# Multi-drug Rapid Test Panel (Urine)

## **INTENDED USE**

The Multi-drug Rapid Test Panel (Urine) is rapid chromatographic immunoassays for the qualitative and simultaneous detection up to sixteen of the following drugs in a variety of combinations in human urine. The designed cutoff concentrations for these drugs are as follows:

Test	Cut-off (ng/mL)	
AMP(Amphetamine)	1000	
THC(Marijuana)	50	
COC (Cocaine)	300	
PCP(Phencyclidine)	25	
MOR/OPI(Morphine)	300	
MET(Methamphetamine )	1000	
MTD(Methadone)	300	
BAR(Secobarbital)	300	
BZO(Oxazepam)	300	
TCA(Nortriptyline)	1000	
MDMA(Ecstasy)	500	
BUP(Buprenorphine)	10	
EDDP(Methadone metabolite)	100	
PPX (Propoxyphene)	300	
ETG(Ethylglucoronide)	500	
K2(Synthetic cannabis)	50	
TML(Tramadol)	100	
MQL(Methaqualone)	300	
COT(Cotinine)	200	
FYL(Fentanyl)	200	
OXY (Oxycodone)	100	
KET (Ketamine)	1000	

The test is used to obtain visual qualitative result and is intended for health care professionals use including professionals at point of care sites to assist in the determination of drug compliance.

## PRINCIPLE

The Multi-drug Rapid Test Panel (Urine) is one-step immunoassay in which chemically labeled drugs (drug-protein conjugates) compete for limited antibody binding sites with drugs which may be present in urine. The test panel contains membrane strips which are pre-coated with drug-protein conjugates on the test band(s). Each strip, the drug antibody-colloidal gold conjugate pad is placed at one end of the membrane. In the absence of drug in the urine, the solution of the colored antibody-colloidal gold conjugate move along with the sample solution upward chromatographically by capillary action across the membrane to the immobilized drugprotein conjugate zone on the test band region. The colored antibody-gold conjugate then attach to the drug-protein conjugates to form visible lines as the antibody complex with the drug conjugate. Therefore, the formation of the visible precipitant in the test zone occurs when the test urine is negative for the drug. When the drug is present in the urine, the drug/metabolite antigen competes with drug-protein conjugate on the test band region for the limited antibody. When a sufficient concentration of the drug is present, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody (drug-protein conjugate)-colloidal gold conjugate to the drug-protein conjugate zone on the test band region. Therefore, absence of the color band on the test region indicates a positive result. A control band with a different antigen/antibody reaction is added to the immunochromatographic membrane strip at the control region (C) to indicate that the test has performed properly. This control line should always appear regardless of the presence of drug or metabolite. If the control line does not appear the test panel should be discarded.

# **I** WARNINGS AND PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse tests.

- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary
  state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It
  is therefore, recommended that these products be treated as potentially infectious, and handled
  observing the usual safety precautions (do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- · Read the entire procedure carefully prior to performing any tests.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all
  specimens as if they contain infectious agents. Observe established precautions against
  microbiological hazards throughout the procedure and follow the standard procedures for
  proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable
  gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- The used testing materials should be discarded in accordance with local regulations.

## COMPOSITION

#### Materials Provided

- Individually packed test panel
   Package insert
  - Materials Required but Not provided

• Timer

- Specimen collection container
- STORAGE AND STABILITY
- The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Care should be taken to protect the components of the kit from contamination. Do not use if
  there is evidence of microbial contamination or precipitation. Biological contamination of
  dispensing equipment, containers or reagents can lead to false results.

## SPECIMEN

- The Multi-drug Rapid Test Panel (Urine) is intended for use with human urine specimens
   only.
- Urine collected at any time of the day may be used.
- · Urine specimens must be collected in clean, dry containers.
- Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Urine specimens may be stored at 2-8 °C for up to 2 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

## TEST PROCEDURE

Bring tests, specimens to room temperature (15-30°C) before use.

- Remove the test from its sealed pouch, and place it on a clean, level surface. For best results, the assay should be performed within one hour.
- Remove the cap from the end of the test card, and immerse the strip(s) of the test card vertically in the urine specimen for at least 10-15 seconds. Do not touch the plastic device when immersing the panel.
- Place the test card on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear. The results should be read at 5 minutes. Do not interpret results after 8 minutes.



#### INTERPRETATION OF RESULTS



appears in the control region (C) and another band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

- The intensity of color in the test region (T) may vary depending on the concentration of analytes
  present in the specimen. Therefore, any shade of color in the test region should be considered
  negative. Note that this is a qualitative test only, and cannot determine the concentration of
  analytes in the specimen.
- Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

## PERFORMANCE CHARACTERISTICS

#### 1. Precision

Precision studies were carried out for samples with concentrations of -100% cut-off, -75% cut-off, -50% cut-off, -25% cut-off, at the cut-off, +25% cut-off, +50% cut-off, +75% cut-off and +100% cut-off. The results obtained are summarized in the following tables:

AMP1000									
Result	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cutoff
Lot 1	50-/0+	50-/0+	50-/0+	47-/3+	24-/26+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	49-/1+	26-/24+	47+/3-	50+/0-	50+/0-	50+/0-
THC50									
Result	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cutoff
Lot 1	50-/0+	50-/0+	50-/0+	49-/1+	24-/26+	47+/3-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	48+/2-	50+/0-	50+/0-	50+/0-
COC300					1		1	1	1
Result	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cutoff
Lot 1	50-/0+	50-/0+	50-/0+	48-/2+	24-/26+	47+/3-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	47+/3-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	47-/3+	26-/24+	48+/2-	50+/0-	50+/0-	50+/0-
PCP25									
Result	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cutoff
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
MOR/OPI 30	0								
Drug	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cutoff
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
MET1000									
Result	-100% Cutoff	-75% Cutoff	-50 % Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cutoff
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
MTD300			1		1				1
Result	-100%	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cutoff
Drug	50-/0+	50./0+	50-/0+	50-/0+	26-/24+	50+/0-	50±/0+	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0+	50+/0-	50+/0+
Lot 2	50./01	50 /01	50 /01	50 /01	24/241	50:/0	501/0	501/0	501/0

## **BAR300**

Diffeoto									
Result	-100%	-75% Cutoff	-50%	-25%	Cutoff	+25% Cutoff	+50% Cutoff	+75%	+100% Cutoff
Drug	50.101	Cuton 50. (0)	50.01	Cuton 50. (0)	25 (25)	Cuton 50:10	Cuton 501/0	Cuton 50 L /0	Cuton 501/0
Lot 1	50-/0+	50-/0+	50-/0+	50./01	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50+/0+	50-/0+	50-/0+	50-/0+	20-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
BZO300									
Result	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cutoff
Drug	50,/0+	50-/0+	50,/0+	50-/0+	25_/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50 /0+	50 /0+	50 /0+	50 /0+	24 /26+	50+/0	50+/0	50±/0	50+/0
Lot 2	50 /01	50 /01	50./01	50 /01	24=/20+	50 1/0	501/0	50 1/0	501/0
Lot 3	J0=/0+	30=/0+	J0=/0+	30-/0+	24=/20+	30+/0-	30+/0-	30+/0-	30+/0-
TCA1000									
Drug	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cutoff
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
MDM 4500									
Result	-100%	-75%	-50%	-25%		+25%	+50%	+75%	+100%
Drug	Cutoff	Cutoff	Cutoff	Cutoff	Cutoff	Cutoff	Cutoff	Cutoff	Cutoff
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
BUP10			•		•				
Result	-100%	-75%	-50%	-25%		+25%	+50%	+75%	+100%
Drug	Cutoff	Cutoff	Cutoff	Cutoff	Cutoff	Cutoff	Cutoff	Cutoff	Cutoff
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
EDDP100									
Result	-100%	-75%	-50%	-25%	Cutoff	+25%	+50%	+75%	+100%
Drug	50.101	Cuton 50. (0)	50.01	Cuton 50. (0)	25 (25)	Cuton 50:10	Cuton 501/0	Cuton 50 L /0	Cuton 501/0
Lot I	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
PPX300									
Result	-100%	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cutoff
Lot 1	50=/0+	50=/0+	50=/0+	50=/0+	25=/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50 /0+	50 /0+	50 /0+	50 /0+	20 /20 /	50+/0	50+/0	50+/0	50+/0
Lot 3	50 /0+	50 /0+	50 /0+	50 /0+	24-7201	50+/0	50±/0	50+/0	50+/0
ETCER	50*/01	504/01	50*/01	50-701	23=/231	501/0-	301704	50170	301704
EIG500 Result	1000/			2.50/			. 500/		. 1000/
Drug	-100% Cutoff	-/5% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+/5% Cutoff	+100% Cutoff
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
K2-50			1					L	1
Result	-100%	-75%	-50%	-25%		+25%	+50%	+75%	+100%
Drug	Cutoff	Cutoff	Cutoff	Cutoff	Cutoff	Cutoff	Cutoff	Cutoff	Cutoff
Lot 1	50-/0+	50-/0+	50-/0+	47-/3+	31-/29+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	28-/22+	47+/3-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	47-/3+	28-/22+	49+/1-	50+/0-	50+/0-	50+/0-
TML100									
Result	-100%	-75%	-50%	-25%	0.00	+25%	+50%	+75%	+100%
Drug	Cutoff	Cutoff	Cutoff	Cutoff	Cutoff	Cutoff	Cutoff	Cutoff	Cutoff
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
MQL300									
Result	-100%	-75% Cutoff	-50%	-25%	Cutoff	+25% Cutoff	+50% Cutoff	+75%	+100%
Drug	50_/0_	50_/0±	50_/0±	50./0±	25_/25+	50+/0	50±/0	50±/0	50±/0
Lot 2	50 /0+	50 /01	50 /01	50 /01	25=123+	501/0-	50:/0	50:/0*	50:/0
LOT 2	50-/0+	50-/0+	50-/0+	50-/0+	20+/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
COT200				ı					-
Result	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cµtoff
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
	20701	20101	20101	2010		20.70-	20170	20.10-	20170

Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
FYL200									
Result	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cutoff

O VII II OO									
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot I	50%/01	50*/01	50%/01	50*/01	254251	501/0*	50170*	50170*	501/0*

#### OXY100

Result	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cutoff
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
VET1000									

KE11000									
Result	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cutoff
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-

#### 2. Stability

The Multi-drug Rapid Test Panel (Urine) is stable at 4-30°C (39-86°F) for 24 months based on the accelerated stability study at 50°C and real time stability studies at 4°C and 30 °C.

#### 3. Interference

Compounds that showed no interference at a concentration of 100µg/mL are summarized in the following tables.

Acetaminophen	β-Estradiol	Oxolinic acid
Acetophenetidin	Erythromycin	Oxymetazoline
N-Acetylprocainamide	Fenoprofen	Papaverine
Acetylsalicylic acid	Furosemide	Penicillin G
Albumin (100 mg/dL)	Gentisic acid	Perphenazine
Aminopyrine	Hemoglobin	Phenelzine
Amoxicillin	Hydralazine	Prednisone
Ampicillin	Hydrochlorothiazide	(±)-Propranolol
Apomorphine	Hydrocortisone	D-Pseudoephedrine
Ascorbic acid	O-Hydroxyhippuric acid	Quinine
Aspartame	3-Hydroxytyramine	Ranitidine
Atropine	Ibuprofen	Salicylic acid
Benzilic acid	D,L-Isoproterenol	Serotonin
Benzoic acid	Isoxsuprine	Sulfamethazine
Bilirubin	Ketamine	Sulindac
Chloral hydrate	Ketoprofen	Tetrahydrocortisone
Chloramphenicol	Labetalol	Tetrahydrocortisone
Chlorothiazide	Loperamide	Tetrahydrozoline
Chlorpromazine	Meperidine	Thiamine
Cholesterol	Meprobamate	Thioridazine
Clonidine	Methoxyphenamine	Triamterene
Cortisone	Nalidixic acid	Trifluoperazine
(-)-Cotinine	Naloxone	Trimethoprim
Creatinine	Naltrexone	DL-Tryptophan
Deoxycorticosterone	Naproxen	Tyramine
Dextromethorphan	Niacinamide	DL-Tyrosine
Diclofenac	Nifedipine	Uric acid
Diflunisal	Norethindrone	Verapamil
Digoxin	Noscapine	Zomepirac
Diphenhydramine	(±)-Octopamine	EMDP
Ecgonine methyl ester	Oxalic acid	Disopyramide
Maprotiline		

## LIMITATIONS OF THE TEST

- 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.
- If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drug of abuse and certain foods and medicines.

### **INDEX OF SYMBOLS**

$\otimes$	Do not reuse	IVD	For in vitro diagnostic use only
4°C-	Stored between 4-30°C	ī	Consult instruction for use
$\triangle$	Caution	LOT	Lot number
$\sum$	Use by	$\sum_{i=1}^{n}$	Contains sufficient for <n> tests</n>
紊	Keep away from sunlight	Ť	Keep dry
***	Manufacturer	(	Do not use if package is damaged

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