Cotinine level exceeds 200 ng/mL because it will saturate all the binding sites of anti-Cotinine antibodies. A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that that proper volume of specimen has been added and membrane wicking has occurred.

INTENDED USE
The COT One Step Cotinine Test Device (Ur ine) is a lateral flow chromatographic immunassay for the detection of Cotinine in human urine at a cut-off concentration of 200 ng/mL. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography and 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 used.

SUMMARY
Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as cotinine gum, transdermal patches and nasal sprays. In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%. While cotinine is thought to be an inactive metabolite, its elimination profile is more stable than that of nicotine which is largely urine pH dependent. As a result, cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration. Nicotine and cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in urine at a cutoff level of 200 ng/mL is expected to be up to 2-3 days after nicotine use.

The COT One Step Cotinine Test Device (Ur ine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Cotinine in urine. The COT One Step Cotinine Test Device (Ur ine) yields a positive result when the Cotinine in urine exceeds 200 ng/mL.

PRINCIPLE
The COT One Step Cotinine Test Device (Ur ine) is an immunassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody. During testing, a urine specimen migrates upward by capillary action. Cotinine, if present in the urine specimen below 200 ng/mL, will not saturate the binding sites of antibody coated particles in the test device. The antibody coated particles will then be captured by immobilized Cotinine conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Cotinine level exceeds 200 ng/mL because it will saturate all the binding sites of anti-Cotinine antibodies. A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that that proper volume of specimen has been added and membrane wicking has occurred.

INTENDED USE
The COT One Step Cotinine Test Device (Ur ine) is a lateral flow chromatographic immunassay for the detection of Cotinine in human urine at a cut-off concentration of 200 ng/mL. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography and 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 used.

SUMMARY
Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as cotinine gum, transdermal patches and nasal sprays. In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%. While cotinine is thought to be an inactive metabolite, its elimination profile is more stable than that of nicotine which is largely urine pH dependent. As a result, cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration. Nicotine and cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in urine at a cutoff level of 200 ng/mL is expected to be up to 2-3 days after nicotine use.

The COT One Step Cotinine Test Device (Ur ine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Cotinine in urine. The COT One Step Cotinine Test Device (Ur ine) yields a positive result when the Cotinine in urine exceeds 200 ng/mL.

PRINCIPLE
The COT One Step Cotinine Test Device (Ur ine) is an immunassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody. During testing, a urine specimen migrates upward by capillary action. Cotinine, if present in the urine specimen below 200 ng/mL, will not saturate the binding sites of antibody coated particles in the test device. The antibody coated particles will then be captured by immobilized Cotinine conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Cotinine level exceeds 200 ng/mL because it will saturate all the binding sites of anti-Cotinine antibodies. A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that that proper volume of specimen has been added and membrane wicking has occurred.

INTENDED USE
The COT One Step Cotinine Test Device (Ur ine) is a lateral flow chromatographic immunassay for the detection of Cotinine in human urine at a cut-off concentration of 200 ng/mL. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography and 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 used.

SUMMARY
Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as cotinine gum, transdermal patches and nasal sprays. In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%. While cotinine is thought to be an inactive metabolite, its elimination profile is more stable than that of nicotine which is largely urine pH dependent. As a result, cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration. Nicotine and cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in urine at a cutoff level of 200 ng/mL is expected to be up to 2-3 days after nicotine use.

The COT One Step Cotinine Test Device (Ur ine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Cotinine in urine. The COT One Step Cotinine Test Device (Ur ine) yields a positive result when the Cotinine in urine exceeds 200 ng/mL.

PRINCIPLE
The COT One Step Cotinine Test Device (Ur ine) is an immunassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody. During testing, a urine specimen migrates upward by capillary action. Cotinine, if present in the urine specimen below 200 ng/mL, will not saturate the binding sites of antibody coated particles in the test device. The antibody coated particles will then be captured by immobilized Cotinine conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Cotinine level exceeds 200 ng/mL because it will saturate all the binding sites of anti-Cotinine antibodies. A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that that proper volume of specimen has been added and membrane wicking has occurred.
A side-by-side comparison was conducted using the COT One Step Cotinine Test Device (Urine) and a leading commercially available COT rapid test. Testing was performed on 300 clinical specimens collected from smoking and non-smoking volunteers. The following results were tabulated:

### Accuracy

<table>
<thead>
<tr>
<th>Method</th>
<th>Other COT Rapid Test</th>
<th>Results</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>COT One Step Test Device</td>
<td></td>
<td>Accuracy</td>
<td>99%</td>
<td>94%</td>
<td>96%</td>
</tr>
<tr>
<td>Results Positive Negative</td>
<td>103</td>
<td>0</td>
<td>103</td>
<td>115</td>
<td></td>
</tr>
<tr>
<td>Total Results Positive Negative</td>
<td>197</td>
<td>300</td>
<td>197</td>
<td>300</td>
<td></td>
</tr>
</tbody>
</table>

A drug-free urine pool was spiked with Cotinine at the following concentrations: 0 ng/mL, 100 ng/mL, 150 ng/mL, 200 ng/mL, 250 ng/mL, 300 ng/mL and 400 ng/mL. The result demonstrates > 99% accuracy at 100% above and 50% below the cut-off concentration. The data are summarized below:

### Analytical Sensitivity

<table>
<thead>
<tr>
<th>Cotinine Concentration (ng/mL)</th>
<th>Visual Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Negative</td>
</tr>
<tr>
<td>100</td>
<td>Negative</td>
</tr>
<tr>
<td>150</td>
<td>Negative</td>
</tr>
<tr>
<td>200</td>
<td>Positive</td>
</tr>
<tr>
<td>250</td>
<td>Positive</td>
</tr>
<tr>
<td>300</td>
<td>Positive</td>
</tr>
<tr>
<td>400</td>
<td>Positive</td>
</tr>
</tbody>
</table>

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Cotinine positive urine. The following compounds show no cross-reactivity when tested with the COT One Step Cotinine Test Device (Urine) at a concentration of 100 µg/mL:

### Non Cross-Reacting Compounds

- 4-Acetaminophenol
- Acetone
- Acetophenetidin
- Acetylsalicylic acid
- Acriderine
- Acriderine
- Acromegalin
- Amantadine
- Aminobenzoic acid
- Aminophenazone
- Aminopyrine
- Amitriptyline
- Amobarbital
- Amphetamine
- Amphetamine
- Amygdalin
- Anabolic steroid
- Anabolic steroid
- Anticholinergic agent
- Anesthetics
- Anesthesia
- Antihistamines
- Aminosalicylic acid
- Aminosalicylic acid
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analgesics
- Analge...