Instructions

FOR IN VITRO DIAGNOSTIC USE ONLY

AMPHETAMINE / BARBITURATES / BENZODIAZEPINES /BUPRENORPHINE/ COCAINE / MDMA / METHAMPHETAMINE / METHADONE / MORPHINE 300 / OPIATES 2000 / OXYCODONE / PHENCYCLIDINE / THC/ TRICYCLIC ANTIDEPRESSANTS

This is a CLIA Waived test. You need a CLIA certificate of waiver to perform the test in waived settings. Go to http://www.cms.hhs.gov/CLIA/ for more information.
A rapid, screening test for the simultaneous, qualitative detection of multi-drug and drug metabolites in human urine. The tests are the first step in a two-step process. The second step is to send the sample for laboratory testing if preliminary positive results are obtained.

Intended Use

The DrugSmart Cup® is a rapid immunoassay for the qualitative and simultaneous detection of multiple drugs and drug metabolites in human urine at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP)	d-Amphetamine	1000 ng/mL
Barbiturates (BAR)	Secobarbital /Pentobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Buprenorphine (BUP)	Buprenorphine	10 ng/mL
Cocaine (COC)	Benzoylecgonine	300 ng/mL
Ecstasy (MDMA)	d,l-Methylenedioxymethamphetamine	500 ng/mL
Methamphetamine (MET)	d-Methamphetamine	1000 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Morphine (MOR/OPI300)	Morphine	300 ng/mL
Opiates 2000 (OPI)	Morphine	2000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9-COOH	50 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1000 ng/mL

The tests are used to obtain visual qualitative results.

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed assay result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Mass Spectrometry (LC/MS) is the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

Summary and Explanation

The DrugSmart Cup® is based on the principle of immunochemical reactions of antigens and antibodies, which are used for the analysis of specific compounds in human urine. The tests are rapid, visual, can be used for the simultaneous, qualitative detection of Amphetamine, Benzoylecgonine, Methamphetamine, Phencyclidine, 11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid, Benzodiazepines, Barbiturates, Buprenorphine, MDMA (Ecstasy), Methadone, Morphine 300, Opiates 2000, Oxycodone and Tricyclic Antidepressants in urine. The length of time following drug use for which a positive result may occur is dependent upon several factors including the frequency of use, amount of drug, metabolic rate, excretion rate, drug half-life, the drug user's age, weight, activity and diet. Each drug is detected and cleared by the body at different rates. Please refer to the table below:

Drug of Abuse	*Detection Times*	*Clearance Rates*
AMP	*Within 4 to 6 hours after use*	*For 2 to 3 days after use*
BAR	*Within 2 to 6 hours after use*	*For 1 day after use, 2 to 3 weeks for chronic abusers.*
BZO	*Within 4 to 6 hours after use*	*For 3 days after use, 4 to 6 weeks for chronic abusers.*
BUP	*Within 2 to 4 hours after use*	*For 2 to 7 days after use*
COC	*Within 2 to 6 hours after use*	*For 2 to 3 days after use*
MDMA	*Within 1 to 6 hours after use*	*For 2 to 3 days after use*
MET	*Within 4 to 6 hours after use*	*For 2 to 3 days after use*
MTD	*Within 2 to 6 hours after use*	*For 2 to 6 days after use*
MOR/OPI300	*Within 2 to 6 hours after use*	*For 1 to 3 days after use*
OPI 2000	*Within 2 to 6 hours after use*	*For 1 to 3 days after use*
OXY	*Within 2 to 6 hours after use*	*For 2 to 3 days after use*
PCP	*Within 4 to 6 hours after use*	*For 7 to 14 days after use*
TCA	*Within 8 to 12 hours after use*	*For 2 to 10 days after use*
THC	*Within 1 to 3 hours after use*	*For 3 to 10 days after use, 10 to 20 days for chronic abusers*

Specimen Collection and Preparation

Fresh urine does not require any special handling or pretreatment. A fresh urine sample should be collected in the test cup with a minimum of 30ml volume. The DrugSmart Cup® employs a thermal strip to validate the urine collection. This device should be checked immediately after collection.

Test Procedure

IMPORTANT: *The test device should be brought to room temperature (15-30 ℃) prior to testing. Do not open pouches until ready to perform the assay.*

1. Tear open the foil pouch and remove the Test Cup.
2. Issue the device to the individual to be tested.
3. Have them urinate directly into the Test Cup. Ensure the specimen is above the minimum level line indicated on the test cup label.
4. The cup must be returned immediately to the collector. Authorized personnel at the collection site is to remove tear-off label and read the results at five minutes post collection.

NOTE: In order to prevent any incorrect results, the test results should **not** be interpreted after 10 minutes

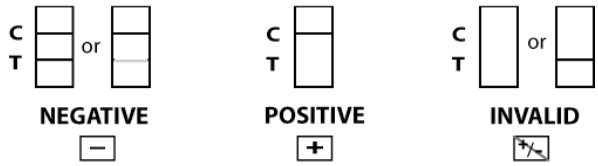
Interpretation of Results

Negative: A colored line appears in the control (C) region and a colored line appears in the test region (T). This negative result indicates that the drug concentration in the urine specimen is below the designated cut-off levels for the drug tested. The color intensity of the line for the drug may be weaker or stronger than that of the control line.

Positive: A colored line(s) appears in the control region (C). The absence of a colored line in the test region (T) indicates a positive result.

Invalid: No line appears in the control region (C). Under no circumstances should a positive sample be identified until the control line (C) forms in the viewing area. If the control line (C) does not form, the test result is inconclusive and the assay should be repeated with a new device.

There is no meaning attributed to line color intensity or width. Any evidence of a line should be considered a line. Each test strip is read individually and independently of one another.



Kit Contents

Each DrugSmart Cup® Kit contains:
1. One (1) Package Insert (PI)
2. Twenty-five (25) DrugSmart Cups.

Product Storage

The pouched DrugSmart Cup® should be stored at normal humidity and room temperature or refrigerated (2-30ºC) until the expiration date stated on the pouch. The product is sensitive to humidity and should be used immediately after being opened. Any test in an improperly sealed pouch should be discarded.

Warning and Precautions

This test is only the first step in a two-step process for determining the presence of drugs of abuse in urine. You must consult your health care provider or refer all "preliminary" results produced by this product to the reference laboratory in order to obtain a confirmed result. Judgment should be applied to any drugs of abuse test result, particularly when initial results are "preliminary".
Remember, without confirmation testing, you cannot accept any preliminary positive test result as final. The DrugSmart Cup® provides a screening result only. It is not designed to determine the actual concentration of a drug and it is not to be used for definitive sample analysis.

- Keep test device in the sealed pouch until use. Discard the test device if the foil pouch is ripped or torn.
- Urine specimens are potentially hazardous and should be handled in the same manner as an infectious agent. Dispose of specimen according to local, state and federal regulations.
- Do not reuse the same container for different urine sample collection. Don't combine specimens.
- Don't reuse the device and don't use expired devices.

Quality Control

If you work in a laboratory, you should perform quality control testing and read this section. A built-in procedural control is included in the test by using a different antigen/antibody reaction at the control region (C) on each test strip. This control line should always appear regardless of the presence of drug or metabolite. If the control line does not appear, the test device should be discarded. The presence of this control line in the control region serves as 1) verification that sufficient volume is added and 2) that proper flow is obtained.
Good Laboratory Practice recommends the use of control materials to ensure proper device performance. External controls are not provided in the kit. However, they are available from commercial sources and it is recommended that positive and negative controls be used to verify proper test performance. Use the same assay procedure as with a urine specimen. Quality control testing should be performed with each new lot shipment of product. Users should follow the appropriate federal, state, and local guidelines concerning the running of external quality controls.

Limitations of Procedure

- The assay is designed for use with human urine only.
- A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication.
- False positives and false negatives can occur with any screening drug test. A false positive in an instance where the screening test result is positive, even though the initial target drug is not present in the sample. A false negative is an instance where the initial target drug is present but the screening test result is negative. There is a possibility that substances may interfere with the test and cause false results. See SPECIFICITY for lists of substances that will produce either positive results, or that do not interfere with test performance.
- If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drugs of abuse and certain foods and medicines.

Performance Characteristics

Accuracy (Method Comparison)

The following compounds were qualified by GC/MS and contributed to the total amount of drugs found in presumptive positive urine samples tested.

Amphetamine (AMP): In this study, one hundred-thirty four (134) negative and positive urine samples (0 to 6,854 ng/mL) were tested and compared with GC/MS. The results are summarized below:
Positive Agreement: 97.6% and Negative Agreement: 100%

Drug Screen Test	**Concentrations By GC/MS** (ng/mL)				% Agreement
	(-)		(+)		
	Negative (<50% of the C/O)	Near cutoff (50% of the C/O to the C/O)	Near cutoff (Cutoff to 150% of the C/O)	High positive (> 150% of the C/O)	
(+)	0	0	16	25	97.6%
(-)	67	25	1	0	100%
Total	67	25	17	25	98.8%

One (1) discordant result is listed below:

Cutoff Value (ng/mL)	Analyte assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL)	
		Drug/ Metabolite	GC/MS Value (ng/mL)
Amphetamine 1000	-	Amphetamine	1,061

The discordant result was confirmed at the drug cutoff level.

Barbiturates (BAR): In this study, ninety-five (95) negative and positive urine samples (0 to 735 ng/mL) were tested and compared with GC/MS. The results are summarized below:
Positive Agreement: 100% and Negative Agreement: 100%

Drug Screen Test	**Concentrations By GC/MS** (ng/mL)				% Agreement
	(-)		**(+)**		
	Negative (<50% of the C/O)	Near cutoff (50% of the C/O to the cutoff)	Near cutoff (Cutoff to 150% of the C/O)	High positive (>150% of the C/O)	
(+)	0	0	12	28	100%
(-)	44	11	0	0	100%
Total	44	11	12	28	100%

Benzodiazepines (BZO): In this study, ninety (90) negative and positive urine samples (0 to 2,367 ng/mL) were tested and compared with GC/MS. The results are summarized below:
Positive Agreement: 100% and Negative Agreement: 98%

Drug Screen Test	**Concentrations By GC/MS** (ng/mL)				% Agreement
	(-)		**(+)**		
	Negative (<50% of the C/O)	Near cutoff (50% of the C/O to the cutoff)	Near cutoff (Cutoff to 150% of the C/O)	High positive (>150% of the cutoff)	
(+)	0	1	15	25	100%
(-)	40	9	0	0	98%
Total	40	10	15	25	98.8%

One discordant result is listed below:

Cutoff Value (ng/mL)	Analyte assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL)	
		Drug/Metabolite	GC/MS Value (ng/mL)
Benzodiazepines 300	+	Oxazepam	253

The discordant result was confirmed at the drug cutoff level.

Buprenorphine (BUP): In this study, a total of ninety-four (94) clinical urine samples (0 to 692 ng/mL) were tested and compared with GC/MS. The results are summarized below:
Positive Agreement: 100% and Negative Agreement: 96.3%

Drug Screen Test	**Concentrations By GC/MS** (ng/mL)				% Agreement
	(-)		**(+)**		
	Negative (< 50% of the C/O)	Near cutoff (50% of the C/O to the cutoff)	Near cutoff (Cutoff to 150% of the C/O)	High positive (> 150% of the C/O)	
(+)	0	2	6	34	100 %
(-)	45	7	0	0	96.3 %
Total	45	9	6	34	97.7 %

Two (2) discordant results are listed below:

Cutoff Value (ng/mL)	Analyte assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL)	
		Drug/ Metabolite	GC/MS Value (ng/mL)
Buprenorphine 10	+	BUP	9.5
Buprenorphine 10	+	BUP	9.8

The discordant results were confirmed at the drug cutoff level.

Cocaine (COC): In this study, ninety (90) negative and positive urine samples (0 to 1,245 ng/mL) were tested and compared with GC/MS. The results are summarized below:
Positive Agreement: 100% and Negative Agreement: 98%

Drug Screen Test	**Concentrations By GC/MS** (ng/mL)				% Agreement
	(-)		**(+)**		
	Negative (< 50% of the C/O)	Near cutoff (50% of the C/O to the cutoff)	Near cutoff (Cutoff to 150% of the C/O)	High positive (> 150% of the C/O)	
(+)	0	1	15	25	100%
(-)	40	9	0	0	98%
Total	40	10	15	25	98.8%

One (1) discordant result is listed below:

Cutoff Value (ng/mL)	Analyte assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL)	
		Drug/ Metabolite	GC/MS Value (ng/mL)
Cocaine 300	+	Benzoylecgonine	292

The discordant result was confirmed at the drug cutoff level.

Ecstasy (MDMA): In this study, ninety-seven (97) negative and positive urine samples (0 to 12,133 ng/mL), were tested and compared with GC/MS. The results are summarized below:
Positive Agreement: 100% and Negative Agreement: 98.3%

Drug Screen Test	**Concentrations By GC/MS** (ng/mL)				% Agreement
	(-)		**(+)**		
	Negative (< 50% of the C/O)	Near cutoff (50% of the C/O to the cutoff)	Near cutoff (Cutoff to 150% of the C/O)	High positive (>150% of the C/O)	
(+)	0	1	12	28	100%
(-)	42	14	0	0	98.3%
Total	42	15	12	28	98.9%

The one discordant result is listed below:

Cutoff Value (ng/mL)	Analyte assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL)	
		Drug/Metabolite	GC/MS Value (ng/mL)
MDMA 500	+	MDMA	498

Methamphetamine (MET): In this study, ninety (90) negative and positive urine samples (0 to 2,594 ng/mL), were tested and compared with GC/MS. The results are summarized below:
Positive Agreement: 100% and Negative Agreement: 100%

Drug Screen Test	**Concentrations By GC/MS** (ng/mL)				% Agreement
	(-)		**(+)**		
	Negative (< 50% of the C/O)	Near cutoff (50% of the C/O to the cutoff)	Near cutoff (Cutoff to 150% of the C/O)	High positive (> 150% of the C/O)	
(+)	0	0	15	25	100%
(-)	40	10	0	0	100%
Total	40	10	15	25	100%

Methadone (MTD): In this study, ninety (90) negative and GC/MS confirmed positive urine samples (0 to 1,127 ng/mL) were tested and compared with GC/MS. The results are summarized below:
Positive Agreement: 100% and Negative Agreement: 100%

Drug Screen Test	**Concentrations By GC/MS** (ng/mL)				% Agreement
	(-)		**(+)**		
	Negative (< 50% of the C/O)	Near cutoff (50% of the C/O to the cutoff)	Near cutoff (Cutoff to 150% of the C/O)	High positive (>150% of the C/O)	
(+)	0	0	14	26	100%
(-)	40	10	0	0	100%
Total	40	10	14	26	100%

Morphine 300 (MOR): In this study, one hundred and forty (140) negative and positive urine samples (0 to 7,010 ng/mL) were tested and compared with GC/MS. The results are summarized below:
Positive Agreement: 100% and Negative Agreement: 100%

Drug Screen Test	**Concentrations By GC/MS** (ng/mL)				% Agreement
	(-)		**(+)**		
	Negative (< 50% of the C/O)	Near cutoff (50% of the C/O to the cutoff)	Near cutoff (Cutoff to 150% of the C/O)	High positive (> 150% of the C/O)	
(+)	0	0	16	74	100%
(-)	40	10	0	0	100%
Total	40	10	16	74	100%

Opiates 2000 (OPI): In this study, ninety-one (91) negative and positive urine samples (0 to 7,010 ng/mL) were tested and compared with GC/MS. The results are summarized below:
Positive Agreement: 100% and Negative Agreement: 98%

Drug Screen Test	**Concentrations By GC/MS** (ng/mL)				% Agreement
	(-)		**(+)**		
	Negative (< 50% of the C/O)	Near cutoff (50% of the C/O to the cutoff)	Near cutoff (Cutoff to 150% of the C/O)	High positive (>150% of the C/O)	
(+)	0	1	14	27	100%
(-)	40	9	0	0	98%
Total	40	10	14	27	98.9%

One discordant result is listed below:

Cutoff Value (ng/mL)	Analyte assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL)	
		Drug/ Metabolite	GC/MS Value (ng/mL)
Opiates 2000	+	Morphine and Codeine	1,701

The discordant result was confirmed at the drug cutoff level.

Oxycodone (OXY): In this study, ninety (90) negative and positive urine samples (0 to 2,566 ng/mL) were tested and compared with GC/MS. The results are summarized below:
Positive Agreement: 100% and Negative Agreement: 100%

Drug Screen Test	**Concentrations By GC/MS** (ng/mL)				% Agreement
	(-)		**(+)**		
	Negative (< 50% of the C/O)	Near cutoff (50% of the C/O to the cutoff)	Near cutoff (Cutoff to 150% of the C/O)	High positive (>150% of the C/O)	
(+)	0	0	9	31	100%
(-)	40	10	0	0	100%
Total	40	10	9	31	100%

Phencyclidine (PCP): In this study, ninety-one (91) negative and GC/MS confirmed positive urine samples (0 to 111.5 ng/mL) were tested and compared with GC/MS. The results are summarized below:
Positive Agreement: 100% and Negative Agreement: 98%

Drug Screen Test	**Concentrations By GC/MS** (ng/mL)				% Agreement
	(-)		**(+)**		
	Negative (< 50% of the C/O)	Near cutoff (50% of the C/O to the cutoff)	Near cutoff (Cutoff to 150% of the C/O)	High positive (> 150% of the C/O)	
(+)	0	1	16	24	100 %
(-)	40	10	0	0	98 %
Total	40	11	16	24	98.8%

One discordant result is listed below:

Cutoff Value (ng/mL)	Analyte assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL)	
		Drug/Metabolite	GC/MS Value (ng/mL)
PCP 25	+	Phencyclidine	24.6

The discordant result was confirmed at the drug cutoff level.

THC: In this study, ninety-one (91) negative and positive urine samples (0 to 172 ng/mL) were tested and compared with GC/MS. The results are summarized below:
Positive Agreement: 100% and Negative Agreement: 100%

Drug Screen Test	**Concentrations By GC/MS** (ng/mL)				% Agreement
	(-)		**(+)**		
	Negative (< 50% of the C/O)	Near cutoff (50% of the C/O to the cutoff)	Near cutoff (Cutoff to 150% of the C/O)	High positive (> 150% of the C/O)	
(+)	0	0	15	25	100%
(-)	40	11	0	0	100%
Total	40	11	15	25	100%

Tricyclic Antidepressants (TCA): In this study, ninety-five (95) clinical urine samples (0 to 17,828 ng/mL) were tested and compared with GC/MS. The results are summarized below:
Positive Agreement: 100% and Negative Agreement: 100%

Drug Screen Test	**Concentrations By GC/MS** (ng/mL)				% Agreement
	(-)		(+)		
	Negative (< 50% of the C/O)	Near cutoff (50% of the C/O and cutoff)	Near cutoff (Cutoff to 150% of the C/O)	High positive (> 150% of the C/O)	
(+)	0	0	12	28	100%
(-)	46	9	0	0	100%
Total	46	9	12	28	100%

OTC Lay-User Studies

The study was conducted by 100 OTC lay-users from three (3) separate sites by using GC/MS value assigned spiked urine samples. Five (5) levels of the urine samples (drug-free, 50%, 75%, 125%, and 150% of the cutoff) were blind labeled and distributed to each lay-user. Each lay-user tested up to two (2) samples with the DrugSmart Cup® devices. The test results are tabulated below:

Drug Screen Test		(-)			(+)		% Agreement with GC/MS values
		No drug present	GC/MS Negative (50% of the C/O)	Near cutoff Negative (75% of the cutoff)	Near cutoff positive (125% of the C/O)	GC/MS Positive (150% of the C/O)	
AMP	(+)	0	0	0	10	10	100%
	(-)	60	10	10	0	0	100%
BAR	(+)	0	0	0	10	10	100%
	(-)	60	10	10	0	0	100%
BUP	(+)	0	0	0	10	10	100%
	(-)	60	10	10	0	0	100%
BZO	(+)	0	0	0	10	10	100%
	(-)	60	10	10	0	0	100%
COC	(+)	0	0	0	10	10	100%
	(-)	60	10	10	0	0	100%
MDMA	(+)	0	0	0	10	10	100%
	(-)	60	10	10	0	0	100%
MET	(+)	0	0	0	10	10	100%
	(-)	60	10	10	0	0	100%
MTD	(+)	0	0	0	10	10	100%
	(-)	60	10	10	0	0	100%
MOR	(+)	0	0	0	10	10	100%
	(-)	60	10	10	0	0	100%
OPI 2000	(+)	0	0	0	10	10	100%
	(-)	60	10	10	0	0	100%
OXY	(+)	0	0	0	10	10	100%
	(-)	60	10	10	0	0	100%
PCP	(+)	0	0	0	10	10	100%
	(-)	60	10	10	0	0	100%
TCA	(+)	0	0	0	10	10	100%
	(-)	60	10	10	0	0	100%
THC	(+)	0	0	1	10	10	100%
	(-)	60	10	9	0	0	99%

Cutoff Characterization

The sensitivity of the DrugSmart Cup® devices were determined by testing GC/MS confirmed controls at concentrations of 50%, 75% of the cutoff, cutoff, 125% and 150% of the cutoff. The results are summarized below:

Control Level	# of Tests	No. of Negative Results			# of Preliminary Results
		AMP	BAR	No. of Neg.	
0	420	210	210	420	0
50% of the cutoff	60	30	30	60	0
75% of the cutoff	60	30	30	60	0
Cut-off	60	14	14	28	32
125% of the cutoff	60	0	0	0	60
150% of the cutoff	60	0	0	0	60

Control Level	# of Tests	No. of Negative Results			# of Preliminary Results
		BZO	COC	No. of Neg.	
0	420	210	210	420	0
50% of the cutoff	60	30	30	60	0
75% of the cutoff	60	30	30	60	0
Cut-off	60	15	12	27	33
125% of the cutoff	60	0	0	0	60
150% of the cutoff	60	0	0	0	60

Control Level	# of Tests	No. of Negative Results			# of Preliminary Results
		MDMA	MET	No. of Neg.	
0	420	210	210	420	0
50% of the cutoff	60	30	30	60	0
75% of the cutoff	60	30	30	60	0
Cut-off	60	13	14	27	33
125% of the cutoff	60	0	0	0	60
150% of the cutoff	60	0	0	0	60

Control Level	# of Tests	No. of Negative Results			# of Preliminary Results
		MTD	MOR	No. of Neg.	
0	420	210	210	420	0
50% of the cutoff	60	30	30	60	0
75% of the cutoff	60	30	30	60	0
Cut-off	60	17	14	31	29
125% of the cutoff	60	0	0	0	60
150% of the cutoff	60	0	0	0	60

Control Level	# of Tests	No. of Negative Results			# of Preliminary Results
		PCP	OXY	No. of Neg.	
0	420	210	210	420	0
50% of the cutoff	60	30	30	60	0
75% of the cutoff	60	30	30	60	0
Cut-off	60	12	14	26	34
125% of the cutoff	60	0	0	0	60
150% of the cutoff	60	0	0	0	60

Control Level	# of Tests	No. of Negative Results			# of Preliminary Results
		THC	OPI 2000	No. of Neg.	
0	420	210	210	420	0
50% of the cutoff	60	30	30	60	0
75% of the cutoff	60	30	30	60	0
Cut-off	60	15	12	27	33
125% of the cutoff	60	0	0	0	60
150% of the cutoff	60	0	0	0	60

Control Level	# of Tests	No. of Negative Results		No. of Neg.	# of Preliminary Results
		BUP	TCA		
0	60	30	30	60	0
50% Cut-off	60	30	30	60	0
75% Cutoff	60	30	30	60	0
Cutoff	60	20	29	49	11
125% Cutoff	60	0	0	0	60
150% Cutoff	60	0	0	0	60

Precision (Reproducibility)

The study data demonstrates that the DrugSmart Cup® is able to produce consistent results from lot-to-lot, operator-to-operator in day-to-day runs during repeated measurements. Studies were conducted with three (3) lots of the product by three (3) operators over up to ten (10) non-consecutive days using blind coded GC/MS confirmed controls at concentrations of 50%, 75% of the cutoff, cut-off, 125% and 150% of the cut-off levels. The results are summarized below:

Control Level (Cut-Off Range)	AMP 1000		BAR 300		BZO 300	
	Total (n = 360)		Total (n = 360)		Total (n = 360)	
	+	-	+	-	+	-
Negative	0	210	0	210	0	210
50% cutoff	0	30	0	30	0	30
75% cutoff	0	30	0	30	0	30
Cutoff	16	14	16	14	15	15
125% cutoff	30	0	30	0	30	0
150% cutoff	30	0	30	0	30	0

Control Level (Cut-Off Range)	COC 300		MDMA 500		MET 1000	
	Total (n = 360)		Total (n = 360)		Total (n = 360)	
	+	-	+	-	+	-
Negative	0	210	0	30	0	210
50% cutoff	0	30	0	30	0	30
75% cutoff	0	30	0	30	0	30
Cutoff	18	12	17	13	16	14
125% cutoff	30	0	30	0	30	0
150% cutoff	30	0	30	0	30	0

Control Level (Cut-Off Range)	MTD 300		MOR		OPI 2000		OXY 100	
	Total (n = 360)		Total (n = 360)		Total (n = 360)		Total (n = 360)	
	+	-	+	-	+	-	+	-
Negative	0	210	0	210	0	210	0	210
50% cutoff	0	30	0	30	0	30	0	30
75% cutoff	0	30	0	30	0	30	0	30
Cutoff	13	17	16	14	18	12	16	14
125% cutoff	30	0	30	0	30	0	30	0
150% cutoff	30	0	30	0	30	0	30	0

Control Level (Cut-Off Range)	PCP 25		THC 50		BUP 10		TCA 1000	
	Total (n = 360)		Total (n = 360)		Total (n = 180)		Total (n = 180)	
	+	-	+	-	+	-	+	-
Negative	0	210	0	210	0	30	0	30
50% cutoff	0	30	0	30	0	30	0	30
75% cutoff	0	30	0	30	0	30	0	30
Cutoff	18	12	15	15	10	20	1	29
125% cutoff	30	0	30	0	30	0	30	0
150% cutoff	30	0	30	0	30	0	30	0

Specificity

The specificity for the DrugSmart Cup® has been tested by adding various drugs, drug metabolites, and other structurally related compounds that are likely to be present in normal human urine. The following compounds were found to produce positive results when tested at levels greater than the concentrations (in ng/mL) listed below:
Amphetamine related compounds:

Substances	**Concentration** (ng/mL)	**% Cross Reactivity**
d-Amphetamine	1,000	100
d,l-Amphetamine	2,500	40
l-Amphetamine	>100,000	< 1
d-Methamphetamine	>100,000	< 1
l- Methamphetamine	>100,000	< 1
(d,l)-MDMA [(d,l)-3,4-Methylenedioxymethamphetamine]	>100,000	< 1
Ephedrine	>100,000	< 1
Pseudoephedrine	>100,000	< 1
(d,l)3,4-Methylenedioxyamphetamine (MDA)	3,000	33.3
Phentermine	5,000	20
MDEA	>100,000	< 1

d,l-Methamphetamine	>100,000	< 1
Phenylephrine	>100,000	< 1

Barbiturates related compounds:

Substances	Concentration (ng/mL)	% Cross Reactivity
Secobarbital	300	100
Pentobarbital	300	100
Alphenal	500	60
Amobarbital	800	37.5
Aprobarbital	500	60
Barbital	10,000	3
Butabarbital	500	60
Butalbital	3,000	10
Cyclopentobarbital	750	40
Phenobarbital	2,000	15

Benzodiazepines related compounds:

Substances	Concentration (ng/mL)	% Cross Reactivity
Oxazepam	300	100
Alprazolam	300	100
Alpha-Hydroxyalprazolam	100	300
Bromazepam	500	60
Chlordiazepoxide	2,500	12
Clobazam	200	150
Clonazepam	10,000	3
Clorazepate	350	85.7
Desalkylflurazepam	65	462
Diazepam	200	150
Estazolam	500	60
Flunitrazepam	375	80
Flurazepam	90	333
Lorazepam	600	50
Lormetazepam	7,500	4
Midazolam	900	33.3
Nitrazepam	200	150
Nordiazepam	150	200
Temazepam	350	85.7
Triazolam	1,000	30

Buprenorphine related compounds:

Substances	Concentration (ng/mL)	% Cross Reactivity
Buprenorphine	10	100
Norbuprenorphine	10	100
Morphine	>100,000	< 0.01
Codeine	>100,000	< 0.01

Cocaine related compounds:

Substances	Concentration (ng/mL)	% Cross Reactivity
Benzoylecgonine	300	100
Cocaine	500	60
Cocaethylene	20000	1.5

MDMA (Methylenedioxymethamphetamine) related compounds:

Substances	Conc. (ng/mL)	% Cross Reactivity
d,l-(3,4)-Methylenedioxymethamphetamine (MDMA)	500	100
3,4-Methylenedioxyamphetamine (MDA)	15,000	3.3
3,4-Methylenedioxyethylamphentamine (MDEA)	1,000	50
d-Methamphetamine	100,000	0.5
d-Amphetamine	100,000	0.5
l-Methamphetamine	>100,000	< 0.5
Ephedrine	>100,000	< 0.5
Pseudoephedrine	>100,000	< 0.5
d,l- Amphetamine	>100,000	< 0.5
l-Amphetamine	>100,000	< 0.5
Phentermine	>100,000	< 0.5
d,l- Methamphetamine	>100,000	< 0.5
Phenylephrine	>100,000	< 0.5

Methamphetamine related compounds:

Substances	Conc. (ng/mL)	% Cross Reactivity
d-Methamphetamine	1,000	100
d,l-Methamphetamine	5,000	20
d-Amphetamine	10,000	10
l- Amphetamine	> 100,000	< 1
Ephedrine	> 100,000	< 1
(*R*)-(−)-Phenylephrine	10,000	10
Pseudoephedrine	> 100,000	< 1
d,l-MDMA (3,4- Methylenedioxymethamphetamine)	5,000	20
d,l-MDEA (Methylenedioxyethylamphetamine)	100,000	1
d,l-MDA (3,4- Methylenedioxyamphetamine)	>100,000	< 1
l-Methamphetamine	>100,000	< 1
d,l- Amphetamine	>100,000	< 1
Phentermine	>100,000	< 1

Methadone related compounds:

Substances	Concentration (ng/mL)	% Cross Reactivity
Methadone	300	100
Doxylamine	100,000	0.3
EDDP	>100,000	< 0.3
Pheniramine	>100,000	< 0.3

Morphine 300 related compounds:

Substances	Concentration (ng/mL)	% Cross Reactivity
Morphine	300	100
Codeine	300	100
6-Acetylmorphine	500	60
Diacetyl morphin (Heroin)	2,000	15
Hydrocodone	5,000	6
Hydromorphone	5,000	6
Oxycodone	30,000	1
Oxymorphone	>100,000	< 0.3
Procaine	>100,000	< 0.3

Opiates 2000 related compounds:

Substances	Concentration (ng/mL)	% Cross Reactivity
Morphine	2000	100
Codeine	2000	100
6-Acetylmorphine	1500	133.3
Diacetyl morphin (Heroin)	2000	100
Ethylmorphine	1500	133.3
Hydrocodone	50,000	4
Hydromorphone	50,000	4
Norcodeine	100,000	2
Normorphine	100,000	2
Oxycodone	100,000	2
Oxymorphone	100,000	2
Paracetamol (or Acetaminophen)	100,000	2
Thebaine	100,000	2

Oxycodone related compounds:

Substances	Concentration (ng/mL)	% Cross Reactivity
Oxycodone	100	100
Codeine	100,000	0.1
Hydrocodone	100,000	0.1
Oxymorphone	100	100

PCP related compounds:

Substances	Concentration (ng/mL)	% Cross Reactivity
Phencyclidine	25	100
Pheniramine	>100,000	0.025

THC related compounds:

Substances	Concentration (ng/mL)	% Cross Reactivity
11-nor-Δ^9-THC-9-COOH	50	100
11-nor-Δ^8-THC-9-COOH	30	167
Δ^9-Tetrahydrocannabinol	12,000	0.4
Cannabidol	>100,000	0.05
Cannabinol	>100,000	0.05

Tricyclic Antidepressants related compounds:

Substances	Concentration (ng/mL)	% Cross Reactivity
Nortriptyline	1000	100
Amitriptyline	1000	100
Desipramine	300	333
Doxepin HCl	2,000	50
Imipramine	50	2000
Protriptyline	4750	21.1
Trimipramine	2,000	50

Non Cross-Reacting Compounds

The following compounds were found not to cross-react when tested at concentrations at 100 µg/mL in ±25% of the drug cut-off concentrations.

Endogenous Compounds:

Albumin, Bilirubin, Cholesterol, Creatinine, Glucose, Hemoglobin, Riboflavin, Sodium Chloride, Uric Acid

Un-structurally related compound:

Acetaminophen, Acetone, Acetylsalicylic Acid, Amoxicillin, Ampicillin, R-(-)-Apomorphine, L-Ascorbic Acid, Aspirin, Aspartame, Atropine, Baclofen, Benzocaine, Benzoic Acid, Carisoprodol, Chloramphenicol, Chlordiazepoxide, (+)-Chlorpheniramine, Chlorpromazine, Cyclodextrin-r, Cyproheptadine, Deoxycorticosterone, Dextromethorphan, Diclofenac, Diflunisal, 4-Dimethyl-aminoantipyrine, Diphenhydramine, 5, 5-Diphenylhydantoin, Dopamine, 1-Erythromycin, Estradiol, Estrone, Ethanol, Fenofibrate, Fentanyl, Fotemustine, Furosemide, (+/-)-Isoproterenol, Ketamine, Meprobamate, Methapyrilene, Methylphenidate, Nalidixic Acid, Naloxone, Naltrexone, (+)-Naproxen, Niacinamide, Nicotinic Acid, Nifedipine, 19-Norethindrone, Norpropoxyphene, Noscapine, Octopamine, Oxalic Acid, Papaverine, Promazine, Promethazine, d-Propoxyphene, d,l-Propranolol, Pyridoxine, Pyrilamine, Pyrogallol, Quinidine, Quinine, Quinolinic Acid, Ranitidine, Salicylic Acid, Sulfamethazine, Sulindac, Tetracycline, Tetrahydrozoline, Thiamine, Thioridazine

Clofibrate	Gemfibrozil	Penicillin-G	Tramadol
Clonidine	Guaiacolglyceryl ether	Perphenazine	Trifluoperazine
Cortisone	Gentisic acid	Phenelzine	Tryptamine
(-)-Cotinine	Hydralazine	Phenylethylamine	Tyramine
Creatine Hydrate	Hydrocortisone	Prednisone	Zomepirac sodium salt
Cyclobenzaprine	3-Hydroxytyramine		

Effect of Urine pH

The pH ranges of 3.0 to 8.5 were prepared by adjusting the drug urine controls at ±25% of the drug cut-off levels, respectively. The testing results demonstrate that the varying ranges of urine pH do not affect the test performance.

Effect of Urine Specific Gravity (SG)

The specific gravity ranges of 1.002, 1.010, 1.015, 1.020, 1.025 and 1.030 were prepared by adjusting the drug urine controls at ±25% of the drug cut-off levels, respectively. The testing results with the DrugSmart® Cup demonstrate that the varying ranges of urine SG do not affect the test results.

Bibliography of Suggested Reading

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