

Multi-Drug

One Step Multi-Line Screen Test Panel with Integrated E-Z Split Key™ Cup II (Urine) Package Insert

Package insert for testing of any combination of the following drugs:

Amphetamine, Amphetamine 500, Amphetamine 300, Barbiturates, Benzodiazepines, Benzodiazepines 200, Buprenorphine, Cocaine, Cocaine 150, Marijuana, Methadone, Methamphetamine, Methamphetamine 500, Methamphetamine 300, Methylenedioxymethamphetamine, Morphine 300, Opiate 2000, Oxycodone, Phencyclidine, Propoxyphene and Tricyclic Antidepressants.

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 Multi-Drug One Step Multi-Line Screen Test Panel with Integrated E-Z Split Key™ Cup II (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)	d-Amphetamine	1,000
Amphetamine (AMP 500)	d-Amphetamine	500
Amphetamine (AMP 300)	d-Amphetamine	300
Barbiturates (BAR)	Secobarbital	300
Benzodiazepines (BZO)	Oxazepam	300
Benzodiazepines (BZO 200)	Oxazepam	200
Buprenorphine (BUP)	Buprenorphine	10
Cocaine (COC)	Benzoyllecgonine	300
Cocaine (COC 150)	Benzoyllecgonine	150
Marijuana (THC)	11-nor- Δ^9 -THC-9 COOH	50
Methadone (MTD)	Methadone	300
Methamphetamine (MET)	d-Methamphetamine	1,000
Methamphetamine (MET 500)	d-Methamphetamine	500
Methamphetamine (MET 300)	d-Methamphetamine	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
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000

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 judgment 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 Panel with Integrated E-Z Split Key™ Cup II (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 colored line will show up in the test line region of the specific drug strip. The colored 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 colored 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 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 panel contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test panel 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 panel 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 panel is stable through the expiration date printed on the sealed pouch. The test panel must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration 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 assay. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS

Materials Provided

- Cups with multi-drug panels
- Keys
- Security seal labels
- Package insert

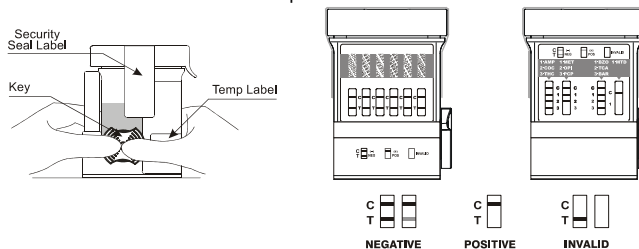
Materials Required But Not Provided

- Timer

DIRECTIONS FOR USE

Allow the test panel, 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 cup from the sealed pouch and use it as soon as possible.
- Remove the key by twisting it from the center of the cup cap.
- Collect specimen in the cup** and secure the cap tightly by pressing down on the pull tab until an audible click is heard.
- 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 adulterated specimen is 32-38°C (90-100°F).
- Date and initial the security seal label, then place it over the cap.
- Place the cup on a flat surface and **push the key into the socket** of the cup to initiate the test. Start the timer.
- Remove the peel off label covering the test results and wait for the colored line(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 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 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 cup. 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 Panel with Integrated E-Z Split Key™ Cup II (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.^{2,3}
- It is possible 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 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.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of 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.
- The 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 Panel with Integrated E-Z Split Key™ Cup II (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:

Specimen	% Agreement with Commercial Kit										
	AMP	AMP 500	AMP 300	BAR	BZO	BZO 200	BUP**	COC	COC 150	THC	MTD
Positive	>99%	*	>99%	98%	99%	*	88%	>99%	>99%	>99%	87%
Negative	>99%	*	>99%	>99%	>99%	*	>99%	99%	>99%	>99%	>99%
Total	>99%	*	>99%	99%	99%	*	97%	99%	>99%	>99%	94%

Specimen	% Agreement with GC/MS										
	MET	MET 500	MET 300	MDMA	MOP 300	OPI 2000	OXY	PCP	PPX	TCA	
Positive	>99%	>99%	*	98%	95%	99%	96%	>99%	>99%	92%	
Negative	>99%	82%	*	>99%	>99%	>99%	99%	>99%	>99%	>99%	
Total	>99%	89%	*	99%	97%	99%	98%	>99%	>99%	98%	

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

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

Specimen	% Agreement with GC/MS										
	AMP	AMP 500	AMP 300	BAR	BZO	BZO 200	BUP*	COC	COC 150	THC	MTD
Positive	94%	95%	>99%	92%	99%	98%	98%	95%	99%	95%	93%
Negative	99%	>99%	99%	99%	98%	99%	99%	>99%	>99%	96%	>99%
Total	97%	98%	99%	96%	98%	99%	99%	98%	99%	95%	97%

Specimen	% Agreement with GC/MS										
	MET	MET 500	MET 300	MDMA	MOP 300	OPI 2000	OXY	PCP	PPX	TCA**	
Positive	90%	99%	98%	99%	98%	99%	98%	90%	94%	>99%	
Negative	>99%	96%	>99%	97%	97%	99%	99%	99%	99%	94%	
Total	95%	97%	99%	98%	97%	99%	99%	96%	96%	95%	

***NOTE:** BUP was 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 \pm 50% cut-off and \pm 25% cut-off. The results are summarized below.

