

[QUALITY CONTROL]

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

[LIMITATIONS]

- The Multi-Line Rapid Test Cassette provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS), gas chromatography/liquid chromatography/mass spectrometry (GC/LC/MS), liquid chromatography/mass spectrometry (LC/MS) or liquid chromatography/liquid chromatography/mass spectrometry (LC/LC/MS) are the preferred confirmatory methods.
- A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
- A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cutoff level of the assay.

[PERFORMANCE CHARACTERISTICS]

Accuracy

Assemble each single test into the cassette before testing, and evaluate the cassette with approximately 44-280 specimens per drug type previously collected from subjects presenting for Drug Screen Testing which were confirmed by GC/MS. These specimens were randomized and tested using the Oral Fluid Drug Screen Test. Specimens were rated as either positive or negative at 10 minutes. The test results are shown in table below.

Table: Specimen Correlation

Method	GC/MS		% agreement with GC/MS	% Total agreement with GC/MS
	Positive	Negative		
Oral Fluid Drug Screen Test				
AMP 50	Positive	90	94.7%	94.8%
	Negative	5	94.8%	
BAR50	Positive	80	96.4%	95.7%
	Negative	3	95.3%	
BZO20	Positive	94	94.0%	94.8%
	Negative	6	95.5%	
COC20	Positive	38	95.0%	96.7%
	Negative	3	97.3%	
COT30	Positive	131	99.2%	98.7%
	Negative	1	98.0%	
KET 30	Positive	49	94.2%	94.5%
	Negative	5	94.6%	
KET 50	Positive	90	93.8%	94.8%
	Negative	5	95.6%	
MDMA50	Positive	96	97.0%	98.3%
	Negative	3	99.2%	
MET 50	Positive	126	99.2%	98.2%
	Negative	1	97.4%	
MTD 30	Positive	116	97.5%	97.4%
	Negative	3	97.3%	
OPI40	Positive	89	93.7%	93.8%
	Negative	6	93.9%	
OXY 20	Positive	91	97.8%	98.7%
	Negative	2	99.3%	
PCP 10	Positive	107	96.4%	97.4%
	Negative	4	98.3%	
THC 15	Positive	75	96.2%	96.8%
	Negative	3	97.1%	
THC 40	Positive	84	>99%	99.6%
	Negative	0	99.4%	

Analytical Sensitivity

A Phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of ± 50% cut-off, ± 25% cut-off and +300% cut-off and tested with the Multi-Line Rapid Test Cassette. The results are summarized below.

Drug conc. (Cut-off range)	n	AMP		MET		THC15		THC40	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	27	3	28	2	26	4	26	4
Cut-off	30	15	15	16	14	12	18	12	18
+25% Cut-off	30	7	23	6	24	8	22	8	22
+50% Cut-off	30	0	30	0	30	0	30	0	30
+300% Cut-off	30	0	30	0	30	0	30	0	30

Drug conc. (Cut-off range)	n	PCP		BZO		OPI		KET50	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	25	5	26	4	27	3	25	5
Cut-off	30	14	16	14	16	13	17	18	12
+25% Cut-off	30	10	20	5	25	7	23	8	22

+50% Cut-off	30	0	30	0	30	0	30	0	30
+300% Cut-off	30	0	30	0	30	0	30	0	30

Drug conc. (Cut-off range)	n	MTD		OXY		COT		MDMA	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	25	5	27	3	25	5	26	4
Cut-off	30	15	15	20	10	20	10	19	11
+25% Cut-off	30	7	23	4	26	7	23	6	24
+50% Cut-off	30	0	30	0	30	0	30	0	30
+300% Cut-off	30	0	30	0	30	0	30	0	30

Drug conc. (Cut-off range)	n	BAR		COC20		KET30	
		-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0
-25% Cut-off	30	23	7	27	3	25	5
Cut-off	30	16	14	15	15	16	14
+25% Cut-off	30	6	24	8	22	4	26
+50% Cut-off	30	0	30	0	30	0	30
+300% Cut-off	30	0	30	0	30	0	30

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the Multi-Line Rapid Test Cassette for AMP/MET/COC/OPI/THC/PCP/MTD/OXY/COT/MDMA/BZO/KET/BAR identified positive results at a read time of 10 minutes.

Compound	ng/mL	Compound	ng/mL
AMPHETAMINE (AMP)			
d-Amphetamine	50	p-Hydroxyamphetamine	100
d/l-Amphetamine	100	(+)-3,4-Methylenedioxyamphetamine (MDA)	100
β-Phenylethylamine	25,000	l-Amphetamine	25,000
Tryptamine	12,500	Methoxyamphetamine	12,500
METHAMPHETAMINE (MET)			
d-Methamphetamine	50	(1R,2S)-(-)-Ephedrine	400
Fenfluramine	60,000	Procaine	2,000
p-Hydroxymethamphetamine	400	l-Phenylephrine	6,250
Methoxyamphetamine	25,000	(R)-(-)-Phenylephrine	400
Mephentermine	1,500	Benzphetamine	25,000
3,4-Methylenedioxyamphetamine (MDMA)	50		
MARIJUANA (THC15)			
Δ9-THC	15	11-nor-Δ9-THC-9 COOH	12.5
Cannabinol	20,000	(-) Δ8-THC	100
(±)-11-Hydroxy-Δ9-THC	400	(±) Δ8-THC	40
MARIJUANA (THC40)			
Δ9-THC	40	11-nor-Δ9-THC-9 COOH	32
Cannabinol	40,000	(-) Δ8-THC	250
(±)-11-Hydroxy-Δ9-THC	800	(±) Δ8-THC	80
COCAINE (COC20)			
Benzoylcegonine	20	Ecgonine	1,500
Cocaine	20	Ecgonine methyl ester	12,500
Cocaehtylene	30		
OPIATES (OPI)			
Morphine	40	Norcodeine	6,250
Codeine	25	Normorphine	25,000
Ethylmorphine	25	Nalorphine	10,000
Hydromorphone	100	Oxymorphone	25,000
Hydrocodone	100	Thebaine	2,000
Levorphanol	400	Diacetylmorphine (Heroin)	50
Oxycodone	25,000	6-Monoacetylmorphine	25
Morphine 3-β-D-Glucuronide	50		
PHENCYCLIDINE (PCP)			
Phencyclidine	10	4-Hydroxyphencyclidine	2,500
METHADONE (MTD)			
Methadone	30	LAAM	200
Disopyramide	400	Doxylamine	12,500
(+)-Chlorpheniramine	6,250	Nor-LAAM	12,500
OXYCODONE (OXY)			
Oxycodone	20	Hydromorphone	10,000
Oxymorphone	40	Naloxone	5,000
Levorphanol	10,000	Naltrexone	5,000
Hydrocodone	1,500		
COTININE (COT)			
(-)-Cotinine	30	(-)-Nicotine	450
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)			
(±) 3,4-Methylenedioxyamphetamine HCl (MDMA)			50
(±) 3,4-Methylenedioxyamphetamine HCl (MDA)			300
3,4-Methylenedioxyethylamphetamine (MDE)			30
l-Methamphetamine			25,000

BENZODIAZEPINES (BZO)			
Oxazepam	20	7-Amino-clonazepam	10,000
Alprazolam	200	Bromazepam	20
Chlordiazepoxide	100	Clonazepam	2,000
Desalkylflurazepam	1,000	Diazepam	100
Estazolam	160	Flunitrazepam	1,000
Furosemide	10,000	Lorazepam	1,400
Midazolam	2,000	Midazolam Maleate	5,000
Nefopam	2,000	Nitrazepam	50
Norchlordiazepoxide	50	Oxolinic acid	100,000
Pheniramine	100,000	Theophylline	100,000
α-Hydroxyalprazolam	100		
KETAMINE (KET50)			
Ketamine	50	Mephentermine	1250
Tetrahydrozoline	20	Phencyclidine	625
Benzphetamine	1250	(1R, 2S) - (-)-Ephedrine	5000
d-Methamphetamine	1250	Promazine	1250
(+) Chlorpheniramine	1250	4-Hydroxyphencyclidine	2500
l-Methamphetamine	2500	Promethazine	1250
Clonidine	5000	Levorphanol	2500
Methoxyphenamine	625	Thioridazine	2500
Disopyramide	625	MDE	2500
d-Norpropoxyphene	625	Meperidine	1250
EDDP	2500	Dextromethorphan	75
Pentazocine	1250	(+)-3,4-Methylenedioxyamphetamin helamine (MDMA)	5000
KETAMINE (KET30)			
Ketamine (KET)	30	Norketamine	400
(±)-Chlorpheniramine	50,000	Pantoprazole Sodium	50,000
Levorphanol	50	hydromorphone	2,500
Meperidine (Pethidine)	50,000	Promethazine	50,000
Naloxone	10,000	d-Pseudoephedrine	100,000
Naltrexone	2,500	Phencyclidine	100
EDDP			
(2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine)	5,000	Tetrahydrozoline	5,000
Normorphine	50,000	Heroin (diacetylmorphine)	50,000
Oxymorphone	1,000	Methamphetamine Hydrochloride	50,000
Pheniramine	50,000	R (-)-Methamphetamine	50,000
BARBITURATES (BAR)			
Amobarbital	500	Cyclopentobarbital	4170
5,5-Diphenylhydantoin	1000	Penobarbital	4000
Allobarbitol	75	Alphenol	50
Barbital	1000	Aprobarbital	75
Talbutal	5	Butabarbital	25
Talbutal	1000	Butethal	75
Phenobarbital	50	Secobarbital	50

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on the Multi-Line Rapid Test Cassette when tested with at concentrations up to 100 µg/mL.

Acetaminophen	Acetophenetidin
N-Acetylprocainamide	Acetylsalicylic acid
Aminopyrine	Amoxicillin
Ampicillin	l-Ascorbic acid
Apomorphine	Aspartame
Atropine	Benzilic acid
Benzoic acid	d/l-Brompheniramine
Caffeine	Chloral-hydrate
Chloramphenicol	Chlorothiazide
d/l-Chlorpheniramine	Chlorpromazine
Chloroquine	Cholesterol
Cortisone	l-Cotinine
Creatinine	Deoxycorticosterone
Diclofenac	Diflunisal
Digoxin	Diphenhydramine
l-ψ-Ephedrine	β-Estradiol
Estrone-3-sulfate	Ethyl-p-aminobenzoate
(-)-Epinephrine	Erythromycin
Fenopropfen	Furosemide
Genticic acid	Hemoglobin
Hydrochlorothiazide	Hydralazine
o-Hydroxyhippuric acid	Hydrocortisone
Ibuprofen	p-Hydroxytyramine
d/l-Isoproterenol	lproniazid
Ketoprofen	Isoxsuprine
Loperamide	Labelol
Methylphenidate	Meprobarbale
Naproxen	Nalidixic acid
Nifedipine	Niacinamide
Noscapine	Norethindrone
Oxalic acid	d/l-Octopamine
Oxymelazoline	Oxolinic acid
Penicillin-G	Papaverine
Phenelzine	Perphenazine
hydrochloride	Trans-2-phenylcyclopropylamine
Prednisolone	Phenylpropanolamine
d/l-Propranolol	Prednisone
d-Pseudoephedrine	d-Propoxyphene
Quinine	Quinacrine
	Quindine