MULTI-DRUG 7 PANEL INTEGRATED SPLIT CUP (Urine)

HOMEMED

INTENDED USE

The HOMEMED Multi-Drug 7 Panel Integrated Split Cup (Urine) test is a rapid visual immunoassay for the qualitative, presumptive detection of any combination of drugs of abuse in human urine specimens at the cut-off concentrations listed below:

Test	Calibrator	Cut-off (ng/ml)
Amphetamine (AMP)	d-Amphetamine	500
Methamphetamine (MET)	Methamphetamine	500
Benzodiazepine (BZO)	Oxazepam	300
Cocaine (COC)	Benzoylecgonine	150
Marijuana (THC)	11-nor-Δ9-THC-9-COOH	50
Opiates (OPI)	Morphine	2000
Methaqualone (MQL)	Methaqualone	300
Adulteration	Oxidants / Specific Gravity / pH	

The HOMEMED Multi-Drug 7 Panel Integrated Split Cup (Urine) test is used to obtain a visual qualitative result and is intended to assist in the determination of drug compliance. This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/ Mass Spectrometry (GC/MS) or Liquid Chromatography/Mass Spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

The Urine Adulteration Test Strips are a semi-quantitative colour comparison screen for the detection of pH, Specific Gravity and Oxidants in human urine. This test provides a preliminary screen only. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Abnormal results should be sent to a toxicology laboratory for confirmation.

PRINCIPLE

The HOMEMED Multi-Drug 7 Panel Integrated Split Cup (Urine) test is an immunoassay based on the principle of competitive binding. Drugs that may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody. During testing, a portion of the 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 coloured line will appear in the test line region of the corresponding drug strip. The presence of a drug above the cut-off concentration in the urine specimen will saturate all the binding sites of the antibody. Therefore, no coloured line will form in the test line region. A drug-positive urine specimen will not generate a coloured 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 coloured line will always appear at the control line region, indicating that the correct volume of specimen has been added and membrane wicking has occurred.

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results.

One of the best ways to test for adulteration or dilution is to test for Oxidants, and to determine certain urinary characteristics such as pH and Specific Gravity.

Oxidants (OXI): Tests for the addition of products to the urine sample.
Specific Gravity (SG): Tests for specimen dilution.
pH: Tests for the presence of acidic or alkaline adulterants in urine.

MATERIALS

Materials provided
25 Individually packed tests
1 Colorimetric card
1 Package insert
1 Procedure card
25 Security seals

Material not provided
Timer
Handheld DOA Reader

PRECAUTIONS

For *in vitro* diagnostic use only.

- Do not use after the expiration date indicated on the package. Do not use the test if the 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 do not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled by observing usual safety precautions (e.g. 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 testing.
- Do not eat, drink or smoke in the area where 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 standard procedures for the 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.
- Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Kits should be kept out of direct sunlight.
- The product is humidity-sensitive and should be used immediately after opened.
- Any test in an improperly sealed pouch should be discarded.
- 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.

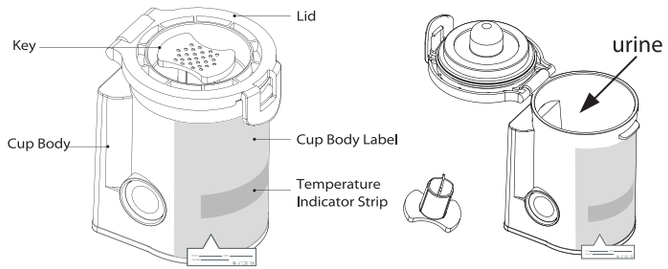
SPECIMEN COLLECTION AND STORAGE

- The HOMEMED Multi-Drug 7 Panel Integrated Split Cup (Urine) test 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.
- Urine specimens exhibiting visible precipitates should be centrifuged, filtered or allowed to settle to obtain a clear specimen 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.

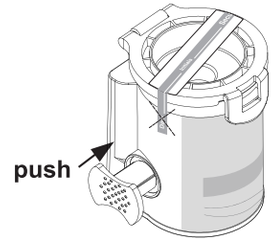
Note: Urine specimens and all materials coming in contact with them should be handled and disposed of as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

PROCEDURE

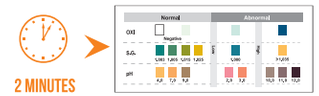
IMPORTANT: Test, urine specimens and/or controls should be brought to room temperature (15-30°C) prior to testing. Do not open pouch until ready to perform the test.



1. Remove the cup and key from the sealed pouch and proceed to use it as soon as possible.
2. The operator removes the key from the lid and completes the particulars on the body label.
3. The donor provides a urine specimen in the cup and closes the lid.
4. Operator confirms the minimum fill volume and checks the temperature strip label at 2-4 minutes after specimen collection. A green colour will appear to indicate the temperature of the urine specimen. The proper range for an unadulterated specimen is 32-38°C.
5. Donor dates, initials and signs the security seal.
6. Operator checks the lid for tightness and attaches the security seal over the lid.
7. While keeping the test in an upright position, the operator pushes the key into the cup and immediately starts the timer.



8. Remove the peel-off label.
9. Read the adulteration strip results at 2-5 minutes. Do not interpret results after 5 minutes.



10. Test result can be confirmed visually or by using a Handheld DOA Reader.
11. **Visual interpretation of test results:** Drug test results are indicated by the presence or absence of coloured lines in the test line region. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

12. **Interpretation of test results using the Assure Tech DOA Handheld Reader:** Insert the test cup into the Reader at 5 minutes and press "Start Test". Follow the Reader's instructions and read the results once displayed.

13. Positive test results must be confirmed by another test method. Send the cup and urine specimen intact to a toxicology laboratory for confirmation.

VISUAL INTERPRETATION OF RESULTS

INTERPRETING DRUGS OF ABUSE TEST RESULTS:
(Refer to illustration above)
Positive: Only one coloured line appears, in the control line region (C). No coloured line appears in the test line region (T) for the drug in question. A positive test result indicates that the drug concentration exceeds the detectable level.
Negative: Two coloured lines appear. One line appears in the control line region (C) and another line appears in the test line region (T) for the drug in question. A negative test result indicates that the drug is absent or the drug concentration is below the detectable level. **Invalid: Control line fails to appear.** Results from any test which has not produced a control line 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 colour intensity of the test line region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of colour in the test line region (T) should be considered negative. Please note that this is a qualitative test only and the concentration of analytes in the specimen can not be determined.
- Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.

INTERPRETING ADULTERATION STRIPS TEST RESULTS:

(Refer to illustration above)

The Adulteration Test Strips are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an all-inclusive representation of possible adulterants.

pH: Tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4,0 to 9,0. Values outside of this range may indicate that the specimen has been altered.

Specific Gravity: Tests for specimen dilution. The normal range is 1,003 to 1,030. Values outside of this range may indicate that the specimen has been altered.

Note: Elevated levels of protein in urine may cause abnormally high Specific Gravity values.

Oxidants: Normal human urine should not contain Oxidants. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the Oxidants pad.

QUALITY CONTROL

- Internal procedural controls are included in the test. A coloured line appearing in the control line region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

- The HOMEMED Multi-Drug 7 Panel Integrated Split Cup (Urine) test is for in vitro diagnostic use, and should only be used for the qualitative detection of drugs of abuse.
- This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.
- There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause incorrect results.
- Adulterants, such as bleach and/or alum in urine specimens, may produce erroneous results regardless of the analytical method used. Therefore, please preclude the possibility of urine adulteration prior to testing.
- A positive test result indicates the presence of a drug/metabolite only, and does not indicate or measure intoxication.
- A negative test result does not at any time rule out the presence of drugs/metabolites in urine, as they may be present below the minimum detection level of the test.
- This test does not distinguish between drugs of abuse and certain medications.

Adulteration Limitations

The Adulteration Test Strips are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an all-inclusive representation of possible adulterants.

PERFORMANCE CHARACTERISTICS

Accuracy: Accuracy of the HOMEMED Multi-Drug 7 Panel Integrated Split Cup (Urine) test was established by comparing a urine sample against GC/MS specification. The following results were tabulated:

% Agreement with GC/MS

Specimen	AMP 500	MET 500	BZO 300	COC 150	THC 50	OPI 2000	MQL 300
Positive	95.9%	96.9%	95.3%	96%	96.8%	97.6%	98.4%
Negative	100%	100%	92.9%	94%	98.3%	98.4%	98%
Total	98.1%	98.3%	93.9%	95%	97.5%	98.1%	98.2%

Analytical Sensitivity: The sensitivity of the HOMEMED Multi-Drug 7 Panel Integrated Split Cup (Urine) test was determined by adding GC/MS confirmed controls to the urine sample at negative, -50% cut-off, -25% cut-off, cut-off, +25% cut-off, +50% cut-off and 3 times of cut-off concentrations.

The results are summarized below:

Drug Concentration (Cut-off range)	n	AMP 500		MET 500		BZO 300		COC 150		THC 50		OPI 2000		MQL 300	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
Negative	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0
50% Cut-off	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0
75% Cut-off	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cut-off	50	14	36	10	40	17	33	24	26	17	33	23	27	14	36
125% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
150% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
3x Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Analytical Specificity: The specificity for the HOMEMED Multi-Drug 7 Panel Integrated Split Cup (Urine) test has been tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in drug-free normal human urine. The HOMEMED Multi-Drug 7 Panel Integrated Split Cup (Urine) test's performance at cut-off point is not affected when pH range of urine specimens is at 3.0 to 8.5 and specific gravity range of urine specimens is at 1.005 to 1.03. The following compounds were found to produce positive results when tested at levels greater than the concentrations (in ng/ml) listed below:

Amphetamine 500 related compounds			
d-Amphetamine	500	Phentermine	1,250
l-Amphetamine	50,000	Paramethoxyam- phetamine	625
3,4-Methylenedioxyam-phetamine	625	Tyramine	>100,000

Methamphetamine 500 related compounds			
Chloroquine	12,500	Mephenterminehemi- sulfate salt	25,000
(+)-Ephedrine	2,000	MDEA	12,500
Fenfluramine	12,500	MDMA	1,875
d-Methamphetamine	500	PMMA	625
l-Methamphetamine	3,125		

Benzodiazepine 300 related compounds			
Alprazolam	125	Lorazepam	1250
Bromazepam	625	Lormetazepam	1250
Chlordiazepoxide	2500	Medazepam	>100,000
Clobazam	63	Midazolam	>100,000
Clonazepam	2500	Nitrazepam	25000
Clorazepate	3330	Norchlordiazepoxide	250
Desalkflurazepam	250	Nordiazepam	500
Diazepam	250	Oxazepam	300
Estazolam	5000	Prazepam	>100,000
Fentanyl	>100,000	Temazepam	63
Flurazepam	>100,000	Triazolam	5000
Flunitrazepam	375		

Cocaine 150 related compounds			
Benzoylecgonine	150	Ecgonine	100,000
Cocaine	125	Ecgonine Methyl Ester	>100,000

Opiate 2000 related compounds			
Acetylcodeine	1,563	Merperidine	>100,000
Buprenorphine	25,000	6-Monoacetylmorphine (6-MAM)	1,250
Codeine	500	Morphine-3-β-d-glucuronide	12,500
Diacetylmorphine (Heroin)	1,250	Nalorphine Hydrochloride	>100,000
Dihydrocodeine	1,563	Oxycodone	>100,000
Ethylmorphine	800	Oxymorphone	>100,000
Hydromorphone	25,000	Rifampicine	>100,000
Hydrocodone	50,000	Thebaine	50,000
Morphine	2,000		

Marijuana parent 50 related compounds			
11-nor-Δ9-THC-9-COOH	50	Δ9-Tetrahydrocannabinol	15,000
11-nor-Δ8-THC-9-COOH	50	Cannabinol	20,000
11-hydroxy-Δ9-Tetrahydrocannabinol	50	Cannabidiol	>100,000
Δ8-Tetrahydrocannabinol	15,000		

Non Cross-Reacting Compounds

The following compounds were found not to cross-react when tested at concentrations of 100 µg/ml:

Acetone	Dextrorphan tartrate	Phenothiazine
Albumin	Dopamine	L-Phenylephrine
Ampicillin	Erythromycin	Procaine
Aspartame	Ethanol	Protonix
Aspirin	Furosemide	Pseudoephedrine
Atropine	Glucose	Quinidine
Benzocaine	Hemoglobin	Ranitidine
Bilirubin	Ibuprofen	Sertraline
b-Phenylethyl-amine	(+/-)-Isoproterenol	Tyramine
Caffeine	Lidocaine	Trimeprazine
Chloroquine	N-Methyl-Ephedrine	Vitamin C (Ascorbic Acid)
Chlorpheniramine	Oxalic Acid	Venlafaxine
Creatine	Penicillin-G	
Dextromethorphan	Pheniramine	

Note: Ephedrine might produce a false positive test result for Methamphetamine (MET).

LITERATURE REFERENCES

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4. McBay AJ. Drug-analysis technology--pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (11 Suppl): 33B-40B.
5. Gilman AG, Goodman LS, Gilman A, eds. Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan; 1980.

GLOSSARY OF SYMBOLS

Σ 1	Catalog number	2°C 30°C	Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer		Do not reuse

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