COC2

Cocaine II

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Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
04490827 190	ONLINE DAT Cocaine II (200 tests)	System-ID 07 6947 9	Roche/Hitachi **cobas c** 311, **cobas c** 501/502
03304671 190	Preciset DAT Plus I calibrators CAL 1-6 (6 x 5 mL)	Codes 431-436	
03304698 190	C.f.a.s. DAT Qualitative Plus (6 x 5 mL)		
04590856 190	C.f.a.s. DAT Qualitative Plus Clinical (3 x 5 mL)	Code 699	
03312950 190	Control Set DAT I (for 150 ng/mL assay) PreciPos DAT Set I (2 x 10 mL) PreciNeg DAT Set I (2 x 10 mL)		
03312976 190	Control Set DAT III (for 300 ng/mL assay) PreciPos DAT Set III (2 x 10 mL) PreciNeg DAT Set III (2 x 10 mL)		
04500873 190	Control Set DAT Clinical (for 300 ng/mL assay) PreciPos DAT Clinical (2 x 10 mL) PreciNeg DAT Clinical (2 x 10 mL)		

English

System information

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

CO1Q2: ACN 189 (Urine): for qualitative assay, 150 ng/mL

CO3Q2: ACN 267 (Urine): for qualitative assay, 300 ng/mL

CO1S2: ACN 268 (Urine): for semiquantitative assay, 150 ng/mL

CO3S2: ACN 477 (Urine): for semiquantitative assay, 300 ng/mL

CO3QC: ACN 791 (Urine): for qualitative assay, 300 ng/mL; using C.f.a.s. DAT Qualitative Plus Clinical

For **cobas c** 502 analyzer:

CO1Q2: ACN 8189 (Urine): for qualitative assay, 150 ng/mL

CO3Q2: ACN 8267 (Urine): for qualitative assay, 300 ng/mL

CO1S2: ACN 8268 (Urine): for semiquantitative assay, 150 ng/mL

CO3S2: ACN 8477 (Urine): for semiquantitative assay, 300 ng/mL

CO3QC: ACN 8791 (Urine): for qualitative assay, 300 ng/mL; using C.f.a.s. DAT Qualitative Plus Clinical

Intended use

Cocaine II (COC2) is an in vitro diagnostic test for the qualitative and semiquantitative detection of benzoylecgonine, the primary metabolite of cocaine, in human urine on Roche/Hitachi **cobas c** systems at cutoff concentrations of 150 and 300 ng/mL. 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).

Cocaine 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. 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

Cocaine, a natural product found in the leaves of the coca plant, is a potent central nervous system (CNS) stimulant and a local anesthetic. Its pharmacological effects are identical to those of the amphetamines (also CNS stimulants), though cocaine has a shorter duration of action.[2] Cocaine induces euphoria, confidence and a sense of increased energy in the user; these psychological effects are accompanied by increased heart rate, dilation of pupils, fever, tremors, and sweating. The "crash" following a cocaine "high" is profound, ranging from irritability, lassitude, and the desire for more drug, to anxiety, hallucinations, and paranoia.[3,4] Users may resort to other drugs at this time to relieve the depressive effects of the "crash".[2]

Cocaine is traditionally administered intranasally or smoked in its purer, free-base form; oral ingestion is ineffective, as cocaine is broken down in the gastrointestinal tract. It is absorbed readily across the mucous membranes of the nose and lungs into the circulation. Its effects are intense but short-lived. Cocaine is rapidly inactivated by hydrolysis of its ester linkages.[1,5,6] Blood cholinesterases hydrolyze cocaine to ecgonine methyl ester, while hydrolysis of the parent drug to benzoylecgonine is thought to be non-enzymatic; both of these metabolites may be further hydrolyzed to ecgonine. Unmetabolized cocaine has an affinity for fatty tissue and rapidly enters the brain; cocaine metabolites, however, are more water soluble and are readily excreted in the urine along with some portion of unchanged drug.[5,7] The prominent benzoylecgonine metabolite is the primary urinary marker for detecting cocaine use.[1,5]

Tolerance has been observed with some chronic, high-dose users.[8] Physical dependence does not appear to occur in abusers, although the development of strong psychological dependence is well known. Cessation of drug use may result in depression, hallucinations, and in extreme cases, psychosis.[2]

Test principle

The assay is based on the kinetic interaction of microparticles in a solution (KIMS)[9,10] 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.[11]

Reagents - working solutions

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

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

R1 is in position B and R2 is in position C.

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.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

Reagent handling

Ready for use

Carefully invert reagent container several times prior to use to ensure that the reagent components are mixed.

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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 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 5 days of collection.[12]

For prolonged storage, freezing of the sample is recommended.

Centrifuge highly turbid specimens before testing.

See the limitations and interferences section for details about possible sample interferences.

Sample stability claims were established by experimental data by the manufacturer or based on reference literature and only for the temperatures/time frames as stated in the method sheet. It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory.

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.*[13]

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'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.

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

cobas c 311 test definition - 150 and 300 ng/mL cutoff assays

	Semi-quantitative	Qualitative	
Assay type	2-Point End	2-Point End	
Reaction time / Assay points	10 / 10-50	10 / 10-50	
Wavelength (sub/main)	– /546 nm	– /546 nm	
Reaction direction	Increase	Increase	
Unit	ng/mL	mAbs	
Reagent pipetting		Diluent (H₂O)	
R1	75 µL	–	
R2	33 µL	–	
Sample volumes	*Sample*	*Sample dilution*	
		Sample	Diluent (NaCl)
Normal	4.6 µL	–	–
Decreased	4.6 µL	–	–
Increased	4.6 µL	–	–

cobas c 501/502 test definition - 150 and 300 ng/mL cutoff assays

	Semi-quantitative	Qualitative	
Assay type	2-Point End	2-Point End	
Reaction time / Assay points	10 / 13-46	10 / 13-46	
Wavelength (sub/main)	– /546 nm	– /546 nm	
Reaction direction	Increase	Increase	
Unit	ng/mL	mAbs	
Reagent pipetting		Diluent (H₂O)	
R1	75 µL	–	
R2	33 µL	–	
Sample volumes	*Sample*	*Sample dilution*	
		Sample	Diluent (NaCl)
Normal	4.6 µL	–	–
Decreased	4.6 µL	–	–
Increased	4.6 µL	–	–

Calibration

Calibrators	*Semiquantitative applications*
	150 and 300 ng/mL cutoff assays
	S1-6: Preciset DAT Plus I calibrators, CAL 1-6
	0, 75, 150, 300, 1000, 5000 ng/mL
	Qualitative applications
	150 ng/mL cutoff assay
	S1: C.f.a.s. DAT Qualitative Plus or Preciset DAT Plus I calibrator - CAL 3
	150 ng/mL
	300 ng/mL cutoff assay
	S1: C.f.a.s. DAT Qualitative Plus Clinical or Preciset DAT Plus I calibrator - CAL 4
	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 -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
	• as required following quality control procedures

a) See Results section.

Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

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

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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 Control Set DAT I, III, and Clinical 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 less than that of the highest calibrator. Make an appropriate dilution of the sample using the 0 ng/mL calibrator and rerun the sample. A normal drug-free urine may be substituted for the 0 ng/mL calibrator if the urine and procedure have been validated by the laboratory. 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. Dilutions should only be used to interpret results of Calc.? or 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.

Preliminary positive results should be confirmed by another method.

Limitations - interference

See the "Specific performance data" section of this document for information on substances tested with 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 preliminary positive result with this assay indicates the presence of benzoylecgonine and/or its metabolites in urine. It does not measure the level of intoxication.

Interfering substances were added to drug free urine at the concentration listed below. These samples were then spiked to 150 ng/mL using a benzoylecgonine stock solution. Samples were tested on a Roche/Hitachi 917 analyzer and the following results were obtained:

Substance	Concentration Tested	% Cocaine Recovery
Acetone	1 %	96
Ascorbic acid	1.5 %	106

Bilirubin	0.25 mg/mL	99
Creatinine	5 mg/mL	97
Ethanol	1 %	99
Glucose	2 %	99
Hemoglobin	7.5 g/L	97
Human albumin	0.5 %	94
Oxalic acid	2 mg/mL	94
Sodium chloride	0.5 M	91
Sodium chloride	1 M	90
Urea	6 %	104

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

Substance	Concentration Tested	% Cocaine Recovery
Acetone	1 %	104
Ascorbic acid	1.5 %	113
Bilirubin	0.25 mg/mL	112
Creatinine	5 mg/mL	104
Ethanol	1 %	103
Glucose	2 %	104
Hemoglobin	7.5 g/L	107
Human albumin	0.5 %	105
Oxalic acid	2 mg/mL	105
Sodium chloride	0.5 M	103
Sodium chloride	1 M	103
Urea	6 %	103

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 required in certain cases.

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 (≥ 150 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 a series of calibrator and controls with repeatability (n = 20) and intermediate precision (n = 100). The following results were obtained on a Roche/Hitachi **cobas c** 501 analyzer.

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Semiquantitative precision - 150 ng/mL

Repeatability	Mean ng/mL	SD ng/mL	CV %
Level 1	115	4	3.6
Level 2	160	4	2.3
Level 3	195	5	2.5

Intermediate precision	Mean ng/mL	SD ng/mL	CV %
Level 1	126	9	6.9
Level 2	161	5	3.2
Level 3	197	7	3.5

Qualitative precision - 150 ng/mL

Cutoff (150)	Number tested	Correct results	Confidence level
0.75x	100	100	> 95 % negative reading
1.25x	100	100	> 95 % positive reading

Semiquantitative precision - 300 ng/mL

Repeatability	Mean ng/mL	SD ng/mL	CV %
Level 1	245	6	2.3
Level 2	308	7	2.1
Level 3	374	6	1.7

Intermediate precision	Mean ng/mL	SD ng/mL	CV %
Level 1	240	16	6.6
Level 2	293	15	5.2
Level 3	380	16	4.2

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

Accuracy

100 urine samples, obtained from a clinical laboratory where they screened negative in a drug test panel, were evaluated with the Cocaine II assay. 100 % of these normal urines were negative relative to the 150 ng/mL and 300 ng/mL cutoffs. 50 samples obtained from a clinical laboratory, where they screened preliminary positive with a commercially available immunoassay and were subsequently confirmed positive by GC-MS, were evaluated with the Cocaine II assay. 100 % of these samples were positive relative to the 150 ng/mL cutoff. 50 samples obtained from a clinical laboratory, where they screened preliminary positive with a commercially available immunoassay and were subsequently confirmed positive by GC-MS, were evaluated with the Cocaine II assay. 100 % of these samples were positive relative to the 300 ng/mL cutoff. In addition, 10 samples were diluted to a benzoylecgonine concentration of 75-100 % of the cutoff concentration for each cutoff; and 10 samples were diluted to a benzoylecgonine concentration of 100-125 % of the cutoff concentration for each cutoff. 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 Cocaine II assay on the Roche/Hitachi 917 analyzer relative to the GC-MS values.

Cocaine II Clinical Correlation (Cutoff = 150 ng/mL)

			GC-MS values (ng/mL)		
				Near Cutoff	
		Negative Samples	113	188	344-106072
Roche/Hitachi 917 analyzer	+	0	0	10	50
	-	100	10	0	0

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

			GC-MS values (ng/mL)		
				Near Cutoff	
		Negative Samples	225	309-402	428-106072
Roche/Hitachi 917 analyzer	+	0	0	11	49
	-	100	10	0	0

Additional clinical samples were evaluated with this assay on a Roche/Hitachi **cobas c** 501 analyzer and a Roche/Hitachi 917 analyzer. 100 urine samples, obtained from a clinical laboratory where they screened negative in a drug test panel, were evaluated with the Cocaine II assay. 100 % of these normal urines were negative for both cutoffs relative to the Roche/Hitachi 917 analyzer. 56 urine samples for the 150 ng/mL cutoff and 56 urine samples for the 300 ng/mL cutoff, obtained from a clinical laboratory where they screened preliminary positive with a commercially available immunoassay and were subsequently confirmed positive by GC-MS, were evaluated with the Cocaine II assay. At the 150 ng/mL cutoff, 100 % of the samples were positive on both the Roche/Hitachi **cobas c** 501 analyzer and the Roche/Hitachi 917 analyzer. At the 300 ng/mL cutoff, 98 % of the samples were positive on both the Roche/Hitachi **cobas c** 501 analyzer and the Roche/Hitachi 917 analyzer.

Cocaine II Clinical Correlation (Cutoff = 150 ng/mL)

		Roche/Hitachi 917 analyzer	
		+	-
cobas c 501 analyzer	+	56	0
	-	0	100

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

		Roche/Hitachi 917 analyzer	
		+	-
cobas c 501 analyzer	+	55	0
	-	0	101

Analytical specificity

The specificity of this assay for cocaine and its metabolites 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 150 ng/mL and a 300 ng/mL benzoylecgonine assay cutoff. The following results were obtained on a Roche/Hitachi 917 analyzer.

Compound	ng/mL Equivalent to 150 ng/mL Benzoylecgonine	Approximate % Cross-reactivity
Cocaine	7733	1.9
Cocaethylene	34933	0.4

Compound	ng/mL Equivalent to 300 ng/mL Benzoylecgonine	Approximate % Cross-reactivity

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Cocaine	18132	1.7
Cocaethylene	67435	0.4

Additionally, the following compounds were tested at a concentration of 100000 ng/mL in pooled normal human urine and shown to have cross-reactivity values of less than 0.05 %.

Ecgonine	Ecgonine methyl ester	Norcocaine

Drug interference
The following compounds were prepared in aliquots of pooled normal human urine to yield a final concentration of 100000 ng/mL. None of these compounds gave values in the assay that were greater than 0.05 % cross-reactivity.

Acetaminophen	LSD
Acetylsalicylic acid	Maprotiline
Aminopyrine	MDA
Amitriptyline	MDMA
Amobarbital	Melanin
d-Amphetamine	Meperidine
l-Amphetamine	Methadol
Ampicillin	Methadone
Ascorbic acid	d-Methamphetamine
Aspartame	l-Methamphetamine
Atropine	Methaqualone
Benzocaine	Methotrimeprazine
Benzphetamine	Methylphenidate
Butabarbital	Methyprylon
Caffeine	Mianserin
Calcium hypochlorite	Morphine sulfate
Cannabidiol	Naloxone
Carbamazepine	Naltrexone
Chlordiazepoxide	Naproxen
Chloroquine	Niacinamide
Chlorpheniramine	Nicotine
Chlorpromazine	Nordiazepam
Chlorprothixene	Nordoxepin
Clomipramine	Norethindrone
Codeine	l-Norpseudoephedrine
Cotinine	Nortriptyline
Cyclobenzaprine	Orphenadrine
Cyproheptadine	Oxazepam
Desipramine	Oxycodone
Dextromethorphan	Penicillin G
Dextropropoxyphene	Pentobarbital
Diazepam	Perphenazine
Diphenhydramine	Phencyclidine
Diphenylhydantoin	β-Phenethylamine
Disopyramide	Phenobarbital
Dopamine	Phenothiazine
Doxepin	Phentermine
Doxylamine	Phenylbutazone
d-Ephedrine	Phenylpropanolamine
d,l-Ephedrine	d-Phenylpropanolamine
l-Ephedrine	Phendimetrazine
Epinephrine	Procaine
EDDP	Promazine
EMDP	Promethazine
Erythromycin	Propoxyphene
Estriol	Protriptyline
Fenoprofen	d-Pseudoephedrine
Fluconazole	l-Pseudoephedrine
Fluoxetine	Quinidine
Furosemide	Quinine
Gentisic acid	Secobarbital
Glutethimide	Sulindac
Guaiacol glycerol ether	Tetracycline
Haloperidol	Δ^9 THC-9-carboxylic acid
Hydrochlorothiazide	Tetrahydrozoline
Hydroxymethadone	Thioridazine
Ibuprofen	Thiothixene
Imipramine	Trifluoperazine
Isoproterenol	Trimipramine
Ketamine	Tyramine
LAAM	Verapamil
Lidocaine	Zomepirac

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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.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see https://usdiagnostics.roche.com for definition of symbols used):

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.

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