UKDrugTesting

CE

Multi-Drug Test Panel

For Professional Use
Specimen: Urine
Format: Multi-Panel

INTENDED USE & SUMMARY

Multi-Drug Test Panel is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	250
Barbiturates (BAR)	Secobarbital	300
Benzodiazepines (BZO)	Oxazepam	150
Buprenorphine (BUP)	Buprenorphine	10
Caffeine（CAF）	Caffeine	8,000
Cocaine (COC)	Benzoylecgonine	150
Cotinine(COT)	Cotinine	200
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine （EDDP）	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	100
Ketamine（KET）	Ketamine	1,000
Fentanyl（FTY）	fentanyl	100
Marijuana (THC)	11-nor-Δ⁹-THC-9 COOH	20
Tramadol (TRA)	Tramadol	100
Methcathinone(MCT)	Methcathinone	500
Methylenedioxymetham-phetamine(MDMA)	d,l-Methylenedioxyme-thamphetamine	150
Methamphetamine (MET)	d-Methamphetamine	1,000
Morphine (MOP 300)	Morphine	300
Methaqualone（MQL）	Methaqualone	300
Methadone (MTD)	Methadone	100
Opiate (MOP 300)	Morphine	300
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Propoxyphene (PPX)	Propoxyphene	300
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000
Synthetic Marijuana (K2)	JWH-018 5-Pentanoic acid metabolite	50
Synthetic Marijuana (AB-PINACA)	AB-PINACA 5-Pentanoic acid metabolite	50
Synthetic Marijuana (UR-144)	UR-144 5-Pentanoic acid metabolite	50
Ethyl glucuronide (ETG)	Ethyl glucuronidewith	1,000
Lysergic acid diethylamide (LSD)	Lysergic acid diethylamide	50
Methylphenidate (MPH)	Methylphenidate	1,000

The configurations of Multi-Drug Test Panel come with any combination of the above listed drug analytes. 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

Multi-Drug Test Panel 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

The test contains a membrane strip coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific drugs.

PRECAUTIONS

- For in vitro diagnostic use.
- Avoid cross contamination of urine samples by using a new specimen collection container for each urine sample.
- Urine specimens may be potentially infectious. Avoid contact with skin by wearing gloves and proper laboratory attire.
- The used test panel should be discarded according to local regulations.

STORAGE & STABILITY

Store as packaged in the sealed pouch at 2-30℃. 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℃ for up to 48 hours prior to assay. For prolonged storage, specimens may be frozen and stored below -20℃. Frozen specimens should be thawed and mixed before testing.

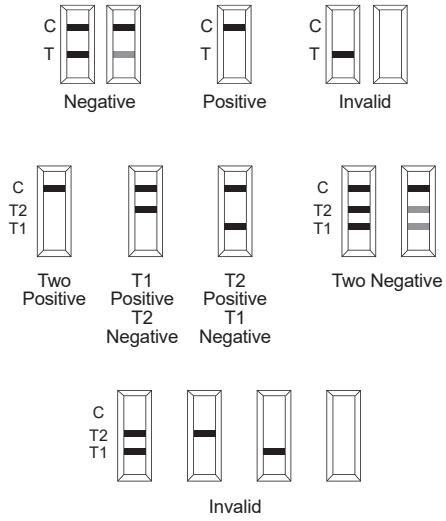
MATERIALS PROVIDED

- Multi-Drug Test Panel
- Test Instruction

DIRECTIONS FOR USE

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

1. Bring the pouch to room temperature before opening it. Remove the test panel from the sealed pouch and use it as soon as possible.
2. Remove the cap from the end of the test card. With arrows pointing toward the urine specimen, immerse the strip (s) of the test card vertically in the urine specimen for at least 10 seconds. Do not pass the arrow (s) on the test panel when immersing the panel.
3. Place the test card on a non-absorbent flat surface, start the timer and wait for the red line (s) to appear. Read results between 3~8 minutes. Do not interpret results after 10 minutes.



INTERPRETATION OF RESULTS

NEGATIVE: Two lines appear. One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the drug concentration is below the detectable level.

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: One colored line appears in the control line region (C). No line appears in the test line region (T). This positive result indicates that the drug concentration is above the detectable level.

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. 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

1. Multi-Drug Test Panel 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. 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 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.
5. A positive result might be obtained from certain foods or food supplements.

INDEX OF SYMBOLS

	Do not re-use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use-by date
2°C 30°C	Store at 2-30˚C	Σ n	Contains sufficient for <n>tests
	Consult instructions for use	CE	CE Mark
	Manufacturer		Caution
EC REP	Authorized representative in the European Union		

Core Technology Co., Ltd.
Room 100, C Building, No.29 Life Park Rd.,
Changping District, Beijing 102206, P.R. China

EC REP SUNGO Cert GmbH
Harffstr. 47, 40591 Düsseldorf, Germany