INSTANT-VIEW®Amphetamine Urine Test *(Cassette)* CE

One Step Assay
Rapid Visual Results
For Qualitative In Vitro Diagnostic Use

INTENDED USE
This device is a qualitative immunoassay intended to be used for detecting amphetamine in human urine at a cutoff level of 1000 ng/ml. It is for health care professional use only.

This assay provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

SUMMARY AND EXPLANATION OF THE TEST
The detection of amphetamines in human urine has been widely used to assess the abuse of amphetamines. Amphetamines are central nervous system stimulating drugs. They may induce alertness, wakefulness, increased energy, reduced hunger and overall feeling of well being. Overdose and extended usage of amphetamines may lead to substance abuse, which may cause severe and/or permanent damage to the human nerve system. Amphetamines appear in the urine within three hours after administration (any type), and be present for about 24-48 hours after the last dose.

PRINCIPLE OF THE PROCEDURE
This assay is a one-step lateral flow chromatographic immunoassay. The test strip includes 1) a burgundy-colored conjugate pad containing mouse anti-amphetamine antibodies coupled to colloidal gold; and 2) nitrocellulose membrane containing a Test (T) line and a Control (C) line. The Test line is coated with amphetamine-BSA, and the Control line is coated with goat anti-rabbit IgG antibody.

This test is a competitive binding immunoassay. The amphetamine in the urine specimen competes with the amphetamine–BSA antigen coated on the nitrocellulose membrane for the limited binding sites of the conjugated anti- amphetamine antibodies.

When an adequate amount of urine specimen is applied to the sample pad of the device, the urine specimen migrates by capillary action through the test strip. If the level of amphetamine in the urine specimen is below the cutoff (1,000 ng/ml), the Test line appears as a visible burgundy line. If the level of amphetamine in the urine specimen is at or above the cutoff, no Test line develops.

The C line binds to the gold-conjugated rabbit IgG and form a burgundy color line, regardless of the presence of amphetamine.

REAGENTS AND MATERIALS SUPPLIED
- 25 test devices, each sealed in a pouch with a dropper pipette.
- 1 package insert (Instructions for Use).

MATERIAL REQUIRED BUT NOT PROVIDED
- Specimen collection containers
- Timer

STORAGE AND STABILITY
Store the kit at room temperature 59-86°F (15-30°C). Each device may be used until the expiration date printed on the label if it remains sealed in its foil pouch.

Do not freeze and/or expose the kit to temperatures over 30°C (86°F). **15°C**  **30°C**

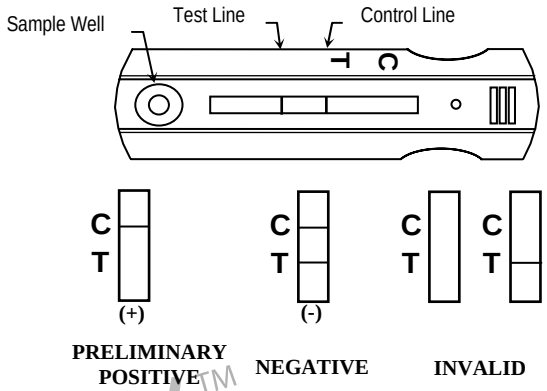
SPECIMEN COLLECTION
1. Each urine specimen must be collected in a clean container. Do not mix specimens.
2. Specimens may be kept at 15-30°C (59-86°F) for 8 hours, at 2-8°C for up to 3 days and at -20°C or lower for long term storage.

PRECAUTION
1. The instructions must be followed exactly to obtain accurate results.
2. Do not open the sealed pouch, unless ready to operate the assay.
3. Do not use expired devices.
4. Dispose of all specimens and used assay materials in a proper biohazard container.

ASSAY PROCEDURE
1. Refrigerated specimens and other test materials, including devices, **must be equilibrated to room temperature before testing**.
2. Remove the test device from its pouch and place it on a flat surface. Label the device with specimen identification.
3. Holding the dropper vertically, add four drops of the specimen to the sample well.
4. Read the test result between four (4) to seven (7) minutes after adding the specimen.

INTERPRETATION OF RESULTS

***IMPORTANT*: Do not read test results after seven (7) minutes. The T Line should always be interpreted independently of the C Line.**



PRELIMINARY POSITIVE **NEGATIVE** **INVALID**

Positive:
If only the C line appears, the test indicates that the amphetamine level in the sample is at a cutoff of 1000 ng/ml or higher.
Samples with preliminary positive results should be confirmed with a more specific method before a positive conclusion is made.

Negative:
If both the C line and T line appear, the test indicates that the amphetamine level is below 1000 ng/ml.
Note: A very faint T line should be considered negative.

Invalid:
If no C line develops within 5 minutes, repeat the assay with a new test device.

QUALITY CONTROL
- **Built-in Control Features**
  This test contains built-in control feature, the C line. The appearance of the burgundy C line indicates that the proper volume of specimen has been absorbed and that capillary flow has occurred. The C line should always appear regardless of the presence of the chemicals being detected. If the C line does not develop within 5 minutes, review the whole procedure and repeat test with a new device.

- **External Quality Control**
  Users should always follow the appropriate federal, state, and local guidelines concerning the running of external quality controls. SAMHSA recommends that the concentration of drug(s) in positive and negative controls be approximately 25% above and below the cutoff concentration of the assay.

LIMITATIONS
1. This test is for *professional in vitro* diagnostic use only.
2. Results obtained by this device provide only a preliminary qualitative result. A more specific alternate chemical method must be used in order to obtain a confirmed result.
3. This product is designed for testing human urine only.
4. Adulterants such as bleach or other strong oxidizing agents may produce erroneous test results if present in the sample. When suspected, collect a fresh specimen and repeat the test with a new device.
5. Samples in which bacterial contamination is suspected should not be used. These contaminants may interfere with the test and cause false results.

EXPECTED VALUES
This test is capable of detecting amphetamine at a cutoff level of 1000 ng/ml.
PERFORMANCE CHARACTERISTICS
1. Accuracy

A study was performed at three different Physician's Office Laboratories (POL) and a Reference Laboratory. One hundred nineteen (119) clinical samples were blind labeled and tested. Each sample was tested at each site, and compared with GC/MS results.
The results agreed 100% with the GC/MS data of specimens at levels below 75% of the cutoff (negative) and above 125% of the cutoff (positive). Thirty seven (37) discrepancies were observed on the specimens at the level between 75% and 125% of the cutoff.

The overall agreement was 92.2%.

		AMP Test		Tot	Agreeme
		Positi	Negati		
GC/M (ng/m	Drug-free	0	176	176	100%
	<75% (0~750)	0	76	76	100%
	75%~Cutoff (750~1000)	36	24	60	40%
	Cutoff~125% (1000~1250)	15	1	16	93.8%
	Positive (>1250)	148	0	148	100%
Total		199	277	476	92.2%

2. Precision

Precision was determined at three different POL locations, by persons with diverse educational backgrounds and work experience. Forty pooled drug-free human urine specimens were spiked with amphetamine at different levels. All specimens were blind labeled and tested. The results are as follows:

Amp. Con (ng/ml)	No of San	POL 1		POL 2		POL 3	
		+	-	+	-	+	-
0	8	0	8	0	8	0	8
750	8	3	5	0	8	3	5
1000	8	8	0	8	0	8	0
1250	8	8	0	8	0	8	0
2000	8	8	0	8	0	8	0

The results indicate a 95.0% concordance with the expected results.

3. Cross-Reactivity

A study was conducted using amphetamine-related compounds to determine the cross-reactivity of the test.

Amphetamine related compounds showing the lowest concentration of the producing a positive response equivalent to the cut-off level.

Compounds	Conc. (ng/ml)
d-Amphetamine	*1000*
l-Amphetamine	*20,000*
d-,l-Amphetamine	*1000*
3,4-methylenedioxyamphetamine (MDA)	*3000*

4. Interfering Substances

The following analytes including commonly prescribed therapeutic drugs were spiked in urine pools containing 0 or 1000 ng/ml amphetamine and tested. No effects were observed from those analytes at 1.0 mg/ml.

Compounds tested and found not to interfere with the results of the tes ng/ml or 1000 ng/ml Amphetamine in urine (Concentration at 1.0 mg/ml)

Acetaminophen	*Codeine*
Acetylsalicylic Acid	*Cortisone*
Amikacin	*Dextromethorphan*
Amitriptyline	*Methadone*
Ampicillin	*Methanol*
Arterenal	*Oxalic Acid*
Atropine	*Penicillin-G (Benzylpenicillin)*
Benzoic Acid	*Pheniramine*
Benzoylecgonine	*Phenylpropanalamine*
Caffeine	*Ranitidine*
(+)-Chlorpheniramine	*Salicyclic Acid*
(+/-)-Chlorpheniramine	*Thioridazine*
Cocaine	*Trifluoperazine*

Biological Analytes	Concentration
Albumin(serum)	*2,000 μg/ml*
Bilirubin	*1,000 μg/ml*
Creatine	*1,000 μg/ml*
Glucose	*2,000 μg/ml*
Hemoglobin	*1,000 μg/ml*
pH	*5.0-9.0*
Uric Acid	*1,000 μg/ml*
Vitamin C (L-Ascorbic Acid)	*1,000 μg/ml*

There is a possibility that other substances and/or factors not listed may interfere with the test and cause false results.

REFERENCES

- FDA Guidance for labeling Urine Drugs of Abuse Screening Testing, Kshit Mohan, 7/21/87.
- Urine Testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA): Research Monograph 73, 1986.
- Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man, 4th ED., Biomedical Publ., Davis, CA; p44-46, 1995.
- Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, Fed. Regist., 53 (69): 11970 (1988).

	Temperature limitation		Use by YYYY-MM
LOT	Batch/Lot code	IVD	*In vitro* diagnostic medica device
	Manufacturer	REF	Catalog number
	Contains sufficient for < n > tests		Consult instructions for us
	For IVD performance evaluation or		Do not reuse
	Caution, consult accompanying documents	CE	CE Mark

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