AMPS2

cobas®

ONLINE DAT Amphetamines II

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
04939425 190	ONLINE DAT Amphetamines II (200 tests)	System-ID 07 6980 0	**cobas c** 311, **cobas c** 501/502
03304671 190	Preciset DAT Plus I calibrators CAL 1-6 (6 x 5 mL)	Codes 431-436	
03304680 190	Preciset DAT Plus II calibrators CAL 1-6 (6 x 5 mL)	Codes 437-442	
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	
03312968 190	Control Set DAT II (for 300 ng/mL assay) PreciPos DAT Set II (2 x 10 mL) PreciNeg DAT Set II (2 x 10 mL)		
03312950 190	Control Set DAT I (for 500 ng/mL assay) PreciPos DAT Set I (2 x 10 mL) PreciNeg DAT Set I (2 x 10 mL)		
04500873 190	Control Set DAT Clinical (for 500 ng/mL assay) PreciPos DAT Clinical (2 x 10 mL) PreciNeg DAT Clinical (2 x 10 mL)		
03312976 190	Control Set DAT III (for 1000 ng/mL assay) PreciPos DAT Set III (2 x 10 mL) PreciNeg DAT Set III (2 x 10 mL)		

English

System information

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

AM3Q2: ACN 814 (Urine): for qualitative assay, 300 ng/mL

AM5Q2: ACN 815 (Urine): for qualitative assay, 500 ng/mL

AM1Q2: ACN 816 (Urine): for qualitative assay, 1000 ng/mL

AM3S2: ACN 817 (Urine): for semiquantitative assay, 300 ng/mL

AM5S2: ACN 818 (Urine): for semiquantitative assay, 500 ng/mL

AM1S2: ACN 819 (Urine): for semiquantitative assay, 1000 ng/mL

AM5QC: ACN 787 (Urine): for qualitative assay, 500 ng/mL; using C.f.a.s. DAT Qualitative Plus Clinical

For **cobas c** 502 analyzer:

AM3Q2: ACN 8814 (Urine): for qualitative assay, 300 ng/mL

AM5Q2: ACN 8815 (Urine): for qualitative assay, 500 ng/mL

AM1Q2: ACN 8816 (Urine): for qualitative assay, 1000 ng/mL

AM3S2: ACN 8817 (Urine): for semiquantitative assay, 300 ng/mL

AM5S2: ACN 8818 (Urine): for semiquantitative assay, 500 ng/mL

AM1S2: ACN 8819 (Urine): for semiquantitative assay, 1000 ng/mL

AM5QC: ACN 8787 (Urine): for qualitative assay, 500 ng/mL; using C.f.a.s. DAT Qualitative Plus Clinical

Intended use

Amphetamines II (AMPS2) is an in vitro diagnostic test for the qualitative and semiquantitative detection of amphetamines and methamphetamines in human urine on Roche/Hitachi **cobas c** systems at cutoff concentrations of 300 ng/mL, 500 ng/mL, and 1000 ng/mL when calibrated with *d*-methamphetamine. 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).

Amphetamines 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

The amphetamines are known as the sympathomimetic amines as they mimic the effects of stimulation of the sympathetic nervous system. These small molecules, based on ß-phenylethylamine, structurally resemble the body's own catecholamines. A wide variety have been created via substitutions anywhere on the structure. The amphetamines are potent central nervous stimulants. As such they can increase wakefulness, physical activity, and decrease appetite. The amphetamines have some limited indications and approval for use in ADHD, narcolepsy, and obesity. However, because these CNS stimulants convey a sense of self-confidence, well being, and euphoria, they are highly addictive, widely abused, and consequently controlled substances.[2] Abuse can lead to medical, psychological, and social consequences. Adverse health effects include memory loss, aggression, psychotic behavior, heart damage, malnutrition, and severe dental problems.[3] Amphetamine may be self-administered either orally or by intravenous injection in amounts of up to 2000 mg daily by tolerant addicts. It is a metabolite of a number of other drugs including methamphetamine. Normally about 30 % is excreted unchanged in the 24 hour urine, but this may change to as much as 74 % in acid urine and may decrease to 1 % in alkaline urine.[4]

Amphetamines II is calibrated with *d*-methamphetamine and therefore the sensitivity towards amphetamines is different than *d*-methamphetamine, as indicated in the “Analytical specificity” section.

Test principle

The assay is based on the kinetic interaction of microparticles in a solution (KIMS)[5,6] 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.[7]

Reagents - working solutions

R1 Conjugated amphetamine and methamphetamine derivatives; buffer; bovine serum albumin; 0.09 % sodium azide

R2 Microparticles attached to amphetamine and methamphetamine antibodies (mouse monoclonal); buffer; bovine serum albumin; 0.09 % sodium azide

R1 is in position B and R2 is in position C

AMPS2

ONLINE DAT Amphetamines II

cobas®

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.

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.[8]

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*.[9]

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.

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.

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

General laboratory equipment

See "Order information" section

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 definitions**

	Semi-quantitative	Qualitative
Assay type	2-Point End	2-Point End
Reaction time / Assay points	10 / 10-31	10 / 10-31
Wavelength (sub/main)	– /600 nm	– /600 nm
Reaction direction	Increase	Increase
Unit	ng/mL	mAbs
Reagent pipetting		Diluent (H_2O)
R1	90 µL	–
R2	40 µL	–
R3	–	–

Sample volumes	*Sample*	*Sample dilution*	
300 ng/mL cutoff		*Sample*	*Diluent (NaCl)*
Normal	6.0 µL	–	–
Decreased	6.0 µL	–	–
Increased	6.0 µL	–	–
500 ng/mL cutoff			
Normal	5.0 µL	–	–
Decreased	5.0 µL	–	–
Increased	5.0 µL	–	–
1000 ng/mL cutoff			
Normal	4.0 µL	–	–
Decreased	4.0 µL	–	–
Increased	4.0 µL	–	–

cobas c 501/502 **test definitions**

	Semi-quantitative	Qualitative
Assay type	2-Point End	2-Point End
Reaction time / Assay points	10 / 16-46	10 / 16-46
Wavelength (sub/main)	– /600 nm	– /600 nm
Reaction direction	Increase	Increase
Unit	ng/mL	mAbs
Reagent pipetting		Diluent (H_2O)
R1	90 µL	–
R2	40 µL	–
R3	–	–

Sample volumes	*Sample*	*Sample dilution*	
300 ng/mL cutoff		*Sample*	*Diluent (NaCl)*
Normal	6.0 µL	–	–
Decreased	6.0 µL	–	–
Increased	6.0 µL	–	–
500 ng/mL cutoff			
Normal	5.0 µL	–	–
Decreased	5.0 µL	–	–
Increased	5.0 µL	–	–
1000 ng/mL cutoff			
Normal	4.0 µL	–	–
Decreased	4.0 µL	–	–
Increased	4.0 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 *500 and 1000 ng/mL cutoff assays* S1-6: Preciset DAT Plus I calibrators, CAL 1-6 0, 250, 500, 1000, 3000, 5000 ng/mL *Qualitative applications* *300 ng/mL cutoff assay* S1: Preciset DAT Plus II calibrator - CAL 3 300 ng/mL *500 ng/mL cutoff assay* S1: Preciset DAT Plus I calibrator - CAL 3 or C.f.a.s. DAT Qualitative Plus *(Test AM5Q2)* S1: C.f.a.s. DAT Qualitative Plus Clinical *(Test AM5QC)* 500 ng/mL *1000 ng/mL cutoff assay* S1: Preciset DAT Plus I calibrator - CAL 4 1000 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).

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 the Control Set DAT I, II, 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. Results of this assay distinguish preliminary positive (≥ 300 ng/mL, ≥ 500 ng/mL or ≥ 1000 ng/mL depending on the cutoff) from negative samples only. The amount of drug detected in a preliminary positive sample cannot be estimated.

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.

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

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.

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.

Preliminary positive results should be confirmed by another method.

Limitations

ACTION REQUIRED

When running Amphetamines II and Tina-quant Hemoglobin A1c II assays, on the same **cobas c** 501 analyzer, avoid processing Amphetamines II as the first test from standby status. If no other testing is pending, a dummy test sample should be processed to prevent the Amphetamines II from being the first test from standby. Order a dummy test for any R1 assay other than HbA1c II.

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 amphetamine or methamphetamine in urine. It does not measure the level of intoxication.

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 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

No drug should be present in individuals that have not ingested amphetamine or methamphetamine.

Specific performance data

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

Precision

A *d*-methamphetamine (MAMP) solution (1 mg/mL) was added to 9 samples obtained from a human urine sample pool to achieve concentrations at approximately -100 %, -75 %, -50 %, -25 %, ±0 %, +25 %, +50 %, +75 %, and +100 % of the cutoff value. These samples were tested for precision in qualitative and semiquantitative modes. Following a CLSI (EP5-A2) precision protocol, samples were tested in 2 replicates per run, 2 runs per day for 21 days, total n = 84. The following results were obtained on a **cobas c** 501 analyzer.

Qualitative - 300 ng/mL Cutoff

Drug	Concentration of Sample	Number of Determinations	Results # Neg / # Pos
MAMP	zero drug	84	84 Neg / 0 Pos
MAMP	-75 %	84	84 Neg / 0 Pos
MAMP	-50 %	84	84 Neg / 0 Pos
MAMP	-25 %	84	84 Neg / 0 Pos
MAMP	cutoff	84	7 Neg / 77 Pos
MAMP	+25 %	84	0 Neg / 84 Pos
MAMP	+50 %	84	0 Neg / 84 Pos
MAMP	+75 %	84	0 Neg / 84 Pos
MAMP	+100 %	84	0 Neg / 84 Pos

Qualitative - 500 ng/mL Cutoff

Drug	Concentration of Sample	Number of Determinations	Results # Neg / # Pos
MAMP	zero drug	84	84 Neg / 0 Pos
MAMP	-75 %	84	84 Neg / 0 Pos
MAMP	-50 %	84	84 Neg / 0 Pos
MAMP	-25 %	84	84 Neg / 0 Pos
MAMP	cutoff	84	14 Neg / 70 Pos
MAMP	+25 %	84	0 Neg / 84 Pos
MAMP	+50 %	84	0 Neg / 84 Pos
MAMP	+75 %	84	0 Neg / 84 Pos
MAMP	+100 %	84	0 Neg / 84 Pos

Qualitative - 1000 ng/mL Cutoff

Drug	Concentration of Sample	Number of Determinations	Results # Neg / # Pos
MAMP	zero drug	84	84 Neg / 0 Pos
MAMP	-75 %	84	84 Neg / 0 Pos
MAMP	-50 %	84	84 Neg / 0 Pos
MAMP	-25 %	84	84 Neg / 0 Pos
MAMP	cutoff	84	11 Neg / 73 Pos
MAMP	+25 %	84	0 Neg / 84 Pos
MAMP	+50 %	84	0 Neg / 84 Pos
MAMP	+75 %	84	0 Neg / 84 Pos
MAMP	+100 %	84	0 Neg / 84 Pos

Semiquantitative - 300 ng/mL Cutoff

Drug	Sample Conc.	Results # Neg / # Pos	Repeatability		Intermediate precision	
			SD, ng/mL	CV, %	SD, ng/mL	CV, %
MAMP	zero drug	84 / 0	19.4	58.2	26.0	78.1
MAMP	-75 %	84 / 0	16.5	20.0	21.2	25.8
MAMP	-50 %	84 / 0	13.7	8.5	17.2	10.7
MAMP	-25 %	84 / 0	15.5	6.7	19.2	8.4
MAMP	cutoff	23 / 61	14.5	4.7	19.7	6.3
MAMP	+25 %	0 / 84	16.1	4.2	21.1	5.5
MAMP	+50 %	0 / 84	15.9	3.8	20.6	5.0
MAMP	+75 %	0 / 84	15.5	2.9	25.1	4.7
MAMP	+100 %	0 / 84	18.0	3.0	28.3	4.7

Semiquantitative - 500 ng/mL Cutoff

Drug	Sample Conc.	Results # Neg / # Pos	Repeatability		Intermediate precision	
			SD, ng/mL	CV, %	SD, ng/mL	CV, %
MAMP	zero drug	84 / 0	30.1	50.2	31.9	53.3
MAMP	-75 %	84 / 0	19.0	12.8	22.6	15.2
MAMP	-50 %	84 / 0	19.5	7.2	22.6	8.4
MAMP	-25 %	84 / 0	18.1	4.6	23.8	6.0
MAMP	cutoff	2 / 82	26.6	5.0	27.1	5.1
MAMP	+25 %	0 / 84	28.9	4.4	36.9	5.6
MAMP	+50 %	0 / 84	30.2	4.2	36.0	5.0
MAMP	+75 %	0 / 84	25.8	2.8	41.1	4.5
MAMP	+100 %	0 / 84	30.0	2.9	43.3	4.1

Semiquantitative - 1000 ng/mL Cutoff

Drug	Sample Conc.	Results # Neg / # Pos	Repeatability		Intermediate precision	
			SD, ng/mL	CV, %	SD, ng/mL	CV, %
MAMP	zero drug	84 / 0	39.9	47.6	45.3	54.0
MAMP	-75 %	84 / 0	26.8	9.2	32.5	11.2
MAMP	-50 %	84 / 0	22.3	4.1	36.8	6.8
MAMP	-25 %	84 / 0	31.2	4.2	42.8	5.7
MAMP	cutoff	7 / 77	39.7	3.7	54.7	5.1
MAMP	+25 %	0 / 84	52.9	3.9	45.2	5.6
MAMP	+50 %	0 / 84	60.0	3.8	80.6	5.1
MAMP	+75 %	0 / 84	74.2	4.1	97.2	5.4
MAMP	+100 %	0 / 84	106.0	5.1	123.0	6.0

A similar experiment was conducted utilizing *d*-amphetamine (AMP) as the target analyte instead of *d*-methamphetamine. The samples were tested for precision in qualitative and semiquantitative modes. Following a CLSI (EP5-A2) precision protocol, samples were tested in 2 replicates per run, 2 runs per day for 10 days, total n = 40. The following results were obtained on a **cobas c** 501 analyzer.

Qualitative - 300 ng/mL Cutoff

Drug	Concentration of Sample	Number of Determinations	Results # Neg / # Pos
AMP	zero drug	40	40 Neg / 0 Pos
AMP	-75 %	40	40 Neg / 0 Pos
AMP	-50 %	40	40 Neg / 0 Pos
AMP	-25 %	40	34 Neg / 6 Pos
AMP	cutoff	40	1 Neg / 39 Pos

AMP	+25 %	40	0 Neg / 40 Pos
AMP	+50 %	40	0 Neg / 40 Pos
AMP	+75 %	40	0 Neg / 40 Pos
AMP	+100 %	40	0 Neg / 40 Pos

Qualitative - 500 ng/mL Cutoff

Drug	Concentration of Sample	Number of Determinations	Results # Neg / # Pos
AMP	zero drug	40	40 Neg / 0 Pos
AMP	-75 %	40	40 Neg / 0 Pos
AMP	-50 %	40	40 Neg / 0 Pos
AMP	-25 %	40	38 Neg / 2 Pos
AMP	cutoff	40	1 Neg / 39 Pos
AMP	+25 %	40	0 Neg / 40 Pos
AMP	+50 %	40	0 Neg / 40 Pos
AMP	+75 %	40	0 Neg / 40 Pos
AMP	+100 %	40	0 Neg / 40 Pos

Qualitative - 1000 ng/mL Cutoff

Drug	Concentration of Sample	Number of Determinations	Results # Neg / # Pos
AMP	zero drug	40	40 Neg / 0 Pos
AMP	-75 %	40	40 Neg / 0 Pos
AMP	-50 %	40	40 Neg / 0 Pos
AMP	-25 %	40	40 Neg / 0 Pos
AMP	cutoff	40	2 Neg / 38 Pos
AMP	+25 %	40	0 Neg / 40 Pos
AMP	+50 %	40	0 Neg / 40 Pos
AMP	+75 %	40	0 Neg / 40 Pos
AMP	+100 %	40	0 Neg / 40 Pos

Semiquantitative - 300 ng/mL Cutoff

Drug	Sample Conc.	Results # Neg / # Pos	Repeatability		Intermediate precision	
			SD, ng/mL	CV, %	SD, ng/mL	CV, %
AMP	zero drug	40 / 0	11.7	19.5	18.9	31.5
AMP	-75 %	40 / 0	23.0	16.6	20.3	14.6
AMP	-50 %	40 / 0	16.2	7.7	17.6	8.3
AMP	-25 %	37 / 3	18.4	6.6	20.7	7.5
AMP	cutoff	2 / 38	18.5	5.3	22.1	6.3
AMP	+25 %	0 / 40	15.9	3.9	21.7	5.3
AMP	+50 %	0 / 40	20.8	4.6	27.7	6.2
AMP	+75 %	0 / 40	24.6	4.9	24.3	4.9
AMP	+100 %	0 / 40	31.2	5.4	30.3	5.3

Semiquantitative - 500 ng/mL Cutoff

Drug	Sample Conc.	Results # Neg / # Pos	Repeatability		Intermediate precision	
			SD, ng/mL	CV, %	SD, ng/mL	CV, %
AMP	zero drug	40 / 0	27.1	39.6	25.5	37.4
AMP	-75 %	40 / 0	13.1	6.2	24.3	11.5
AMP	-50 %	40 / 0	21.6	6.7	25.8	8.0
AMP	-25 %	39 / 1	22.0	4.8	25.9	5.7
AMP	cutoff	1 / 39	28.3	5.0	29.5	5.2
AMP	+25 %	0 / 40	28.2	4.2	39.8	5.9
AMP	+50 %	0 / 40	17.6	2.3	37.9	5.0
AMP	+75 %	0 / 40	27.7	3.2	36.1	4.2
AMP	+100 %	0 / 40	44.2	4.5	57.6	5.8

Semiquantitative - 1000 ng/mL Cutoff

Drug	Sample Conc.	Results # Neg / # Pos	Repeatability		Intermediate precision	
			SD, ng/mL	CV, %	SD, ng/mL	CV, %
AMP	zero drug	40 / 0	32.0	28.2	52.4	46.2
AMP	-75 %	40 / 0	23.4	5.4	57.7	13.3
AMP	-50 %	40 / 0	30.0	4.4	52.1	7.6
AMP	-25 %	39 / 1	32.3	3.6	43.1	4.7
AMP	cutoff	0 / 40	48.1	4.2	65.3	5.8
AMP	+25 %	0 / 40	29.8	2.3	50.1	3.8
AMP	+50 %	0 / 40	54.2	3.5	65.7	4.3
AMP	+75 %	0 / 40	58.2	3.4	60.0	3.5
AMP	+100 %	0 / 40	81.6	4.2	87.8	4.5

Accuracy

An initial study was conducted in which samples were selected based upon screening with a commercially available enzyme immunoassay. The study resulted in 190 unaltered clinical samples (114 negative and 76 preliminary positive) for the 300 ng/mL cutoff, 189 unaltered clinical samples (114 negative and 75 preliminary positive) for the 500 ng/mL cutoff, and 189 unaltered clinical samples (115 negative and 74 preliminary positive) for the 1000 ng/mL cutoff. 100 % of the samples that screened preliminary positive were confirmed positive with GC-MS. For the 300 ng/mL and 500 ng/mL cutoffs, 47 of the samples that screened negative were confirmed negative with GC-MS. For the 1000 ng/mL cutoff, 48 of the samples that screened negative were confirmed negative with GC-MS. The following results were obtained with the Amphetamines II assay on a **cobas c** 501 analyzer relative to the total GC-MS values:

Amphetamines II Qualitative Assay Results (Total GC-MS)

Roche ONLINE DAT AMPII assay	Low Neg	Near Cutoff Negative by GC-MS (between -50 % and cutoff)	Near Cutoff Positive by GC-MS (between cutoff and +50 %)	High Positive by GC-MS (greater than +50 %)	Percent Agreement with GC-MS (Total)
300 ng/mL Cutoff					
Positive	2	1	7	69	100 %
Negative	108	3	0	0	97.4 %
500 ng/mL Cutoff					
Positive	0	0	6	69	100 %
Negative	110	4	0	0	100 %
1000 ng/mL Cutoff					
Positive	0	0	7	66	98.6 %
Negative	110	5	0	1	100 %

Amphetamines II Semiquantitative Assay Results (Total GC-MS)

Roche ONLINE DAT AMPII assay	Low Neg	Near Cutoff Negative by GC-MS (between -50 % and cutoff)	Near Cutoff Positive by GC-MS (between cutoff and +50 %)	High Positive by GC-MS (greater than +50 %)	Percent Agreement with GC-MS (Total)
300 ng/mL Cutoff					
Positive	1	0	7	69	100 %
Negative	109	4	0	0	99.1 %
500 ng/mL Cutoff					
Positive	0	0	6	69	100 %
Negative	110	4	0	0	100 %
1000 ng/mL Cutoff					
Positive	0	0	7	66	98.6 %
Negative	110	5	0	1	100 %

Accuracy samples were categorized based upon the total GC-MS concentration. The table below identifies those samples with a total GC-MS concentration that is discrepant from the results obtained with ONLINE DAT Amphetamines II assay on a **cobas c** 501 analyzer. The expected results column identifies the result expected with the Amphetamines II assay based upon the cross reactivity of Amphetamines II towards both *d*-methamphetamine (MAMP) and *d*-amphetamine (AMP) values relative to the cutoff.

GC-MS Summary of Discrepant Results (Total GC-MS)

Cutoff Value (ng/mL)	Roche ONLINE DAT AMP II OBSERVED Result	Roche ONLINE DAT AMP II EXPECTED Result	GC-MS (ng/mL)	Drug / Metabolite
300 (Q)[b]	Positive	Negative	174	MAMP
300 (SQ, Q)	Positive	Negative	58710 278	Pseudoephedrine Ephedrine
300 (Q)	Positive	Negative	76730 124	Pseudoephedrine Ephedrine
1000 (SQ, Q)[c]	Negative	Positive	2834	AMP

b)The cause of the discrepancy could not be determined.

c) After accuracy testing was completed, the sample volume was inadequate to undertake a root cause analysis of the discrepant sample. The cause of the discrepancy could not be determined.

Two additional studies were conducted in which samples were selected based on GC-MS values for either *d*-methamphetamine or *d*-amphetamine. A total of 80 unaltered clinical samples (40 negative and 40 positive) were evaluated by the Amphetamines II assay and by GC-MS. Approximately 10 % of the study samples were distributed between plus and minus 50 % of the claimed cutoff concentration. The following results were obtained with the Amphetamines II assay on a **cobas c** 501 analyzer relative to the GC-MS values for either *d*-methamphetamine (MAMP) and *d*-amphetamine (AMP).

Amphetamines II Qualitative Assay Results (MAMP)

Roche ONLINE DAT AMPII assay	Low Neg	Near Cutoff Negative by GC-MS (between -50 % and cutoff)	Near Cutoff Positive by GC-MS (between cutoff and +50 %)	High Positive by GC-MS (greater than +50 %)	Percent Agreement with GC-MS (MAMP)
300 ng/mL Cutoff					
Positive	0	4	4	36	100 %
Negative	36	0	0	0	90 %
500 ng/mL Cutoff					
Positive	0	3	4	36	100 %
Negative	36	1	0	0	92.5 %
1000 ng/mL Cutoff					
Positive	0	4	4	36	100 %
Negative	36	0	0	0	90 %

Amphetamines II Semiquantitative Assay Results (MAMP)

Roche ONLINE DAT AMPII assay	Low Neg	Near Cutoff Negative by GC-MS (between -50 % and cutoff)	Near Cutoff Positive by GC-MS (between cutoff and +50 %)	High Positive by GC-MS (greater than +50 %)	Percent Agreement with GC-MS (MAMP)
300 ng/mL Cutoff					
Positive	0	4	4	36	100 %
Negative	36	0	0	0	90 %
500 ng/mL Cutoff					
Positive	0	3	4	36	100 %
Negative	36	1	0	0	92.5 %
1000 ng/mL Cutoff					
Positive	0	4	4	36	100 %
Negative	36	0	0	0	90 %

Accuracy samples were categorized based upon the *d*-methamphetamine GC-MS concentration only. The table below identifies those samples with a *d*-methamphetamine concentration below the cutoff, in which the observed result on a **cobas c** 501 analyzer was positive. The expected results column identifies the result expected with the Amphetamines II assay based upon the *d*-methamphetamine (MAMP) value relative to the cutoff.

GC-MS Summary of Discrepant Results (MAMP)

Cutoff Value (ng/mL)	Roche ONLINE DAT AMP II OBSERVED Result	Roche ONLINE DAT AMP II EXPECTED Result	GC-MS (ng/mL)	Drug / Metabolite
300 (SQ, Q)	Positive	Positive	173 181	MAMP AMP
300 (SQ, Q)	Positive	Positive	278 101	MAMP AMP
300 (SQ, Q)	Positive	Positive	220 171	AMP MAMP
300 (SQ, Q)	Positive	Positive	291 145	MAMP AMP
500 (SQ, Q)	Positive	Positive	488 466	MAMP AMP
500 (SQ, Q)	Positive	Positive	325 171	MAMP AMP
500 (SQ, Q)	Positive	Positive	291 145	MAMP AMP
500 (SQ, Q)	Positive	Positive	472 650	MAMP AMP
1000 (SQ, Q)	Positive	Positive	706 443	MAMP AMP
1000 (SQ, Q)	Positive	Positive	540 693	MAMP AMP

1000 (SQ, Q)	Positive	Positive	769 395	MAMP AMP
1000 (SQ, Q)	Positive	Positive	572 432	MAMP AMP

Amphetamines II Qualitative Assay Results (AMP)

Roche ONLINE DAT AMPII assay	Low Neg	Near Cutoff Negative by GC-MS (between -50 % and cutoff)	Near Cutoff Positive by GC-MS (between cutoff and +50 %)	High Positive by GC-MS (greater than +50 %)	Percent Agreement with GC-MS (AMP)
300 ng/mL Cutoff					
Positive	0	3	4	36	100 %
Negative	36	1	0	0	92.5 %
500 ng/mL Cutoff					
Positive	0	3	4	36	100 %
Negative	36	1	0	0	92.5 %
1000 ng/mL Cutoff					
Positive	0	1	4	36	100 %
Negative	36	3	0	0	97.5 %

Amphetamines II Semiquantitative Assay Results (AMP)

Roche ONLINE DAT AMPII assay	Low Neg	Near Cutoff Negative by GC-MS (between -50 % and cutoff)	Near Cutoff Positive by GC-MS (between cutoff and +50 %)	High Positive by GC-MS (greater than +50 %)	Percent Agreement with GC-MS (AMP)
300 ng/mL Cutoff					
Positive	0	3	4	36	100 %
Negative	36	1	0	0	92.5 %
500 ng/mL Cutoff					
Positive	0	3	4	36	100 %
Negative	36	1	0	0	92.5 %
1000 ng/mL Cutoff					
Positive	0	1	4	36	100 %
Negative	36	3	0	0	97.5 %

Accuracy samples were categorized based upon the *d*-amphetamine GC-MS concentration only. The table below identifies those samples with a *d*-amphetamine concentration below the cutoff, in which the observed result on a **cobas c** 501 analyzer was positive. The expected results column identifies the result expected with the Amphetamines II assay based upon the *d*-amphetamine (AMP) value relative to the cutoff.

GC-MS Summary of Discrepant Results (AMP)

Cutoff Value (ng/mL)	Roche ONLINE DAT AMP II OBSERVED Result	Roche ONLINE DAT AMP II EXPECTED Result	GC-MS (ng/mL)	Drug / Metabolite
300 (SQ, Q)	Positive	Positive	157 363	AMP MAMP
300 (SQ, Q)	Positive	Positive	181 173	AMP MAMP
300 (SQ, Q)	Positive	Positive	220 171	AMP MAMP
500 (SQ, Q)	Positive	Positive	438 121	AMP MAMP
500 (SQ, Q)	Positive	Positive	457 1152	AMP MAMP
500 (SQ, Q)	Positive	Positive	443 706	AMP MAMP
1000 (SQ, Q)	Positive	Positive	837 1163	AMP MAMP

Analytical specificity

The specificity of Amphetamines II for various phenethylamines and structurally similar compounds was determined by generating inhibition curves for each of the compounds listed for both semiquantitative and qualitative modes and determining the approximate quantity of each compound that is equivalent in assay reactivity to the 300 ng/mL, 500 ng/mL, and 1000 ng/mL *d*-methamphetamine assay cutoff. The tables below show the semiquantitative results of the study for each assay cutoff. The same samples were run in the qualitative mode and all recovered appropriately negative or positive, based on the calculated cross-reactivity.

Compound	ng/mL Equivalent to 300 ng/mL *d*-methamphetamine	Approx. Percent Cross-reactivity
± MDMA[d]	104	288
PMA[m]	166	180
PMMA[n]	191	157
± MDA[e]	249	120
d-Amphetamine	251	120[f]
± MDEA[h]	303	99
d-Methamphetamine	305	98
± MBDB HCl[g]	323	93
± BDB HCl[i]	717	42
Trazodone metabolite: mCPP[j]	1631	18
1-Methyl-3-phenylpropylamine[k]	1942	15
l-Methamphetamine	2524	12
l-Amphetamine	7085	4
Dimethylamylamine[l]	30980	0.97
Phendimetrazine	31818	0.94
Phentermine	70391	0.43
d-Pseudoephedrine	73822	0.41
Tyramine	85115	0.35
Ranitidine	86997	0.34
l-Ephedrine	89655	0.33
d,l-Phenylpropanolamine HCl	211268	0.14
d-Ephedrine	215827	0.14

Compound	ng/mL Equivalent to 500 ng/mL *d*-methamphetamine	Approx. Percent Cross-reactivity
± MDMA[d]	196	255

PMA[m]	341	147
PMMA[n]	344	145
± MDA[e]	394	127
d-Methamphetamine	488	102
d-Amphetamine	494	101 [f]
± MBDB HCl[g]	598	84
± MDEA[h]	668	75
± BDB HCl[i]	1358	37
Trazodone metabolite: mCPP[j]	2560	20
1-Methyl-3-phenylpropylamine[k]	2992	17
l-Methamphetamine	4383	11
l-Amphetamine	13342	4
Dimethylamylamine[l]	50436	0.99
Phendimetrazine	65566	0.76
d-Pseudoephedrine	112613	0.44
Phentermine	123457	0.41
Ranitidine	127143	0.39
l-Ephedrine	141643	0.35
Tyramine	141643	0.35
d,l-Phenylpropanolamine HCl	344828	0.15
d-Ephedrine	458716	0.11

Compound	ng/mL Equivalent to 1000 ng/mL *d*-methamphetamine	Approx. Percent Cross-reactivity
± MDMA[d]	509	197
PMMA[n]	690	145
PMA[m]	908	110
± MDA[e]	771	130
d-Amphetamine	981	102 [f]
d-Methamphetamine	998	100
± MBDB HCl[g]	1175	85
± MDEA[h]	1553	64
± BDB HCl[i]	2420	41
Trazodone metabolite: mCPP[j]	5478	18
1-Methyl-3-phenylpropylamine[k]	5116	20
l-Methamphetamine	8748	11
l-Amphetamine	24220	4
Dimethylamylamine[l]	100735	0.99
Phendimetrazine	138504	0.72
Phentermine	238663	0.42
Ranitidine	257561	0.39
d-Pseudoephedrine	261780	0.38
Tyramine	284091	0.35
l-Ephedrine	308642	0.32
d,l-Phenylpropanolamine HCl	606061	0.17
d-Ephedrine	657895	0.15

d) d,l-3,4-Methylenedioxymethamphetamine

e) d,l-3,4-Methylenedioxyamphetamine

f) Representative data from multiple lots demonstrate cross-reactivity in the range from approximately 75-125 %

g) d,l-N-Methyl-1-(3,4-methylenedioxyphenyl)-2-butamine hydrochloride

h) d,l-3,4-Methylenedioxyethylamphetamine

i) d,l-3,4-Methylenedioxyphenyl-2-butamine hydrochloride

j) 1-(3-Chlorphenyl)piperazine

k) APB, metabolite of Labetalol

l) 4-Methylhexan-2-amine, DMAA

m) para-Methoxyamphetamine

n) para-Methoxymethamphetamine

Lisdexamfetamine is a pharmacologically inactive prodrug of d-amphetamine. After oral ingestion, lisdexamfetamine is converted to l-lysine and active d-amphetamine which may cause a positive test result with this assay.[10]

Cross-reactivity with unrelated drugs

The following compounds were added at the listed concentrations to a human urine pool spiked with *d*-methamphetamine at approximately the negative and positive control concentrations for each cutoff (±25 % of assay cutoff). For each compound, the control level samples recovered properly for the 300 ng/mL, 500 ng/mL, and 1000 ng/mL cutoff in both semiquantitative and qualitative modes.

		Semiquantitative All Cutoffs		Qualitative All Cutoffs	
Compound	Concentration (ng/mL)	Low Control	High Control	Low Control	High Control
Acetaminophen	100000	NEG	POS	NEG	POS
Acetylsalicylic acid	100000	NEG	POS	NEG	POS
Amitriptyline	100000	NEG	POS	NEG	POS
Ascorbic acid	100000	NEG	POS	NEG	POS
Aspartame	40000	NEG	POS	NEG	POS
Benzocaine	100000	NEG	POS	NEG	POS
Benzoylecgonine	100000	NEG	POS	NEG	POS
Caffeine	100000	NEG	POS	NEG	POS
Cannabidiol	100000	NEG	POS	NEG	POS
Cocaine	100000	NEG	POS	NEG	POS
Codeine	100000	NEG	POS	NEG	POS
Desipramine HCl	100000	NEG	POS	NEG	POS
Dextromethorphan	100000	NEG	POS	NEG	POS
Dextropropoxyphene	100000	NEG	POS	NEG	POS
Diazepam	100000	NEG	POS	NEG	POS
Digoxin	100000	NEG	POS	NEG	POS
Diphenhydramine	100000	NEG	POS	NEG	POS
Diphenylhydantoin	100000	NEG	POS	NEG	POS
Doxepin	100000	NEG	POS	NEG	POS
Ecgonine	100000	NEG	POS	NEG	POS
Ecgonine methyl ester	100000	NEG	POS	NEG	POS
Erythromycin	100000	NEG	POS	NEG	POS
Furosemide	100000	NEG	POS	NEG	POS
Guaiacol glycerol ether	100000	NEG	POS	NEG	POS
Hydrochlorothiazide	100000	NEG	POS	NEG	POS
Ibuprofen	100000	NEG	POS	NEG	POS
Ketamine	100000	NEG	POS	NEG	POS
Levothyroxine	100000	NEG	POS	NEG	POS
LSD	2500	NEG	POS	NEG	POS
Meperidine	100000	NEG	POS	NEG	POS

Methadone	100000	NEG	POS	NEG	POS
Methaqualone	75000	NEG	POS	NEG	POS
Morphine	100000	NEG	POS	NEG	POS
Naloxone	100000	NEG	POS	NEG	POS
Naltrexone	100000	NEG	POS	NEG	POS
Naproxen	100000	NEG	POS	NEG	POS
Niacinamide	100000	NEG	POS	NEG	POS
Nicotine	100000	NEG	POS	NEG	POS
Nifedipine	100000	NEG	POS	NEG	POS
Nordiazepam	100000	NEG	POS	NEG	POS
Omeprazole	100000	NEG	POS	NEG	POS
Oxazepam	100000	NEG	POS	NEG	POS
Penicillin G	100000	NEG	POS	NEG	POS
Phencyclidine	40000	NEG	POS	NEG	POS
Phenobarbital	100000	NEG	POS	NEG	POS
Quinine	100000	NEG	POS	NEG	POS
Secobarbital	100000	NEG	POS	NEG	POS
Tetracycline	100000	NEG	POS	NEG	POS
Δ^9-THC	10000	NEG	POS	NEG	POS

The compounds, including methylphenidate (Ritalin), were additionally added to aliquots of pooled drug-free human urine at a concentration of 100000 ng/mL. None of these compounds gave values in the assay that were equal to or greater than 0.17 % cross-reactivity and no results were greater than the assay cutoffs (300 ng/mL, 500 ng/mL, and 1000 ng/mL), with the following exceptions.

The compounds Labetalol HCl and Trazodone were additionally added to aliquots of pooled drug-free human urine at a concentration of 100000 ng/mL. The results obtained were between 0.21 % and 0.25 % for the 300 ng/mL, 500 ng/mL and the 1000 ng/mL assay cutoffs.

The cross-reactivity for LSD was tested at a concentration of 2500 ng/mL. The results obtained were 1.89 %, 1.76 %, and 1.43 %, for the 300 ng/mL, 500 ng/mL, and 1000 ng/mL assay cutoffs respectively.

The cross-reactivity for Δ^9-THC-9-carboxylic acid was tested at a concentration of 10000 ng/mL. The results obtained were 0.56 %, 0.49 %, and 0.44 %, for the 300 ng/mL, 500 ng/mL, and 1000 ng/mL assay cutoffs respectively.

Interference

Interfering substances were added to urine containing *d*-methamphetamine (MAMP) at -25 % and +25 % of the cutoff level at the concentration listed below. The same substances were additionally added to urine containing *d*-amphetamine (AMP) at -25 % and +25 % of the cutoff level at the concentration listed below. All samples were tested and the following results were obtained on a Roche/Hitachi 917 analyzer. The value in the table indicates the level at which no interference was found for samples containing either *d*-methamphetamine or *d*-amphetamine.

Qualitative		300 ng/mL Cutoff		500 ng/mL Cutoff		1000 ng/mL Cutoff	
Compound	**Cmpd. Conc.**	**Neg Level**	**Pos Level**	**Neg Level**	**Pos Level**	**Neg Level**	**Pos Level**
Acetone	7.9 mg/mL	NEG	POS	NEG	POS	NEG	POS
Ascorbic Acid	10 mg/mL	NEG	POS	NEG	POS	NEG	POS
Conjugated Bilirubin	0.1 mg/mL	NEG	POS	NEG	POS	NEG	POS
Creatinine	2.75 mg/mL	NEG	POS	NEG	POS	NEG	POS
Ethanol	7.9 mg/mL	NEG	POS	NEG	POS	NEG	POS
Glucose	20 mg/mL	NEG	POS	NEG	POS	NEG	POS
Hemoglobin	1 mg/mL	NEG	POS	NEG	POS	NEG	POS
Human serum albumin	5 mg/mL	NEG	POS	NEG	POS	NEG	POS
Magnesium chloride*	2 mg/mL	NEG	POS	NEG	POS	NEG	POS
Oxalic Acid	2 mg/mL	NEG	POS	NEG	POS	NEG	POS
Sodium Chloride	14.6 mg/mL	NEG	POS	NEG	POS	NEG	POS
Urea	50 mg/mL	NEG	POS	NEG	POS	NEG	POS

The same experiment was performed in the semiquantitative mode for each cutoff. All negative and positive controls recovered properly in the presence of the interfering substance.

A protocol was executed in which samples containing MAMP at control levels (±25 % of cutoff) with specific gravities ranging from 1.001 to 1.020 were tested. As with the other interferences, there were no control cross-overs on any of the three assay cutoffs at either extreme specific gravity level.

An additional protocol was executed in which samples containing MAMP at control levels (±25 % of cutoff) with pH ranging from 4.5 to 8.0 were tested. As with the other interferences, there were no control cross-overs on any of the assay cutoffs at either extreme pH level.

*Results were obtained on a **cobas** c 501 analyzer.

References

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

2 Borenstein M. Central Nervous System Stimulants. In: Troy D. ed. Remington: The Science and Practice of Pharmacy. 21st ed. Baltimore, MD: Lippincott Williams & Wilkins Co 2005;1551.

3 NIDA Research Report - Methamphetamine Abuse and Addiction: NIH Publication No. 06-4210. National Institute on Drug Abuse 6001 Executive Blvd. Room 5213, Bethesda, MD 20892-9561.

4 Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 7th ed. Foster City, CA: Biomedical Publications 2004;67.

5 Armbruster DA, Schwarzhoff RH, Pierce BL, et al. Method comparison of EMIT II and ONLINE with RIA for drug screening. J Forensic Sci 1993;38:1326-1341.

6 Armbruster DA, Schwarzhoff RH, Hubster EC, et al. Enzyme immunoassay, kinetic microparticle immunoassay, radioimmunoassay, and fluorescence polarization immunoassay compared for drugs-of-abuse screening. Clin Chem 1993;39:2137-2146.

7 Rouse S, Motter K, McNally A, et al. An Abuscreen OnLine Immunoassay for the Detection of Amphetamine in Urine on the COBAS MIRA Automated Analyzer. Clin Chem 1991;37(6):995. Abstract.

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

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

10 Krishnan S, Zhang Y. Relative bioavailability of lisdexamfetamine 70-mg capsules in fasted and fed healthy adult volunteers and in solution: A single-dose, crossover pharmacokinetic study. J Clin Pharmacol 2008;48(3):293-302.

AMPS2

ONLINE DAT Amphetamines II

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 dialog.roche.com for definition of symbols used):

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

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