DRI™ Cocaine Metabolite Assay

thermo scientific

IVD **For In Vitro Diagnostic Use Only**

Rx Only

REF **10014593 (3 x 18 mL)**
0055 (100 mL Kit)
0056 (500 mL Kit)

Intended Use

The DRI™ Cocaine Metabolite Assay is a homogeneous enzyme immunoassay intended for the qualitative and/or semi-quantitative determination of benzoylecgonine (Cocaine Metabolite) in human urine at a cutoff concentration of either 150 ng/mL or 300 ng/mL.

The semi-quantitative mode is for the purpose of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as Liquid Chromatography/tandem mass spectrometry (LC-MS/MS) or permitting laboratories to establish quality control procedures.

The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography / Mass spectrometry (GC/MS) or Liquid chromatography/tandem mass spectrometry (LC-MS/MS) are the preferred confirmatory method.[1,2] Tests for cocaine metabolite cannot distinguish between abused drugs and certain prescribed medications.

Clinical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are used. For *In Vitro Diagnostic* Use Only.

Summary and Explanation of the Test

Cocaine (benzoylmethylecgonine), is derived from the plant species Erythroxylon coca, which is widely grown in South America.[3-5]

Cocaine is a very common illicit drug and is popularly abused in the US.[3,4,6] Cocaine abuse can produce euphoria, arousal, garrulousness, alertness, anxiety, insomnia, hyperactivity, paranoia, severe psychosis, and even suicide.[3,6,7]

Cocaine is rapidly metabolized, with less than 5% excreted unchanged in the urine.[4,6,7] The two major metabolites, which result from enzymatic and nonenzymatic hydrolysis, are benzoylecgonine and ecgonine methyl ester.[4,6-9] The metabolites may be detectable in urine for up to 3 weeks after long term, heavy use of cocaine.[10,11]

The DRI Cocaine Metabolite Assay is a homogeneous enzyme immunoassay using ready-to-use liquid reagents.[12] The assay uses a specific antibody, which can detect benzoylecgonine in urine. The assay is based on the competition of an enzyme glucose-6-phosphate dehydrogenase (G6PDH) labeled drug and the drug from the urine sample for a fixed amount of specific antibody binding sites. In the presence of free drug from the sample, the free drug occupies the antibody binding sites, allowing the drug-labeled G6PDH to interact with the substrate, resulting in enzyme activity. In the absence of drug from the sample, the specific antibody binds to the drug labeled with G6PDH and the enzyme activity is inhibited. This phenomenon creates a direct relationship between the drug concentration in the urine and the enzyme activity. The enzyme G6PDH activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.

Reagents

REAGENT ***Antibody/Substrate Reagent (A)***

Contains mouse monoclonal anti-benzoylecgonine antibody, glucose-6-phosphate (G6P) and nicotinamide adenine dinucleotide (NAD) in Tris buffer with sodium azide as a preservative.

REAGENT ***Enzyme Conjugate Reagent (E)***

Contains benzoylecgonine analog labeled with glucose-6-phosphate dehydrogenase (G6PDH) in HEPES buffer with sodium azide as a preservative.

Additional Materials Required (sold separately):

REF	Kit Description
1664	DRI Negative Calibrator, 10 mL
1388	DRI Negative Calibrator, 25 mL
1588	DRI Multi-Drug Urine Calibrator 1, 10 mL
1589	DRI Multi-Drug Urine Calibrator 1, 25 mL
1591	DRI Multi-Drug Urine Calibrator 2, 10 mL
1592	DRI Multi-Drug Urine Calibrator 2, 25 mL
1594	DRI Multi-Drug Urine Calibrator 3, 10 mL
1595	DRI Multi-Drug Urine Calibrator 3, 25 mL
1597	DRI Multi-Drug Urine Calibrator 4, 10 mL
1598	DRI Multi-Drug Urine Calibrator 4, 25 mL
DOAT-2	MAS® DOA Total – Level 2, 6 x 18 mL
DOAT-3	MAS® DOA Total – Level 3, 6 x 18 mL
DOAT-4	MAS® DOA Total – Level 4, 6 x 18 mL
DOAT-5	MAS® DOA Total – Level 5, 6 x 18 mL

⚠ Precautions and Warnings

DANGER:

1. This test is for in vitro diagnostic use only. The reagents are harmful if swallowed.
2. The DRI Cocaine Metabolite Enzyme Immunoassay contains ≤0.2% bovine serum albumin (BSA) and ≤0.5% Drug-specific antibody (Mouse).
3. Reagents used in the assay components contain ≤0.09% sodium azide. Avoid contact with skin and mucous membranes. Flush affected areas with copious amounts of water. Get immediate medical attention for eyes, or if ingested. Sodium azide may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up. Clean exposed metal surfaces with 10% sodium hydroxide.
4. Do not use the reagents beyond their expiration dates.

H317 - May cause allergic skin reaction.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Avoid breathing mist or vapor. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/eye protection/face protection. In case of inadequate ventilation wear respiratory protection. If on skin: Wash with plenty of soap and water. IF INHALED: If breathing becomes difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If skin irritation or rash occurs: Get medical advice/attention. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. Wash contaminated clothing before reuse. Dispose of contents/container to location in accordance with local/regional/national/international regulations.

Reagent Preparation and Storage

The reagents are ready-to-use; no additional preparation is required. Reagents should be stored refrigerated at 2-8°C. All assay components, opened or unopened, are stable until the expiration date indicated on their respective labels. Do not use the reagents beyond their expiration dates.

Specimen Collection and Handling

Collect urine specimens in plastic or glass containers. Care should be taken to preserve the chemical integrity of the urine sample from the time it is collected until the time it is assayed.

Specimens kept at room temperature that do not receive initial test within 7 days[13] of arrival at the laboratory may be placed into a secure refrigeration unit at 2-8ºC for up to two months.[14] For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20ºC.[14,15]

Laboratories following the SAMHSA mandatory guidelines should refer to SAMHSA "Short-Term Refrigerated Storage" and "Long-Term Storage" requirements.[16]

To protect the integrity of the sample, do not induce foaming and avoid repeated freezing and thawing. An effort should be made to keep pipetted samples free of gross debris. It is recommended that grossly turbid specimens be centrifuged before analysis. Frozen samples should be thawed and mixed prior to analysis. Adulteration of the urine sample may cause erroneous results. If adulteration is suspected, obtain another sample and forward both specimens to the laboratory for testing.

Handle all urine specimens as if they were potentially infectious.

Assay Procedure

Clinical chemistry analyzers capable of maintaining a constant temperature, pipetting samples, mixing reagents, measuring enzymatic rates at 340 nm, and timing the reaction accurately can be used to perform this assay.

Before performing this assay, refer to the analyzer-specific protocol sheet that contains parameters and/or additional instructions for use.

Quality Control and Calibration[17]

Good laboratory practice suggests the use of control specimens to ensure proper assay performance. Use controls near the cutoff calibrator to validate the calibration. It is recommended that two controls be run; one with a concentration 25% below the selected cutoff (DOAT-2 for 300 ng/mL and DOAT-4 for 150 ng/mL) and the other with a concentration 25% above the selected cutoff (DOAT-3 for 300 ng/mL and DOAT-5 for 150 ng/mL). Ensure that control results are within the established ranges determined by laboratory practices and guidelines. If control results fall outside the established ranges, specimen results are invalid. All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements. Each laboratory should establish its own quality control testing frequency.

Qualitative Analysis

For qualitative analysis of samples, use the DRI Multi-Drug Urine Calibrator 1, which contains 150 ng/mL benzoylecgonine, or DRI Multi-Drug Urine Calibrator 2, which contains 300 ng/mL benzoylecgonine as a cutoff level. The cutoff calibrator is used as a reference for distinguishing "positive" from "negative" samples.

Semi-quantitative Analysis
For semi-quantitative analysis of samples, use all calibrators: Negative Calibrator, Multi-Drug Urine Calibrator 1, 2, 3 and 4 to create a standard curve to analyze the results.

Results and Expected Values

Qualitative Analysis
A sample that exhibits a change in absorbance value (ΔA) equal to or greater than the value obtained with the cutoff calibrator is considered a "positive" result. A sample that exhibits a change in absorbance value (ΔA) lower than the value obtained with the cutoff calibrator is considered a "negative" result. Refer to analyzer specific application sheet for additional information.

Semi-quantitative Analysis
An estimate of benzoylecgonine drug concentration in the samples can be obtained by running a standard curve with calibrators and then quantifying samples off that curve. Samples with results above the highest calibrator concentration (1000 ng/mL) should be diluted with negative urine and retested. The semi-quantitation of positive results enables laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GC/MS or LC-MS/MS. It also permits the laboratory to establish quality control procedures and assess control performance. Refer to the analyzer specific application sheet for detailed information.

Limitations

1. A positive result from this assay indicates only the presence of benzoylecgonine and does not necessarily correlate with the extent of physiological and psychological effects.
2. A positive result by this assay should be confirmed by another non-immunological method such as GC/MS or LC-MS/MS.
3. The test is designed for use with human urine only.
4. It is possible that other factors (eg, technical or procedural errors) and/or substances not listed in the specificity table may interfere with the test and cause false results.

Specific Performance Characteristics

Typical performance results obtained on the Beckman Coulter AU680 analyzer are shown below. The results obtained in each laboratory may differ from these data.

Precision
Samples were prepared by spiking benzoylecgonine into drug free urine at cutoff (100%), 25%, 50%, 75% and 100% above and below the cutoff and tested in both qualitative and semi-quantitative modes using a Clinical Laboratory and Standards Institute (CLSI) protocol. Results presented below were generated by testing all samples in replicates of 2, twice per day for 20 days, total n=80.

150 ng/mL Cutoff

Qualitative Study Analysis

Spiked Concentration (ng/mL)	% of Cutoff (150 ng/mL)	Total Precision (n = 80)	
		# of Determinants	Immunoassay Results (Negative/Positive)
0	-100	80	80/0
37.5	-75	80	80/0
75	-50	80	80/0
112.5	-25	80	80/0
150	100	80	22/58
187.5	+25	80	0/80
225	+50	80	0/80
262.5	+75	80	0/80
300	+100	80	0/80

Semi-quantitative Study Analysis

Spiked Concentration (ng/mL)	% of Cutoff (150 ng/mL)	Total Precision (n = 80)	
		# of Determinants	Immunoassay Results (Negative/Positive)
0	-100	80	80/0
37.5	-75	80	80/0
75	-50	80	80/0
112.5	-25	80	80/0
150	100	80	19/61
187.5	+25	80	0/80
225	+50	80	0/80
262.5	+75	80	0/80
300	+100	80	0/80

300 ng/mL Cutoff

Qualitative Study Analysis

Spiked Concentration (ng/mL)	% of Cutoff (300 ng/mL)	Total Precision (n = 80)	
		# of Determinants	Immunoassay Results (Negative/Positive)
0	-100	80	80/0
75	-75	80	80/0
150	-50	80	80/0
225	-25	80	80/0
300	100	80	31/49
375	+25	80	0/80
450	+50	80	0/80
525	+75	80	0/80
600	+100	80	0/80

Semi-quantitative Study Analysis

Spiked Concentration (ng/mL)	% of Cutoff (300 ng/mL)	Total Precision (n = 80)	
		# of Determinants	Immunoassay Results (Negative/Positive)
0	-100	80	80/0
75	-75	80	80/0
150	-50	80	80/0
225	-25	80	80/0
300	100	80	22/58
375	+25	80	0/80
450	+50	80	0/80
525	+75	80	0/80
600	+100	80	0/80

Accuracy

One hundred clinical specimens were tested using the DRI Cocaine Metabolite Assay on the Beckman Coulter AU 680 clinical chemistry analyzer and confirmed by LC-MS/MS. The results are presented as follows:

150 ng/mL Cutoff

Qualitative analysis

Candidate Device Results	Negative	<50% of cutoff concentration by LC-MS/MS (<75 ng/mL)	Near cutoff Negative (Between 50% below the cutoff and the cutoff concentration by LC-MS/MS) (75-149 ng/mL)	Near cutoff Positive (Between the cutoff and 50% above the cutoff concentration by LC-MS/MS) (150-225 ng/mL)	High Positive (Greater than 50% above the cutoff concentration by LC-MS/MS) (>225 ng/mL)
Positive	0	0	0	6	44
Negative	45	0	5	0	0

Semi-quantitative analysis

Candidate Device Results	Negative	<50% of cutoff concentration by LC-MS/MS (<75 ng/mL)	Near cutoff Negative (Between 50% below the cutoff and the cutoff concentration by LC-MS/MS) (75-149 ng/mL)	Near cutoff Positive (Between the cutoff and 50% above the cutoff concentration by LC-MS/MS) (150-225 ng/mL)	High Positive (Greater than 50% above the cutoff concentration by LC-MS/MS) (>225 ng/mL)
Positive	0	0	0	6	44
Negative	45	0	5	0	0

300 ng/mL Cutoff

Qualitative analysis

DRI Cocaine Metabolite Assay	Negative by LC-MS/MS	<50% of Cutoff concentration by LC-MS/MS (<150 ng/mL)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration as determined by LC-MS/MS) (150 - 299 ng/mL)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration as determined by LC-MS/MS) (300 - 450 ng/mL)	High Positives (Greater than 50% above cutoff concentration) (>450 ng/mL)
Positive	0	0	0	6	44
Negative	45	0	5	0	0

Semi-quantitative analysis

DRI Cocaine Metabolite Assay	Negative by LC-MS/MS	<50% of Cutoff concentration by LC-MS/MS (<150 ng/mL)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration as determined by LC-MS/MS) (150 - 299 ng/mL)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration as determined by LC-MS/MS) (300 - 450 ng/mL)	High Positives (Greater than 50% above cutoff concentration) (>450 ng/mL)
Positive	0	0	0	6	44
Negative	45	0	5	0	0

Analytical Recovery and Dilution Linearity

To demonstrate the dilution linearity for purposes of sample dilution and quality control of the entire assay range, drug free urine was spiked to the high calibrator level using benzoylecgonine (1000 ng/mL) and diluted with drug free urine to generate 9 intermediate levels. Each sample was run in replicates of 5 in semi-quantitative mode and the average was used to determine percent recovery compared to the expected target value.

Expected Benzoylecgonine Value (ng/mL)	Observed Value (ng/mL) n=5	Recovery (%)
0	0.6	N/A
102.5	103.6	101.1
205.0	213.6	104.2
307.5	294.8	95.9
410.0	413.8	100.9
512.5	510.4	99.6
615.0	640.6	104.2
717.5	781.4	108.9
820.0	880.0	107.3
922.5	952.0	103.2
1025.0	1025.0	100.0

Specificity

The cross reactivity of Cocaine and its metabolites was evaluated by adding known amounts of each substance to drug-free urine.

150 ng/mL Cutoff

Compound	Tested Concentration (ng/mL)	Positive/Negative	Cross-reactivity (%)
Benzoylecgonine	150	Positive	100
Cocaine	25,000	Positive	0.6
Cocaethylene	30,000	Positive	0.5
Ecgonine	90,000	Positive	0.17
Ecgonine Methyl Ester	100,000	Negative	< 0.15
m-hydroxybenzoylecgonine	300	Positive	50
Norcocaine	100,000	Negative	< 0.15

300 ng/mL Cutoff

Compound	Tested Concentration (ng/mL)	Positive/Negative	Cross-reactivity (%)
Benzoylecgonine	300	Positive	100
Cocaine	50,000	Positive	0.6
Cocaethylene	60,000	Positive	0.5
Ecgonine	160,000	Positive	0.19
Ecgonine Methyl Ester	100,000	Negative	< 0.3
m-hydroxybenzoylecgonine	600	Positive	50
Norcocaine	100,000	Negative	< 0.3

Structurally unrelated compounds and/or concurrently used drugs were evaluated by adding each substance to benzoylecgonine spiked at low (112.5 ng/mL for 150 ng/mL cutoff, and 225 ng/mL for 300 ng/mL cutoff) and high (187.5 ng/mL for 150 ng/mL cutoff, and 375 ng/mL for 300 ng/mL cutoff) controls at the concentrations indicated. As shown in the table below, the Controls were detected accurately, Low Control as Negative and High Control as Positive for both 150 ng/mL and 300 ng/mL cutoffs, indicating that all the compounds evaluated exhibited minimal cross-reactivity at the concentrations tested.

Structurally unrelated compounds spiked at the concentration listed below into Low and High controls

Cross Reactants	Tested Concentration (ng/mL)	150 ng/mL cutoff		300 ng/mL cutoff	
		Low Control	High Control	Low Control	High Control
11-nor-Δ9-THC-COOH	100,000	Negative	Positive	Negative	Positive
1R,2S(-)-Ephedrine	100,000	Negative	Positive	Negative	Positive
1S,2R(+)-Ephedrine	100,000	Negative	Positive	Negative	Positive
Acetaminophen	1,000,000	Negative	Positive	Negative	Positive
Acetylsalicylic acid	1,000,000	Negative	Positive	Negative	Positive
Acyclovir	75,000	Negative	Positive	Negative	Positive
Albuterol	1,000,000	Negative	Positive	Negative	Positive
Amikacin	1,000,000	Negative	Positive	Negative	Positive
Amitryptyline	100,000	Negative	Positive	Negative	Positive
Amobarbital	100,000	Negative	Positive	Negative	Positive
Amoxicillin	1,000,000	Negative	Positive	Negative	Positive
Amphetamine	1,000,000	Negative	Positive	Negative	Positive
Azithromycin	75,000	Negative	Positive	Negative	Positive
Benzocaine	1,000,000	Negative	Positive	Negative	Positive
Buprenorphine	100,000	Negative	Positive	Negative	Positive
Bupropion	100,000	Negative	Positive	Negative	Positive
Caffeine	100,000	Negative	Positive	Negative	Positive
Calcium Carbonate	5,000,000	Negative	Positive	Negative	Positive
Carbamazeprine	100,000	Negative	Positive	Negative	Positive
Carisoprodol	100,000	Negative	Positive	Negative	Positive
Chlorpromazine	500,000	Negative	Positive	Negative	Positive
Chlorzoxazone	1,000,000	Negative	Positive	Negative	Positive
cis-Tramadol	1,000,000	Negative	Positive	Negative	Positive
Clomipramine	100,000	Negative	Positive	Negative	Positive
Clonidine	100,000	Negative	Positive	Negative	Positive
Codeine	1,000,000	Negative	Positive	Negative	Positive
Cotinine	100,000	Negative	Positive	Negative	Positive
Dapsone	100,000	Negative	Positive	Negative	Positive
Desipramine	100,000	Negative	Positive	Negative	Positive
Dextromethorphan	100,000	Negative	Positive	Negative	Positive
Dihydrocodeine	100,000	Negative	Positive	Negative	Positive
Diphenhydramine	1,000,000	Negative	Positive	Negative	Positive
Doxepine	500,000	Negative	Positive	Negative	Positive
Doxycycline Hyclate	100,000	Negative	Positive	Negative	Positive
EDDP	100,000	Negative	Positive	Negative	Positive

Table continued

Cross Reactants	Tested Concentration (ng/mL)	150 ng/mL cutoff		300 ng/mL cutoff	
		Low Control	High Control	Low Control	High Control
Ethyl β-D-glucuronide	100,000	Negative	Positive	Negative	Positive
Fentanyl	100,000	Negative	Positive	Negative	Positive
Fluconazole	100,000	Negative	Positive	Negative	Positive
Fluoxetine	50,000	Negative	Positive	Negative	Positive
Gabapentin	100,000	Negative	Positive	Negative	Positive
Gentamicin	100,000	Negative	Positive	Negative	Positive
Haloperidol	100,000	Negative	Positive	Negative	Positive
Heroin	100,000	Negative	Positive	Negative	Positive
Hydrocodone	100,000	Negative	Positive	Negative	Positive
Hydromorphone	100,000	Negative	Positive	Negative	Positive
Hydroxyzine	100,000	Negative	Positive	Negative	Positive
Hyoscyamine HCl	75,000	Negative	Positive	Negative	Positive
Ibuprofen	5,000,000	Negative	Positive	Negative	Positive
Imipramine	100,000	Negative	Positive	Negative	Positive
Indomethacin	75,000	Negative	Positive	Negative	Positive
Lamotrigine	1,000,000	Negative	Positive	Negative	Positive
Levofloxacin	75,000	Negative	Positive	Negative	Positive
Lidocaine	1,000,000	Negative	Positive	Negative	Positive
Lithium heparin	5,000,000	Negative	Positive	Negative	Positive
Loratadine	500,000	Negative	Positive	Negative	Positive
LSD	100,000	Negative	Positive	Negative	Positive
Maprotiline	100,000	Negative	Positive	Negative	Positive
Meperidine	1,000,000	Negative	Positive	Negative	Positive
Mesoridazine	1,000,000	Negative	Positive	Negative	Positive
Methadone	1,000,000	Negative	Positive	Negative	Positive
Methamphetamine	100,000	Negative	Positive	Negative	Positive
Methylphenidate	100,000	Negative	Positive	Negative	Positive
Metoclopramide	1,000,000	Negative	Positive	Negative	Positive
Metronidazole	100,000	Negative	Positive	Negative	Positive
Morphine	200,000	Negative	Positive	Negative	Positive
Morphine-3β-D-glucuronide	100,000	Negative	Positive	Negative	Positive
Morphine-6β-D-glucuronide	100,000	Negative	Positive	Negative	Positive
Nalbuphine	1,000,000	Negative	Positive	Negative	Positive
Nalorphine	100,000	Negative	Positive	Negative	Positive
Naloxone	100,000	Negative	Positive	Negative	Positive
Naltrexone	1,000,000	Negative	Positive	Negative	Positive
Naproxen	5,000,000	Negative	Positive	Negative	Positive
Nitrazepam	100,000	Negative	Positive	Negative	Positive
Norbuprenorphine	100,000	Negative	Positive	Negative	Positive
Norcodeine	100,000	Negative	Positive	Negative	Positive
Nordiazepam	100,000	Negative	Positive	Negative	Positive
Norfluoxetine HCl	1,000,000	Negative	Positive	Negative	Positive
Norketamine	100,000	Negative	Positive	Negative	Positive
Norpropoxyphene	100,000	Negative	Positive	Negative	Positive
Nortriptyline	100,000	Negative	Positive	Negative	Positive
Ofloxacin	100,000	Negative	Positive	Negative	Positive
Omeprazole	75,000	Negative	Positive	Negative	Positive
Oxazepam	1,000,000	Negative	Positive	Negative	Positive
Oxycodone	100,000	Negative	Positive	Negative	Positive
Oxymorphone	100,000	Negative	Positive	Negative	Positive
Paroxetine	100,000	Negative	Positive	Negative	Positive

Table continued

Cross Reactants	Tested Concentration (ng/mL)	150 ng/mL cutoff		300 ng/mL cutoff	
		Low Control	High Control	Low Control	High Control
PCP	1,000,000	Negative	Positive	Negative	Positive
Phenelzine	75,000	Negative	Positive	Negative	Positive
Phenobarbital	1,000,000	Negative	Positive	Negative	Positive
Promethazine	100,000	Negative	Positive	Negative	Positive
Propoxyphene	750,000	Negative	Positive	Negative	Positive
Ranitidine	100,000	Negative	Positive	Negative	Positive
Risperidone	100,000	Negative	Positive	Negative	Positive
Scopolamine	1,000,000	Negative	Positive	Negative	Positive
Secobarbital	1,000,000	Negative	Positive	Negative	Positive
Sertraline	100,000	Negative	Positive	Negative	Positive
Spironolactone	750,000	Negative	Positive	Negative	Positive
Stavudine	100,000	Negative	Positive	Negative	Positive
Tapentadol	100,000	Negative	Positive	Negative	Positive
Terbinafine	750,000	Negative	Positive	Negative	Positive
Thiopental	1,000,000	Negative	Positive	Negative	Positive
Thioridazine	750,000	Negative	Positive	Negative	Positive
Tobramycin	1,000,000	Negative	Positive	Negative	Positive
Tolmetin	750,000	Negative	Positive	Negative	Positive
Trazodone	1,000,000	Negative	Positive	Negative	Positive
Trimethoprim	1,000,000	Negative	Positive	Negative	Positive
Vancomycin	1,000,000	Negative	Positive	Negative	Positive
Venlafaxine	1,000,000	Negative	Positive	Negative	Positive
Verapamil	100,000	Negative	Positive	Negative	Positive
Zolpidem Tartrate	100,000	Negative	Positive	Negative	Positive

Interference

The potential interference of pH, endogenous and exogenous physiological substances on the recovery of benzoylecgonine using DRI Cocaine Metabolite Assay was assessed. Potentially interfering substances were spiked into the low (112.5 ng/mL for 150 ng/mL cutoff, and 225 ng/mL for 300 ng/mL cutoff) and high (187.5 ng/mL for 150 ng/mL cutoff, and 375 ng/mL for 300 ng/mL cutoff) controls urine at the concentrations indicated. In the presence of the compounds listed below, the controls were detected accurately, indicating that these compounds did not show interference in the assay.

Compound	Tested Concentration (mg/dL)	150 ng/mL cutoff		300 ng/mL cutoff	
		Low Control	High Control	Low Control	High Control
Acetaminophen	10	Negative	Positive	Negative	Positive
Acetone	1000	Negative	Positive	Negative	Positive
Ascorbic Acid	1000	Negative	Positive	Negative	Positive
Aspirin	10	Negative	Positive	Negative	Positive
Caffeine	10	Negative	Positive	Negative	Positive
Creatinine	500	Negative	Positive	Negative	Positive
Ethanol	1000	Negative	Positive	Negative	Positive
Galactose	10	Negative	Positive	Negative	Positive
γ-Globulin	500	Negative	Positive	Negative	Positive
Glucose	3000	Negative	Positive	Negative	Positive
Hemoglobin	150	Negative	Positive	Negative	Positive
Human Serum Albumin	500	Negative	Positive	Negative	Positive
Ibuprofen	10	Negative	Positive	Negative	Positive
Oxalic Acid	100	Negative	Positive	Negative	Positive
Riboflavin	7.5	Negative	Positive	Negative	Positive
Sodium Chloride	1000	Negative	Positive	Negative	Positive
Urea	1250	Negative	Positive	Negative	Positive
pH	3	Negative	Positive	Negative	Positive
pH	4	Negative	Positive	Negative	Positive
pH	5	Negative	Positive	Negative	Positive
pH	6	Negative	Positive	Negative	Positive
pH	7	Negative	Positive	Negative	Positive
pH	8	Negative	Positive	Negative	Positive
pH	9	Negative	Positive	Negative	Positive
pH	10	Negative	Positive	Negative	Positive
pH	11	Negative	Positive	Negative	Positive

Specific Gravity

Drug free urine samples with specific gravity ranging in value from 1.004 to 1.029 were split and spiked with benzoylecgonine to a final concentration of either 112.5 ng/mL (Low Control) or 187.5 ng/mL (High Control) for 150 ng/mL cutoff, 225 ng/mL (Low Control) or 375 ng/mL (High Control) for 300 ng/mL cutoff. These samples were then evaluated in qualitative and semi-quantitative modes. The Controls were detected accurately, indicating that no interference was observed.

Specific Gravity	150 ng/mL cutoff		300 ng/mL cutoff	
	Low Control	High Control	Low Control	High Control
1.004	Negative	Positive	Negative	Positive
1.005	Negative	Positive	Negative	Positive
1.007	Negative	Positive	Negative	Positive
1.010	Negative	Positive	Negative	Positive
1.011	Negative	Positive	Negative	Positive
1.013	Negative	Positive	Negative	Positive
1.019	Negative	Positive	Negative	Positive
1.023	Negative	Positive	Negative	Positive
1.025	Negative	Positive	Negative	Positive
1.029	Negative	Positive	Negative	Positive

References

1. National Institute on Drug Abuse (NIDA). Urine Testing for Drugs of Abuse. *Research Monograph* **73** (1986).
2. National Institute on Drug Abuse. Mandatory Guidelines for Federal Workplace Drug Testing Programs. *Federal Register* Vol. **73**, No 228, 2008:71877.
3. Gawin FH, Ellinwood EH Jr. Cocaine and other stimulants: Actions, abuse, and treatment. *N. Engl. J. Med.* 1988, **318**: 1173-1182.
4. Jatlow, PI. Drugs of abuse profile: Cocaine. *Clin. Chem.* 1987, **33** (suppl): 66B-71B.
5. Bouknight LG, Bouknight RR. Cocaine - A particularly addictive drug. *Postgrad Med.*1988; **83**: 115-124, 131.
6. Benowitz, NL, Clinical pharmacology and toxicology of cocaine. *Pharmacol. & Toxicol.*1993; **72**: 3-12.
7. Jones RT. The pharmacology of cocaine. In: Grabowski, J.ed. Cocaine: *Pharmacology, Effects and Treatment of Abuse.* NIDA Research Monograph. 1984; **50**: 34-53.
8. Ambre J. Urinary excretion of cocaine and metabolites in humans: A kinetic analysis of published data. *J. Anal. Toxicol.* 1985; **9**: 241-245.
9. Ambre J, Ruo TI, Nelson J, Belknap S. Urinary excretion of cocaine, benzoylecgonine and ecgonine methyl ester in humans. *J. Anal. Toxicol.* 1988; **12**: 301-306.
10. Weiss RD. Gawin, FH. Protracted elimination of cocaine metabolites in long-term, high-dose cocaine abusers. Am. J. Med. 1988, **85**: 879-880.
11. Burke WM, et al. Prolonged presence of metabolite in urine after compulsive cocaine use. *J. Clin. Psychiatry.* 1990; 51:145-148.
12. Rubenstein KE, Schneider RS, and EF Ullman. Homogeneous Enzyme Immunoassay: A New Immunochemical Technique. *Biochem Biophis Res Commun* **47**: 846 (1972).
13. Kiszka M, Buszewicz G, Mądro R. This article is based on a presentation given at the 11th Meeting of the Polish Society of Forensic Medicine and Criminology, ĘódŸ, 1998.
14. Gonzales E, Ng G, Pesce A, West C, West R, Mikel C, Llaatyshev, S, Almazan P. Stability of pain-realted medications, metabolites and illicit substances in urine. *Clinica Chimca Acta* 416: (2013) 30-35.
15. C52-A2, Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline – Second Edition, *Clinical and Laboratory Standards Institute (CLSI)* (April 2007)
16. *Notice of Mandatory Guidelines for Federal Workplace Drug Testing Program: Final Guidelines; Federal Register,* Substance Abuse and Mental Health Administration (SAMHSA), (1994) 110 (June 9):11983.
17. Data on traceability are on file at Microgenics, a part of Thermo Fisher Scientific.

Glossary:

http://www.thermofisher.com/symbols-glossary

Microgenics Corporation
46500 Kato Road
Fremont, CA 94538 USA
US Customer and
Technical Support:
1-800-232-3342

EC REP
B·R·A·H·M·S GmbH
Neuendorfstrasse 25
16761 Hennigsdorf, Germany

For insert updates go to:
www.thermofisher.com/diagnostics

10025574-0-EN
2018 07

thermo scientific