

INTENDED USE

The Multi-Drug Rapid Test Panel is a rapid 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 500)	d-Amphetamine	500
Benzodiazepines (BZO 500)	Oxazepam	500
Cocaine (COC 100)	Benzoylcocaine	100
Marijuana (THC 50)	11-nor- Δ^9 -THC-9 COOH	50
Methadone (MTD 300)	Methadone	300
Methylenedioxyamphetamine (MDMA 500)	d,l-Methylenedioxyamphetamine	500
Opiate (OPI 2,000)	Morphine	2,000

PRINCIPLE

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 region of the specific drug dipstick. 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 region.

A drug-positive urine specimen will not generate a colored line in the specific test region of the dipstick because of drug competition, while a drug-negative urine specimen will generate a line in the test region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- Immunoassay for in vitro diagnostic use only. 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 federal, state and local regulations.

STORAGE & STABILITY

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- Immunoassay for in vitro diagnostic use only. 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 federal, state and local regulations.
- **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION and PREPARATION

Urine Assay

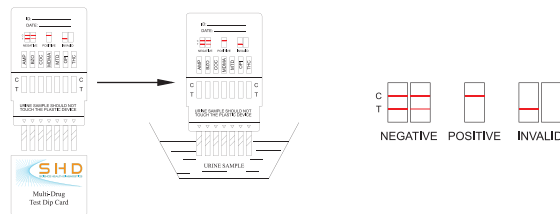
The urine specimen should be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

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.

DIRECTIONS for USE

1. Bring the pouch to room temperature before opening it. Remove the test panel from the sealed pouch and use it within one hour.
2. Remove the cap.
3. With the arrow pointing toward the urine specimen, immerse the test panel vertically in the urine specimen for at least 10 to 15 seconds. Immerse the dipstick to at least the level of the wavy lines, but not above the arrow on the test panel.
4. Replace the cap and place the test panel on a non-absorbent flat surface.
5. Start the timer and wait for the colored line(s) to appear.
6. The drug result should be read at 5 minutes. Do not interpret the result after 10 minutes.



READING THE TEST RESULTS

NEGATIVE: A colored line appears in the Control region (C) and colored lines appear in the Test region (T). This negative result means that the concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.

*NOTE: The shade of the colored line(s) in the Test region (T) may vary. The result should be considered negative whenever there is even a faint line.










POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (T). The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.

INVALID: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for Control line failure. Read the directions again and repeat the test with a new test card. If the result is still invalid, ZZcontact your manufacturer.

LIMITATIONS

1. The Multi-Drug Rapid Test Panel provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as 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 does not indicate level or 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. This test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements.

Index or Symbols

	Attention, see instructions for use		Tests per Kit		Manufacturer
	For in vitro		Use by		Do not reuse
	Store between 2 - 30°C		Lot Number		Catalogue Number

