274 mm x 218mm

CE Insight | AMP

Rapid Competitive Immunochromatographic Assay for the detection of Amphetamine in human urine

DEVICE

DEVICE

INTENDED USE
INSIGHT-AMP is a rapid, qualitative, immunochromatographic assay for the detection of amphetamine in human urine. This test is used to screen the amphetamine intoxication. For healthcare professional use only.

SUMMARY
Amphetamine (AMP) is a central nervous system (CNS) stimulant (psychostimulant), a sympathomimetic amine. AMP may either be taken orally, intravenously or by smoking. AMP is readily absorbed from the gastrointestinal tract and is then metabolized to either deaminated (hippuric and benzoic acids) and hydroxylated metabolites or excreted unchanged in urine and can result in anorexia, hyperthermia, cardiovascular dysfunction euphoria, increased alertness and may have other adverse effects during pregnancy such as miscarriages, stillbirths and sudden infant death syndrome (SIDS). Amphetamine has a half-life of 7 to 32 hours.
INSIGHT-AMP detects the presence of amphetamines in human urine specimen, qualitatively, at concentrations as low as 1000ng/ml.

PRINCIPLE
INSIGHT-AMP is based on the principle of agglutination of antibodies/ antisera with respective antigen in a competitive immuno-chromatography format along with use of nano gold particles as agglutination. The conjugate pad is impregnated with two components - Agglutinating sera for Amphetamine conjugated to colloidal gold and rabbit globulin conjugated to colloidal gold. As the test specimen flows through the membrane assembly of the device, the Agglutinating sera for Amphetamine- colloidal gold conjugate complexes with the Amphetamine present in the test specimen and travels on the membrane due to capillary action along with the rabbit globulin-colloidal gold conjugate. This complex moves further on the membrane to the test region (T) where it is not immobilized by Amphetamine conjugated to BSA coated on the membrane, therefore forming no band. The absence of this band in the test region (T) indicates a positive result.
In absence of Amphetamine in the test specimen, the Agglutinating sera for Amphetamine-colloidal gold conjugate and along with rabbit globulin-colloidal gold conjugate moves further on the membrane to the test region (T) where it is immobilized by the Amphethamine conjugated to BSA coated on the membrane, forming a pink coloured band indicating a negative result.
The rabbit globulin colloidal gold conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the Agglutinating sera for rabbit globulin coated on the membrane at the control region (C) forming a pink coloured band. This control band acts as a procedural control and serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED
A. Each INSIGHT-AMP kit contains individual pouches each containing a
   1. DEVICE : Membrane test assembly impregnated with colloidal gold conjugated to the Agglutinating sera for Amphetamine and rabbit globulin, Amphetamine conjugated to BSA and the Agglutinating sera for rabbit globulin at the respective regions.
   2. PIPETTE : Sample applicator.
   3. Desiccant pouch.

B. Package insert.

REF	10803010	10803050
Σ	10	50

OPTIONAL MATERIAL REQUIRED
Variable volume precision micropipettes, stopwatch.

STORAGE AND STABILITY
The sealed pouches in the test kit and the kit components may be stored between 4 - 30°C till the duration of the shelf life as indicated on the pouch/carton. DO NOT FREEZE.

NOTE
1. For in vitro diagnostic and professional use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.

4. Handle all specimen as if potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.
6. If desiccant colour at the point of opening the pouch has turned from blue to pink or colourless, another test device must be run.
7. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.

SPECIMEN COLLECTION AND PREPARATION

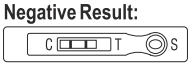
1. INSIGHT-AMP uses human urine as specimen.
2. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
3. A clean dry plastic or glass container may be used for specimen collection.
4. Though fresh specimen is preferable, in case of delay in testing, it may be stored at 2-8°C for maximum up to 24 hours.
5. Refrigerated specimens must be brought to room temperature prior to testing.
6. Repeated freezing and thawing of the specimen should be avoided.
7. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.

TESTING PROCEDURE

1. Bring the kit components of INSIGHT-AMP device to room temperature before testing.
2. Open a foil pouch by tearing along the "notch".
3. Remove the testing device and the sample applicator.
4. Check the colour of the desiccant pouch. It should be blue. If the desiccant has turned colourless or pink, discard the test device and use another device. *Once opened, the device must be used immediately.*
5. Label the device with specimen identity.
6. Place the testing device on a flat horizontal surface.
7. Holding the sample applicator vertically, carefully dispense exactly two drops of the test specimen into the specimen port (S). Alternatively, using a micropipette, carefully dispense exactly 50 µl of test specimen into the specimen port (S).
8. Start the stopwatch. Read the results at the end of 5 minutes. Do not interpret the results beyond 8 minutes.

INTERPRETATION OF RESULTS

Negative Result:

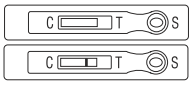


Two pink coloured bands appear at the control region (C) and test region (T). This indicates absence of amphetamine in the specimen.

Positive Result:

One pink coloured band appears at the control region © This indicates that the specimen contains detectable amount of amphetamine.

Invalid Result:



The test result is invalid if no band appears either at the control region (C) or test region (T). In such cases, verify the test procedure and repeat the test with a INSIGHT-AMP device.

Important: A very faint line on the test region indicates that the amphetamine in the sample is near the cut-off level for the test. These samples should be re-tested or confirmed with a more specific method before a positive determination is made.

REMARKS

1. The deliberate slow reaction kinetics of INSIGHT-AMP is designed to maximize and enhance reaction time between sample capture and tracer elements to improve test sensitivity.
2. Most positive results develop within 5 minutes. However, some samples may take a longer time to flow. Therefore, negatives should be confirmed only at 8 minutes. Do not interpret the results beyond 8 minutes.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
4. The assay is designed for use with human urine only.
5. A preliminary positive result indicates only the presence of amphetamine and does not indicate or measure intoxication.
6. There is a possibility that technical/or procedural errors as well as other substances or factors not listed may interfere with the test and cause false results. See specificity section that will produce positive results, or that do not interfere with the test performance.

7. If adulteration is suspected, the test should be repeated with a new sample.
8. Certain over the counter or prescription medications (or certain foods) may cause false results.
9. The length of time following drug use for which a positive result may occur is dependent upon several factors, including the frequency and amount of drug, metabolic rate, excretion rate, drug half life, the user's age, weight, activity and diet.
10. **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) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.**

PERFORMANCE CHARACTERISTICS

1. **Sensitivity** : INSIGHT-AMP detects amphetamine at concentrations equal to or greater than 1000 ng/ml.
2. **Specificity** : Interference of substances that may be present in urine specimen, as well as effect of sample pH and specific gravity was also studied.
   a. Cross-reactivity of non amphetamine related compounds at concentrations much higher than normally found in the urine of people using or abusing them were tested using assay devices.
   b. No cross-reactivity was detected with the substances listed in table I. Table II lists amphetamine related substances and concentrations that produced positive results approximately equivalent to the cut-off level for amphetamine.

Table I:

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

Acetone	Acetaminophen
Albumin	Amitriptyline
Ampicillin	Aspartame
Aspirin	Atropine
Benzocaine	Bilirubin
Caffeine	(+)- Chlorpheniramine
Chloroquine	Creatine
(+/-) - Chlorpheniramine	Pheniramine
Dextromethorphan	4 - Dimethylaminoantipyine
Dexbrompheniramine	(-)- Epinephrine
Dopamine	Ethanol
Erythromycin	Guaiacol glyceryl ether
Furosemide	Hemoglobin
Glucose	(+/-) - Isoproterenol
Imipramine	Lidocaine
(1R,2S) - (-) - N- Methyl - Ephedrine	(+)- Naproxen
(+/-) 3,4 - Methylenedioxymethamphetamine	Oxalic Acid
(+/-) - Norephedrine	Pheniramine
Penicillin - G	l- Phenylephrine
Phenothiazine	Riboflavin
Quinidine	Sulindac
Sodium Chloride	Trifluoperazine
Thioridazine	Tyramine
Trimethobenzamide	Vitamin C

Table II:
The following structurally related compounds produced positive results when tested at levels equal to or greater than the concentration listed below.

Compound	Concentration (ng/ml)
d - Amphetamine	1,000
l - Amphetamine	1,000
(+/-) 3,4 Methylenedioxyamphetamine (MDA)	2,000
d - Methamphetamine	1,000
(+/-) - 3,4 - MDMA	2,000

WARRANTY

This product is designed to perform as described on the label and the package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

(1). www. drug detection. net/drug. html (2). Klabunde R.E., Cardiovascular Pharmacology Concepts; Beta Adrenoceptor Antagonists (Beta Blockers), Sympathomimetics, 2006. (3). Wu. AH, Onigbhinde TA, Wong SS, Johnson KG, Evaluation of full scanning GC/ion trap MS of NIDA drugs of abuse urine testing in urine. J. Anal. Toxicol. 1992, May, Jun; 16(3) pgs 202-206. (4). Drugs and Human Performance, FACT SHEETS Cannabis, Amphetamines. (5). Kreek M.J. and Hartmann N. Chronic use of opiods and anti psychotic drugs, side effects , effects of endogenous opiods and toxicity; Annals New York academy of Science pgs 151-172. (6). Drugs of Abuse, Drug Enforcement Administration (DEA) Barbiturates pg 52, Benzodiazepines pg 53, Cocaine pg 45. (7) Data on file: Tulip Diagnostics (P) Ltd.

SYMBOL KEYS

Temperature Limitation	Consult Instructions for use	Date of Manufacture	Do not reuse
Manufacturer	*In vitro* Diagnostic Medical Device	This side up	Production site
Use by	Catalogue Number	Device	Authorised Representative in the European Community
Contains sufficient for <n> tests	Batch Number / Lot Number	Disposable Plastic Sample Applicator	

TULIP DIAGNOSTICS (P) LTD.

PS

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