Effective date: 2014-02-14 Issue: 1156090601

SureScreen Diagnostics

Integrated Cup (Urine)
Product Insert

Product insert for testing of any combination of the following drugs:
Amphetamine 300, Amphetamine 500, Amphetamine, Barbiturates, Benzodiazepines 200, Benzodiazepines, Buprenorphine 5, Buprenorphine, Clonazepam, Cocaine 150, Cocaine, Cotinine, Fentanyl, Ketamine, Marijuana 20, Marijuana, Marijuana 150, Methadone, EDDP 100 (Methadone metabolite), EDDP 300 (Methadone metabolite), Methamphetamine 300, Methamphetamine 500, Methamphetamine, Methaqualone, Methylenedioxymethamphetamine, Morphine 300, Opiate 2000, Oxycodone, Phencyclidine, Propoxyphene, Tramadol and Tricyclic Antidepressants.
Including Adulteration tests (ADLT) for Oxidants/Pyridinium Chlorochromate (OX/PCC), Specific Gravity (S.G.), pH, Nitrite (NIT), Glutaraldehyde (GLUT) and Creatinine (CRE).
A rapid, one step screen test for the simultaneous, qualitative detection of multiple drugs and metabolites in human urine. For medical and other professional in vitro diagnostic use only.

INTENDED USE & SUMMARY

Urine based screen tests for multiple drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method to screen urine for multiple drugs of abuse.

The SureScreen Integrated Cup (Urine) is a lateral flow chromatographic immunoassay for the qualitative detection of following drugs without the need of instruments:[1]

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP 300)	d-Amphetamine	300
Amphetamine (AMP 500)	d-Amphetamine	500
Amphetamine (AMP)	d-Amphetamine	1,000
Barbiturates (BAR)	Secobarbital	300
Benzodiazepines (BZO 200)	Oxazepam	200
Benzodiazepines (BZO)	Oxazepam	300
Buprenorphine (BUP 5)	Buprenorphine	5
Buprenorphine (BUP)	Buprenorphine	10
Clonazepam (ACL)	7-Aminoclonazepam	100
Cocaine (COC 150)	Benzoylecgonine	150
Cocaine (COC)	Benzoylecgonine	300
Cotinine (COT)	Cotinine	100
Fentanyl(FTY)	Norfentanyl	20
Ketamine (KET)	Ketamine	1,000
Marijuana (THC 20)	11-nor-Δ^9-THC-9 COOH	20
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50
Marijuana (THC 150)	11-nor-Δ^9-THC-9 COOH	150
Methadone (MTD)	Methadone	300
Methadone metabolite (EDDP 100)	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP)	100
Methadone metabolite (EDDP 300)	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP)	300
Methamphetamine (MET 300)	d-Methamphetamine	300
Methamphetamine (MET 500)	d-Methamphetamine	500
Methamphetamine (MET)	d-Methamphetamine	1,000
Methaqualone (MQL)	Methaqualone	300
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	500
Morphine (MOP 300)	Morphine	300
Opiate (OPI 2000)	Morphine	2,000
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Propoxyphene (PPX)	Propoxyphene	300
Tramadol (TRA)	Tramadol	100
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000

This test will detect other related compounds, please refer to the Analytical Specificity table in this product insert.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

ADLT SUMMARY

Each ADLT strip contains chemically treated reagent pads. Between three and five minutes after the urine sample activates the reagent pad, the colours can be compared with the printed colour chart. The colour comparison provides a semi-quantitative screen for any combination of oxidants/pyridinium chlorochromate (PCC), specific gravity, pH, nitrite, glutaraldehyde and creatinine in human urine which can help assess the integrity of the urine sample.

PRINCIPLE

The SureScreen Integrated Cup (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody coated on the particles. The antibody coated particles will then be captured by the immobilized drug conjugate and a visible coloured line will show up in the test line region of the specific drug strip. The coloured line will not form in the test line region if the drug level is above its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles.

A drug-positive urine specimen will not generate a coloured line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a coloured line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

ADLT PRINCIPLE

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results.

One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such as pH and specific gravity and to detect the presence of oxidants/PCC, specific gravity, pH, nitrite, glutaraldehyde and creatinine in urine.

- **Oxidants/PCC** (Pyridinium chlorochromate) tests for the presence of oxidising agents such as bleach and hydrogen peroxide. Pyridinium Chlorochromate is a commonly used adulterant.[2] Normal human urine should not contain oxidants or PCC.
- **Specific gravity** tests for sample dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.
- **pH** tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate the sample has been altered.
- **Nitrite** tests for commonly used commercial adulterants such as Klear or Whizzies. They work by oxidising the major cannabinoid metabolite THC-COOH.[3] Normal urine should contain no trace of nitrite. Positive results generally indicate the presence of an adulterant.
- **Glutaraldehyde** tests for the presence of an aldehyde. Adulterants such as UrinAid and Clear Choice contain glutaraldehyde which may cause false negative screening results by disrupting the enzyme used in some immunoassay tests.[2] Glutaraldehyde is not normally found in urine; therefore, detection of glutaraldehyde in a urine specimen is generally an indicator of adulteration.
- **Creatinine** is a waste product of creatine, an amino acid contained in muscle tissue and found in urine.[1] A person may attempt to foil a test by drinking excessive amounts of water or diuretics such as herbal teas to “flush” the system. Creatinine and specific gravity are two ways to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low creatinine and specific gravity levels may indicate dilute urine. The absence of creatinine (< 5 mg/dL) is indicative of a specimen not consistent with human urine.

REAGENTS

Each test contains specific drug antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

ADLT REAGENTS

Adulteration Pad	Reactive	Buffers and non-reactive ingredients
Oxidants/PCC	0.36%	99.64%
Specific Gravity	0.25%	99.75%
pH	0.06%	99.94%
Nitrite	0.07%	99.93%
Glutaraldehyde	0.02%	99.98%
Creatinine	0.04%	99.96%

PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only.
- Do not use after the expiry date.
- The test cup should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cup should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test cup is stable until the expiry date printed on the sealed pouch. The test cup must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use after the expiry date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing. When tests include ADLT tests, storage of urine specimens should not exceed 2 hours at room temperature or 4 hours refrigerated prior to testing. For best results, test specimens immediately following collection.

MATERIALS

Materials Provided

- Cups with multi-drug panels
- Security seal labels
- Keys
- Adulteration colour chart (if applicable)
- Product insert

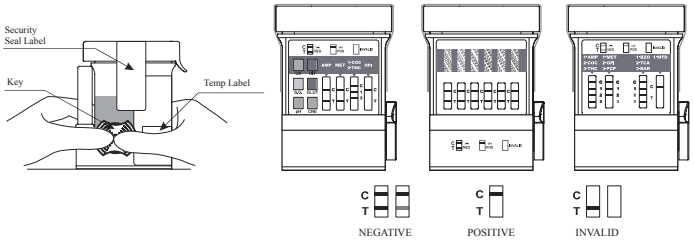
Materials Required But Not Provided

- Timer

DIRECTIONS FOR USE

Allow the test cup, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch and use it as soon as possible.
2. **Remove the key** by twisting it from the center of the cup cap.
3. **Collect specimen in the cup** and secure the cap tightly by pressing down on the pull tab until an audible click is heard.
4. **Check the temperature label** (Temp Label) up to 4 minutes after specimen collection. A green color will appear to indicate the temperature of the urine specimen. The proper range for an unadulterated specimen is 33-38°C (91-100°F).
5. Date and initial the security seal label then place it over the cap.
6. Place the cup on a flat surface and **push the key into the socket** of the cup to initiate the test. **Start the timer.**
7. Remove the peel off label covering the test results. **Read the adulteration strip between 3 and 5 minutes.**
8. Compare the colors on the adulteration strip to the enclosed color chart. If the result indicates adulteration, do not interpret the drug test results. Either retest the urine or collect another specimen.
9. **Read the drug strip results at 5 minutes.** The drug strip results remain stable for up to sixty minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* A coloured line in the control line region (C) and a coloured line in the test line region (T) for a specific drug indicate a negative result. This indicates that the drug concentration in the urine specimen is below the designated cut-off level for that specific drug.

***NOTE:** The shade of colour in the test region (T) may vary, but it should be considered negative whenever there is even a faint coloured line.

POSITIVE: A coloured line in the control line region (C) but no line in the test line region (T) for a specific drug indicates a positive result. This indicates that the drug concentration in the urine specimen exceeds the designated cut-off for that specific drug.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test cup. If the problem persists, discontinue using the lot immediately and contact your local distributor.

SVT/ADULTERANT INTERPRETATION

(Please refer to the colour chart)

Semi-quantitative results are obtained by visually comparing the reacted colour blocks on the strip to the printed colour blocks on the colour chart. No instrumentation is required.

QUALITY CONTROL

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

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The SureScreen Integrated Cup (Urine) provides only a preliminary analytical result. A more specific chemical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. [4,5]
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. The test does not distinguish between drugs of abuse and certain medications.
7. A positive result might be obtained from certain foods or food supplements.

ADLT LIMITATIONS

1. The adulteration tests included with this product are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an "all-inclusive" representation of possible adulterants.
2. Oxidants/PCC: Normal human urine should not contain oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants/PCC pad.
3. Specific Gravity: Elevated levels of protein in urine may cause abnormally high specific gravity values.
4. Nitrite: Nitrite is not a normal component of human urine. However, nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of > 20 mg/dL may produce false positive glutaraldehyde results.
5. Glutaraldehyde: Is not normally found in urine. However certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high-protein diets) may interfere with the test results.
6. Creatinine: Normal creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the SureScreen Integrated Cup (Urine) and commercially available drug rapid tests. Testing was performed on approximately 300 specimens previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

% Agreement with Commercial Kit

Specimen	AMP 300	AMP 500	AMP	BAR	BZO 200	BZO	BUP 5	BUP**	ACL	COC 150	COC
Positive	>99%	*	>99%	>99%	*	>99%	*	88%	*	>99%	>99%
Negative	>99%	*	>99%	>99%	*	>99%	*	>99%	*	>99%	99%
Total	>99%	*	>99%	>99%	*	>99%	*	97%	*	>99%	99%

Specimen	COT	FTY	KET	THC 20	THC	THC 150	MTD	EDDP 100	EDDP 300	MET 300	MET 500
Positive	>99%	*	*	*	>99%	*	89%	*	*	*	>99%
Negative	>99%	*	*	*	99%	*	>99%	*	*	*	80%
Total	>99%	*	*	*	99%	*	94%	*	*	*	87%

Specimen	MET	MQL	MDMA	MOP 300	OPI 2000	OXY	PCP	PPX	TRA	TCA
Positive	>99%	*	96%	95%	98%	96%	99%	>99%	*	92%
Negative	>99%	*	>99%	>99%	>99%	99%	>99%	>99%	*	>99%
Total	>99%	*	98%	97%	99%	98%	99%	>99%	*	98%

*** NOTE:** Commercial kit unavailable for comparison testing.

**** NOTE:** BUP was compared to the self-reported use of Buprenorphine.

% Agreement with GC/MS

Specimen	AMP 300	AMP 500	AMP	BAR	BZO 200	BZO	BUP 5	BUP*	ACL	COC 150	COC
Positive	99%	95%	95%	92%	98%	98%	>99%	98%	>99%	97%	95%
Negative	99%	>99%	99%	98%	99%	98%	>99%	99%	>99%	>99%	>99%
Total	99%	98%	97%	95%	99%	98%	>99%	99%	>99%	99%	98%

Specimen	COT*	FTY*	KET	THC 20	THC	THC 150	MTD	EDDP 100	EDDP 300	MET 300	MET 500
Positive	>99%	99%	>99%	87%	95%	91%	93%	98%	>99%	97%	99%
Negative	>99%	90%	95%	99%	95%	96%	>99%	>99%	94%	>99%	>99%
Total	>99%	93%	95%	95%	95%	96%	97%	99%	96%	98%	99%

Specimen	MET	MQL	MDMA	MOP 300	OPI 2000	OXY	PCP	PPX	TRA*	TCA**
Positive	90%	>99%	99%	98%	99%	99%	90%	>99%	99%	>99%
Negative	>99%	>99%	99%	97%	99%	98%	99%	>99%	96%	94%
Total	96%	>99%	99%	97%	99%	99%	96%	>99%	97%	95%

*** NOTE:** BUP, TRA, FTY and COT were based on LC/MS data instead of GC/MS.

**** NOTE:** TCA was based on HPLC data instead of GC/MS.

Analytical Sensitivity

A drug-free urine pool was spiked with drugs to the concentrations at ± 50% cut-off and ± 25% cut-off. The results are summarised below.

Drug Conc. (Cut-off range)	AMP 300		AMP 500		AMP		BAR		BZO 200		BZO		BUP 5		BUP	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	90	0	30	0	30	0	30	0	87	0	30	0	90	0	90	0
-50% Cut-off	90	0	30	0	30	0	30	0	66	0	30	0	90	0	90	0
-25% Cut-off	76	14	25	5	24	6	25	5	63	2	25	5	64	26	81	9
Cut-off	46	44	11	19	17	13	13	17	31	32	14	16	27	63	42	48
+25% Cut-off	16	74	5	25	5	25	7	23	0	63	10	20	0	90	17	73
+50% Cut-off	0	90	0	30	0	30	0	30	0	66	0	30	0	90	0	90

Drug Conc. (Cut-off range)	ACL		COC 150		COC		COT		FTY		KET		THC 20		THC	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	90	0	90	0	30	0	90	0	90	0	90	0	30	0	30	0
-50% Cut-off	90	0	90	0	30	0	90	0	90	0	90	0	30	0	30	0
-25% Cut-off	86	4	73	17	25	5	90	0	88	2	70	20	27	3	27	3
Cut-off	51	39	40	50	19	11	49	41	51	39	38	52	24	6	14	16
+25% Cut-off	0	90	17	73	3	27	4	86	16	74	6	84	17	13	6	24
+50% Cut-off	0	90	0	90	0	30	0	90	0	90	0	90	5	25	0	30

Drug Conc. (Cut-off range)	THC 150		MTD		EDDP 100		EDDP 300		MET 300		MET 500		MET	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	90	0	30	0	90	0	90	0	30	0	90	0	30	0
-50% Cut-off	90	0	30	0	90	0	90	0	30	0	90	0	30	0
-25% Cut-off	90	0	20	10	90	0	90	0	27	3	73	17	24	6
Cut-off	46	44	19	11	37	53	51	39	15	15	48	42	18	12
+25% Cut-off	5	85	7	23	8	82	14	76	4	26	15	75	5	25
+50% Cut-off	0	90	0	30	0	90	0	90	0	30	0	90	0	30

Drug Conc. (Cut-off range)	MQL		MDMA		MOP 300		OPI 2000		OXY		PCP		PPX		TRA		TCA	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	96	0	30	0	30	0	30	0	90	0	30	0	90	0	90	0	30	0
-50% Cut-off	96	0	30	0	30	0	30	0	90	0	30	0	90	0	90	0	30	0
-25% Cut-off	96	0	20	10	27	3	25	5	74	16	26	4	73	17	90	0	25	5
Cut-off	43	53	18	12	17	13	17	13	47	43	14	16	42	48	61	29	18	12
+25% Cut-off	6	90	10	20	10	20	4	26	14	76	6	24	15	75	21	69	5	25
+50% Cut-off	0	96	0	30	0	30	0	30	0	90	0	30	0	90	2	88	0	30

Analytical Specificity

The following tables lists the concentration of compounds (ng/mL) that are detected positive in urine by the SureScreen Integrated Cup (Urine) at 5 minutes.

AMPHETAMINE 300	
d-Amphetamine	300
d,l-Amphetamine	390
l-Amphetamine	50,000
p-Hydroxyamphetamine	1,560
p-Hydroxynorephedrine	100,000
3,4-Methylenedioxyamphetamine (MDA)	1,560
β-Phenylethylamine	100,000
Phenylpropanolamine (d,l-Norephedrine)	100,000
Tyramine	100,000
AMPHETAMINE 500	
d-Amphetamine	500
d,l-Amphetamine	1,500
3,4-Methylenedioxyamphetamine (MDA)	800
Phentermine	1,500
β-Phenylethylamine	50,000
Tryptamine	50,000
Tyramine	25,000
AMPHETAMINE	
d-Amphetamine	1,000
d,l-Amphetamine	3,000

FENTANYL	
Norfentanyl	20
Alfentanyl	562,500
Buspirone	12,500
Fenfluramine	37,500
Fentanyl	100
Sufentanyl	57,500
KETAMINE	
Ketamine	1,000
Norketamine	50,000
Pentobarbital	50,000
Secobarbital	100,000
MARIJUANA 20	
11-nor-Δ^8-THC-9 COOH	20
11-nor-Δ^9-THC-9 COOH	20
Cannabinol	12,500
Δ^8–THC	10,000
Δ^9–THC	12,500
MARIJUANA	
11-nor-Δ^9-THC-9 COOH	50
11-nor-Δ^8-THC-9 COOH	30

l-Amphetamine	50,000
d,l-3,4-Methylenedioxyamphetamine (MDA)	2,000
Phentermine	3,000
BARBITURATES	
Secobarbital	300
Alphenal	150
Amobarbital	300
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Phenobarbital	100
Pentobarbital	300
BENZODIAZEPINES 200	
Oxazepam	200
Alprazolam	30
7-Aminoclonazepam	4,000
7-Aminoflunitrazepam	390
7-Aminonitrazepam	625
Bromazepam	390
Chlordiazepoxide	300
Clobazam	48
Clorazepate	97
Desalkylflurazepam	1,560
Diazepam	97
Estazolam	125
Flunitrazepam	25,000
α-Hydroxyalprazolam	30
d-Lorazepam	3,125
Midazolam	195
Nitrazepam	780
Norchlordiazepoxide	780
Nordiazepam	780
Temazepam	33
Triazolam	150
BENZODIAZEPINES	
Oxazepam	300
Alprazolam	196
Bromazepam	1,562
Chlordiazepoxide	1,562
Clobazam	98
Clonazepam	781
Clorazepate	195
Delorazepam	1,562
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	390
α-Hydroxyalprazolam	1,262
d,l-Lorazepam	1,562
RS-Lorazepam glucuronide	156
Midazolam	12,500
Nitrazepam	98
Norchlordiazepoxide	195
Nordiazepam	390

Cannabinol	20,000
Δ^8–THC	15,000
Δ^9–THC	15,000
MARIJUANA 150	
11-nor- Δ^9-THC-9 COOH	150
11-nor-Δ^8-THC-9 COOH	500
Cannabinol	25,000
Δ^8–THC	25,000
Δ^9–THC	25,000
METHADONE	
Doxylamine	50,000
Methadone	300
EDDP 100	
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	100
EDDP 300	
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300
METHAMPHETAMINE 300	
d-Methamphetamine	300
d,l-Amphetamine	100,000
Chloroquine	25,000
Ephedrine	100,000
(1R,2S)-l-Ephedrine	100,000
l-Epinephrine	50,000
Fenfluramine	12,500
p-Hydroxymethamphetamine	25,000
Mephentermine	50,000
l-Methamphetamine	3,125
3,4-Methylenedioxymethamphetamine (MDMA)	780
Trimethobenzamide	25,000
METHAMPHETAMINE 500	
d-Methamphetamine	500
d,l-Amphetamine	75,000
d-Amphetamine	50,000
Chloroquine	12,500
(1R,2S)-l-Ephedrine	50,000
p-Hydroxymethamphetamine	15,000
Mephentermine	25,000
l-Methamphetamine	4,000
3,4-Methylenedioxymethamphetamine (MDMA)	1,000
l-Phenylephrine	100,000
β-Phenylethylamine	75,000
METHAMPHETAMINE	
d-Methamphetamine	1,000
p-Hydroxymethamphetamine	30,000
Mephentermine	50,000
l-Methamphetamine	8,000
d,l-3,4-Methylenedioxymethamphetamine (MDMA)	2,000
METHAQUALONE	
Methaqualone	300
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
d,l-3,4-Methylenedioxymethamphetamine (MDMA)	500
d,l-3,4-Methylenedioxyamphetamine (MDA)	3,000
3,4-Methylenedioxyethylamphetamine (MDEA)	300
MORPHINE 300	
Morphine	300
Codeine	300

Temazepam	98
Triazolam	2,500
BUPRENORPHINE 5	
Buprenorphine	5
Buprenorphine 3-D-glucuronide	7
Norbuprenorphine	10
Norbuprenorphine 3-D-glucuronide	120
BUPRENORPHINE	
Buprenorphine	10
Buprenorphine 3-D-glucuronide	15
Norbuprenorphine	20
Norbuprenorphine 3-D-glucuronide	200
CLONAZEPAM	
7-Aminoclonazepam	100
Alprazolam	6
7-Aminoflunitrazepam	6
7-Aminonitrazepam	5
Bromazepam	6
Chlordiazepoxide	24
Clobazam	6
Clonazepam	49
Clorazepate	50
Delorazepam	100
Desalkylflurazepam	12
Diazepam	25
Estazolam	2
Flunitrazepam	100
α-Hydroxyalprazolam	5
α-Hydroxymidazolam	10
α-Hydroxytriazolam	1
d,l-Lorazepam	400
Lorazepam glucuronide	10,000
Midazolam	200
Nitrazepam	12
Norchlordiazepoxide	50
Nordiazepam	6
Oxazepam	98
Oxazepam glucuronide	10,000
Temazepam	12
Temazepam glucuronide	5,000
Triazolam	24
COCAINE 150	
Benzoylecgonine	150
Cocaethylene	6,250
Cocaine	400
Ecgonine	12,500
Ecgonine methylester	50,000
COCAINE	
Benzoylecgonine	300
Cocaethylene	12,500
Cocaine	780
Ecgonine	32,000
COTININE	
l-Cotinine	100
S-l-Nicotine	12,500

Ethylmorphine	6,250
Hydrocodone	50,000
Hydromorphone	3,125
Levorphanol	1,500
6-Monoacetylmorphine (6-MAM)	400
Morphine 3-β-D-glucuronide	1,000
Norcodeine	6,250
Normorphine	100,000
Oxycodone	30,000
Oxymorphone	100,000
Procaine	15,000
Thebaine	6,250
OPIATE 2000	
Morphine	2,000
Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500
Hydromorphone	5,000
Levorphanol	75,000
6-Monoacetylmorphine (6-MAM)	5,000
Morphine 3- -D-glucuronide	2,000
Norcodeine	12,500
Normorphine	50,000
Oxycodone	25,000
Oxymorphone	25,000
Procaine	150,000
Thebaine	100,000
OXYCODONE	
Oxycodone	100
Hydrocodone	6,250
Hydromorphone	50,000
Levorphanol	50,000
Naloxone	37,500
Naltrexone	37,500
Oxymorphone	200
PHENCYCLIDINE	
Phencyclidine	25
4-Hydroxyphencyclidine	12,500
PROPOXYPHENE	
d-Propoxyphene	300
d-Norpropoxyphene	300
TRAMADOL	
Cis-tramadol	100
d,l-O-Desmethyl venlafaxine	25,000
n-Desmethyl-cis-tramadol	195
o-Desmethyl-cis-tramadol	6,250
Phencyclidine	100,000
Procyclidine	100,000
TRICYCLIC ANTIDEPRESSANTS	
Nortriptyline	1,000
Amitriptyline	1,500
Clomipramine	12,500
Desipramine	200
Doxepin	2,000
Imipramine	400
Maprotiline	2,000
Nordoxepin	1,000
Promazine	1,500
Promethazine	25,000
Trimipramine	3,000

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Amphetamine 300, Amphetamine 500, Amphetamine, Barbiturates, Benzodiazepines 200, Benzodiazepines, Buprenorphine 5, Buprenorphine, Clonazepam, Cocaine 150, Cocaine, Cotinine, Fentanyl, Ketamine, Marijuana 20, Marijuana, Marijuana 150, Methadone, EDDP 100 (Methadone metabolite), EDDP 300 (Methadone metabolite), Methamphetamine 300, Methamphetamine 500, Methaqualone, Methamphetamine, Methylenedioxymethamphetamine, Morphine 300, Opiate 2000, Oxycodone, Phencyclidine, Propoxyphene, Tramadol and Tricyclic Antidepressants positive urine.The following compounds show no cross-reactivity when tested with the SureScreen Integrated Cup (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol	Diclofenac	Labetalol	Prednisone
Acetone	Dicyclomine	Lidocaine	d,l-Propanolol
Acetophenetidin	Diflunisal	Lindane	Quinacrine
Acetylsalicylic acid	Digoxin	Lithium	Quinidine
Albumin	4-Dimethylaminoantipyrine	Loperamide	Quinine
alpha-Naphthaleneacetic Acid	Diphenhydramine	l-Thyroxine	R(-) Deprenyl
Aminopyrine	5,5-Diphenylhydantoin	Meperidine	Riboflavin
Amoxapine	EMDP	Meprobamate	Salicylic acid
Amoxicillin	Erythromycin	Methoxyphenamine	Serotonin
Ampicillin	β-Estradiol	Methylphenidate	Seroquel
Apomorphine	Estrone-3-sulfate	Metoprolol	Sertraline
Ascorbic acid	Ethyl alcohol	N-Acetylprocainamide	Sodium Chloride
Aspartame	Ethyl-p-aminobenzoate	Nalidixic acid	Sulfamethazine
Atropine	Etodolac	Nalorphine	Sulindac
Benzilic acid	Famprofazone	Naproxen	Tetracycline
Benzoic acid	Fenoprofen	Niacinamide	Tetrahydrocortison-3-acetate
Benzydamine	Fluoxetine	Nifedipine	Tetrahydrozoline
Brompheniramine	Furosemide	Nimesulide	Theophylline
Caffeine	Gentisic acid	Norethindrone	Thiamine
Cannabidiol	d-Glucose	Noscapine	Thioridazine
Chloral Hydrate	Guaiacol Glyceryl Ether	d,l-Octopamine	Tolbutamide
Chloramphenicol	Hemoglobin	Orphenadrine	Trans-2-phenylcyclopropylamine
Chloroquine	Hydralazine	Oxalic acid	Trazodone
Chlorothiazide	Hydrochlorothiazide	Oxolinic acid	Triamterene
Chlorpromazine	Hydrocortisone	Oxymetazoline	Trifluoperazine
Chlorprothixene	o-Hydroxyhippuric acid	Papaverine	Trimethoprim
Cholesterol	3-Hydroxytyramine	Pemoline	d,l-Tryptophan
Cimetidine	Ibuprofen	Penicillin	d,l-Tyrosine
Clonidine	Iproniazid	Pentazocine	Uric acid
Cortisone	Isoproterenol	Phenelzine	Verapamil
Creatinine	Isoxsuprine	Pheniramine	Zomepirac
Deoxycorticosterone	Kanamycin	Phenothiazine	
Dextromethorphan	Ketoprofen	Prednisolone	

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Adulteration Colour Chart

Abnormal	Abnormal	**OX PCC**	Oxidants/Pyridinium chlorochromate	**NIT**	Nitrite
Normal	Normal	**S.G.**	Specific gravity	**GLUT**	Glutaraldehyde
		pH	pH	**CRE**	Creatinine

Index of Symbols

	Consult instructions for use		Tests per kit		Manufacturer
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	**REF**	Catalog #

Manufacturer

SureScreen Diagnostics Ltd
1 Prime Parkway
Prime Enterprise Park
Derby. DE1 3QB
United Kingdom

CE