Opiates II

OPI2

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• Indicates **cobas c** systems on which reagents can be used

Order information

			Roche/Hitachi **cobas c** systems
			cobas c 501
ONLINE DAT Opiates II			
200 Tests	Cat. No. **04490894** 190	System-ID 07 6949 5	•
Preciset DAT Plus I calibrators	Cat. No. **03304671** 190	Codes 431-436	
CAL 1-6	6 x 5 mL		
Preciset DAT Plus II calibrators	Cat. No. **03304680** 190	Codes 437-442	
CAL 1-6	6 x 5 mL		
C.f.a.s. DAT Qualitative Plus	Cat. No. **03304698** 190		
	6 x 5 mL		
C.f.a.s. DAT Qualitative Clinical	Cat. No. **04500865** 160		
CAL 1-5 (only available in the US)	10 x 5 mL		
Control Set DAT I (for 2000 ng/mL assay)	Cat. No. **03312950** 190		
PreciPos DAT Set I	2 x 10 mL		
PreciNeg DAT Set I	2 x 10 mL		
Control Set DAT II (for 300 ng/mL assay)	Cat. No. **03312968** 190		
PreciPos DAT Set II	2 x 10 mL		
PreciNeg DAT Set II	2 x 10 mL		

English

System information
OP3Q2: ACN 497: for qualitative assay, 300 ng/mL
OP2Q2: ACN 495: for qualitative assay, 2000 ng/mL
OP3S2: ACN 498: for semiquantitative assay, 300 ng/mL
OP2S2: ACN 496: for semiquantitative assay, 2000 ng/mL

Intended use
Opiates II (OPI2) is an in vitro diagnostic test for the qualitative and semiquantitative detection of morphine and its metabolites in human urine on Roche/Hitachi **cobas c** systems at cutoff concentrations of 300 and 2000 ng/mL. Semiquantitative test results may be obtained that permit laboratories to assess assay performance as part of a quality control program. **Opiates II provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[1] Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.**

Summary
Morphine, a natural product of the opium poppy, is a narcotic analgesic used for centuries as a medicine for the relief of severe pain. Extracted from opium obtained from the poppy's resin, morphine may, in turn, be further chemically refined to heroin (the more potent, diacetylated analog of the parent drug). These chemically similar "opiates" reduce sensitivity to physical and psychological stimuli, dulling pain, fear and anxiety. Users are usually lethargic and indifferent. Accompanying effects may include constriction of the pupils, itching, constipation, nausea, vomiting, and respiratory depression. Death by overdose, usually resulting from dose miscalculation or dose-strength variability, is caused by respiratory failure.[2,3,4]
The opiates are usually administered intravenously or subcutaneously, but may also be smoked or sniffed. Upon entering the circulation, they tend to concentrate in the lungs, spleen, kidneys, and liver; lower concentrations are found in the body's musculature and central nervous system. A variety of pathways are involved in the body's detoxification of the opiates, including the removal of chemical side groups (dealkylation), addition of hydroxyl groups, hydrolytic breakdown, and conjugation to glucuronic acid (a common body sugar).[5] Morphine is excreted in the urine as morphine-3-glucuronide, unchanged free morphine, and other minor metabolites. Although some opiate metabolites appear in the bile and feces, urinary excretion is the primary route of elimination.[1,6]
The opiates produce strong physical dependence; withdrawal symptoms can begin to appear within a few hours of the last dose and may continue for 5-10 days. The addict may pursue continued opiate use as much to avoid the discomfort of withdrawal as to achieve the desired insensate euphoria.[7,8]

Test principle
ONLINE DAT II automated assays are based on the kinetic interaction of microparticles in a solution (KIMS)[9] as measured by changes in light transmission. In the absence of sample drug, soluble drug conjugates bind to antibody-bound microparticles, causing the formation of particle aggregates. As the aggregation reaction proceeds in the absence of sample drug, the absorbance increases.
When a urine 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.[10]

Reagents - working solutions

R1 Conjugated morphine derivative; buffer; bovine serum albumin; 0.09% sodium azide

R2 Microparticles attached to morphine antibody (mouse monoclonal); buffer; bovine serum albumin; 0.09% sodium azide

Precautions and warnings
For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.
Safety data sheet available for professional user on request.

Reagent handling
Ready for use. Mix reagents by gentle inversion before placing on-board the analyzer.

Storage and stability

Shelf life at 2 to 8°C:	See expiration date on **cobas c** pack label
On-board in use and refrigerated on the analyzer:	8 weeks

Do not freeze.

Specimen collection and preparation
Only the specimens listed below were tested and found acceptable.
Urine: Collect urine samples in clean glass or plastic containers. Fresh urine specimens do not require any special handling or pretreatment, but an effort should be made to keep pipetted samples free of gross debris. Samples should be within the normal physiological pH range of 5-8. No additives or preservatives are required. It is recommended that urine specimens be stored at 2-8°C and tested within 3 days of collection. For prolonged storage, freezing of samples is recommended. Centrifuge highly turbid specimens before testing.

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Adulteration or dilution of the sample can cause erroneous results. If adulteration is suspected, another sample should be collected. Specimen validity testing is required for specimens collected under the *Mandatory Guidelines for Federal Workplace Drug Testing Programs.*[11] Specimens containing human-sourced materials should be handled as if potentially infectious using safe laboratory procedures such as those outlined in *Biosafety in Microbiological and Biomedical Laboratories* (HHS Publication Number [CDC] 93-8395).

CAUTION: Specimen dilutions should only be used to interpret results of Calc.? and Samp.? alarms, or when estimating concentration in preparation for GC/MS. Dilution results are not intended for patient values. Dilution procedures, when used, should be validated.

Materials provided

See "Reagents - working solutions" section for reagents.

Materials required (but not provided)

See "Order information" section
General laboratory equipment

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator manual for analyzer-specific assay instructions.
The performance of applications not validated by Roche is not warranted and must be defined by the user.

Application for urine

Deselect Automatic Rerun for these applications in the Utility menu, Application screen, Range tab.

cobas c 501 **test definition - 300 ng/mL cutoff assay**

	Semiquantitative	Qualitative
Assay type	2 Point End	2 Point End
Reaction time / Assay points	10 / 13-31	10 / 13-31
Wavelength (sub/main)	– /570 nm	– /570 nm
Reaction direction	Increase	Increase
Unit	ng/mL	mAbs
Reagent pipetting		Diluent (H_2O)
R1	100 µL	–
R2	41 µL	–

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	6 µL	–	–
Decreased	6 µL	–	–
Increased	6 µL	–	–

cobas c 501 **test definition - 2000 ng/mL cutoff assay**

	Semiquantitative	Qualitative
Assay type	2 Point End	2 Point End
Reaction time / Assay points	10 / 13-31	10 / 13-31
Wavelength (sub/main)	– /570 nm	– /570 nm
Reaction direction	Increase	Increase
Unit	ng/mL	mAbs
Reagent pipetting		Diluent (H_2O)
R1	100 µL	–
R2	41 µL	–

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	2 µL	–	–
Decreased	2 µL	–	–
Increased	2 µL	–	–

Calibration

Calibrators	*Semiquantitative applications* *300 ng/mL cutoff assay* S1-6: Preciset DAT Plus II calibrators, CAL 1-6 0, 150, 300, 600, 1000, 2000 ng/mL *2000 ng/mL cutoff assay* S1-6: Preciset DAT Plus I calibrators, CAL 1-6 0, 600, 1000, 2000, 4000, 8000 ng/mL *Qualitative applications* *300 ng/mL cutoff assay* S1: C.f.a.s. DAT Qualitative Clinical, CAL 2 or Preciset DAT Plus II calibrator, CAL 3, 300 ng/mL *2000 ng/mL cutoff assay* S1: C.f.a.s. DAT Qualitative Plus, C.f.a.s. DAT Qualitative Clinical, CAL 3, or Preciset DAT Plus I calibrator, CAL 4, 2000 ng/mL The drug concentrations of the calibrators have been verified by GC/MS.
Calibration K Factor	For the qualitative applications, enter the K Factor as -1000 into the Calibration menu, Status screen, Calibration Result window.
Calibration mode	*Semiquantitative applications* Result Calculation Mode (RCM)[a] *Qualitative applications* Linear
Calibration frequency	Full (semiquantitative) or blank (qualitative) calibration - after reagent lot change - and as required following quality control procedures

a) See Results section.

Traceability: This method has been standardized against a primary reference method (GC/MS).

Quality control

For quality control, use control materials as listed in the Order information section. Other suitable control material can be used in addition.
Drug concentrations of the controls have been verified by GC/MS.
The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.
Include quality control samples with each test run.
Users should follow the appropriate federal, state and local guidelines concerning the running of external quality controls.

Results

For the qualitative assay, the cutoff calibrator is used as a reference in distinguishing between positive and negative samples. Samples producing a positive or "0" absorbance value are considered positive. Positive samples are flagged with the letter H. Samples producing a negative absorbance value are considered negative. Negative samples are preceded by a minus sign.

For the semiquantitative assay, the analyzer computer constructs a calibration curve from absorbance measurements of the standards using a four parameter logit-log fitting function (RCM). The logit-log function fits a smooth line through the data points. The analyzer computer uses absorbance measurements of samples to calculate drug or drug metabolite concentration by interpolation of the logit-log fitting function.

NOTE: If a result of Calc.? or Samp.? alarm is obtained, review the Reaction Monitor data for the sample and compare with the Reaction Monitor data for the highest calibrator. The most likely cause is a high concentration of the analyte in the sample, in which case the absorbance value for the sample will be less than that of the highest calibrator. Make an appropriate dilution of the sample using the 0 ng/mL calibrator and rerun the sample. To ensure that the sample was not over-diluted, the diluted result, prior to multiplying by the dilution factor, must be at least half the analyte cutoff value. If the diluted result falls below half the analyte cutoff value, repeat the sample with a smaller dilution. A dilution that produces a result closest to the analyte cutoff is the most accurate estimation. To estimate the positive sample's

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concentration, multiply the result by the appropriate dilution factor. Dilutions should only be used to interpret results of Calc.? and Samp.? alarms, or when estimating concentration in preparation for GC/MS.

Use caution when reporting results as there are various factors that influence a urine test result, such as fluid intake and other biological factors.

As with any sensitive test for drugs of abuse on automated clinical chemistry analyzers, the possibility exists for analyte carryover from a sample with an extremely high concentration to a normal (negative) sample which immediately follows it.

Confirm all positive results by another method.

Limitations - interference[12]

See the Analytical specificity section of this document for information on substances tested for cross-reactivity in this assay. There is the possibility that other substances and/or factors may interfere with the test and cause erroneous results (e.g., technical or procedural errors).
A positive result with this assay indicates the presence of opiates and/or their metabolites in urine but does not reflect the degree of intoxication.

Interfering substances were added to drug free urine at the concentration listed below. These samples were then spiked to 300 ng/mL using a morphine stock solution. Samples were tested on a Roche/Hitachi 917 analyzer and the following results were obtained:

Substance	Concentration Tested	% Morphine Recovery
Acetone	1%	98
Ascorbic Acid	1.5%	97
Bilirubin	0.25 mg/mL	95
Creatinine	5 mg/mL	95
Ethanol	1%	100
Glucose	2%	97
Hemoglobin	7.5 g/L	99
Human Albumin	0.5%	96
Oxalic Acid	2 mg/mL	93
Sodium Chloride	0.5 M	84
Sodium Chloride	1 M	78
Urea	6%	94

Interfering substances were added to drug free urine at the concentration listed below. These samples were then spiked to 2000 ng/mL using a morphine stock solution. Samples were tested on a Roche/Hitachi 917 analyzer and the following results were obtained:

Substance	Concentration Tested	% Morphine Recovery
Acetone	1%	99
Ascorbic Acid	1.5%	96
Bilirubin	0.25 mg/mL	98
Creatinine	5 mg/mL	100
Ethanol	1%	96
Glucose	2%	98
Hemoglobin	7.5 g/L	101
Human Albumin	0.5%	96
Oxalic Acid	2 mg/mL	96
Sodium Chloride	0.5 M	95
Sodium Chloride	1 M	91
Urea	6%	97

Special wash requirements
No interfering assays are known which require special wash steps.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Expected values

Qualitative assay
Results of this assay distinguish positive (≥ 300 ng/mL or ≥ 2000 ng/mL) from negative samples only. The amount of drug detected in a positive sample cannot be estimated.

Semiquantitative assay
Results of this assay yield only approximate cumulative concentrations of the drug and its metabolites (see Analytical specificity section).

Specific performance data

Representative performance data on a Roche/Hitachi analyzer are given below. Results obtained in individual laboratories may differ.

Precision

Reproducibility was determined in an internal protocol by running a series of morphine calibrator and controls (within run n = 20, between run n = 100). The following results were obtained on a Roche/Hitachi **cobas c** 501 analyzer.

Semiquantitative precision - 300 ng/mL

Within run	*Mean ng/mL*	*SD ng/mL*	*CV %*
Level 1	225	7.1	3.1
Level 2	301	10.0	3.3
Level 3	385	12.8	3.3
Between run	*Mean ng/mL*	*SD ng/mL*	*CV %*
Level 1	227	9.4	4.2
Level 2	305	12.0	3.9
Level 3	393	14.4	3.7

Qualitative precision - 300 ng/mL

Cutoff (300)	Number tested	Correct results	Confidence level
0.75x	100	100	>95% negative reading
1.25x	100	100	>95% positive reading

Semiquantitative precision - 2000 ng/mL

Within run	*Mean ng/mL*	*SD ng/mL*	*CV %*
Level 1	1480	35.3	2.4
Level 2	2006	43.0	2.1
Level 3	2523	55.0	2.2
Between run	*Mean ng/mL*	*SD ng/mL*	*CV %*
Level 1	1479	44.1	3.0
Level 2	2025	57.6	2.8
Level 3	2518	57.5	2.3

Qualitative precision - 2000 ng/mL

Cutoff (2000)	Number tested	Correct results	Confidence level
0.75x	100	100	>95% negative reading
1.25x	100	100	>95% positive reading

Analytical sensitivity (lower detection limit)

15.3 ng/mL (300 ng/mL cutoff assay)
53.0 ng/mL (2000 ng/mL cutoff assay)
The detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying two standard deviations above that of the lowest standard (standard 1 + 2 SD, within-run precision, n = 21).

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Accuracy

One hundred urine samples, obtained from a clinical laboratory where they screened negative in a drug test panel, were evaluated with the Opiates II assay. One hundred percent of these normal urines were negative relative to the 300 ng/mL and 2000 ng/mL cutoffs.
Seventy samples, obtained from a clinical laboratory where they screened positive with a commercially available immunoassay and were subsequently confirmed positive by GC/MS, were evaluated with the Opiates II assay. All seventy of these samples were positive relative to the 300 ng/mL cutoff.
Fifty-four samples, obtained from a clinical laboratory where they screened positive with a commercially available immunoassay and were subsequently confirmed positive by GC/MS, were evaluated with the Opiates II assay. All fifty-four of these samples were positive relative to the 2000 ng/mL cutoff.
In addition, positive urine samples were diluted with drug-free urine. For each cutoff (300 ng/mL and 2000 ng/mL), 10 positive samples were diluted to obtain drug concentrations less than the respective cutoffs. For each cutoff (300 ng/mL and 2000 ng/mL), the same 10 positive samples were diluted to obtain drug concentrations greater than the respective cutoffs.
Data from the accuracy studies described above that fell within the near cutoff value ranges were combined with data generated from diluted positive samples. The following results were obtained with the Opiates II assay on the Roche/Hitachi 917 analyzer relative to the GC/MS values.

Opiates II Clinical Correlation (Cutoff = 300 ng/mL)

		Negative Samples	GC/MS values (ng/mL)[b]		
			Near Cutoff		
			40-253	301-794	825-48247
Roche/Hitachi 917 analyzer	+	0	5	7	68
	–	100	8	2	0

b) GC/MS values are represented by the sum of morphine and codeine and do not include all metabolites.

Opiates II Clinical Correlation (Cutoff = 2000 ng/mL)

		Negative Samples	GC/MS values (ng/mL)[c]		
			Near Cutoff		
			153-1982	2051-3220	3254-48247
Roche/Hitachi 917 analyzer	+	0	4	18	42
	–	100	10	0	0

c) GC/MS values are represented by the sum of morphine and codeine and do not include all metabolites.

Additional clinical samples were evaluated with this assay on a Roche/Hitachi **cobas c** 501 analyzer and a Roche/Hitachi 917 analyzer. One hundred urine samples, obtained from a clinical laboratory where they screened negative in a drug test panel, were evaluated with the Opiates II assay. One hundred percent of these normal urines were negative for both cutoffs relative to the Roche/Hitachi 917 analyzer. Seventy-two urine samples for the 300 ng/mL cutoff and 48 urine samples for the 2000 ng/mL cutoff, obtained from a clinical laboratory where they screened positive with a commercially available immunoassay and were subsequently confirmed by GC/MS, were evaluated with the Opiates II assay. At the 300 ng/mL cutoff, 100% of the samples were positive on the Roche/Hitachi **cobas c** 501 analyzer and 97% of the samples were positive on the Roche/Hitachi 917 analyzer. At the 2000 ng/mL cutoff, 100% of the samples were positive on both the Roche/Hitachi **cobas c** 501 analyzer and the Roche/Hitachi 917 analyzer.

Opiates II Correlation (Cutoff = 300 ng/mL)

		Roche/Hitachi 917 analyzer	
		+	–
cobas c 501 analyzer	+	70	2
	–	0	100

Opiates II Correlation (Cutoff = 2000 ng/mL)

		Roche/Hitachi 917 analyzer	
		+	–
cobas c 501 analyzer	+	48	0
	–	0	100

Analytical specificity

The specificity of this assay for structurally similar compounds was determined by generating inhibition curves for each of the compounds listed and determining the approximate quantity of each compound that is equivalent in assay reactivity to a 300 ng/mL and a 2000 ng/mL assay cutoff. The following results were obtained on a Roche/Hitachi 917 analyzer.

Compound	ng/mL Equivalent to 300 ng/mL Morphine	Approximate % Cross-reactivity
Codeine	224	134
Ethyl morphine	297	101
Diacetylmorphine	366	82
6-Acetylmorphine	386	78
Dihydrocodeine	510	59
Morphine-3-glucuronide	552	54
Hydrocodone	1086	28
Thebaine	1210	25
Hydromorphone	1425	21
n-Norcodeine	18,590	2
Oxycodone	>75,000	<0.4
Meperidine	>100,000	<0.3

Compound	ng/mL Equivalent to 2000 ng/mL Morphine	Approximate % Cross-reactivity
Codeine	1541	130
Ethyl morphine	2474	81
6-Acetylmorphine	2598	77
Diacetylmorphine	2915	69
Dihydrocodeine	3170	63
Morphine-3-glucuronide	3785	53
Hydrocodone	7166	28
Thebaine	7579	26
Hydromorphone	10,768	19
n-Norcodeine	99,264	2
Oxycodone	>670,000	<0.3
Meperidine	>670,000	<0.3

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Cross-reactivity with unrelated drugs

The following compounds were prepared in aliquots of pooled normal human urine to yield a final concentration of 100,000 ng/mL. None of these compounds gave values in the assay that were greater than 0.5% cross-reactivity.

Acetaminophen	Ibuprofen
Acetylsalicylic acid	Imipramine
Aminopyrine	Isoproterenol
Amitriptyline	Ketamine
Amobarbital	Lidocaine
d-Amphetamine	LSD[d]
l-Amphetamine	Melanin
Ampicillin	Methadone
Ascorbic acid	*d*-Methamphetamine
Aspartame	*l*-Methamphetamine
Atropine	Methaqualone
Benzocaine	Methylphenidate
Benzoylecgonine (cocaine metabolite)	Methyprylon
Benzphetamine	Naloxone
Butabarbital	Naltrexone
Caffeine	Naproxen
Calcium hypochlorite	Niacinamide
Cannabidiol	Norethindrone
Chlordiazepoxide	*l*-Norpseudoephedrine
Chloroquine	Oxazepam
Chlorpheniramine	Penicillin G
Chlorpromazine	Pentobarbital
Cocaine	Phencyclidine
Dextromethorphan	Phenobarbital
Dextropropoxyphene	Phenothiazine
Diazepam	Phenylbutazone
Diphenhydramine	*d*-Phenylpropanolamine
Diphenylhydantoin	Phenylpropanolamine
Ecgonine	Procaine
Ecgonine methyl ester	Promethazine
d-Ephedrine	*d*-Pseudoephedrine
dl-Ephedrine	*l*-Pseudoephedrine
l-Ephedrine	Quinidine
Epinephrine	Quinine
Erythromycin	Secobarbital
Estriol	Sulindac
Fenoprofen	Tetracycline
Furosemide	Δ^9 THC-9-carboxylic acid[e]
Gentisic acid	Tetrahydrozoline
Glutethimide	Trifluoperazine
Guaiacol glycerol ether	Verapamil
Hydrochlorothiazide	

d) LSD was tested at 2500 ng/mL.

e) Δ^9 THC-9-carboxylic acid was tested at 10,000 ng/mL.

The cross-reactivity for Rifampin was tested with the Opiates II assay. The results obtained were 16.8% and 6.9% for the 300 ng/mL and 2000 ng/mL cutoffs, respectively.

Maintenance

After completion of daily testing, perform a cell wash.

References

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