is excreted unchanged. Thus, the presence of the parent compound in the urine indicates methamphetamine use. Methamphetamine is generally detectable in the urine for 3–5 days, depending on urine pH level.

Methamphetamine is a potent sympathomimetic agent with therapeutic applications. The drug can be taken orally, injected, or smoked. It acts on the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power.

The effects of methamphetamine generally last 2–4 hours, and the drug has a half-life of 9–24 hours in the body. Methamphetamine is excreted in the urine primarily as amphetamine and oxidized and deaminated derivatives. More acute responses include anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.

Materials Provided

The AccuSign® MET test kit contains all the reagents necessary to perform the tests. AccuSign® MET device. The test device contains a membrane strip coated with anti-methamphetamine antibody and a dye pad containing colloidal gold coated with drug-protein (from purified bovine protein source) conjugate.

Precautions

For in vitro diagnostic use only.

Avoid cross contamination of urine samples by using a new urine specimen container and dropper for each urine sample.

The test kit does not contain any HIV or hepatitis infective components.

Urine specimens are potentially infectious. Proper handling and disposal methods should be established according to good laboratory practices.
The AccuSign® MET test kit should be stored 2–30°C (35–86°F) in the original sealed pouch. The expiration dating was established under these storage conditions.

Specimen Collection and Preparation

Approximately 110 μL of urine sample is required for each test. Fresh urine specimens do not require any special handling or pretreatment. Specimens should be collected in a clean glass or plastic container. Testing will not be performed immediately, specimens should be refrigerated (2–8°C) or frozen. Specimens should be brought to room temperature before testing.

Specimens containing a large amount of particulate matter may give inconsistent test results. Such specimens should be clarified by centrifuging or allowing to settle before testing.

Test Procedure

The test procedure consists of adding the urine sample to the Sample well of the device and watching for the appearance of colored lines in the Test and Control positions.

Test Protocol

1. For each test, open one AccuSign® MET pouch and label the device with the patient ID.
2. Holding the dropper vertically, dispense 3 full drops (110 μL) of the urine sample into the Sample well ($S$).
3. Read the result after 3 minutes, but within 10 minutes of sample application.

Interpretation of Results

Negative: The appearance of a reddish-purple Control line (C) and a line next to Test position (T) indicates a negative test result; i.e., no drug above the cutoff level has been detected. The color intensities of the Control line and a specific drug line may not be equal. Any faint line in the Result window, visible in 10 minutes, should be interpreted as negative. A negative test result does not indicate the absence of drug in the sample; it only indicates the sample does not contain drug above the cutoff level in qualitative terms.

Positive: The appearance of a reddish-purple Control line and no distinct line next to T indicates the test result is positive for MET (i.e., the specimen contains the drug at a concentration above the cutoff level). A positive test result does not provide any indication of the level of intoxication or urinary concentration of the drug in the sample; it only indicates the sample contains drug above the cutoff level in qualitative terms.

Invalid: A distinct Control line (C) should always appear. The test is invalid if no Control line forms at the C position. Such tests should be repeated with a new AccuSign® MET test device.

Limitations

- The test is designed for use with unadulterated urine only.
- There is a possibility that factors such as technical or procedural errors, as well as other substances in the urine sample which are not listed in Table 5 below, may interfere with the test and cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the method of analysis. If adulteration is suspected, the test should be repeated with a new sample.
- The test result read after 10 minutes may not be consistent with the original reading obtained within the 10 minute reading period. The test must be read within 10 minutes of sample application.

User Quality Control

Internal Control: Each AccuSign® MET test device has a built-in control. The internal control is a positive control procedural control. A distinct reddish-purple Control line should appear in the Control position, if the test procedure is performed properly, an adequate sample volume is used, the sample and reagent are wicking on the membrane, and the test reagents at the control line and the conjugate-color indicator are reactive. In addition, if the test is performed correctly and the device is working properly, the background in the Result window will become clear and provide a distinct result. This may be considered an internal negative procedural control.

The positive and negative procedural controls contained in each AccuSign® MET test device satisfy the requirements of testing a positive control and a negative control on a daily basis. If the Control line does not appear in the Control position, the test is invalid and a new test should be performed. If the problem persists, contact PBMs Technical Services.

External Control: External controls may also be used to assure that the reagents are working properly and that the assay procedure is followed correctly. It is recommended that a control be tested at regular intervals as good laboratory testing practice. For information on how to obtain controls, contact PBMs Technical Services.

Expected Values

AccuSign® MET is a qualitative assay. The amount of methamphetamine and/or their metabolites present in urine cannot be estimated by the assay. The assay results distinguish between positive samples with negative samples. Positive results indicate the samples contain methamphetamine and/or their metabolites above the cutoff concentration.

Performance Characteristics

The AccuSign® MET test has been shown to detect an average cutoff of 1000 ng/mL of D-methamphetamine in urine. The performance of the assay was evaluated in comparison to a commercially available immunoassay, Syva® EMIT®. A total of 320 samples was tested with both procedures. Overall agreement of 91.3% was observed, as shown below. (Table 1.)

Table 1. Accuracy: Comparison of AccuSign® MET with Syva® EMIT® II

<table>
<thead>
<tr>
<th>Sample</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>MET</td>
<td>108</td>
<td>0</td>
<td>108</td>
</tr>
<tr>
<td>Syva</td>
<td>108</td>
<td>0</td>
<td>108</td>
</tr>
<tr>
<td>MET/Syva</td>
<td>100%</td>
<td>0%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Interpretation of Results

Negative: The appearance of a reddish-purple Control line (C) and no line next to Test position (T) indicates a negative test result; i.e., no drug above the cutoff level has been detected. The color intensities of the Control line and a specific drug line may not be equal. Any faint line in the Result window, visible in 10 minutes, should be interpreted as negative. A negative test result does not indicate the absence of drug in the sample; it only indicates the sample does not contain drug above the cutoff level in qualitative terms.

Positive: The appearance of a reddish-purple Control line and no distinct line next to T indicates the test result is positive for MET (i.e., the specimen contains the drug at a concentration above the cutoff level). A positive test result does not provide any indication of the level of intoxication or urinary concentration of the drug in the sample; it only indicates the sample contains drug above the cutoff level in qualitative terms.

Invalid: A distinct Control line (C) should always appear. The test is invalid if no Control line forms at the C position. Such tests should be repeated with a new AccuSign® MET test device.

Limitations

- The test is designed for use with unadulterated urine only.
- There is a possibility that factors such as technical or procedural errors, as well as other substances in the urine sample which are not listed in Table 5 below, may interfere with the test and cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the method of analysis. If adulteration is suspected, the test should be repeated with a new sample.
- The test result read after 10 minutes may not be consistent with the original reading obtained within the 10 minute reading period. The test must be read within 10 minutes of sample application.
The AccuSign® MET test kit should be stored 2–30°C (35–86°F) in the original sealed pouch. The expiration dating was established under these storage conditions.

### Specimen Collection and Preparation

Approximately 110 μL of urine sample is required for each test. Fresh urine specimens do not require any special handling or pretreatment. Specimens should be collected in a clean glass or plastic container. If testing will not be performed immediately, specimens should be refrigerated (2–8°C) or frozen. Specimens should be brought to room temperature before testing. Specimens containing a large amount of particulate matter may give inconsistent test results. Such specimens should be clarified by centrifuging or allowing to settle before testing.

### Test Procedure

The test procedure consists of adding the urine sample to the Sample well of the device and watching for the appearance of colored lines in the Test and Control positions.

#### Test Protocol

1. For each test, open one AccuSign® MET pouch and label the device with the patient ID.
2. Holding the dropper vertically, dispense 3 full drops (110 μL) of the urine sample into the Sample well ($\Omega$).
3. Read the result after 3 minutes, but within 10 minutes of sample application.

#### Interpretation of Results

**Negative:** The appearance of a reddish-purple Control line (C) and a line next to Test position (T) indicates a negative test result; i.e., no drug above the cutoff level has been detected. The color intensities of the Control line and a specific drug line may not be equal. Any faint line in the Result window, visible in 10 minutes, should be interpreted as negative. A negative test result does not indicate the absence of drug in the sample; it only indicates the sample does not contain drug above the cutoff level in qualitative terms.

**Positive:** The appearance of a reddish-purple Control line and no distinct line next to T indicates the test result is positive for MET (i.e., the specimen contains the drug at a concentration above the cutoff level). A positive test result does not provide any indication of the level of intoxication or urinary concentration of the drug in the sample; it only indicates the sample contains drug above the cutoff level in qualitative terms.

**Invalid:** A distinct Control line (C) should always appear. The test is invalid if no Control line forms at the C position. Such tests should be repeated with a new AccuSign® MET test device.

#### Limitations

- The test is designed for use with unadulterated urine only.
- There is a possibility that factors such as technical or procedural errors, as well as other substances in the urine sample which are not listed in Table 5 below, may interfere with the test and cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the method of analysis. If adulteration is suspected, the test should be repeated with a new sample.
- The test result read after 10 minutes may not be consistent with the original reading obtained within the 10 minute reading period. The test must be read within 10 minutes of sample application.

### User Quality Control

#### Internal Control: Each AccuSign® MET test device has a built-in control. The Control line is an internal positive procedural control. A distinct reddish-purple Control line should appear in the Control position, if the test procedure is performed properly, an adequate sample volume is used, the sample and reagent are wicking on the membrane, and the test reagents at the control line and the conjugate-color indicator are reactive. In addition, if the test is performed correctly and the device is working properly, the background in the Result window will become clear and provide a distinct result. This may be considered an internal negative procedural control.

The positive and negative procedural controls contained in each AccuSign® MET test device satisfy the requirements of testing a positive control and a negative control on a daily basis. If the Control line does not appear in the Control position, the test is invalid and a new test should be performed. If the problem persists, contact PBM’s Technical Services.

#### External Control: External controls may also be used to assure that the reagents are working properly and that the assay procedure is followed correctly. It is recommended that a control be tested at regular intervals as good laboratory testing practice. For information on how to obtain controls, contact PBM’s Technical Services.

### Expected Values

AccuSign® MET is a qualitative assay. The amount of methamphetamine and/or their metabolites present in urine cannot be estimated by the assay. The assay results distinguish positive from negative samples. Positive results indicate the samples contain methamphetamine and/or their metabolites above the cutoff concentration.

### Performance Characteristics

The AccuSign® MET test has been shown to detect an average cutoff of 1000 ng/mL of D-methamphetamine in urine. The accuracy of AccuSign® MET was evaluated in comparison to a commercially available immunoassay, Syva® EMIT II. A total of 320 samples was tested with both procedures. Overall agreement of 91.3% was observed, as shown below. (Table 2.)

#### Specficity

The following table lists compounds that are detected by the AccuSign® MET test. The specificity of the AccuSign® MET test was determined by analyzing the drugs and drug metabolites listed to drug-negative urine specimens and testing with the AccuSign® MET test kit. The results are expressed in terms of the concentration required to produce a positive result. (Table 3.)

### Table 1. Accuracy: Comparison of AccuSign® MET with Syva® EMIT II

<table>
<thead>
<tr>
<th>Compound</th>
<th>Concentration (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>D-Amphetamine</td>
<td>&gt;100,000</td>
</tr>
<tr>
<td>D,L-Amphetamine</td>
<td>&gt;100,000</td>
</tr>
<tr>
<td>(+)- Ephedrine</td>
<td>&gt;100,000</td>
</tr>
<tr>
<td>(-)- Ephedrine</td>
<td>&gt;100,000</td>
</tr>
<tr>
<td>Isometheptene</td>
<td>12500</td>
</tr>
<tr>
<td>D-Methamphetamine</td>
<td>1,000</td>
</tr>
<tr>
<td>p-OH-Methamphetamine</td>
<td>3,000</td>
</tr>
<tr>
<td>Methyleneoxymetamphetamine</td>
<td>&gt;100,000</td>
</tr>
<tr>
<td>Methyleneoxylethylamphetamine (MDEA)</td>
<td>&gt;100,000</td>
</tr>
<tr>
<td>Methyleneoxymethamphetamine</td>
<td>1,000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>AccuSign®</th>
<th>GC/MS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>88</td>
</tr>
<tr>
<td>Negative</td>
<td>1</td>
</tr>
</tbody>
</table>

### Table 2. Accuracy: Comparison of AccuSign® MET with GC/MS Assay

<table>
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<tr>
<th>MET</th>
<th>GC/MS</th>
</tr>
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<td>Positive</td>
<td>88</td>
</tr>
<tr>
<td>Negative</td>
<td>1</td>
</tr>
</tbody>
</table>

### Precision and Accuracy

The precision of AccuSign® MET was determined by carrying out the test with serially diluted standard drug solutions. About 98% of the samples containing methamphetamine concentrations 25% over the cutoff level consistently showed positive results. The study also included over 40 samples containing ±25% of the cutoff level as a challenge of cutoff precision. These results were found to be consistently in agreement with expected test results.

### Distribution of Random Error:

Twenty blind samples prepared by spiking various concentrations of methamphetamine were separately tested by two operators. The test results from the two operators showed complete agreement.

### Reproducibility

The reproducibility of the test results of AccuSign® MET was examined at three different sites using a total of 15 blind controls, consisting of 5 negative samples, 5 moderately positive samples (containing the drug at a concentration 1.5-2 times the cutoff level), and 5 strongly positive samples (containing the drug at a concentration 4.5-5 times the cutoff level). The results obtained at these three sites with these controls demonstrated 100% agreement with each other.

### Table 3. Specificity

<table>
<thead>
<tr>
<th>Compound</th>
<th>Concentration (ng/mL)</th>
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<td>Methyleneoxylethylamphetamine (MDEA)</td>
<td>&gt;100,000</td>
</tr>
<tr>
<td>Methyleneoxymethamphetamine</td>
<td>1,000</td>
</tr>
</tbody>
</table>
The effects of methamphetamine generally last 2–4 hours, and the acute cardiovascular responses to methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses include anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.

Methamphetamine is excreted in the urine primarily as amphetamine and oxidized and deaminated derivatives. Highest, 10–20% of methamphetamine is excreted in the urine. Therefore, the presence of the parent compound in the urine indicates methamphetamine use. Methamphetamine is generally detectable in the urine for 3–5 days, depending on urine pH level.

Materials Provided

The AccuSign® MET test kit contains all the reagents necessary to perform the test.

Precautions

- For in vitro diagnostic use only.
- Avoid cross contamination of urine samples by using a new urine specimen container and dropper for each urine sample.
- The test kit does not contain any HIV or hepatitis infective components.
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