reagent 1 (R1) 19.1 mL Polyclonal antibodies to benzoylecgonine (sheep) (variable by lot); G6P (15 mmol/L); NAD (12 mmol/L); bovine serum albumin; stabilizers; preservatives	Onboard per well	30 days
Well 2 (W2) Reagent 1 (R1) 19.1 mL Polyclonal antibodies to benzoylecgonine (sheep) (variable by lot); G6P (15 mmol/L); NAD (12 mmol/L); bovine serum albumin; stabilizers; preservatives		
Pack 2 (P2)		
Well 1 (W1) Reagent 2 (R2) 10.0 mL Benzoylecgonine labeled with bacterial G6PDH (variable by lot); HEPES buffer; bovine serum albumin; stabilizers; preservatives		
Well 2 (W2) Reagent 2 (R2) 10.0 mL Benzoylecgonine labeled with bacterial G6PDH (variable by lot); HEPES buffer; bovine serum albumin; stabilizers; preservatives		

[a] Refer to *Storage and Stability*.

Warnings and Precautions

For *in vitro* diagnostic use.

For Professional Use.

CAUTION

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

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

H317
P280, P272, P302+P352, P333+P313, P363, 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. Wash contaminated clothing before reuse. Dispose of contents and container in accordance with all local, regional, and national regulations.
Contains: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (R1 and R2)

CAUTION

This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.

Note For information about reagent preparation, refer to *Preparing the Reagents* in the *Procedure* section.

Storage and Stability

Unopened reagents are stable until the expiration date on the product when stored at 2–8°C.

Do not use products beyond the expiration date printed on the product labeling.

Onboard Stability

Reagents are stable onboard the system for 30 days per well. Discard reagents at the end of the onboard stability interval. Do not use products beyond the expiration date printed on the product labeling.

Specimen Collection and Handling

Human urine is the recommended sample type for this assay.

Collecting the Specimen

- Observe universal precautions when collecting specimens. Handle all specimens as if they are capable of transmitting disease.[11]
- Urine specimens may be collected in plastic (such as polypropylene, polycarbonate, or polyethylene) or glass containers. Some plastics can adsorb certain drugs.
- Frozen specimens must be thawed and mixed thoroughly prior to analysis.
- Specimens with high turbidity or particulates should be centrifuged before analysis.
- The pH range for urine specimens is 3.0–11.0.
- Boric acid should not be used as a preservative.
- No additives or preservatives are required.
- Adulteration of the urine specimen may cause erroneous results. If adulteration is suspected, obtain another specimen.

Storing the Specimen

Specimens may be stored for up to 7 days at 25°C[12] or for up to 30 days at 2–8°C[12] or stored frozen at -20°C.[13]

The handling and storage information provided here is based on data or references maintained by the manufacturer. It is the responsibility of the individual laboratory to use all available references and/or its own studies when establishing alternate stability criteria to meet specific needs.

Transporting the Specimen

Package and label specimens for shipment in compliance with applicable federal and international regulations covering the transport of clinical specimens and etiological agents.

Preparing the Samples

This assay requires 25 µL of sample for a single determination. This volume does not include the unusable volume in the sample container or the additional volume required when performing duplicates or other tests on the same sample. For information about determining the minimum required volume, refer to the online help.

Note Do not use specimens with apparent contamination.

Before placing samples on the system, ensure that samples are free of:

- Bubbles or foam.
- Particulate matter.

Procedure

Materials Provided

The following materials are provided:

REF	Contents	Number of Tests
11097504	**Pack 1 (P1)** Well 1 (W1) 19.1 mL of Atellica CH Coc Reagent 1 Well 2 (W2) 19.1 mL of Atellica CH Coc Reagent 1 **Pack 2 (P2)** Well 1 (W1) 10.0 mL of Atellica CH Coc Reagent 2 Well 2 (W2) 10.0 mL of Atellica CH Coc Reagent 2	4 x 380

Materials Required but Not Provided

The following materials are required to perform this assay, but are not provided:

REF	Description	
	Atellica CH Analyzer[a]	
10445406 (9A509UL)	Emit Calibrator/Control Level 0	1 x 14.0 mL
10445408 (9A549UL)	Emit Calibrator/Control Level 2	1 x 14.0 mL
10445409 (9A569UL)	Emit Calibrator/Control Level 3	1 x 14.0 mL
10445410 (9A589UL)	Emit Calibrator/Control Level 4	1 x 14.0 mL
10445411 (9A609UL)	Emit Calibrator/Control Level 5	1 x 14.0 mL
	Commercially available quality control materials	

[a] Additional system fluids are required to operate the system: Atellica CH Diluent, Atellica CH Wash, Atellica CH Conditioner, Atellica CH Cleaner, Atellica CH Reagent Probe Cleaner 1, Atellica CH Reagent Probe Cleaner 2, Atellica CH Reagent Probe Cleaner 4, Atellica CH Lamp Coolant, and Atellica CH Water Bath Additive. For system fluid instructions for use, refer to the Document Library.

Assay Procedure

The system automatically performs the following steps:

1. For urine, dispenses 50 µL of primary sample and 200 µL of Atellica CH Diluent into a dilution cuvette.
2. Dispenses 75 µL of Reagent 1 into a reaction cuvette.

3. Dispenses 25 µL of pre-diluted sample into a reaction cuvette.
4. Dispenses 31 µL of Reagent 2 into a reaction cuvette.
5. Mixes and incubates the mixture at 37°C.
6. Measures the absorbance after Reagent 2 addition.
7. Reports results.

Test Duration: 7 minutes

Preparing the Reagents

All reagents are liquid and ready to use.

Preparing the System

Ensure that the system has sufficient reagent packs loaded in the reagent compartment. For information about loading reagent packs, refer to the online help.

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

Performing Calibration

For calibration of the Atellica CH Coc assay, use Emit Calibrator/Control Level 0, Emit Calibrator/Control Level 2, Emit Calibrator/Control Level 3, Emit Calibrator/Control Level 4, and Emit Calibrator/Control Level 5. Use the benzoylecgonine calibrator values in accordance with the calibrator instructions for use.

Emit Calibrators/Controls Required for Use in Qualitative or Semiquantitative Analysis

Required Calibrators/Controls Coc150 (ng/mL)	Required Calibrators/Controls Coc300 (ng/mL)
Level 0 (0)	Level 0 (0)
Level 2 (150)	Level 2 (150)
Level 3 (300)	Level 3 (300)
Level 4 (500)	Level 4 (500)
Level 5 (1000)	Level 5 (1000)

Calibration Frequency

Perform a calibration if one or more of the following conditions exist:

- When changing lot numbers of primary reagent packs.
- At the end of the lot calibration interval, for a specified lot of calibrated reagent on the system.
- At the end of the pack calibration interval, for calibrated reagent packs on the system.
- When indicated by quality control results.
- After major maintenance or service, if indicated by quality control results.

At the end of the onboard stability interval, replace the reagent pack on the system with a new reagent pack. Recalibration is not required, unless the lot calibration interval is exceeded.

Stability Interval	Days
Lot Calibration	40
Pack Calibration	20
Reagent Onboard Stability	30

For information about lot calibration and pack calibration intervals, refer to the online help.

Follow government regulations or accreditation requirements for calibration frequency. Individual laboratory quality control programs and procedures may require more frequent calibration.

Performing Quality Control

For quality control of the Atellica CH Coc assay, use at least 2 levels (negative and positive) of the appropriate quality control material of known analyte concentration. Use the quality control material in accordance with the quality control instructions for use.

A satisfactory level of performance is achieved when the analyte values obtained are within the expected control range for the system or within your range, as determined by an appropriate internal laboratory quality control scheme. Follow your laboratory's quality control procedures if the results obtained do not fall within the acceptable limits. For information about entering quality control definitions, refer to the online help.

Follow government regulations or accreditation requirements for quality control frequency. Individual laboratory quality control programs and procedures may require more frequent quality control testing.

Taking Corrective Action

If the quality control results do not fall within the assigned values, do not report results. Perform corrective actions in accordance with established laboratory protocol. For suggested protocol, refer to the online help.

Results

Calculation of Results

The system determines the result using the calculation scheme described in the online help. The system reports results in qualitative mode as "positive" or "negative" relative to the assay cutoff. The system reports results in semiquantitative mode in ng/mL. The assay mode (qualitative or semiquantitative) is selected when setting up the assay.

For information about results outside the specified measuring interval, refer to *Measuring Interval*.

Interpretation of Results

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

Qualitative Analysis

The Atellica CH Coc assay cutoff analyte value for Coc150 is 150 ng/mL and for Coc300 is 300 ng/mL. This is used for distinguishing "positive" from "negative" specimens.

- **Positive Results:** A specimen that gives an analyte value greater than or equal to the cutoff analyte value is interpreted as "positive". The specimen is presumptive positive cocaine metabolite.
- **Negative Results:** A specimen that gives an analyte value less than the cutoff analyte value is interpreted as "negative". Either the specimen does not contain cocaine metabolite or cocaine metabolite is present in concentrations below the cutoff value 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 *Measuring Interval* section for the semiquantitative range.

Using the Atellica CH Coc assay, it is possible to make semiquantitative determinations of cocaine metabolite. An estimate of the relative total drug concentration is obtained.

Limitations

The Atellica CH Coc assay is limited to the detection of cocaine metabolite in human urine.

A positive result from the assay indicates the presence of cocaine metabolite 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.

Expected Values

When the Atellica CH Coc assay is used as a qualitative assay, the amount of cocaine metabolite detected by the assay in a given specimen cannot be estimated. The assay results distinguish positive from negative specimens—positive indicating specimens that contain cocaine metabolite.

When used semiquantitatively, the assay yields an approximate concentration of cocaine metabolite in the specimen.

Performance Characteristics

Assay Comparison

Qualitative and Semiquantitative Results

The data appearing in this section were previously collected using the Emit® II Plus Cocaine Metabolite Assay and by GC/MS (reference method).

150 ng/mL Cutoff

One hundred twenty-five (125) samples were analyzed by the Emit II Plus Cocaine Metabolite Assay and by GC/MS (reference method). Both methods used a cutoff of 150 ng/mL. Twenty-two (22) samples were within ± 25% of the cutoff (113–188 ng/mL) by GC/MS. Sixty-two (62) samples showed positive results by both methods, while fifty-four (54) samples showed negative results by both methods. Of the sixty-nine (69) specimens showing positive results by the reference method, sixty-two (62) were also positive by the Emit II Plus Cocaine Metabolite Assay.

The agreement of the assay may vary depending on the study design, comparative assay, and sample population. Assay results obtained at individual laboratories may vary from the data presented.

Qualitative Results for the 150 ng/mL Cutoff

		Reference Method GC/MS	
		+	-
Emit II Plus Cocaine Metabolite Assay	+	62	2[a]
	-	7[b]	54

Percent agreement: 93%

[a] GC/MS results were 123 and 140 ng/mL.

[b] GC/MS results were 150, 151, 157, 162, 164, 166, and 190 ng/mL.

300 ng/mL Cutoff

One hundred twenty-five (125) samples were analyzed by the Emit II Plus Cocaine Metabolite Assay and by GC/MS (reference method). Both methods used a cutoff of 300 ng/mL. Twenty-four (24) samples were within ± 25% of the cutoff (225–375 ng/mL) by GC/MS. Thirty-four (34) samples showed positive results by both methods, and eighty-four (84) samples showed negative results by both methods. Of the thirty-five (35) specimens showing positive results by the reference method, thirty-four (34) were also positive by the Emit II Plus Cocaine Metabolite Assay.

Qualitative Results for the 300 ng/mL Cutoff

		Reference Method GC/MS	
		+	-
Emit II Plus Cocaine Metabolite Assay	+	34	6[a]
	-	1[b]	84

Percent agreement: 94%

[a] GC/MS results were 218, 241, 261, 294, 295, and 298 ng/mL.

[b] GC/MS result was 354 ng/mL.

Precision

Precision was determined in accordance with CLSI Document EP05-A3.[14] Repeatability and within lab precision were determined by assaying negative urine pools spiked with cocaine metabolite. Samples were assayed on an Atellica CH Analyzer in duplicate in 2 runs per day for 20 days (N = 80 for each sample). The following results were obtained:

Qualitative Analysis

			Repeatability		Within-Lab Precision	
Calibrator or Control	**N**	**Mean (mAU/min)**	**SD[a] (mAU/min)**	**CV[b] (%)**	**SD (mAU/min)**	**CV (%)**
Calibrator (0 ng/mL)	80	129.6	0.4	0.3	0.8	0.6
Control Level 1	80	154.7	0.4	0.2	0.8	0.5
Calibrator (150 ng/mL)	80	163.9	0.4	0.3	1.0	0.6
Control Level 2	80	169.4	0.5	0.3	1.0	0.6
Control Level 3	80	175.0	0.5	0.3	1.1	0.6
Calibrator (300 ng/mL)	80	183.0	0.4	0.2	1.1	0.6
Control Level 4	80	188.2	0.5	0.3	1.2	0.7

[a] Standard deviation.
[b] Coefficient of variation.

Semiquantitative Analysis

			Repeatability		Within-Lab Precision	
Calibrator or Control	**N**	**Mean (ng/mL)**	**SD[a] (ng/mL)**	**CV[b] (%)**	**SD (ng/mL)**	**CV (%)**
Control Level 1	80	92.2	1.7	1.9	3.6	3.9
Calibrator (150 ng/mL)	80	140.8	2.5	1.8	5.7	4.0
Control Level 2	80	175.1	3.6	2.1	6.8	3.9
Control Level 3	80	216.6	3.8	1.8	8.5	3.9
Calibrator (300 ng/mL)	80	291.4	4.7	1.6	12.1	4.2
Control Level 4	80	355.3	7.1	2.0	17.1	4.8

[a] Standard deviation.
[b] Coefficient of variation.

Recovery

Recovery of cocaine metabolite samples were prepared by spiking known amounts of benzoylecgonine into negative urine pools. Each spiked sample was analyzed using the Atellica CH Coc assay. Results of recovery are shown below.

Expected Cocaine Metabolite Concentration (ng/mL)	Mean Cocaine Metabolite Concentration by Atellica CH Coc Assay (ng/mL)	% Recovery
45	48	107
60	62	103
75	78	104
135	158	117
165	190	115
225	245	109
600	577	96
750	695	93
900	809	90

Measuring Interval

When the Atellica CH Coc 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 positive from negative specimens—positive indicating specimens that contain benzoylecgonine.

The Atellica CH Coc assay, when run as a semiquantitative method, provides results from 36 ng/mL to 900 ng/mL. The system flags all values that are outside the specified measuring interval. There are no extended measuring interval options for this assay.

Specificity

The Atellica CH Coc assay detects benzoylecgonine, the major metabolite of cocaine, in human urine.

Specificity data were collected on automated chemistry systems using reaction conditions comparable to those used on the Atellica CH Analyzer.[12]

The following table lists the concentrations of compounds that produce a result that is approximately equivalent to the 150 ng/mL and 300 ng/mL calibrator/control cutoffs, respectively. These concentrations are within the range of levels found in urine following use of the compound or, in the case of metabolites, the parent compound. If a specimen contains more than one compound detected by the assay, lower concentrations than those listed in the table may combine to produce a rate equal to or greater than that of the cutoff calibrator. Data presented are representative of typical performance of this assay.[12]

Concentrations of Structurally-Related Compounds that Produce a Result Approximately Equivalent to the 150 ng/mL and 300 ng/mL Benzoylecgonine Cutoffs

Compound	Concentration Tested at 150 ng/mL Cutoff (µg/mL)	Concentration Tested at 300 ng/mL Cutoff (µg/mL)
Cocaine[a]	18–53	40–119
Ecgonine[a]	24	102
Norcocaine	2091	2091
Cocaethylene[a]	380	1092
Ecgonine Methyl Ester[a]	629	1961

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

Specificity data were collected on automated chemistry systems using reaction conditions comparable to those used on the Atellica CH Analyzer.[12]

The following table lists the compounds that produce a negative result by the Atellica CH Coc 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.

Concentrations of Compounds Showing a Negative Response

Compound	Concentration Tested at 150 ng/mL Cutoff (µg/mL)
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

Compound	Concentration Tested at 150 ng/mL Cutoff (µg/mL)
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 ng/mL or 300 ng/mL cutoff. Interference data were collected on automated chemistry systems using reaction conditions comparable to those used on the Atellica CH Analyzer.[12]

Substance	Substance Test 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

Assay results obtained at individual laboratories may vary from the data presented.

Detection Capability

Detection capability was determined in accordance with CLSI Document EP17-A2.[15] The assay is designed to have a limit of blank (LoB) ≤ limit of detection (LoD) and LoD ≤ 36 ng/mL.

The LoD corresponds to the lowest concentration of cocaine metabolite that can be detected with a probability of 95%. The LoD for the Atellica CH Coc assay is 7 ng/mL, and was determined using 120 determinations, with 60 blank and 60 low level replicates, and a LoB of 4 ng/mL.

Assay results obtained at individual laboratories may vary from the data presented.

Standardization

The Atellica CH Coc assay is traceable to the Syva Emit Calibrators/Controls, which are referenced to gravimetrically prepared standards. These standards are qualified by GC/MS from an independent laboratory and must quantitate within ± 10% of nominal.[12]

Technical Assistance

For customer support, contact your local technical support provider or distributor.

siemens.com/healthineers

References

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5. Stewart DJ, et al. Cocaine metabolism: Cocaine and norcocaine hydrolysis by liver and serum esterases. *Clin Pharmacol Ther.* 1979;25:464–468.
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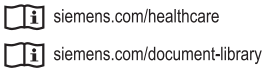
9. Kogan MJ, et al. Quantitative determination of benzoylecgonine and cocaine in human biofluids by gas-liquid chromatography. *Anal Chem.* 1977;49:1965–1969.
10. Lindgren JE. Guide to the analysis of cocaine and its metabolites in biological material. *J Ethnopharmacol.*1981;3:337–351.
11. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document M29-A4.
12. Data on file at Siemens Healthcare Diagnostics.
13. Clinical and Laboratory Standards Institute. *Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline—Second Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2007. CLSI Document C52-A2.
14. Clinical and Laboratory Standards Institute. *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document EP05-A3.
15. Clinical and Laboratory Standards Institute. *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2012. CLSI Document EP17-A2.

Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title and Description
	Consult instructions for use
 Rev. 01	Version of instructions for use
 siemens.com/healthcare  siemens.com/document-library	Internet URL address to access the electronic instructions for use

Symbol	Symbol Title and Description
Rev. REVISION	Revision
	Caution Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device.
	Biological risks Potential biological risks are associated with the medical device.
	Corrosive
	Dangerous to environment
	Irritant Oral, dermal, or inhalation hazard
	Inhalation hazard Respiratory or internal health
	Flammable Flammable to extremely flammable
	Oxidizing
	Explosive
	Toxic
	Compressed gas
	Keep away from sunlight Prevent exposure to sunlight and heat.
	Up Store in an upright position.
	Do not freeze
	Temperature limit Upper and lower limits of temperature indicators are adjacent to the upper and lower horizontal lines.

Symbol	Symbol Title and Description
	Handheld barcode scanner
IVD	*In vitro* diagnostic medical device
Σ (n)	Contains sufficient for <n> tests Total number of IVD tests the system can perform with the IVD kit reagents appears adjacent to the symbol.
RxOnly	Prescription device (US only) Applies only to United States-registered IVD assays. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.
	Mixing of substances Mix product before use.
g mL	Reconstitute and mix lyophilized product before use.
	Target
	Interval
	Legal Manufacturer
EC REP	Authorized Representative in the European Community
	Use-by date Use by the designated date.
LOT	Batch code
REF	Catalog number
	Recycle
PRINTED WITH SOY INK	Printed with soy ink
CE	CE Mark
CE 0088	CE Mark with notified body ID number Notified body ID number can vary.
YYYY-MM-DD	Date format (year-month-day)
CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.
UNITS C	Common Units

Symbol	Symbol Title and Description
UNITS SI	International System of Units
MATERIAL	Material
MATERIAL ID	Unique material identification number
CONTROL NAME	Name of control
CONTROL TYPE	Type of control

Legal Information

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