The Express Results™ Integrated Multi-Drug Screen Cup is a lateral flow immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine samples at commonly abused cut-off levels.

**PRINCIPLE**

For healthcare professionals including professionals at point of care sites.

**S.V.T. REAGENTS**

For healthcare professionals including professionals at point of care sites.

**PRECAUTIONS**

- Use for healthcare professionals including professionals at point of care sites.

**SUMMARY**

- Adulteration Pad
- Reactive indicator

**METHYLAmine (AMP)**

**OPIATES (OPI)**

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.

Opiates may cause a large group of substances which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerances, physiological dependency in users, and may lead to substance dependence. Opiates also include the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate intoxication.

**INTENDED USE**

The Express Results™ Integrated Multi-Drug Screen Cup is a lateral flow immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine samples at commonly abused cut-off levels.

**Materials Provided**

- Key
- Package insert
- Procedure cards
- Security seals
- SVT/Adulterant color charts (if applicable)

**Urine Specimen**

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens must be stored at 24°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

**TEST TARGET DRUG CUT-OFF**

When the methylenedioxymethamphetamine in urine exceeds 500 ng/mL, the test yields a positive result when compared to a control urine specimen with a negative test result.

**METHYLANEMETHAMPHETAMINE (MDMA)**

Methylenedioxymethamphetamine (MDMA) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. Those who take the drug frequently report adverse effects, including elevated levels of specific drugs in urine.

**PRECAUTIONS**

- Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

**S.V.T. SUMMARY**

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens must be stored at 24°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

**MATERIALS**

- EXPRESS RESULTS™ INTEGRATED MULTIDRUG SCREEN CUP
- Key
- Package insert
- Procedure cards
- Security seals
- SVT/Adulterant color charts (if applicable)
- Materials Required But Not Provided
- Timer

**Key**

- Adulteration Pad
- Reactive Indicator
- Buffers and non-reactive ingredients

**METHYLANEMETHAMPHETAMINE (MDMA)**

Methylenedioxymethamphetamine (MDMA) is a stimulant drug that strongly activates certain systems in the brain. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and increased physical activity. Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses include agitation, paranoia, hallucinations, and changes in verbal and nonverbal behavior.

The effects of Methamphetamine generally last 2-4 hours and the drug has a half-life of 8-9 hours in the body. Methamphetamine may also cause profound psychological disturbances and produce paranoia, hallucinations, and delusions. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the carboxylic acid metabolite of dopa in urine is not a reliable indication. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.

**THE EXPRESS RESULTS™ INTEGRATED MULTIDRUG SCREEN CUP**

The Express Results™ Integrated Multi-Drug Screen Cup is an immunosorbent test based on the principle of competitive binding (the Sandwich method). The test cup contains chemically treated reagent pads. 3-5 minutes following the activation of the reagent pads by the urine sample, the colors that appear on the pads can be compared to the printed color chart card. The color comparison provides a semi-quantitative scale for any combination of Fentanyl, Methadone, Codeine, Oxycodone, Methamphetamine, and creatinine in human urine which can help assess the integrity of the urine sample.

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens must be stored at 24°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

**S.V.T. REAGENTS**

- Adulteration Pad
- Reactive indicator
- Buffers and non-reactive ingredients
INTERPRETATION OF RESULTS

(Please refer to the Illustration above)

NEGATIVE: Two lines appear. One colored line should be in the Control region (C). and another colored line should be in the Test region (T). This result indicates that the drug concentration is below the detectable level. The presence of both colored lines in the Control and Test regions indicates that the test is valid. If one or no colored lines are present, the test is invalid.

POSITIVE: No colored line appears in the Control region (C). This result indicates that the drug concentration is above the detectable level. If no colored lines are present, the test is invalid.

INVALID: No line appears in the Control region (C). This test is invalid. The test results are invalid if one or both colored lines are not present in the Control and Test regions.

SAVITRY-ADULTERANT INTERPRETATION

(Please refer to the color chart, if applicable)

Semi-quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color blocks on the color chart. No instrument is required.

QUALITY CONTROL

A procedural control is included in the test. The results of the procedural control in the Control region (C) are considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedure of the test. It is recommended that external positive and negative controls be tested with each new lot or shipment of product, with each new operator (i.e. one who has not performed the test recently), when problems, storage, operations, instrument, or other factors are suspected or identified, and as otherwise required by your laboratory’s quality assurance system or procedures. Depending on storage conditions, operators may also test controls monthly as a check on continued storage conditions. Control specimens should be performed in a manner as indicated in your laboratory’s quality assurance system or procedures (Directions for Use and Interpretation of Results). If unexpected results are seen when running the external positive or negative controls, review the Directions for Use, Interpretation of Results and Limitations sections and repeat the test with another control. If the problem persists, discontinue use of the test kit immediately and contact the distributor (1-800-877-7446).

LIMITATIONS

1. The Express Results® Integrated Multi-Drug Screen Cup provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry testing (GC/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine sample may cause erroneous results.
3. Adulterants, such as bleach and/or alcohol, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result does not indicate level of intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the test’s cutoff level.
6. This test does not distinguish between drugs of abuse and certain medications.
7. Positive test results may be obtained with non-drug adulterants or foods containing therapeutic adulterants.

S.V.T. ADULTERATION LIMITATIONS

1. The adulteration tests, if included with this product, are meant to aid in the determination of abnormal urine specimens. While comprehensive, these tests are not meant to be an all-inclusive representation of possible adulterants.

2. Oxidants/PCP: Normal human urine should not contain oxidents or PCP. The presence of high levels of oxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants/PCP pad.

3. Specific Gravity: Elevated levels of protein in urine may cause abnormally high specific gravity values. Creatinine: Normal creatinine levels are between 2 and 3.5 mg/dL. Under rare conditions, kidney diseases may show higher creatinine levels.

PERFORMANCE CHARACTERISTICS

A side-by-side comparison was conducted with the Express Results® Integrated Multi-Drug Screen Cup and commercially available drug test kits. Testing was performed on approximately 300 specimens per drug type previously collected from subjects presenting for drug screening. Pooled positive results were confirmed 24 hours later by GC/MS. The following compounds were quantified by GC/MS and converted to the total amount of drugs found in presumptive positive urine samples tested. The following results are tabulated from these clinical studies:

The following table shows the concentrations of compounds (ng/mL) that are detected positive in urine by the Express Results® Integrated Multi-Drug Screen Cup at 5 minutes.

<table>
<thead>
<tr>
<th>Compound</th>
<th>ng/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMP</td>
<td>1,000</td>
</tr>
<tr>
<td>THC</td>
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</tr>
<tr>
<td>COC</td>
<td>1,000</td>
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<tr>
<td>MPH</td>
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</tbody>
</table>

Non Cross-Reacting Compounds

Phencyclidine (PCP) 25

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted with the Express Results® Integrated Multi-Drug Screen Cup and commercially available drug test kits. Testing was performed on approximately 300 specimens per drug type previously collected from subjects presenting for drug screening. Pooled positive results were confirmed 24 hours later by GC/MS. The following compounds were quantified by GC/MS and converted to the total amount of drugs found in presumptive positive urine samples tested.

The following table shows the concentrations of compounds (ng/mL) that are detected positive in urine by the Express Results® Integrated Multi-Drug Screen Cup at 5 minutes.

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</tr>
</tbody>
</table>

Effect of Urinary Specific Gravity

Urine samples of normal, high, and low specific gravity ranges (1.001-1.030) were spiked with drugs at 50% below and 50% above the assay cutoff levels. The spiked urine samples were tested with the Express Results® Integrated Multi-Drug Screen Cup. The results demonstrated that these varying ranges of urinary specific gravity levels do not affect the test results.

Precision

A study was conducted to determine the cross-reactivity of the test with compounds in both drug-free urine or drug positive urine containing Amphetamine, Cocaine, Marijuana, Methamphetamine, Methylenedioxymethamphetamine, Opera and Phenylpropanolamine. The following compounds show cross-reactivity when tested with the Express Results® Integrated Multi-Drug Screen Cup at a concentration of 100 ng/mL:

ACETAMINOPHEN 25

ACETAMINOPHEN 25

Aspartame Estrone-3-sulfate Niacinamide Tetracycline

Atropine Ethyl-p-aminobenzoate Nifedipine Tetrahydrocortisone, Benzilic acid (-)-Epinephrine Norethindrone 3-acetate Benzoic acid Erythromycin Noscapine Tetrahydrocortisone Benzphetamine* Fenoprofen d,l-Octopamine 3-((4-D-glucuronide)

*NOTE: The shade of color in the Test region (T) will vary, but it should be considered negative whenever there is even a faint line.

Thirty-four (34) clinical samples for each drug were run using the Express Results® Integrated Multi-Drug Screen Cup. Each sample was analyzed as an unadulterated urine specimen. Based on GC/MS, the operator statistically positive agreement, negative agreement and overall agreement rates as trained laboratory personnel.

Sensitivity

A drug-free urine pool was spiked with drugs to various concentrations, >95% agreement with expected results was found at 1% - 50% cutoff for each drug tested (with a 95% confidence interval).

*NOTE: The shade of color in the Test region (T) will vary, but it should be considered negative whenever there is even a faint line.

BIBLIOGRAPHY