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Buprenorphine Enzyme Immunoassay

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
08362955190	Buprenorphine Enzyme Immunoassay (200 tests)	System-ID 07 7610 6	**cobas c** 501/502
Materials required (but not provided):			
08239886190	Buprenorphine Semi-Quantitative Calibrators Set BUP Negative Calibrator 0 ng/mL (1 x 5 mL) BUP Low/Cutoff Calibrator #1 5 ng/mL (1 x 5 mL) BUP Cutoff Calibrator #2 10 ng/mL (1 x 5 mL) BUP Intermediate Calibrator #1 20 ng/mL (1 x 5 mL) BUP Intermediate Calibrator #2 40 ng/mL (1 x 5 mL) BUP High Calibrator 75 ng/mL (1 x 5 mL)	 Code 641 Code 642 Code 643 Code 644 Code 645 Code 646	
08356661190	Buprenorphine 5 Qualitative Calibrator Set BUP Cutoff Calibrator 5 ng/mL (1 x 5 mL)	 Code 636	
08239894190	Buprenorphine 10 Qualitative Calibrator Set BUP Cutoff Calibrator 10 ng/mL (1 x 5 mL)	 Code 637	
08356670190	Buprenorphine 5 Control Set Negative Control 3 ng/mL (2 x 15 mL) Positive Control 7 ng/mL (2 x 15 mL)		
08239908190	Buprenorphine 10 Control Set Negative Control 7 ng/mL (2 x 15 mL) Positive Control 13 ng/mL (2 x 15 mL)		
09330119190	DAT Opiates Multi Control I Set (for 5 ng/mL assay) Negative Control 3 ng/mL (2 x 15 mL) Positive Control 7 ng/mL (2 x 15 mL)		
04908856160[a]	Open/Close tool (5 pieces)		

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

English

Roche does not hold the product registration for Partner Channels. The legal manufacturer indicated on the kit is solely responsible for all of the design, legal, and regulatory aspects of the product.

System information

For **cobas c** 501 analyzer:

BUP5Q: ACN 197: for qualitative assay, 5 ng/mL

BUP1Q: ACN 198: for qualitative assay, 10 ng/mL

BUPS: ACN 213: for semi-quantitative assay, 5/10 ng/mL

For **cobas c** 502 analyzer:

BUP5Q: ACN 8197: for qualitative assay, 5 ng/mL

BUP1Q: ACN 8198: for qualitative assay, 10 ng/mL

BUPS: ACN 8213: for semi-quantitative assay, 5/10 ng/mL

Intended use

The Buprenorphine Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of norbuprenorphine (a buprenorphine metabolite) in human urine at a cutoff value of 5 ng/mL and 10 ng/mL. The assay is designed for prescription use with the Roche **cobas c** 501/502 automated clinical chemistry analyzers.

The assay provides only a preliminary analytical result. A more specific alternative analytical chemistry method must be used in order to obtain a confirmed analytical result. Gas or Liquid Chromatography/Mass Spectrometry (GC-MS or LC-MS) are the preferred confirmatory methods.[1,2] Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.

Summary

Buprenorphine is a semi-synthetic opioid derived from thebaine, an alkaloid of the poppy plant, *Papaver somniferum*. It is an analgesic often used as a substitution treatment for heroin addiction or opiate dependence. Buprenorphine structurally resembles morphine but has both antagonist and agonist properties.[3] As an opioid partial agonist, buprenorphine can produce typical opioid effects and side effects such as euphoria and respiratory depression. However, its maximal effects are less than those of full agonists like heroin and methadone. At low doses, buprenorphine produces sufficient agonist effects to enable opioid-addicted individuals to discontinue the misuse of opioids without experiencing withdrawal symptoms. The agonist effects of buprenorphine increase linearly with increasing doses of the drug until they reach a plateau and no longer continue to increase with further increases in dosage. Buprenorphine also acts as an antagonist, blocking other opioids, while allowing for some opioid effect of its own to suppress withdrawal symptoms and cravings.[4] Buprenorphine is metabolized in the human liver by N-dealkylation to the pharmacologically active norbuprenorphine, which, along with the parent compound, is conjugated with glucuronic acid[5], and excreted in urine. Clearance rates are dependent on many factors, such as frequency of drug use, the amount of drug taken, metabolism rates, and even body fat content. For typical opioid-dependent patients who received a stable daily sublingual dose of 16 mg of buprenorphine and 4 mg of naloxone for at least 2 weeks, 24-hour urinary elimination is approximately 11 % of daily dose.[6] Therapeutically, buprenorphine is as effective as methadone but exhibits a much lower level of physical dependence. However, studies have shown that buprenorphine has abuse potential and may itself cause dependency.[7]

Test principle

The buprenorphine assay is a homogeneous enzyme immunoassay ready-for-use liquid reagent. The assay is based on competition between drug in the sample and drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for a fixed amount of antibody in the reagent.[8] Enzyme activity decreases upon binding to the antibody, and the drug concentration in the sample is measured in terms of enzyme activity. In the absence of drug in the sample, buprenorphine-labeled G6PDH conjugate is bound to antibody, and the enzyme activity is inhibited. On the other hand, when free drug is present in the sample, antibody binds to the free drug; the unbound buprenorphine-labeled G6PDH then exhibits its maximal enzyme activity. Active enzyme converts nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that can be measured spectrophotometrically at a 340 nm primary wavelength.

Reagents - working solutions

R1 Contains a mouse monoclonal anti-buprenorphine antibody, glucose-6-phosphate (G6P), nicotinamide adenine dinucleotide (NAD), stabilizers, and sodium azide (0.09 %) as a preservative.

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R2 Contains glucose-6-phosphate dehydrogenase (G6PDH) labeled with buprenorphine in buffer with sodium azide (0.09 %) as a preservative.

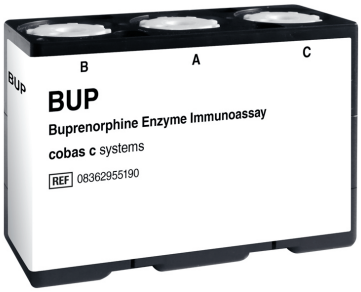
Precautions and warnings

- This test is for *in vitro* diagnostic use only. Harmful if swallowed.
- Reagents used in the assay contain sodium azide as a preservative, which may react with lead or copper plumbing to form potentially explosive metal azide. When disposing of such reagents or wastes always flush with a large volume of water to prevent azide build-up. See National Institute for Occupational Safety and Health Bulletin: Explosive Azide Hazards.[9]
- Do not use the reagents beyond their expiration dates.

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

Reagent handling

Ready for use



Filling the **cobas c** pack:

1. Turn the **cobas c** pack 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 A in the center of the **cobas c** pack using the Open/Close tool.
4. Use one of the enclosed funnels to pour the contents of the R1 bottle (24.0 mL) into the opened bottle of the **cobas c** pack (position A). Discard the funnel.
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 using the Open/Close tool.
7. Use one of the enclosed funnels to pour the contents of the R2 bottle (10.1 mL) into the opened bottle of the **cobas c** pack (position C). Discard the funnel.
8. Close the bottle tightly using the Open/Close tool.
9. Leave position B empty.

The BUP **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

Always use a new **cobas c** pack when preparing fresh reagents. Never reuse accessories designed for single use, as this may result in reagent contamination and could affect test results. If the **cobas c** pack 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:	92 days

Do not freeze.

Specimen collection and preparation

Urine samples may be collected in plastic or glass containers. Some plastics may adsorb drugs. Use of plastics such as polyethylene is recommended.[10] Use fresh urine specimens for the test. If a sample cannot be analyzed immediately, it may be refrigerated at 2-8 °C for up to seven days.[11,12] For longer storage, keep sample frozen at -20 °C and then thaw before use. Studies have shown buprenorphine analytes in urine are stable at -20 °C up to 85 days.[6] Samples should be equilibrated to room temperature (18-25 °C) for testing. Samples with high turbidity should be centrifuged before analysis. Adulteration may cause erroneous results. If sample adulteration is suspected, obtain a new sample and both samples should be forwarded to a laboratory for 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.

Handle all urine specimens as if they were potentially infectious.

Materials provided

See “Reagents – working solutions” section for reagents.

cobas c pack, 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.

Applications for urine

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

cobas c 501/502 **test definition - 5 ng/mL and 10 ng/mL cutoff assays**

	Semi-Quantitative	Qualitative
Assay type	Rate A	Rate A
Reaction time / Assay points	10 / 14-21	10 / 14-21
Wavelength (sub/main)	415/340 nm	415/340 nm
Reaction direction	Increase	Increase
Unit	ng/mL	mA/min
Reagent pipetting		
R1	90 µL	90 µL
R2	34 µL	34 µL
5 ng/mL cutoff assay		
Sample volumes	*Sample*	*Sample dilution*
		Sample *Diluent (H_2O)*
Normal	10 µL	– –
Decreased	10 µL	– –
Increased	10 µL	– –
10 ng/mL cutoff assay		
Sample volumes	*Sample*	*Sample dilution*
		Sample *Diluent (H_2O)*
Normal	10 µL	– –
Decreased	10 µL	– –
Increased	10 µL	– –

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Calibration

Calibrators	*Semi-Quantitative applications*
	5 ng/mL and 10 ng/mL cutoff assays
	S1: Buprenorphine Calibrator 0
	S2: Buprenorphine Calibrator 5
	S3: Buprenorphine Calibrator 10
	S4: Buprenorphine Calibrator 20
	S5: Buprenorphine Calibrator 40
	S6: Buprenorphine Calibrator 75
	0, 5, 10, 20, 40, 75 ng/mL
	Qualitative applications
	5 ng/mL cutoff assay
	S1: Buprenorphine Calibrator 5
	5 ng/mL (but set the concentration to 0.0 ng/mL)
	10 ng/mL cutoff assay
	S1: Buprenorphine Calibrator 10
	10 ng/mL (but set the concentration to 0.0 ng/mL)
	The drug concentrations of the calibrators have been verified by GC-MS or LC-MS.
Calibration K Factor	For the qualitative applications, enter the K Factor as positive 10000 into the Calibration menu, Status screen, Calibration Result window.
Calibration mode	*Semi-Quantitative applications*
	Result Calculation Mode (RCM)[b]
	Qualitative applications
	Linear
Calibration frequency	Full (semi-quantitative) or blank (qualitative) calibration • every 14 days • after reagent lot change • as required following quality control procedures

b) 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 or LC-MS).

Quality control

Good laboratory practices recommend the use of at least two levels of control specimens (one positive and one negative control near the cutoff) to ensure proper assay performance. Controls should be run with each new calibration and after specific maintenance or troubleshooting procedures as detailed in the instrument manual. Each laboratory should establish its own control frequency. If any trends or sudden change in control value are observed, review all operating parameters, or contact Lin-Zhi International, Inc. (LZI) technical support for further assistance. Laboratories should comply with all federal, state, and local laws, as well as all guidelines and regulations.

Results

NOTE: A preliminary positive test result does not necessarily mean that a person took illegal drugs and a negative test result does not necessarily mean that a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests.

Qualitative: The cutoff calibrator, which contains 5 ng/mL or 10 ng/mL of norbuprenorphine, is used as a reference for distinguishing preliminary positive from negative samples. Samples producing a positive or "0" absorbance value are considered preliminary positive. Preliminary positive samples are flagged with the >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 (≥ 5 ng/mL or ≥ 10 ng/mL depending on the cutoff) from negative samples only. The amount of drug detected in a preliminary positive sample cannot be estimated.

Semi-Quantitative: The semi-quantitative mode is for purposes of (1) enabling laboratories to determine an appropriate dilution of the specimen for verification by a confirmatory method such as GC-MS, LC-MS or (2) permitting laboratories to establish quality control procedures.

When an approximation of concentration is required, a calibration curve can be established with 6 calibrators. The concentration of norbuprenorphine in the sample may then be estimated from the calibration curve.

Limitations

1. A preliminary positive result from the assay indicates only the presence of norbuprenorphine.
2. The test is not intended for quantifying this single analyte in patient samples.
3. A preliminary positive result does not necessarily indicate drug abuse.
4. A negative result does not necessarily mean a person did not take illegal drugs.
5. There is a possibility that other substances and/or factors not listed above may interfere with the test and cause incorrect results (e.g., technical or procedural error, fluid intake, endogenous or exogenous interferents).
6. Preliminary positive results should be confirmed by other affirmative, analytical chemical methods (e.g., chromatography), preferably GC-MS or LC-MS.
7. The test is designed for use with human urine only.
8. The test is not for therapeutic drug monitoring.
9. There is a possibility that metabolites of other opiate drugs may interfere with the test.

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.

Specific performance data

Representative performance data on a Roche/Hitachi 717 analyzer are given below. Data was validated on a **cobas c** 501 and **cobas c** 502 analyzer and did not show any differences between the analyzers. Results obtained in individual laboratories may differ.

Precision

The assay range from 0 ng/mL to 20 ng/mL was tested in qualitative (mAbs/min) and semi-quantitative (ng/mL) mode using a modified NCCLS protocol. Results shown below were obtained by testing all samples in replicates of 2, 2 runs per day for 22 days on the Roche/Hitachi 717 automated clinical chemistry analyzer.

Qualitative analysis: Typical results (mAbs/min) are as follows:

Concentration	Within run (N = 22)			Total precision (N = 88)		
	Mean	SD	% CV	Mean	SD	% CV
0 ng/mL	400.9	3.2	0.8	400.9	5.1	1.3
2.5 ng/mL	419.6	2.7	0.6	419.6	4.0	0.9
5.0 ng/mL	439.2	3.2	0.7	439.2	5.0	1.1
7.5 ng/mL	461.2	3.3	0.7	461.2	4.7	1.0
10 ng/mL	479.2	3.2	0.7	479.2	4.5	0.9
12.5 ng/mL	495.4	3.3	0.7	495.4	4.8	1.0
15 ng/mL	511.7	3.3	0.7	511.7	4.6	0.9
17.5 ng/mL	526.8	3.2	0.6	526.8	4.5	0.9
20 ng/mL	540.3	3.5	0.6	540.3	4.5	0.8

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Additional Qualitative analysis: The following table summarizes the interpretation of the absorbance (mAbs/min) results as being either preliminary positive or negative results:

5 ng/mL Cutoff		Within run		Total precision	
Sample [ng/mL]	**% of Cutoff**	**# Samples**	**EIA result**	**# Samples**	**EIA result**
0 ng/mL	0	22	22 Neg	88	88 Neg
2.5 ng/mL	50	22	22 Neg	88	88 Neg
5.0 ng/mL	100	22	13 Neg/ 9 Pos	88	45 Neg/ 43 Pos
7.5 ng/mL	150	22	22 Pos	88	88 Pos
10 ng/mL	200	22	22 Pos	88	88 Pos

10 ng/mL Cutoff		Within run		Total precision	
Sample [ng/mL]	**% of Cutoff**	**# Samples**	**EIA result**	**# Samples**	**EIA result**
0 ng/mL	0	22	22 Neg	88	88 Neg
2.5 ng/mL	25	22	22 Neg	88	88 Neg
5.0 ng/mL	50	22	22 Neg	88	88 Neg
7.5 ng/mL	75	22	22 Neg	88	88 Neg
10 ng/mL	100	22	4 Neg/ 18 Pos	88	29 Neg/ 59 Pos
12.5 ng/mL	125	22	22 Pos	88	88 Pos
15 ng/mL	150	22	22 Pos	88	88 Pos
17.5 ng/mL	175	22	22 Pos	88	88 Pos
20 ng/mL	200	22	22 Pos	88	88 Pos

Semi-Quantitative analysis: Typical results (ng/mL) are as follows:

Concentration	Within run (N = 22)			Total precision (N = 88)		
	Mean	**SD**	**% CV**	**Mean**	**SD**	**% CV**
0 ng/mL	0.5	0.6	N/A	0.5	0.6	N/A
2.5 ng/mL	3.1	0.3	9.5	3.1	0.4	14.4
5.0 ng/mL	5.2	0.3	6.5	5.2	0.5	9.4
7.5 ng/mL	7.7	0.3	4.3	7.7	0.5	6.0
10 ng/mL	10.0	0.4	4.1	10.0	0.5	5.3
12.5 ng/mL	12.1	0.4	3.4	12.1	0.5	4.4
15 ng/mL	14.5	0.6	4.4	14.5	0.8	5.5
17.5 ng/mL	17.0	0.5	3.0	17.0	0.6	3.7
20 ng/mL	19.9	0.7	3.4	19.9	0.8	4.0

Sensitivity

Sensitivity, defined as the lowest concentration that can be differentiated from negative urine with 95 % confidence, was tested to be 2 ng/mL for both the 5 ng/mL and 10 ng/mL cutoffs.

Linearity

To demonstrate linearity for purposes of sample dilution and quality control (see semi-quantitative results section), a drug-free urine pool spiked with pure norbuprenorphine was serially diluted. Each sample was run in 10 replicates and the average was used to determine the functional linearity range of the assay. When comparing the result (y) and target (x) value, using the least squares regression technique, the regression equation and correlation are as follows:

$y = 1.0026x + 0.9053$, $r^2 = 0.991$

Expected value [ng/mL]	Observed value [ng/mL]	% recovery
2	2.3	115.0
5	5.0	99.6
10	9.9	99.4
20	20.7	103.7
30	33.2	110.8
40	44.4	111.1
50	52.7	105.3
60	56.3	93.8
70	71.4	102.1

Accuracy

90 unaltered clinical urine specimens were tested with the Buprenorphine Enzyme Immunoassay and confirmed with GC-MS. Specimens having a norbuprenorphine concentration greater than or equal to 5 ng/mL or 10 ng/mL by GC-MS are defined as positive, and specimens with lower concentrations by GC-MS are defined as negative in the table below. Near cutoff samples are defined as ± 50 % of the cutoff value. The correlation results are summarized as follows:

5 ng/mL Cutoff	Neg	< 50 % below the Cutoff	Near Cutoff Neg	Near Cutoff Pos	> 50 % above the Cutoff	% agree-ment
Positive	0	0	2*	7	47	96.4
Negative	16	6	12	0	0	100

10 ng/mL Cutoff	Neg	< 50 % below the Cutoff	Near Cutoff Neg	Near Cutoff Pos	> 50 % above the Cutoff	% agree-ment
Positive	0	0	2**	8	31	95.1
Negative	16	20	12	1***	0	98.0

The following table summarizes the results for the 5 discordant samples:

Cutoff value	Assay value	Sample composition	
		NBUP (GC-MS)	**BUP (GC-MS)**
5 ng/mL	Positive*	4.1 ng/mL	0.0 ng/mL
5 ng/mL	Positive*	4.4 ng/mL	0.0 ng/mL
10 ng/mL	Positive**	8.5 ng/mL	3.2 ng/mL
10 ng/mL	Positive**	9.5 ng/mL	0.0 ng/mL
10 ng/mL	Negative***	10.2 ng/mL	0.0 ng/mL

Analytical specificity

Cross-reactivity of various potentially interfering drugs was tested by spiking a final concentration of 100000 ng/mL of each substance into drug-free urine, and then evaluated with the assay's calibrated dose-response curve. Cross-reactivity of the parent drug buprenorphine and its glucuronic acid metabolite is listed below as well. The assay detects the parent drug buprenorphine equally to norbuprenorphine, but has only minimal cross-reactivity to either of the glucuronides.

The following table summarizes the approximate quantity of each compound that is equivalent in assay reactivity to the 5 ng/mL and 10 ng/mL norbuprenorphine cutoffs. For compounds tested at 100000 ng/mL and which gave an immunoassay result below 2 ng/mL, which is the assay's limit of detection, equivalent concentration and percent cross-reactivity are listed as "not detectable" ("ND").

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Structurally related buprenorphine compounds:

Compound	Equivalent to 5 [ng/mL]	Equivalent to 10 [ng/mL]	% cross-reactivity
Buprenorphine	4.9	9.9	101
Buprenorphine-glucuronide	3846	7692	0.1
Norbuprenorphine-glucuronide	556	1111	0.9

Structurally related opiate compounds*:

Compound	Equivalent to 5 [ng/mL]	Equivalent to 10 [ng/mL]	% cross-reactivity
6-Acetylcodeine	ND	ND	ND
Codeine	ND	ND	ND
Dextromethorphan	ND	ND	ND
Dihydrocodeine	ND	ND	ND
Heroin	192308	384615	0.003
Hydrocodone	ND	ND	ND
Hydromorphone	ND	ND	ND
Levorphanol	70423	140845	0.007
6-Monoacetylmorphine	ND	ND	ND
Morphine	ND	ND	ND
Morphine-3-glucuronide	ND	ND	ND
Morphine-6-glucuronide	ND	ND	ND
Nalorphine	ND	ND	ND
Naloxone	ND	ND	ND
Naltrexone	ND	ND	ND
Norcodeine	ND	ND	ND
Noroxycodone HCl	ND	ND	ND
Noroxymorphone HCl	ND	ND	ND
Oxycodone	ND	ND	ND
Oxymorphone	ND	ND	ND

**There is a possibility that metabolites of the compounds listed above may interfere with buprenorphine immunoassays and cause false results.*

Structurally unrelated pharmacological compounds:**

Compound	Equivalent to 5 [ng/mL]	Equivalent to 10 [ng/mL]	% cross-reactivity
α-Methadol	ND	ND	ND
Citalopram	ND	ND	ND
EDDP	ND	ND	ND
EMDP	185185	370370	0.003
Fluoxetine	ND	ND	ND
Gabapentin	ND	ND	ND
Imipramine	ND	ND	ND
LAAM	ND	ND	ND
Meperidine	ND	ND	ND
Methadone	ND	ND	ND
Norpropoxyphene	ND	ND	ND
Paroxetine	ND	ND	ND
Sertraline	ND	ND	ND
Tramadol	ND	ND	ND

***It is possible that other substances and/or factors not listed above may interfere with the test and cause false results, e.g., technical or procedure errors.*

Interference: Endogenous substances

The following endogenous compounds were spiked into negative urine and the 3 levels of controls (3 ng/mL, 7 ng/mL, and 13 ng/mL) for the assay. The spiked solutions were evaluated against the assay's calibration curve. Results indicate there is no major interference with these compounds at physiologically relevant concentrations as all spiked samples gave correct corresponding preliminary positive/negative results against the cutoff value of 5 ng/mL or 10 ng/mL. Results are summarized in the following table:

Interfering substances	Spiked	0 ng/mL Urine	3 ng/mL Control	7 ng/mL Control	13 ng/mL Control
	[mg/dL]	[ng/mL]	[ng/mL]	[ng/mL]	[ng/mL]
Acetone	1000	0.0	3.2	6.5	12.2
Ascorbic acid	400	0.4	3.3	6.5	13.2
Creatinine	500	0.9	3.8	7.1	13.0
Galactose	10	0.4	3.5	6.4	11.7
γ-Globulin	500	0.0	3.0	8.1	11.2
Glucose	1500	0.0	3.1	7.1	11.5
Hemoglobin	300	0.4	4.0	8.2	13.0
NaCl	6000	0.9	3.9	7.8	13.0
Oxalic acid	100	0.5	3.3	6.7	11.8
Human serum albumin	500	0.0	3.2	7.1	11.8
Riboflavin	7.5	0.0	3.0	7.9	12.5
Urea	2000	0.0	3.3	7.2	11.6
Ethanol	1000	0.0	3.0	8.1	11.9
pH 3	N/A	0.0	3.3	5.9	13.6
pH 11	N/A	0.0	3.7	8.0	12.7

Specific gravity: Samples ranging in specific gravity from 1.001 to 1.027 were tested with the assay in the presence of 0 ng/mL, 3 ng/mL, 7 ng/mL, and 13 ng/mL of norbuprenorphine, and no interference was observed.

Note: All endogenous substances listed above, including specific gravity, were also tested in qualitative mode. No interference was observed. The results were identical to the semi-quantitative mode, as all samples gave correct preliminary positive/negative results corresponding to the cutoff value of 5 ng/mL or 10 ng/mL.

References

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

CONTENT	Contents of kit
GTIN	Global Trade Item Number

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