DXC (OXYX) OXYCODONE

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PURPOSE

To provide instruction for the qualitative determination of Oxycodone and its metabolite oxymorphone in human urine on the DXC 600/800.

PRINCIPLE

The DRI Oxycodone Assay is intended for the qualitative determination of oxycodone and its metabolite, oxymorphone in human urine at a cutoff of 300 ng/mL.

BACKGROUND

Clinical Significance

Oxycodone is a semi-synthetic opioid prescribed for pain management in patients with moderate to severe pain. It is similar to codeine and morphine in its analgesic properties but it is more potent than morphine and has higher dependence potential. The drug oxycodone is supplied as OxyContin (Oxycodone HCl) or in combination with aspirin (Percodan) or acetaminophen (Percocet). Drug abusers crush the pills into powder and snort them for faster effect which may result in a potentially fatal outcome. Oxymorphone, noroxycodone and noroxymorphone are the only known metabolites of oxycodone. The metabolite oxymorphone, is a potent narcotic, while the other two metabolites are relatively inactive. From 33-61% of a single dose of oxycodone is excreted in urine within 24 hours as unconjugated oxycodone (13-19%), conjugated oxycodone (7-29%), and conjugated oxymorphone (13-14%).

Methodology

The DRI Oxycodone Assay for SYNCHRON Systems is supplied as a liquid ready-to-use homogeneous enzyme immunoassay. The assay uses specific antibodies that can detect oxycodone and oxymorphone without any significant cross-reactivity to other opiate compounds. The assay is based on competition between a drug labeled with glucose-6-phosphate dehydrogenase (G6PDH), and free drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, the specific antibody binds the drug labeled G6pdh and causes a decrease in enzyme activity. This phenomenon creates a direct relationship between the drug concentration in urine and enzyme activity. The enzyme activity is determined spectrophotometrically at 340nm by measuring the conversion of nicotinamide adenine dinucleotide (NAD) to NADH.

RELATED DOCUMENTS

R-PO-CH0810	Quality Control Program General Laboratory
R-PO-CH0809	Quality Control Westgard Rules Statistics
R-PR-AD0540	Specimen Rejection/Cancellation Protocol
J-F-CH0820	DXC 800 Controls

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J-F-CH0826 DXC 800 Calibrators
M-F-CH0820 Chemistry Controls
M-F-CH0826 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.
Samples with a pH range of 3 to 11 are suitable for testing. Centrifuge highly turbid specimens before analysis.

Specimen Storage and Stability

Sample Type	Volume	Sample Stability
Urine	0.5mL	• Freshly collected urine is the specimen of choice • Analyze at Room Temperature • 7 days at 2-8°C • Urine with preservative is unacceptable for testing

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

User-defined DRI Oxycodone Assay- Microgenics (OXYX)
Beckman Coulter Kit product number is A53730. ThermoScientific kit product number is 10012653.

Reagent Preparation

Reagents are ready-to-use. No additional preparation is required. A DXC User-Defined Reagent Cartridge is also required.
Antibody/Substrate Reagent A**…One 30 mL bottle in** Compartment A **of user defined cartridge.**
Enzyme Conjugate Reagent E**…One 7 mL bottle in** Compartment B **of user defined cartridge.**
Each kit contains two bottles of Reagent A and two bottles of Reagent E.

DRI Oxycodone for SYNCHRON Systems	Compartment A of user defined cartridge	Compartment B of user defined cartridge
Antibody/Substrate Reagent A	One Bottle (30 mL)	
Enzyme Conjugate Reagent E		One Bottle (7mL)

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Acceptable Reagent Performance

The acceptability of a reagent is determined by successful calibration and by ensuring that quality control results are within acceptance criteria.

Reagent Storage and Stability

OXYX reagents should be refrigerated (2-8 degrees Centigrade). All assay components, opened or unopened, are stable until the expiration date indicated on their respective labels. Do not use the reagents beyond their expiration dates.

CALIBRATION

Calibrator Required

DRI Negative Urine Calibrator
DRI 300 Oxycodone Urine Calibrator
DRI1000 Oxycodone Urine Calibrator

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

OXYX calibrators should be refrigerated (2-8 degrees Centigrade). All assay components, opened or unopened, are stable until the expiration date indicated on their respective labels. Do not use the reagents beyond their expiration dates.

Calibration Information

1. The DAT assays require three levels of calibrators. The calibration measures the separation between calibrators to ensure reagent integrity.

   NOTE: 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. For detailed calibration instructions, 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

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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 (≥300 ng/mL) from this assay indicates only the presence of this analyte and does not necessarily correlate with the extent of physiological and psychological effects. A NEGATIVE test result indicates that this analyte is either not present, or is 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"

Sensitivity

The sensitivity of the assay using the negative calibrator is 6.1 ng/mL.

LIMITATIONS

1. The test is designed for use with human urine only.

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2. Do not dilute the urine samples since this is a qualitative assay. Dilution of samples may produce erroneous results.

3. 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.

4. An effort should be made to keep pipetted samples free from gross debris. It is recommended that highly turbid specimens be centrifuged before analysis.

5. Interference may be caused by other substances and/or factors (e.g., technical or procedural errors) not listed above, producing false results.

REFERENCES

1. SYNCHRON DxC Systems Instructions for Use, Copyright 2005, Beckman Coulter, Inc.
2. Urine Testing for Drugs of Abuse, National Institute on Drug Abuse Research Monograph 73 (1986).
3. Mandatory Guidelines for Federal Workplace Drug Testing Programs, National Institute on Drug Abuse, Federal Register Vol. 53, No. 69 (1988).
4. Tietz, N.W. Fundamentals of Clinical Chemistry, 4th Edition, W.B. Saunders Company, Philadelphia, PA (1996).

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