OXY

cobas®

Oxycodone

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
05179459 190	DRI® Oxycodone, 140 tests	System-ID 07 7433 2	Roche/Hitachi **cobas c** 311, **cobas c** 501/502
05201284 190	DRI Oxycodone Calibrator 0 (1 x 10 mL)	Code 570	
05178517 190	DRI Oxycodone Calibrator 100 (1 x 10 mL)	Code 572	
05178525 190	DRI Oxycodone Calibrator 300 (1 x 10 mL)	Code 573	
05178533 190	DRI Oxycodone Calibrator 500 (1 x 10 mL)	Code 574	
05178541 190	DRI Oxycodone Calibrator 1000 (1 x 10 mL)	Code 575	
05178568 190	DRI Oxycodone Control Set 100 Positive Control 125 ng/mL (1 x 10 mL) Negative Control 75 ng/mL (1 x 10 mL)		
05178550 190	DRI Oxycodone Control Set 300 Positive Control 375 ng/mL (1 x 10 mL) Negative Control 225 ng/mL (1 x 10 mL)		
04908856 160[a]	Open/Close tool (5 pieces)		

a) Catalog number is for USA only. Open/Close tool is available upon request in other countries.

English

System information

For **cobas c** 311/501 analyzers:

OXY1Q: ACN 568: for qualitative assay, 100 ng/mL

OXY3Q: ACN 569: for qualitative assay, 300 ng/mL

OXY1S: ACN 621: for semiquantitative assay, 100 ng/mL

OXY3S: ACN 622: for semiquantitative assay, 300 ng/mL

For **cobas c** 502 analyzer:

OXY1Q: ACN 8568: for qualitative assay, 100 ng/mL

OXY3Q: ACN 8569: for qualitative assay, 300 ng/mL

OXY1S: ACN 8621: for semiquantitative assay, 100 ng/mL

OXY3S: ACN 8622: for semiquantitative assay, 300 ng/mL

Intended use

DRI Oxycodone assay (OXY) is an in vitro diagnostic test for the semiquantitative and qualitative detection of oxycodone and its metabolite, oxymorphone, in human urine at cutoff concentrations of 100 ng/mL and 300 ng/mL on Roche/Hitachi **cobas c** systems.

Semiquantitative test results may be obtained that permit laboratories to assess assay performance as part of a quality control program. Semiquantitative assays are intended to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as gas chromatography/mass spectrometry (GC/MS).

DRI Oxycodone provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. 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

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).[2] Drug abusers crush the pills into powder and snort them for faster effect which may result in a potentially fatal outcome. According to Drug Abuse Warning Network (DAWN), there has been a dramatic increase in oxycodone related deaths.[3,4] Oxymorphone, noroxycodone and noroxymorphone are the only known metabolites of oxycodone.[3] The metabolite, oxymorphone, is a potent narcotic analgesic, 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 %).[5]

Test principle

The assay 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 with 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 340 nm by measuring the conversion of nicotinamide adenine dinucleotide (NAD) to NADH.

Reagents - working solutions

R1 Anti-oxycodone derivative antibody (mouse monoclonal), glucose-6-phosphate (G6P), and nicotinamide adenine dinucleotide (NAD) in Tris buffer with sodium azide as a preservative

R2 Oxycodone derivative labeled with glucose-6-phosphate dehydrogenase (G6PDH) in Tris buffer with sodium azide as a preservative

Precautions and warnings

For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.
Reagents from different kit lots must not be interchanged. Reagents within kit lots have been matched to ensure optimum test performance.
Disposal of all waste material should be in accordance with local guidelines.
Safety data sheet available for professional user on request.

For USA: For prescription use only.

Reagent preparation and cobas c pack MULTI assembly

Reagent handling

Ready for use

Labeling the **cobas c** *pack MULTI*

Turn the barcode labeled side of a new **cobas c** pack MULTI toward you. Affix the supplied OXY barcode label directly over the existing barcode label.

OXY

Oxycodone

Filling the **cobas c** *pack MULTI*

1. Turn the **cobas c** pack MULTI toward you as shown above.
2. Position A of the **cobas c** pack is now in the center, position B on the left side, position C on the right side of the **cobas c** pack.
3. Unscrew the screw cap of the bottle in position B on the left side of the **cobas c** pack MULTI using the Open/Close tool.
4. Pour the content of bottle 1 (12 mL) into the opened bottle of the **cobas c** pack (position B).
5. Close the bottle tightly using the Open/Close tool.
6. Unscrew the screw cap of the bottle in position C on the right side of the **cobas c** pack MULTI using the Open/Close tool.
7. Pour the content of bottle 2 (12 mL) into the opened bottle of the **cobas c** pack (position C).
8. Close the bottle tightly using the Open/Close tool.
9. Leave position A empty.

The OXY **cobas c** pack is now ready for use.

NOTE: Solutions must be at the reagent compartment storage temperature of the analyzer before performing assays.

Note

Use only the **cobas c** *pack MULTI. Always use a new* **cobas c** *pack MULTI when preparing fresh reagent. Never reuse accessories designed for single use, as this may result in reagent contamination and could affect test results. If the* **cobas c** *pack MULTI bottles are not filled correctly, this may result in faulty reagent pipetting and could cause erroneous results.*

Storage and stability

Shelf life at 2-8 °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 within the pH range of 3-11 are suitable for testing with this assay. No additives or preservatives are required. It is recommended that urine specimens be stored at 2-8 °C and tested within 5 days of collection.[6]

For prolonged storage, freezing of the sample is recommended.

Centrifuge highly turbid specimens before testing.

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*.[7]

CAUTION: Specimen dilutions should only be used to interpret results of Calc.?, Samp.?, and >Abs 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.

Three barcode labels: one to overlabel the existing barcode of the **cobas c** pack MULTI. Two extra labels are supplied if needed.
cobas c pack MULTI
Funnels

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's manual for analyzer-specific assay instructions.

The performance of applications not validated by Roche is not warranted and must be defined by the user.

Applications for urine

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

cobas c 311 **test definition - 100 ng/mL and 300 ng/mL cutoff assays**

	Semiquantitative	Qualitative
Assay type	Rate A	Rate A
Reaction time / Assay points	10 / 26-31	10 / 26-31
Wavelength (sub/main)	415/340 nm	415/340 nm
Reaction direction	Increase	Increase
Unit	ng/mL	mAbs
Reagent pipetting		Diluent (H_2O)
R1	60 µL	–
R3	60 µL	–

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	7.2 µL	–	–
Decreased	7.2 µL	–	–
Increased	7.2 µL	–	–

cobas c 501/502 **test definition - 100 ng/mL and 300 ng/mL cutoff assays**

	Semiquantitative	Qualitative
Assay type	Rate A	Rate A
Reaction time / Assay points	10 / 40-47	10 / 40-47
Wavelength (sub/main)	415/340 nm	415/340 nm
Reaction direction	Increase	Increase
Unit	ng/mL	mAbs
Reagent pipetting		Diluent (H_2O)
R1	60 µL	–
R3	60 µL	–

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	7.2 µL	–	–
Decreased	7.2 µL	–	–
Increased	7.2 µL	–	–

Calibration

Calibrators	*Semiquantitative applications* *100 ng/mL and 300 ng/mL cutoff assays* S1: DRI Oxycodone Calibrator 0 S2: DRI Oxycodone Calibrator 100 S3: DRI Oxycodone Calibrator 300 S4: DRI Oxycodone Calibrator 500 S5: DRI Oxycodone Calibrator 1000 0, 100, 300, 500, 1000 ng/mL *Qualitative applications* *100 ng/mL cutoff assay* S1: DRI Oxycodone Calibrator 100 100 ng/mL *300 ng/mL cutoff assay* S1: DRI Oxycodone Calibrator 300 300 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 positive 1000 into the Calibration menu, Status screen, Calibration Result window.
Calibration mode	*Semiquantitative applications* Result Calculation Mode (RCM)[b] *Qualitative applications* Linear
Calibration frequency	Full (semiquantitative) or blank (qualitative) calibration • every 28 days • after reagent lot change • as required following quality control procedures

b) 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. In addition, other suitable control material can be used.

Drug concentrations of DRI Oxycodone Control Set 100 and 300 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 defined limits.

Follow the applicable government regulations and local guidelines for quality control.

Results

For the qualitative assay, the cutoff calibrator is used as a reference in distinguishing between preliminary positive and negative samples. Samples producing a positive or “0” absorbance value are considered preliminary positive. Preliminary positive samples are flagged with >Test. Samples producing a negative absorbance value are considered negative. Negative samples are preceded by a minus sign.

The semiquantitation of preliminary positive results should only be used by laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GC/MS. It also permits the laboratory to establish quality control procedures and assess control performance.

For the semiquantitative assay, the analyzer computer constructs a calibration curve from absorbance measurements of the standards using a 4 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 greater 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 preliminary positive sample’s concentration, multiply the result by the appropriate dilution factor.

NOTE: If a result of >Abs alarm is obtained, the cause is either the presence of a high concentration of a 340 nm light absorbing compound or the presence of a high concentration of the analyte in the sample (see "Limitations - interference" section). Make an appropriate dilution of the sample using the 0 ng/mL calibrator and rerun the sample. When running in the semiquantitative mode, multiply the result by the dilution factor. In case of a near cutoff result, once the dilution factor is applied, the result should be assessed in terms of dilution and accuracy of the assay.

Dilutions should only be used to interpret results of Calc.?, Samp.?, and >Abs 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 carry-over from a sample with an extremely high concentration to a normal (negative) sample which immediately follows it.

Confirm all preliminary positive results by another method.

Limitations - interference

See the "Analytical specificity" section of this document for information on substances tested with this assay. There is the possibility that other substances and/or factors, especially substances that absorb light at 340 nm, may interfere with the test and cause >Abs alarms or erroneous results (e.g., technical or procedural errors). Samples flagged with >Abs alarms should be manually diluted (see "Results" section). A preliminary positive result with this assay indicates the presence of oxycodone and/or its metabolite, oxymorphone, in urine. It does not measure the level of intoxication.

The potential interference of pH and endogenous physiologic substances on recovery of oxycodone using the DRI Oxycodone assay was assessed by spiking known amounts of potentially interfering substances into the low (225 ng/mL) and high (375 ng/mL) controls for the 300 ng/mL cutoff. No interference was observed by the addition of the compounds up to the concentrations listed below.

Compound	Concentrations (mg/dL)
Acetone	1000
Ascorbic Acid	1500
Creatinine	500
Ethanol	1000
Galactose	10
Glucose	3000
Hemoglobin	300
Human Serum Albumin	500
Oxalic Acid	100
Riboflavin	7.5
Sodium Chloride	1000
Urea	2000
pH	3-11

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

ACTION REQUIRED

Special Wash Programming: The use of special wash steps is mandatory when certain test combinations are run together on Roche/Hitachi **cobas c** systems. The latest version of the carry-over evasion list can be found with the NaOHD-SMS-SmpCln1+2-SCCS Method Sheets. For further instructions refer to the operator's manual. **cobas c** 502 analyzer: All special wash programming necessary for avoiding carry-over is available via the **cobas** link, manual input is not required.

Where required, special wash/carry-over evasion programming must be implemented prior to reporting results with this test.

Expected values

Qualitative assay

Results of this assay distinguish preliminary positive (≥ 100 ng/mL or ≥ 300 ng/mL depending on the cutoff) from negative samples only. The amount of drug detected in a preliminary 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

Precision was determined in an internal protocol by running 6 replicates of each level of control and cutoff calibrator. The samples were measured in random order, twice a day, for 5 days, for a total of 10 runs (n = 60). The following results were obtained on a Roche/Hitachi **cobas c** 501 analyzer.

Semiquantitative precision - 100 ng/mL			
Repeatability	*Mean ng/mL*	*SD ng/mL*	*CV %*
Level 1	71	1.1	1.5
Level 2	100	1.7	1.7
Level 3	123	2.1	1.7

Intermediate precision	*Mean ng/mL*	*SD ng/mL*	*CV %*
Level 1	71	1.4	2.0
Level 2	100	2.1	2.1
Level 3	123	2.4	2.0

Qualitative precision - 100 ng/mL			
Cutoff (100)	Number tested	Correct results	Confidence level
0.75x	60	60	> 90 % negative reading
1.25x	60	60	> 90 % positive reading

Semiquantitative precision - 300 ng/mL			
Repeatability	*Mean ng/mL*	*SD ng/mL*	*CV %*
Level 1	227	3.5	1.6
Level 2	292	4.5	1.5
Level 3	372	6.9	1.8

Intermediate precision	*Mean ng/mL*	*SD ng/mL*	*CV %*
Level 1	227	3.6	1.6
Level 2	292	6.2	2.1
Level 3	372	7.3	2.0

Qualitative precision - 300 ng/mL			
Cutoff (300)	Number tested	Correct results	Confidence level
0.75x	60	60	> 90 % negative reading
1.25x	60	60	> 90 % positive reading

Limit of Blank

2.7 ng/mL

The Limit of Blank was determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A requirements.

The Limit of Blank is the 95th percentile value from n ≥ 20 measurements of analyte-free samples over several independent series. The Limit of Blank corresponds to the concentration below which analyte-free samples are found with a probability of 95 %.

Accuracy

Qualitative assay

A total of 165 urine samples were assayed with the DRI Oxycodone assay on the Roche/Hitachi 717 and the **cobas c** 501 analyzers. A sensitivity of 100 % (95 out of 95 preliminary positive samples) and a specificity of 95.7 % (67 out of 70 negative samples) were observed between the two analyzers.

100 ng/mL cutoff			
		cobas c 501 analyzer	
		+	-
Roche/Hitachi 717 analyzer	+	95	0
	-	3	67

A total of 165 urine samples were assayed with the DRI Oxycodone assay on the Roche/Hitachi 717 and the **cobas c** 501 analyzers. A sensitivity of 100 % (45 out of 45 preliminary positive samples) and a specificity of 95 % (114 out of 120 negative samples) were observed between the two analyzers.

300 ng/mL cutoff			
		cobas c 501 analyzer	
		+	-
Roche/Hitachi 717 analyzer	+	45	0
	-	6	114

Semiquantitative assay

A total of 165 urine samples were assayed with the DRI Oxycodone assay on the Roche/Hitachi 717 and the **cobas c** 501 analyzers. A sensitivity of 100 % (94 out of 94 preliminary positive samples) and a specificity of 91.5 % (65 out of 71 negative samples) were observed between the two analyzers.

100 ng/mL cutoff			
		cobas c 501 analyzer	
		+	-
Roche/Hitachi 717 analyzer	+	94	0
	-	6	65

A total of 165 urine samples were assayed with the DRI Oxycodone assay on the Roche/Hitachi 717 and the **cobas c** 501 analyzers. A sensitivity of 100 % (44 out of 44 preliminary positive samples) and a specificity of

94.2 % (114 out of 121 negative samples) were observed between the two analyzers.

300 ng/mL cutoff			
		cobas c 501 analyzer	
		+	-
Roche/Hitachi 717 analyzer	+	44	0
	-	7	114

Analytical specificity

The cross-reactivity of oxycodone metabolites, oxymorphone, noroxymorphone, and noroxycodone, was evaluated, on a Roche/Hitachi 717 analyzer, by adding known amounts of each metabolite to oxycodone free urine. As indicated by the results in the table below, oxymorphone exhibits 103 % cross reactivity with oxycodone; noroxymorphone and noroxycodone show no evidence of significant cross-reactivity.

Compound	Concentration tested (ng/mL)	Recovery (ng/mL)	Approximate Percent Cross-reactivity
Oxycodone	300	300	100
Oxymorphone	300	308	103
Noroxymorphone	500000	303.5	< 0.1
Noroxycodone	50000	41.5	< 0.1

Cross-reactivity with structurally related opiate compounds and structurally unrelated compounds

The potential cross-reactivity posed by drugs commonly coadministered with oxycodone was evaluated by adding each substance to oxycodone free urine at the concentration indicated. A drug was considered to cross-react if the observed oxycodone concentration exceeded 100 ng/mL, the lowest cutoff for the DRI Oxycodone assay. As shown in the tables below, all of the pharmacologic compounds evaluated, including a number of the opiate compounds, exhibited no cross-reactivity, on a Roche/Hitachi 717 analyzer, at the concentrations listed.

Structurally related opiate compounds that tested negative at 100 ng/mL cutoff

Compound	Concentrations (µg/mL)
6-Acetyl morphine	50
Codeine	500
Dihydrocodeine	100
Heroin	300
Hydrocodone	75
Hydromorphone	30
Levorphanol	200
Morphine	350
Morphine-3-glucuronide	900
Naloxone	200
Naltrexone	500
Norcodeine	1000
Normorphine	1000

Structurally unrelated compounds that tested negative at 100 ng/mL cutoff

Compound	Concentrations (µg/mL)
Acetaminophen	1000
Acetylsalicylic acid	1000
Amitriptyline	500
Amoxicillin	500
Amphetamine	2000
Benzoylecgonine	2000
Caffeine	1000
Carbamazepine	1000
Chlorpromazine	2000
Clomipramine	1000
Cimetidine	1000
Desipramine	1000
Dextromethorphan	200
Doxepin	200
Ephedrine	2000
Fentanyl	200
Fluoxethine	1000
Fluphenazine	500
Ibuprofen	1000
Imipramine	1000
Maprotiline	1000
Meperidine	1000
Methadone	1000
Metronidazole	2000
Nalbuphine	1000
Nortriptyline	500
Oxazepam	500
Phencyclidine	1000
Phenobarbital	1000
Ranitidine	3000
Secobarbital	1000
Talwin	500
Thebaine	20
Thioridazine	1000
Tramadol	500

References

1 Karch SB, ed. Drug Abuse Handbook. Boca Raton, FL: CRC Press LLC 1998.

2 Anderson DT, Fritz KL, Muto JJ. Oxycontin: The concept of a “ghost pill” and the postmortem tissue distribution of oxycodone in 36 cases. J Anal Toxicol 2002 Oct;26(7):448-459.

3 Jannetto PJ, Gock SB. Clinical & Forensic Toxicology News, Oxycodone: Recognition and Pharmacogenomics March 2003.

4 Cone EJ, Fant RV, Rohay JM, et al. Oxycodone Involvement in Drug Abuse Deaths: A DAWN-Based Classification Scheme applied to an Oxycodone Postmortem Database Containing over 1000 Cases. J Anal Toxicol 2003 Mar;27(2):57-67.

5 Oxycodone. In: Baselt RC and Cravey RH. Disposition of toxic drugs and chemicals in man, 4th ed. Chemical Toxicology Institute, Foster City, California 1995;572-574.

6 Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline. 2nd ed. (C52-A2). Clinical and Laboratory Standards Institute 2007;27:33.

7 Mandatory Guidelines for Federal Workplace Drug Testing Programs. Fed Regist 2008 Nov 25;73:71858-71907.

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

OXY

Oxycodone

cobas®

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

CONTENT	Contents of kit
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number

FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

CE

Microgenics Corporation
46500 Kato Road
Fremont, CA 94538, USA

Roche

EC REP
B·R·A·H·M·S GmbH
Neuendorfstrasse 25
D-16761 Hennigsdorf

European Distributor:
Roche Diagnostics GmbH
Sandhofer Strasse 116
D-68305 Mannheim
www.roche.com

Assembled for and distributed by:
Roche Diagnostics, Indianapolis, IN
US Customer Technical Support 1-800-428-2336