QuickScreen™ Metamphetamine Test (RAP-2837)

IVD

Revised 26 Jan. 2006

Intended Use

The QuickScreen One Step Metamphetamine Test is a rapid, qualitative immunoassay for the detection of (+)-Metamphetamine in urine. The cutoff concentration for this test is 500 ng/ml, as recommended by the U.S. Department of Defense and adopted by U.S. Laboratory Certification Program. This corresponds to the Substance Abuse and Mental Health Services Administration (SAMHSA) recommendation for the confirmation test cutoff for GC/MS [8].

This test provides only a preliminary test result. A more specific alternate testing method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrography (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug-of-abuse test results, certainly when preliminary positive results are observed.

Summary and Explanation of the Test

(+)-Methamphetamine and its metabolites are central nervous system stimulants whose pharmacological properties include alertness, wakefulness, increased energy, reduced hunger and an overall feeling of well being. Large doses and extended usage can result in higher tolerance levels and physiological dependency.

Urine based screening tests for drugs of abuse range from complex analytical procedures to simple immunoassay tests. The sensitivity and rapidity of immunoassays have made them the most accepted method of preliminary screening for drugs of abuse in urine. This allows the laboratory to eliminate the large number of negative specimens and focus on the smaller number of initially positive specimens.

Principles of the Procedure

QuickScreen™ One Step Methamphetamine Test is a competitive immunoassay that is used to screen for the presence of (+)-Metamphetamine in urine. It is a chromatographic absorbent device in which drug or drug metabolites in a sample compete with drug/protein conjugate immobilized on a porous membrane for a limited number of antibody/dye conjugate binding sites. The test device employs a unique combination of monoclonal and polyclonal antibodies to selectively identify (+)-Methamphetamine in urine with a high degree of confidence.

In the procedure, urine is added to the test device in the Sample Well with the aid of a plastic transfer pipette. The urine is absorbed into the device by capillary action, mixes with the antibody/dye conjugate, and flows across the pre-coated membrane. When **Metamphetamine levels are below 500 ng/ml** (the detection sensitivity of the test), antibody / dye conjugate binds to the drug/protein conjugate immobilized in the Test Region (T) of the device. This produces a colored Test Band that, ***regardless of its intensity***, indicates a negative result.

When sample Methamphetamine levels are at or above 500 ng/ml, free drug in the sample binds to the antibody/dye conjugate, preventing the antibody / dye conjugate from binding to the drug / protein conjugate immobilized in the Test Region. This prevents the development of a distinct colored Test Band, indicating a potentially positive sample.

In either case, a colored Control Band is produced in the Control Region (C) by a non-specific antibody-dye/conjugate reaction. This band serves as a built-in quality control device that demonstrates antibody recognition and reactivity as well as confirmation that the test is complete.

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Reagents & Materials Supplied

1. **50 Test Devices:**
   a) Monoclonal anti-Methamphetamine antibody/colloidal gold conjugate in a protein matrix containing 0.1% sodium azide coated in the sample path
   b) Methamphetamine protein conjugate immobilized as a line in the test region
   c) Goat anti-mouse antibody immobilized as a line in the control region
   d)
2. Directional Insert
3. (Optional) Single Specimen Collection Kit – or -
4. (Optional) Split Specimen Collection Kit

Note: In addition to the materials supplied, a clock or other suitable timer is required.

Warnings & Precautions

1. FOR IN VITRO DIAGNOSTIC USE ONLY.
2. For professional use only.
3. Urine samples have the potential to be infectious. Follow Universal Precautions for proper handling and disposal methods.
4. Do not use this kit beyond its expiration date.
5. This method has been established using urine only. No other fluids have been evaluated.
6. Do not reuse the Test Device.

Storage and Handling Requirement

This kit is to be stored at room temperature (15-28°C); do not freeze. Refer to the expiration date for stability.

Sample Collection and Preparation

A fresh urine sample should be collected in one of the above-mentioned collection kit or equivalent. Alternately, a clean, dry plastic or glass container, unused and without preservatives, may be used for specimen collection. Testing requires only a small volume (1-2 ml) of urine in the sample container. If required by your procedure, aliquot a portion of urine into a second container for later confirmation of results. If not required, dispose of all but 1-2 ml of urine and save the remainder for the QuickScreen test.

Samples may be tested immediately or stored for up to 48 hours at 2 to 8° C. For longer storage, freeze samples at -20° C or below.

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Assay Procedure

Preparation
1. Confirm that all samples and test components are at room temperature (15-28°C) before testing.
2. Do not break the seal on the foil pouch until you are ready to perform the test.

Testing
1. Open the foil pouch at the notch and remove the test device and transfer pipette. Take care not to touch the exposed membrane. Place the device on a clean, level surface.
2. Hold the dropper vertically and dispense 4 full drops of urine into the Sample Well. Wait 5 seconds between adding each drop.
3. Read the result immediately at (10) minutes. Results read after more than 10 minutes have elapsed and should be considered invalid.

Interpretation of Test Results

Negative – A negative result is indicated when two (2) colored band appear, one in the Control Region (C) and one in the Test Region (T). This result indicates a Methamphetamine level that is below the detection sensitivity of 500 ng/ml.

Positive: A Positive result is indicated when only one (1) colored band appears in the Control Region (C) and no band appears in the Test Region (T). This result indicates a methamphetamine level that is at or above the detection sensitivity of 500 ng/ml.

Invalid: A test must be considered invalid if no bands appear, or if a band appears in the Test Region without a Control Band. The presence of a Control Band is necessary to confirm assay performance.

Quality Control
An internal procedural control line has been incorporated into the test device to help ensure proper kit performance and reliability. However, using external controls is recommended. Positive and negative controls within 25% of the cutoff concentration should produce the expected result. For positive controls, only one (**1**) colored band will appear in the Control Region (**C**), and no band will appear in the Test Region (**T**). For negative controls, two (**2**) colored bands will appear, one in the Control Region (**C**) and one in the Test Region (**T**).

Limitations of the Procedure

1. The possibility exists that substances and factors not described in this directional insert may interfere with the test, causing false results (e.g. technical or procedural error).
2. This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated.
3. Adulterated urine samples may produce erroneous results.
4. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a sample is suspected of being adulterated, obtained a new sample.
5. All positive samples must be confirmed by another method. GC/MS is the method of choice to confirm the presence and concentration of a drug in urine.

6. This test is a qualitative, competitive screening assay. It is not designed to determine the quantitative concentration of Methamphetamine or the level of intoxication.
7. Because the QuickScreen Test is a competitive assay, no prozone effect is present.
8. Occasionally, samples containing Methamphetamine levels below the cut-off sensitivity for the test may produce a positive result.

Performance Characteristics

Sensitivity: The QuickScreen™ Methamphetamine Test detects (+)-Methamphetamine at a cutoff concentration of 500 ng/ml. The sensitivity of the QuickScreen Methamphetamine Test was evaluated on 80 individual urine samples. The test correctly identified 40 of 40 samples containing (+)-Methamphetamine concentrations at or above cutoff (from 505 to 996 ng/ml).

Specificity: In three separate laboratory studies, including 2 external trials, a combined specificity of greater than 99% was observed when compared to the GC/MS method.
Accuracy: The accuracy of the QuickScreen™ Methamphetamine Test was evaluated on 188 urine samples and compared with a commercially available immunoassay using the 500 ng/ml cutoff concentrations.

Uncorrected Correlation

		Quick Screen	
		(+)	(-)
ABI One Step	(+)	**99**	**0**
Methamphetamine	(-)	**17***	**72**

Correlation to GC/MS

		Quick Screen	
		(+)	(-)
GC/	(+)	**116**	**0**
-MS	(-)	**5**	**67**

- Analysis by GC/MS showed QuickScreen to have correctly identified these 17 samples as positive.

Precision: Eight urine pools, with concentrations of 116, 186, 373, 466, 596, 697, 787 and 932 ng/ml, were assayed twice a day for twenty days using one lot of Quick-Screen. The results were interpreted individually by two technicians. The inter- and intra-assay coefficients of variation were less than 1% for all samples.

Cross-Reacting Substances: The following structurally related compounds were spiked into normal human urine, tested and found to cross-react with the QuickScreen Methamphetamine Test. The results, in ng/ml, are that amount of compound that produces a result equivalent to 500 ng/ml of (+)-Methampetamine.

Analyte	**Conc.**	**Analyte**	**Conc.**
N-Acetylprocainamide	100,000	Fenfluramine	100,000
l-Amphetamine	100,000	(±)-Isoproterenol	1,500
d-Amphetamine	20,000	Mephentermine	10,000
dl-Amphetamine	50,000	(+)-Methamphetamine	500
(-)-Deoxyephedrine	1,000	(±)-3,4-Methylenedioxyamphetamine	100,000
(+)-ψ-Ephedrine	100,000	(±)-3,4-	3,500

		Methylenedioxymethamphetamine	
(+)-Ephedrine	100,000	Nylidrin	5,000
(±)-Ephedrine	100,000	Phentermine	300,000
(-)-ψ-Ephedrine	1,000,000	(R)-(+)-α-Phenylethylamine	100,000
(-)-Ephedrine	1,000,000	Tyramine	62,500

Bibliography

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2. Urine Testing for Drugs of Abuse, NIDA Research Monograph 73, (1986).
3. Dasagupta A., Saldana S., Kinnaman G., Smith M., Johansen K., Clinical Chemistry, 39:104-108 (1993).
4. Liu R.H., Goldberger B.A., Handbook of Workplace Drug Testing, AACC Press (1995).
5. Jeffcoat A.R., et al, Drug Metabolism and Disposition, 17-2 (1989).
6. Inaba T., Journal of Canadian Physiology and Pharmacology, 67:1154-1157 (1989).
7. Karch S.B., Drug Abuse Handbook, CRC Press (1998).

Interfering Substances – The following compounds were spiked into normal human urine and tested with the QuickScreen™ Methamphetamine Test. Except as noted, the compounds were tested to a concentration of 100,000 ng/ml and found not to interfere: