

# SBARB

Serum Barbiturates

Order information

**cobas**<sup>®</sup>  
Drug abuse testing

REF	CONTENT	System-ID	Analyzers on which <b>cobas c</b> pack can be used
20766704 322	Serum Barbiturates (200 tests)	07 6670 4	COBAS INTEGRA 400 plus COBAS INTEGRA 800
20766720 322	Abuscreen OnLine Serum Barbiturates Calibrators 1: 1 × 3.5 mL 2-5: 4 × 1.5 mL		
04521536 190	TDM Control Set I (2 × 5 mL), II (2 × 5 mL), III (2 × 5 mL)		
03312950 190	Control Set DAT I PreciPos DAT Set I (2 × 10 mL) PreciNeg DAT Set I (2 × 10 mL)		

## English

### System information

Test SBARB, test ID 0-670: default sample type - serum

Test UBARB, test ID 0-667: default sample type - urine

Test SBARB and UBARB may be used interchangeably for all sample types.

### Intended use

Serum Barbiturates (SBARB) is an in vitro diagnostic test for the detection of barbiturates and their metabolites in human serum, heparinized plasma, or urine on COBAS INTEGRA systems. This reagent system is intended for use in toxicological screenings where the analytical result is used in the management of barbiturate use or overdose.

**Serum Barbiturates 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.<sup>1</sup> Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used.**

### Summary

The barbiturates, a class of drugs derived from barbituric acid (malonylurea), are sedative hypnotics with central nervous system (CNS)-depressant activity.<sup>1,2,3,4,5,6</sup> As CNS-depressants, the barbiturates are classified relative to their durations of action (ultra short-, short-, intermediate-, and long-acting). They have been used medically as sedatives to reduce emotional tension and induce sleep, and in certain types of epilepsy to reduce seizure frequency by raising the seizure threshold. Excessive dosages may cause impaired motor coordination (slurred speech, loss of balance), perceptual alterations (faulty judgement, inflated perceptions of performance), and disinhibition euphoria. Overdoses can result in stupor, coma, and death. The combined use of the barbiturates with alcohol, opiates, or other CNS-depressants can result in fatal, additive respiratory depression. Although their utilities as sedative-hypnotic drugs have largely been replaced by the benzodiazepines, the barbiturates still maintain an important role as anesthetic and anticonvulsant drugs.

Oral administration is most common, although the barbiturates may be injected intravenously or intramuscularly. Following ingestion, they are rapidly absorbed from the stomach and enter the circulation. Their resulting distribution and concentration in various tissues is largely dependent on the lipid solubility and protein-binding characteristics of the different barbiturates; fat deposits and protein-rich tissues accumulate the highest concentration. Most of the barbiturates are metabolized by the liver via oxidation and conjugation, nitrogen-dealkylation, nitrogen-hydroxylation, and/or desulfuration of thiobarbiturates. The extent of liver metabolism is drug-dependent; secobarbital, for example, is extensively oxidized to a series of pharmacologically inactive metabolites, while a relatively high percentage of phenobarbital and barbital are excreted unchanged in the urine. As a drug class, the barbiturates are excreted as active drug/metabolite mixes whose ratios and concentrations depend on the specific barbiturate in question.

### Test principle

Fluorescence polarization

COBAS INTEGRA serum barbiturates measurements are made on COBAS INTEGRA systems using the principle of fluorescence polarization. When a fluorescent molecule, or fluorophore, is irradiated with light of the

proper wavelength (the excitation wavelength) some of the light is absorbed. Within a few nanoseconds the absorbed light is emitted, although at a longer wavelength (the emission wavelength). Whether or not the emitted light is polarized depends on the freedom of the fluorophore to rotate in solution. A small molecule, such as fluorescein, can rotate rapidly before light emission occurs, resulting in depolarization of the emitted light. In contrast, a fluorescent macromolecule, such as a fluorescein-labeled protein, will rotate much more slowly. Thus, in the time frame between excitation and emission, the macromolecule will have rotated only very slightly and the emitted light will be polarized.<sup>7</sup>

Fluorescence polarization is a reproducible function of the drug concentration. It is suitable for the semi-quantitative detection of barbiturates in serum, plasma, or urine for the purpose of toxicological screening. Surface active agents are used to ensure dissociation of the drug from serum proteins and to prevent nonspecific binding of the tracer.

### Reagents - working solutions

- R1** Antibody reagent  
Anti-secobarbital antibody (sheep polyclonal) in buffer, pH 7.5, with stabilizers and preservative
- R2** Diluent  
Buffer containing stabilizer and preservative
- SR** Tracer  
Fluorescein-labeled secobarbital derivative in buffer, pH 8.0, with stabilizer and preservative

R1 is in position A, R2 is in position B and SR is in position C.

### Precautions and warnings

Pay attention to all precautions and warnings listed in Section 1 / Introduction of this Method Manual.

For USA: For prescription use only.

### Reagent handling

Ready for use

### Storage and stability

Shelf life at 2-8 °C: See expiration date on **cobas c** pack label

COBAS INTEGRA 400 plus analyzer

On-board in use at 10-15 °C 8 weeks

COBAS INTEGRA 800 analyzer

On-board in use at 8 °C 16 weeks

Do not freeze reagents. Reagents that have been frozen should be discarded.

### Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.

Serum and heparinized plasma:

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all

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available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Centrifuge samples containing precipitates before performing the assay.

Serum and heparinized plasma specimens should be tested within 8 hours of collection if kept at room temperature. If specimens must be stored for later testing, they may be kept at 2-8 °C for up to 48 hours or at -20 °C or below for longer periods. Serum and heparinized plasma specimens should not be repeatedly frozen and thawed. Thawed specimens should be inverted several times prior to testing.

### 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.<sup>8</sup>

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*.<sup>9</sup>

**Caution:** Specimen dilutions should only be used as an estimation for GC/MS and are not intended for patient values. Dilution procedures, when used, should be validated.

### Materials provided

See "Reagents – working solutions" section for reagents.

### 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.

### Application for serum, plasma or urine

#### COBAS INTEGRA 400 plus test definition

Measuring mode	FP
Reaction mode	R1-R2-S-SR
Wavelength excitation	485 nm
Wavelength emission	515 nm
Test range	0.065-4 µg/mL (0.27-16.9 µmol/L)
with postdilution	0.065-80 µg/mL (0.27-337 µmol/L)
Postdilution factor	20 recommended
Reading cycle blank/test	45/61
Unit	µg/mL

### Pipetting parameters

Serum, plasma, urine	Diluent (H <sub>2</sub> O)	
R1	90 µL	15 µL
R2	25 µL	20 µL
Sample	5 µL	10 µL
SR	15 µL	30 µL
Total volume	210 µL	

#### COBAS INTEGRA 800 test definition

Measuring mode	FP
Reaction mode	R1-R2-S-SR
Wavelength excitation	485 nm
Wavelength emission	515 nm

Test range	0.03-4 µg/mL (0.13-16.9 µmol/L)
with postdilution	0.03-80 µg/mL (0.13-337 µmol/L)
Postdilution factor	20 recommended
Reading cycle blank/test	40/60
Unit	ng/mL

### Pipetting parameters

Serum, plasma, urine	Diluent (H <sub>2</sub> O)	
R1	90 µL	15 µL
R2	45 µL	15 µL
Sample	4 µL	11 µL
SR	20 µL	10 µL
Total volume	210 µL	

### Calibration

Calibrators	Abuscreen OnLine Serum Barbiturates Calibrators CAL 1-5 0, 0.5, 1, 2, 4 µg/mL secobarbital (0, 2.1, 4.2, 8.4, 16.9 µmol/L) SBARB, system-ID 07 6672 0
Calibration mode	Logit/Log 4
Calibration replicate	Duplicate recommended
Deviation low/high	< 5 % at ≥ 0.5 µg/mL (≥ 2.1 µmol/L)
Calibration interval	COBAS INTEGRA 400 plus analyzer: Each lot, every 8 weeks, and as required following quality control procedures COBAS INTEGRA 800 analyzer: Each lot, every 16 weeks, and as required following quality control procedures

A calibration curve is generated using the calibrators. Calibrators must be placed from the highest concentration (5) first to the lowest (1) last on the CAL/QC rack. This curve is retained in memory by the COBAS INTEGRA systems and recalled for later use.

Traceability: Abuscreen OnLine Serum Barbiturates Calibrators are prepared to contain known quantities of secobarbital in normal human serum and are traceable to USP reference standards.

### Quality control

Quality control serum, plasma	TDM Control Set Level I TDMC1, system-ID 07 6900 2 Level II TDMC2, system-ID 07 6901 0 Level III TDMC3, system-ID 07 6902 9
Quality control urine	Control Set DAT I PreciPos DAT Set I DAT1P, system-ID 07 6753 0 PreciNeg DAT Set I DAT1N, system-ID 07 6754 9
Control sequence	User defined
Control after calibration	Recommended
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 have been verified by GC/MS.	

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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.

### Calculation

After completion of the assay, the COBAS INTEGRA systems will automatically calculate the millipolarization units (mP) of the tracer. After mP values have been calculated for the 5 calibrators, the system calculates a best-fit curve for the calibrators using a nonlinear least squares regression analysis. The concentration of drug in each sample is then interpolated from this curve using its measured mP value.

Conversion factor:  $\text{ng/mL} \times 0.001 = \mu\text{g/mL}$

### 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 barbiturates in the sample. It does not reflect the degree of impairment. The concentration readings,  $\mu\text{g/mL}$  secobarbital, are only estimations because of the varying binding capacity of the antibody for different barbiturates and metabolites. When specific identification and quantitation of the barbiturate is desired, methods with equal sensitivity to the screening assay must be chosen. Extraction procedures must be optimized specifically for the different barbiturates.

Specimens with high fluorescent backgrounds or those giving polarization values greater than the zero calibrator will be flagged by the system.

### Serum, plasma

At 0.7 and 3  $\mu\text{g/mL}$  (3.0 and 12.6  $\mu\text{mol/L}$ ) secobarbital sample:

Hemolysis 10 % or less up to 10 g/L hemoglobin

At 1 and 3  $\mu\text{g/mL}$  (4.2 and 12.6  $\mu\text{mol/L}$ ) secobarbital sample:

Icterus 10 % or less up to 24 mg/dL bilirubin

At 1.1 and 3.2  $\mu\text{g/mL}$  (4.6 and 13.5  $\mu\text{mol/L}$ ) secobarbital sample:

Lipemia 10 % or less up to 1000 mg/dL triglycerides

At 0.83 and 3.1  $\mu\text{g/mL}$  (3.5 and 13.1  $\mu\text{mol/L}$ ) secobarbital sample:

Total protein 10 % or less from 2.0-14 g/dL

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 COBAS INTEGRA analyzers. Refer to the CLEAN Method Sheet for further instructions and for the latest version of the Extra wash cycle list.

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

### Expected values

Results obtained with the COBAS INTEGRA Serum Barbiturates **cobas c** pack on the COBAS INTEGRA systems are based upon the sensitivity of the assay, cross-reactivity and recovery characteristics. Samples with results indicating the presence of barbiturates may be further evaluated for the identification of the specific barbiturate(s) present.

### Specific performance data

Representative performance data on the COBAS INTEGRA analyzers are given below. Results obtained in individual laboratories may differ.

### Specific performance data for serum and plasma

#### Precision

Precision was determined using serum controls according to NCCLS guidelines EP5-T2<sup>10</sup> (repeatability  $n = 80$ , intermediate precision 1<sup>a</sup>)  $n = 80$ , intermediate precision 2<sup>b</sup>)  $n = 80$ ). The following results were obtained on a COBAS INTEGRA 700 analyzer.

Repeatability	Mean $\mu\text{g/mL}$ ( $\mu\text{mol/L}$ )	SD $\mu\text{g/mL}$	CV %
Level I	0.5 (2.1)	0.02	4.1
Level II	1.1 (4.6)	0.04	4.1
Level III	1.9 (8.0)	0.04	2.3

Intermediate precision 1 <sup>a</sup>	Mean $\mu\text{g/mL}$ ( $\mu\text{mol/L}$ )	SD $\mu\text{g/mL}$	CV %
Level I	0.5 (2.1)	0.02	2.9
Level II	1.1 (4.6)	0.01	1.0
Level III	1.9 (8.0)	0.03	1.6

Intermediate precision 2 <sup>b</sup>	Mean $\mu\text{g/mL}$ ( $\mu\text{mol/L}$ )	SD $\mu\text{g/mL}$	CV %
Level I	0.5 (2.1)	0.03	5.0
Level II	1.1 (4.6)	0.04	4.2
Level III	1.9 (8.0)	0.06	2.9

a) between run precision

b) total precision

### Lower detection limit of the test

COBAS INTEGRA 400 plus analyzer:  
0.065  $\mu\text{g/mL}$  (0.27  $\mu\text{mol/L}$ ) for serum

COBAS INTEGRA 800 analyzer:  
0.03  $\mu\text{g/mL}$  (0.13  $\mu\text{mol/L}$ ) for serum

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero at a 95 % confidence level.

### Accuracy

175 negative serum and plasma samples were evaluated using the COBAS INTEGRA Serum Barbiturates reagent (preliminary positive at  $\geq 0.5 \mu\text{g/mL}$ ) on a COBAS INTEGRA 700 analyzer and a commercially available EIA (preliminary positive at  $\geq 3 \mu\text{g/mL}$ ). 100 % of these samples were negative using the COBAS INTEGRA Serum Barbiturates reagent and the commercially available EIA.

47 serum and plasma samples obtained from a clinical laboratory were evaluated using the COBAS INTEGRA Serum Barbiturates reagent (preliminary positive at  $\geq 0.5 \mu\text{g/mL}$ ), a commercially available FPIA (preliminary positive at  $\geq 2 \mu\text{g/mL}$ ), a commercially available EIA (preliminary positive at  $\geq 3 \mu\text{g/mL}$ ), and GC/MS (positive at  $\geq 0.1 \mu\text{g/mL}$  for butalbital, secobarbital and pentobarbital;  $\geq 0.16 \mu\text{g/mL}$  for phenobarbital). 35 of these samples were preliminary positive using the COBAS INTEGRA Serum Barbiturates reagent and GC/MS and 10 were negative. The remaining 2 samples were negative by the COBAS INTEGRA Serum Barbiturates assay, FPIA, EIA and positive by GC/MS. The GC/MS results for these 2 samples were  $\geq 0.77 \mu\text{g/mL}$  and  $\geq 0.33 \mu\text{g/mL}$  for phenobarbital. The table below summarizes the study results.

	GC/MS	COBAS INTEGRA 700 (Preliminary positive at $\geq 0.5 \mu\text{g/mL}$ )	FPIA (Preliminary positive at $\geq 2 \mu\text{g/mL}$ )	EIA (Preliminary positive at $\geq 3 \mu\text{g/mL}$ )
+	37	35	24	13
-	10	12	23	34

### Analytical specificity

The specificity of the COBAS INTEGRA Serum Barbiturates assay for some common barbiturates and structurally similar compounds was determined by adding a known quantity of the test compound to drug-free human serum and/or drug-free urine and assaying with the COBAS INTEGRA Serum Barbiturates **cobas c** pack. Cross-reactivity was designated as "not detectable" (ND) if the obtained value was less than the sensitivity of the assay.

$$\text{Cross-reactivity (\%)} = \frac{100 \times (\text{analytical result} - \text{analyte concentration})}{\text{concentration of interferent}}$$

Drug	Level tested µg/mL	% Cross-reactivity in serum	% Cross-reactivity in urine
Allobarbitol	0.05	96.2	102
Amobarbital	1	27	-
Amobarbital	10	18.2	16.4
Aprobarbital	1	85	112.9
Barbital	1	31	44.6
Barbituric Acid	1	ND	ND
Butabarbital	1	55	-
Butabarbital	10	25.3	25.6
Butalbital	1	89	125.1
Butethal	1	61	77.3
Cyclopentobarbital	1	89	111.3
Diallylbarbituric Acid	1	118	161
1,3-Dimethyl Barbituric acid	1	0.08	1.6
Diphenylhydantoin	1	ND	ND
<i>d,l</i> -Glutethimide	1	ND	ND
Hexobarbital	1	0.5	1.7
<i>p</i> -Hydroxyphenobarbital	1	14	25.5
<i>p</i> -Hydroxyphenytoin	220	ND	ND
Mephobarbital	1	0.9	1.2
Pentobarbital	10	17.9	20.7
Phenobarbital	1	26	-
Phenobarbital	10	10.8	12.9
Thiopental	1	21.3	-
Thiopental	10	9.9	9.9

ND = Not Detectable

- = Not Evaluated

**Drug interference**

The following compounds were added to normal human serum at a concentration of 10 µg/mL (42.2 µmol/L). None of these compounds gave values in the assay that were equal to or greater than 0.2 % cross-reactivity.

Acetaminophen	Lidocaine
Acetylsalicylic acid	LSD
Aminopyrine	MDA
Amitriptyline	MDMA
<i>d</i> -Amphetamine	Melanin
<i>d,l</i> -Amphetamine	Meperidine
<i>l</i> -Amphetamine	Methadone
Ampicillin	<i>d</i> -Methamphetamine
Ascorbic acid	<i>l</i> -Methamphetamine
Aspartame	Methapyrilene
Atropine	Methaqualone
Benzocaine	Methylphenidate
Benzoyllecgonine	Methyprylon
(cocaine metabolite)	Morphine
Benzphetamine	Naloxone
Brompheniramine	Naltrexone
Caffeine	Naproxen
Calcium hypochlorite	Niacinamide

Chlordiazepoxide	Nordiazepam
Chloroquine	Norethindrone
Chlorpheniramine	<i>l</i> -Norpseudoephedrine
Chlorpromazine	Nortriptyline
Clemastine	Oxazepam
Cocaine	Penicillin G
Codeine	Phencyclidine
Cyclizine	$\beta$ -Phenethylamine
Desipramine	Phenothiazine
Dextromethorphan	Phentermine
Dextropropoxyphene	Phenylbutazone
Diazepam	Phenylpropanolamine
Diphenhydramine	<i>d</i> -Phenylpropanolamine
Dopamine	<i>d,l</i> -Phenylpropanolamine
Doxylamine	Phenyltoloxamine
Ecgonine	Procaine
Ecgonine methyl ester	Procyclidine
<i>d</i> -Ephedrine	Promethazine
<i>d,l</i> -Ephedrine	<i>d</i> -Pseudoephedrine
<i>l</i> -Ephedrine	<i>l</i> -Pseudoephedrine
Epinephrine	Quinidine
Erythromycin	Quinine
Estriol	Sulindac
17- $\alpha$ -Ethinylestradiol	Tetracycline
Fenoprofen	$\Delta^9$ THC-9-carboxylic acid
Furosemide	Tetrahydrozoline
Gentisic acid	Thioridazine
Guaiacol glycerol ether	Trifluoperazine
Hydrochlorothiazide	<i>d,l</i> -Trihexyphenidyl
<i>p</i> -Hydroxyamphetamine	Trimipramine
Ibuprofen	Tripelenamine
Imipramine	Tyramine
Isoproterenol	Verapamil
Ketamine	Zomepirac

**Specific performance data for urine****Precision**

Precision was determined using urine controls according to NCCLS guidelines EP5-T2<sup>10</sup> (repeatability  $n = 80$ , intermediate precision 1<sup>o</sup>  $n = 80$ , intermediate precision 2<sup>o</sup>  $n = 80$ ). The following results were obtained on a COBAS INTEGRA 700 analyzer.

Repeatability	Mean ng/mL (nmol/L)	SD ng/mL	CV %
Level I	136.4 (572.9)	8.81	6.46
Level II	222.6 (934.9)	9.76	4.39
Level III	276.6 (1161.7)	11.2	4.04

Intermediate precision 1 <sup>o</sup>	Mean ng/mL (nmol/L)	SD ng/mL	CV %
Level I	136.4 (572.9)	1.11	0.81
Level II	222.6 (934.9)	4.61	2.07
Level III	276.6 (1161.7)	6.14	2.22

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Intermediate precision 2 <sup>1)</sup>	Mean ng/mL (nmol/L)	SD ng/mL	CV %
Level I	136.4 (572.9)	9.10	6.67
Level II	222.6 (934.9)	11.7	5.24
Level III	276.6 (1161.7)	13.2	4.77

c) between run precision

d) total precision

### Lower detection limit of the test

COBAS INTEGRA 400 plus analyzer:  
65 ng/mL (274 nmol/L) for urine

COBAS INTEGRA 800 analyzer:  
80 ng/mL (345.6 nmol/L) for urine

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero at a 95 % confidence level.

### Accuracy

114 negative urine samples were evaluated using the COBAS INTEGRA Serum Barbiturates (SBARB) reagent (preliminary positive in urine at  $\geq 200$  ng/mL) on a COBAS INTEGRA 700 analyzer and another method, the COBAS INTEGRA Barbiturates (BARB) reagent which utilizes the KIMS technology (preliminary positive in urine at  $\geq 200$  ng/mL). 100 % of these samples were negative using the COBAS INTEGRA Serum Barbiturates (SBARB) reagent.

60 urine samples obtained from a clinical laboratory were evaluated using the COBAS INTEGRA Serum Barbiturates (SBARB) reagent (preliminary positive in urine at  $\geq 200$  ng/mL), the COBAS INTEGRA Barbiturates (BARB) reagent (preliminary positive in urine at  $\geq 200$  ng/mL) and GC/MS (positive at  $\geq 25$  ng/mL for phenobarbital, butabarbital, or secobarbital). The clinical study showed 1 sample as negative by GC/MS and preliminary positive by both immunoassays. It is highly suspected that the sample contains a barbiturate other than phenobarbital, butabarbital, and secobarbital. The table below summarizes the study results.

	GC/MS	COBAS INTEGRA 700 (Preliminary positive at $\geq 200$ ng/mL)	FPIA (Preliminary positive at $\geq 200$ ng/mL)
+	49	50	50
-	11	10	10

Any modification of the instrument as set forth in this labeling requires validation by the laboratory.

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- National Committee for Clinical Laboratory Standards. User Evaluation of Precision Performance of Clinical Chemistry Devices; Tentative Guideline. Villanova, PA.: NCCLS;1992;4(12). NCCLS Publication EP5-T2.

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.

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

### FOR US CUSTOMERS ONLY: LIMITED WARRANTY

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