

Meth Cassette Amphetamine Test (Equipment included)

PRINCIPLE

The Meth Cassette Amphetamine Test is a lateral flow type competitive binding immunochromatographic assay, which uses specific monoclonal antibodies to selectively identify methamphetamine in human urine.

INTENDED USE

The Meth Cassette Amphetamine Test is used for the screening test of methamphetamine in human urine at a cut-off concentration of 1,000 ng./ml.

INDICATION

This Meth Cassette Amphetamine Test is a screening test cassette. The qualitative immunoassay provided only a preliminary analytical test result. The positive result indicates that the sample may contain methamphetamine.

MATERIALS

1. Meth Cassette 2 boxes (25 pcs./box)
2. Leaflets 1 set
3. Specimen collection containers 50 bottles
4. Zip plastic bags 50 bags
5. Label stickers 50 pieces
6. Examination gloves 20 pieces

SPECIMEN COLLECTION AND PREPARATION

SPECIMEN COLLECTION: Collect the urine specimen in a clean container.

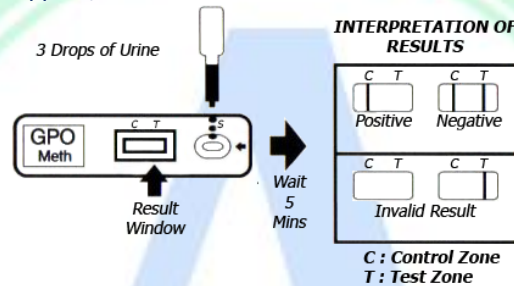
STORAGE AND PREPARATION: If the specimen is not used immediately following collection but is to be used within 48 hours, it should be refrigerated (2-8 °C) and brought back to room temperature before testing. If the specimen is not going to be used if store longer than 2 weeks. Prior to testing, the frozen specimen must be completely thawed, thoroughly mixed, and brought to room temperature.

DIRECTIONS FOR USE

TEST PROCEDURE AND INTERPRETATION OF RESULTS

1. The urine specimen should be tested immediately following collection. In the case of storage specimen at 2-8 °C, bring the specimen back to room temperature 5-10 minutes before testing.
2. Bring the pack of methamphetamine test cassette to room temperature at testing site.

3. Remove the test cassette from the sealed pack and use it as possible.
4. Place the test cassette on a clean and level surface.
5. Hold the dropper vertically and transfer 3 full drops of urine to the sample well, "S", of the test cassette, and start the timer.
6. Wait for the colored band appears in the Control Reaction Zone "C", read the result.
7. Result reading
 - The result should be visually read within 5 minutes.
 - Do not read the result after 5 minutes.
 - If the colored band in the Control Reaction Zone "C", fails to appear, the test result is invalid.



8. Interpretation of result

POSITIVE RESULT *

- A colored band appears in the Control Reaction Zone "C" but not in the Test Reaction Zone "T" this indicates that the methamphetamine level is at or above the cut-off value (1,000 ng./ml.)

NEGATIVE RESULT **

- Two horizontal colored band appear, one in the Control Reaction Zone "C" and one in the Test Reaction Zone "T". This indicates that the methamphetamine concentration is below the cut-off value (1,000 ng./ml.) or the urine specimen does not contain methamphetamine

INVALID RESULT

- A colored band in the Control Reaction Zone "C" fails to appear. Or two horizontal colored band fail to appear, one in the Control Reaction Zone "C" and one in the Test Reaction Zone "T".

NOTE:

- * The positive result has to be confirmed with the standard analytical method.
- ** The shade of colored band in the Test Reaction Zone "T" (test zone) will vary, but it should be considered negative wherever there is even a faint colored band.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not touch chromatography membrane with bare hands.
3. While testing, place the test cassette on a stable level surface.
4. Use the provided dropper. It is for single use only.
5. Test cassette is sensitive to moisture and heat, should be used immediately after taking out of the sealed pack. Do not use after the expiration date imprinted on the test kit package.
6. Test cassette is disposable, for single use only. Do not reuse.
7. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
8. Urine specimens may contain infectious agents and should be handled as potential pathogens.

STORAGE

1. The test cassette must be stored at room temperature or at 4-30 °C until expiration date.
2. The test cassette should remain in the sealed pack until use.
3. Avoid exposing to moisture. Keep test cassette away from moisture.
4. Avoid long-term exposure to direct sunlight and heat.

LIMITATION

1. This test cassette is validated for testing human urine only.
2. Should not be used to test the specimen taken from the dead body.
3. Do not pool urine specimens.

WARNING

1. The Meth Cassette Amphetamine Test provides only a preliminary analytical result. A secondary standard analytical method must be used to obtain a confirmed result.
2. Negative result may indicate that the methamphetamine concentration of urine specimen is below the test cassette cut-off value.
3. The Meth Cassette Amphetamine Test contains substances originated from animals. Although the animals have been subjected to appropriate veterinary control, there is no proof that the test is free transmissible pathogenic agents. Therefore, the appropriate bio-safety precautions should be followed such as avoid ingestion or inhalation.
4. Urine specimens may contain infectious agents. Always wear disposable gloves when specimens are being tested.

PERFORMANCE CHARACTERISTICS

- Cut-off value of the Meth Cassette Amphetamine Test is 1,000 ng./ml.
- Specificity of the Meth Cassette Amphetamine Test is 100%
- A list of the chemicals and drugs that have no cross-reactivity (at concentration of 100 micrograms/milliliter).⁽²⁾

(-)-Menthol	Berberine
(+/-)-Brom-phenir-amine	Beta-Estradiol
(+/-)-Phenyl-propanpl-amine	Betamath-ason
(+/-)-Sotalol	Bilirubin
(+/-)-Sulpride	Bumet-anide
(1S,9R)-beta-Hydrastine	Bupl-vacaine
(R)-(-)-Deprenyl	Butyro-phenone
1,1 Di-methyl-biguamide	Camphor
1,3-Dimethyl-uric Acid	Canrenoic Acid
1,7-Dimethyl-xanthine	Captopril
17-alpha-Ethynyl-estradiol	Carbamyl-beta-Methyl-chlorine Chloride
2-(Chloro-phenoxy)-2-Methyl-propionic Acid Ethyl Ester	Carbo-platin
2,2,2-Trichloro-ethane	Cariso-prodol
2,3-Di-mercapto-propanol (Dimer-caprol)	Cefactor
2-Butynoic Acid	Cefadroxil
2-Ethyl-2-Phenyl-malon-amide	Cefoxitin
3,3-Methyl-ene-bis-(4-Hydroxy-coumarin)(Di-cumarol)	Ceftri-axone
3,4-Dihydroxy-phenyl-acetic Acid	Cefur-oxime
3,5,5-Tri-methyl-oxazoli-dine- 2,4-Dione (Trimeth-adione)	Cepha-loridine
3-Methoxy-tyramine	Cephra-dine
4,4-Diamino-diphenyl Sulfone (Dapsone)	Chlor-cyclizine
4-Dimethyl-amine-antipyrine	Chloro-Thiazide
4-Hydroxy-3-Methoxy-Phenyl-acetic Acid	Chloro-trianisene
5-Hydroxy-indole-2-Carboxylic Acid	Chlor-zoxazoneZopiclone
5-Hydroxy-indole-3-Acetic Acid	Chol-esterol
5-Hydroxy-tryptamine (Sero-tonin)	Cin-chonidine
5-Methoxy-tryptamine	Cinoxacin
5-Pregnan-3 beta-OL-20-ONE	Clobeta-son
6-alpha-Methyl-17-alpha-Hydroxy-Progesterone	Clozapine
6-alpha-Methyl-presni-solone	Colchicine
6-Mercap-topurine	Cortisone
Acet-aldehyde	Cromolyn
Acet-aminophen (4-acet-amido-phenol)	Cyclo-phosph-amide
Acetazol-amide	D-Amygdalin
Aceto-phenetidn	Dan-trolene
Aceto-promazine	Deferox-amine Mesylate
Albumin Standard	Desoxi-metasone
Albuterol (Sal-butamol)	Dexa-methasone
Allo-purinol	Diazoxide
Alpha-Chloralose	Dichloro-methane
Alprenolol	Dichlor-phenamide
Amcino-nide	Diclofenac
Amcionide	Di-cyclomine
Amiloride	Dieldrin
Amonium Chloride	Diethyl-dithio-carbamic Acid
Ampho-tericin B	Di-florasoneDiacetate
Aniline	Difflocort-olone (pivalate)
Antipyrine	Digitoxin
Astem-izole	Dimen-hydrinate

Atenolol	Dipyrid-azole
Aza-thioprine	Dipyron
Barbituric Acid	DL-3,4-Di-hydroxy-mandelic Acid
Beclomethasone	DL-Aspartic Acid
Bendroflu-methiazide	DL-Indole-3-Lactic Acid
Bendro-flumethi-azide	DL-Nor-meta-nephriene
Benzydine	DL-Phenyl-alanine
Benzoic Acid beta-Diethyl-amino-ethyl Ester (Ben-actyzine)	DL-Pro-pranilol
Benzo-caine	DL-Tropic Acid
Benzolic Acid	DL-Trypto-phanZopiclone
Benzphet-amine	d-Norprop-oxyphe
Benz-thiazide	Dobut-amine
Benzyl-amine	Doxy-cycline
d-Propoxy-phene	Mianserin
Dro-peridol	Milrinone
d-Tubo-curarine Chloride	Minaprine
EDTA (Ethylene-diamine-tetra-acetic Acid)	Nabu-metone
Emetine	N-Acetyl-procain-amide
Eserine	Nadolol
Estrone	Nal-buphine
Estrone-beta-D-Glucur-onide	Nalidixic Acid
Ethacrynic Acid	Nalmefene
Etham-butol	Naphthol
Ethamivan	N-Des-methyl-dozapine
Etho-propazine	Neomycin Sulfate
Ethylene Glycol	Nitro-furantoin
Ethyl para-amino-benzoate	Nor-floxacin
Etodolac	Orotic Acid
Etoposide	Oxolinic Acid
Famo-tidine	Ox-prenolol
Ferrous Sulfate	Oxy-butynin Chloride
Flu-fenamic Acid	Oxyphen-butazone
Flunisolide	Oxy-purinol
Fluphen-azine	Paclitaxel (Taxol)
Flurand-renolide	Pan-curonium Bromide
Flurbi-profen	Para-Amino-benzoic Acid
Form-aldehyde	Para-Phenylenediamine
Gem-fibrozil	Pargyline
Gent-amicin Sulfate	Penta-chloro-phenol
Glucose	Pent-oxifylline
Glybend-amide (Gly-buride)	Pentyl-enetetra-zole
GuaiacolGlyceryl Ether Carbamate	Phenol
Guan-ethidine	Phenol-phthalein
Halcino-nide	Phenoxy-methyl-Penicillinic Acid (Penicillin V)
Halo-peridol	Phentol-amine
Hemo-globin	Phenyl-tolox-amine
Hexa-chloro-cyclo-hexane	Picrotoxin
Hexa-chloro-phene	Pilo-carpine
Hippuric Acid	Pimozide
Homa-tropine	Pindolol
Hydral-azine	Pipemidic Acid
Hydrocor-tisone	Potassium Iodine
Hydro-flumethi-azide	Prazosin
Hydroxo_cobalamin	Prilocaine
Hydroxy-zine	Prima-quine
Imidazole-4-Acetic Acid	Proadifin
Indap-amide	Pro-benecid
Ipra-tropium Bromide	Pro-cyclidine
Iproniazid	Propionyl-promazine

Isoniazid Acid (Iso-nicotinic Acid Hydrazide)	Pthalic Acid
Isoprop-amide Iodide	Pyridine-2-Aldoxime-Metho-chloride
Kynurenic Acid	Pyridoxine
L-Asparic Acid	Quinolinic Acid
L-Hyoscy-amine	Rescinn-amine
Lisinopril	Reserpine
Lithium Carbonate	Ritodrine
Loper-amide	S-(-)-Carbidopa
L-Pipecolic Acid	Salicyl-amide
Mebend-azole	Salicylic Acid
Meclizine	Sodium Formate
Meclo-fenamic Acid	Strychnine
Mefen-amic Acid	Succinyl-choline Chloride
Melphalan	Sulfa-methazine
Mephen-esin	Sulfa-meth-oxazole
Mersaly Acid	Sulfanil-amide
Meta-caminol	Sulfathiazole
Meta-proterenol	Sulfi-soxazole
Methazol-amide	Suxi-buzone
Metho-trimepra-zine	Tamoxifen
Methox-amine	Tannic Acid
Methoxy-amine	Ten-oxicam
Methoxy-phenamine	Ter-fenadine
Methyl Salicylate	Theo-bromine
Methyl Viologen	Theo-phylline
Methylene Blue	Thiamine
Methyl-phenidate	Thi-merosal
Meticrane	Thymol
Metro-nidazole	Timolol
Tolaz-amide	Tropine
Tolbut-amide	Trypt-amine
Tolmetin	Tyrosine
Toluene	Vincamine
Trans-2-Phenyl-cyclo-propyl-amine	Warfarin
Trazodone	Xylometa-zoline
Triam-cinolone	Yo-himbine
Trichlor-methiazide	Zear-alenone
Trichloro-acetic Acid Sigma Ultra	

BIBLIOGRAPHY

1. Medical Device Control Division; Thai FDA, Guidelines for the document Preparation of Methamphetamine test device using CSDT, Handout of the training "Preparation of the document for Methamphetamine test device using Common Submission Dossier Template (CSDT)", 19 Apr 2016
2. i-MED Laboratories Co., Ltd., Analytical Specificity Report of GPO Meth Strip and Cassette.



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