



# SureScreen Diagnostics Ltd

## Multiline Cassette

Packages insert for testing of the following drugs: Methadone, Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methamphetamine, Methylendioxyamphetamines, Morphine 300, Oxycodone, Phencyclidine and Tricyclic Antidepressants.

*A rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine.*

*For professional in vitro diagnostic use only.*

### INTENDED USE & SUMMARY

Urine based 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 Multi-Drug One Step Multi-Line Screen Test Device (Urine) is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations in urine:

Test	Calibrator	Cut-off (ng/ml)
Amphetamine (AMP)	D-Amphetamine	1,000
Barbiturates (BAR)	Secobarbital	300
Benzodiazepines (BZO)	Oxazepam	300
Cocaine (COC)	Benzoylgonine	300
Marijuana (THC)	11-nor- $\Delta^9$ -THC-9-COOH	50
Methadone (MTD)	Methadone	300
Methamphetamine (MET)	D-Amphetamine	1,000
Methylendioxyamphetamines (MDMA)	D,L-Methylendioxyamphetamines	300
Morphine (MOP 300)	Morphine	300
Phencyclidine (PCP)	Phencyclidine	2,000
Tricyclic Antidepressants (TCA)	Nortriptyline	25

This test will detect other related compounds, please refer to the Analytical Specificity table in this package 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 judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

### PRINCIPLE

The Multi-Drug One Step Multi-Line Screen Test Device (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. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

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

### REAGENTS

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

### PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- All specimens 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 device 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 device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

### SPECIMEN COLLECTION AND PREPARATION

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.

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.

### SPECIMEN STORAGE

- Test devices
- Dropppers
- Package insert

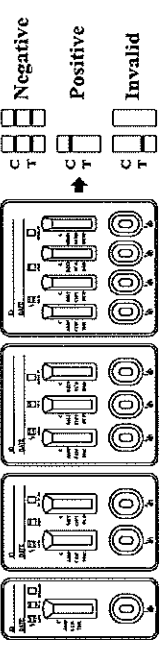
### MATERIALS PROVIDED

- Materials Required But Not Provided
- Timer

### DIRECTIONS FOR USE

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

- Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
- Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100  $\mu$ L total volume) to each specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
- Wait for the colored lines(s) to appear. Read results at 5 minutes. Do not interpret results after 10 minutes.



### INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**NEGATIVE:** A colored line in the control line region (C) and a colored line in the test 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 color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

**POSITIVE:** A colored 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 device. If the problem persists, discontinue using the lot immediately and contact your local distributor.

### QUALITY CONTROL

A procedural control is included in the test. A colored 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

- The Multi-Drug One Step Multi-Line Screen Test Device (Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. GC/MS chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
- There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- Adulterants, such as bleach and/or album, 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.
- A positive result does not indicate level or intoxication, administration route or concentration in urine.
- 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.
- Test does not distinguish between drugs of abuse and certain medications.
- A positive result might be obtained from certain foods or food supplements.

### PERFORMANCE CHARACTERISTICS

#### ACCURACY

A side-by-side comparison was conducted using the Multi-Drug One Step Multi-Line Screen Test Device (Urine) and a commercially available drug rapid test. Testing was performed on approximately 1,000 specimens previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. Negative urine specimens were screened initially by Predicate test, 10% negative specimens were confirmed by GC/MS. The following results were tabulated:

### % Agreement with Commercial Kit

Specimen	AMP	BAR	BZO	COC	THC	MDMA	MOP	PCP	TCA
Positive	>99%	98%	99%	>99%	>99%	87%	>99%	95%	>99%
Negative	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%
Total	>99%	98%	99%	>99%	>99%	94%	>99%	95%	>99%

Specimen	AMP	BAR	BZO	COC	THC	MDMA	MOP	PCP	TCA*
Positive	94%	92%	95%	95%	95%	93%	95%	95%	>99%
Negative	99%	98%	98%	96%	>99%	>99%	97%	97%	99%
Total	97%	96%	98%	98%	95%	97%	97%	97%	99%

\*Note: TCA was based on HPLC data.

### % Agreement with GC/MS

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

Drug Conc. (Cut-off range)	AMP	BAR	BZO	COC	THC	MDMA	MOP	PCP	TCA
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	26	4	23	7	14	16	15	13
0% Cut-off	30	7	23	7	23	6	24	5	25
+25% Cut-off	30	0	30	0	30	0	30	0	30
+50% Cut-off	30	0	30	0	30	0	30	0	30

### ANALYTICAL SPECIFICITY

Drug Conc. (Cut-off range)	MET	MDMA	MOP 300	OPI 2000	PCP	TCA
0% Cut-off	30	30	0	30	0	30
-50% Cut-off	30	30	0	30	0	30
-25% Cut-off	30	25	5	27	3	20
0% Cut-off	30	23	7	17	13	18
+25% Cut-off	30	6	24	6	24	7
+50% Cut-off	30	0	30	0	30	0

### ANALYTICAL SPECIFICITY

The following table lists the concentration of compounds (ng/mL) that are detected positive in urine by the Multi-Drug One Step Multi-Line Screen Test Device (Urine) at 5 minutes.

Compound	Concentration (ng/mL)
METHAMPHETAMINE	1,000
D-Amphetamine	3,000
D,L-Amphetamine sulfate	30,000
L-Amphetamine	8,000
Mephentermine	50,000
D,L-3,4-Methylenedioxyamphetamines	2,000
METHYLENEDIOXYAMPHETAMINE	500
3,4-Methylenedioxyamphetamines HCl (MDA)	3,000
3,4-Methylenedioxyamphetamine (MDA)	300
MORPHINE 300	300
Morphine	300
Codaine	300
Ethylmorphine	6,250
Hydrocodone	50,000
Hydromorphone	3,125
Levorphanol	1,500
6-Monocetylmorphine	400
Morphine 3- $\beta$ -D-glucuronide	1,000
Necocodine	6,250
Normorphine	100,000
Oxycodone	30,000
Oxycodone	100,000
Praxarone	15,000
Thebaine	6,250
OPiate 2000	2,000
Morphine	2,000
Codine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500
Hydromorphone	5,000
6-Monocetylmorphine	75,000
Morphine 3- $\beta$ -D-glucuronide	2,000

