

**DXC (COCM) COCAINE METABOLITE**

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**PURPOSE**

To provide instructions for the qualitative determination of cocaine metabolite on the DXC 600/800.

**PRINCIPLE**

COCM reagent, when used in conjunction with UniCel® DxC 600/800 System(s) and SYNCHRON® Systems Drugs of Abuse Testing (DAT) Urine Calibrators, is intended for the qualitative determination of benzoylecgonine (cocaine metabolite) in human urine, at a cutoff value of 300 ng/mL. The COCM assay provides a rapid screening procedure for determining the presence of Cocaine Metabolite in urine. This test provides only a preliminary analytical result; a positive result by this assay should be confirmed by another generally accepted non-immunological method such as thin layer chromatography (TLC), gas chromatography (GC), or gas chromatography/mass spectrometry (GC/MS). GC/MS is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

**BACKGROUND**

**Clinical Significance**

Measurements of cocaine and cocaine metabolites are used in the diagnosis and treatment of cocaine use or overdose.

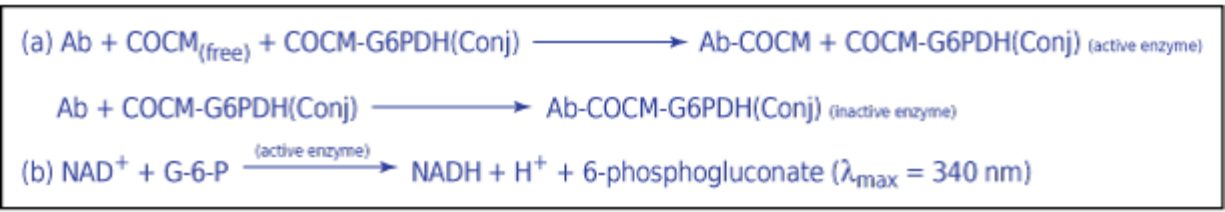
**General Discussion**

Cocaine is used as a local anesthetic. The drug is widely abused by intranasal administration (snorting) or by inhalation (smoking) due to its central nervous system stimulating effects. Excretion rates vary with each individual and with the mode of administration. Most cocaine is excreted in urine as benzoylecgonine, its major metabolite, with less than ten percent excreted in urine unchanged. Benzoylecgonine can be detected in urine within four hours of administration and remains detectable for as long as 27 hours.

**Methodology**

The Cocaine Metabolite assay utilizes a homogenous enzyme immunoassay method. The COCM reagent is comprised of specific antibodies which can detect benzoylecgonine in urine. A drug-labeled glucose-6-phosphate dehydrogenase (G6PDH) conjugate competes with any free drug from the urine sample for a fixed amount of antibody binding sites. In the absence of free drug from the sample, the drug-labeled G6PDH conjugate is bound by the specific antibody and enzyme activity is inhibited. This reaction creates a direct relationship between the presence of drug and enzyme activity. G6PDH enzyme activity is determined spectrophotometrically by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH (reduced form).

The SYNCHRON® System(s) automatically proportions the appropriate sample and reagent volumes into a cuvette. The ratio for COCM is one part sample to 25 parts reagent. The System monitors the change in absorbance at 340 nanometers to calculate and express a reaction rate. A qualitative result is reported based on a comparison of the sample rate to the calibrated cutoff rate.



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**RELATED DOCUMENTS**

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|--------------|--|
| R-PO-CH-0810 | Quality Control Program General Laboratory |
| R-PO-CH-0809 | Quality Control Westgard Rules Statistics  |
| R-PR-AD-0540 | Specimen Rejection/Cancellation Protocol   |
| J-F-CH-0820  | DXC 800 Controls                           |
| M-F-CH-0820  | Chemistry Controls                         |
| J-F-CH-0826  | DXC 800 Calibrators                        |
| M-F-CH-0826  | Chemistry Calibrators                      |

**SPECIMEN**

**Type of Specimen**

Freshly collected urine samples should be used for testing. Collect urine samples in glass or plastic (i.e., polypropylene, polycarbonate, polyethylene) containers. Urine samples should be collected in the manner routinely used for drug screening analysis. Samples should be at room temperature for testing.

**Specimen Storage and Stability**

If the sample cannot be analyzed immediately, it may be stored at +2°C to +8°C for up to 7 days. If longer storage is required or when a split sample collection method is used, samples should be stored frozen at -20°C or less.

Sample Type	Volume	Sample Stability
Urine	0.5mL	<ul style="list-style-type: none"> <li>• Analyze at Room Temp</li> <li>• Refrigerated 7 days</li> <li>• Frozen (-20°C) &gt;7 days</li> </ul>

**Criteria for Unacceptable Specimens**

See Specimen Rejection/Cancellation Protocol

**Sample Volume**

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples and minimum volumes, refer to the Primary Tube Sample Template for your system.

**REAGENTS**

**Contents**

Each kit contains the following items:  
 One COCM Reagent Cartridge (1 x 250 tests)

Volume per Test	
Sample Volume	20 uL
Total Reagent Volume	250 uL
Cartridge Volumes	A 200 uL B 50 uL C --

Reactive Ingredients	
Antibody/Substrate Reagent: Monoclonal anti-benzoyllecgonine antibody (mouse) Glucose-6-phosphate (G6P) Nicotinamide adenine dinucleotide (NAD) Tris buffer	69mL
Enzyme Conjugate Reagent: Glucose-6-phosphate dehydrogenase (G6PDH) labeled with benzoyllecgonine Tris buffer	18mL

Also non-reactive chemicals necessary for optimal system performance.

### Reagent Preparation

No preparation is required.

### Acceptable Reagent Performance

The acceptability of a reagent is determined by successful calibration and by ensuring that quality control results are within acceptance criteria. Refer to the Quality Control section of this chemistry information sheet for Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines.

### Reagent Storage and Stability

COCM reagent when stored unopened at +2°C to +8°C, will remain stable until the expiration date printed on the cartridge label. Once opened, the reagent is stable for 90 days at +2°C to +8°C. Do not use beyond the manufacturer's expiration date. DO NOT FREEZE.

## CALIBRATION

### Calibrator Required

SYNCHRON Systems DAT Negative Urine Calibrator (0 ng/mL benzoyllecgonine)  
SYNCHRON Systems DAT Multi-Drug Low (cutoff) Urine Calibrator (300 ng/mL benzoyllecgonine)  
SYNCHRON Systems DAT Multi-Drug High Urine Calibrator (3000 ng/mL benzoyllecgonine)

### Calibrator Preparation

No preparation is required.

### Calibrator Storage and Stability

SYNCHRON<sup>®</sup> Systems Drugs of Abuse Testing (DAT) Urine Calibrators are stable until the expiration date printed on the calibrator bottles if stored capped in the original containers at +2°C to +8°C.

## Calibration Information

1. The DAT assays require three levels of calibrators. The calibration measures the separation between calibrators to ensure reagent integrity. **The Calibration factor generated is non-functional for sample result calculation.**
2. The system must have a valid calibrator cutoff value in memory before controls or patient samples can be run. The cutoff value for each DAT chemistry represents the mean reaction rate of the Low Calibrator, and is reported in mA/min units on patient and control reports. Cutoff values are stored in memory until the next successful calibration.
3. Under typical operating conditions the COCM reagent cartridge must be calibrated every 14 days and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual. This assay has within-lot calibration available. Refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual for information on this feature.
4. For detailed calibration instructions, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.
5. The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will be printed with error codes and the system will alert the operator of the failure. For information on error codes, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

## Traceability

For Traceability information refer to the Calibrator instructions for use.

## QUALITY CONTROL

See Related Documents J-F-CH0820 DXC 800 Controls & M-F-CH0820 Chemistry Controls

## STEPS

1. If necessary, load the reagent onto the system.
2. After reagent load is completed, calibration may be required.
3. Program controls for analysis.
4. After loading controls onto the system, follow the protocols for system operation. To load samples manually refer to the FHS DXC Series Manual Sample Programming procedure. For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

## CALCULATIONS

The system performs all calculations internally to produce the final qualitative result, reported as POSITIVE or NEGATIVE. The qualitative result is based on a comparison of the sample rate to the calibrated cutoff rate; a sample rate greater than or equal to the cutoff rate is reported as POSITIVE. A POSITIVE result ( $\geq 300$  ng/mL) from this assay indicates only the presence of Cocaine Metabolite and does not necessarily correlate with the extent of physiological and psychological effects. A NEGATIVE test result indicates that Cocaine Metabolite are either not present, or are present at levels below the cutoff threshold of the test.

## PERFORMANCE CHARACTERISTICS

### Reference Range

Sample Type	Normal
Urine	"Not Detected"

Analyte	Normal Results	Suspect Results (Adulterated)
Creatinine	>20 mg/mL	<20 mg/mL

If results for Creatinine are outside normal parameters for urine drug testing, **DIL1** comment will be appended to screen results.

### Reporting results

Result	Reported As
Negative	"Not Detected"
Positive	"Detected"

### Relative Sensitivity and Specificity

Eighty clinical urine specimens were collected and tested. Using the SYNCHRON CX7 DELTA as a reference method, 39 samples tested positive and 40 tested negative. The cutoff value of the SYNCHRON Systems Cocaine Metabolite assay is 300 ng/mL.

Relative Sensitivity: 95%  
Relative Specificity: 100%  
Overall Agreement: 99%

### LIMITATIONS

1. The test is designed for use with human urine only.
2. Do not dilute the urine samples since this is a qualitative assay. Dilution of samples may produce erroneous results.
3. Interference has been demonstrated from mefenamic acid, a nonopioid analgesic.
4. Adulteration of the urine sample may cause erroneous results. Alteration of a urine specimen may be detected by checking the appearance, temperature, pH, specific gravity, and creatinine levels of a sample. If adulteration is suspected, obtain another sample and forward both specimens to the laboratory for testing.
5. An effort should be made to keep pipetted samples free from gross debris. It is recommended that highly turbid specimens be centrifuged before analysis.

### Cross Reactivity

Cocaine and various potential interfering substances in a human urine matrix were tested for cross-reactivity with the SYNCHRON Systems COCM assay. The following table summarizes the results obtained at the concentrations tested for each potential cross-reactant.

Compound	Concentration (µg/mL)	Effect
Benzoylcegonine (cutoff)	0.3	Positive
Cocaine	50	Positive
Acetaminophen	1000	Negative
Acetylsalicylic Acid	1000	Negative
Albuterol	1000	Negative
Amobarbital	1000	Negative
d-Amphetamine	1000	Negative
Benzocaine	1000	Negative
Caffeine	100	Negative
Codeine	1000	Negative
Dextromethorphan	100	Negative
Ecgonine	10	Negative
Ecgonine Methyl Ester	10	Negative
Lidocaine	1000	Negative
Lysergic Acid	100	Negative
Meperidine	1000	Negative
Methadone	1000	Negative
Metoclopramide	1000	Negative
Metronidazole	1000	Negative
Morphine	200	Negative
Nicotine	500	Negative
Oxazepam	100	Negative
Phencyclidine	1000	Negative
Phenobarbital	1000	Negative
Propoxyphene	1000	Negative
Secobarbital	1000	Negative

## ADDITIONAL INFORMATION

For more detailed information on UniCel DxC Systems, refer to the appropriate system manual.

## REFERENCES

1. National Institute on Drug Abuse Research, "Urine Testing for Drugs of Abuse", Monograph 73 (1986).
2. National Institute on Drug Abuse, "Mandatory Guidelines for Federal Workplace Drug Testing Programs", *Federal Register*, Vol. 53, No. 69 (1988).
3. Rubenstein, K. E., Schneider, R. S., Ullman, E. F., 'Homogenous Enzyme Immunoassay: A New Immunochemical Technique', *Biochem. Biophys. Res. Commun.*, Vol. 47, 846 851 (1972).
4. McEnvoy, G. K., Litvak, K., *AHFS Drug Information*, American Society of Hospital Pharmacists, Inc., Bethesda, MD (1992).
5. Van Dyke, C., et al., Urinary Excretion of Immunologically Reactive Metabolite(s) After Intranasal Administration of Cocaine as Followed by Enzyme Immunoassay, *Clin. Chem.*, Vol. 23, 241 244 (1977).
6. National Committee for Clinical Laboratory Standards, *Urine Drug Testing in the Clinical Laboratory*, Proposed Guideline, NCCLS publication T/DM8-P, Villanova, PA (1993).
7. Substance Abuse and Mental Health Service Administration, "Mandatory Guidelines for Federal Workplace Drug Testing Programs", *Federal Register*, Vol. 58, No. 14, (1993).
8. Crane, T., et al., "Mefenamic Acid Prevents Assessment of Drug Abuse with EMIT™ Assays", *Clin. Chem.*, Vol. 39, No. 3, 549 (1993).
9. Tietz, N. W., *Fundamentals of Clinical Chemistry*, 4th Edition, W. B. Saunders Company, Philadelphia, PA (1996).
10. Product insert

**DOCUMENT APPROVAL Purpose of Document / Reason for Change:**

Formatting and minor changes

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