**INTENDED USE**

The Express Results™ Integrated Multi-Drug Screen Cup is a lateral flow chromatographic immunoassay test for the qualitative detection of multiple drugs and metabolites in urine. The following cut-off concentrations are used:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Cut-off Concentration</th>
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</thead>
<tbody>
<tr>
<td>Amphetamines (AMP)</td>
<td>1,000 ng/mL</td>
</tr>
<tr>
<td>Benzodiazepines (BZO)</td>
<td>50 ng/mL</td>
</tr>
<tr>
<td>Barbiturates (BAR)</td>
<td>500 ng/mL</td>
</tr>
<tr>
<td>Buprenorphine (BUP)</td>
<td>1,000 ng/mL</td>
</tr>
<tr>
<td>Methadone (MTH)</td>
<td>3,000 ng/mL</td>
</tr>
<tr>
<td>Methamphetamine (METH)</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>Oxycodone (OXC)</td>
<td>50 ng/mL</td>
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<tr>
<td>Phencyclidine (PCP)</td>
<td>25 ng/mL</td>
</tr>
<tr>
<td>Phencyclidine (PPX)</td>
<td>25 ng/mL</td>
</tr>
<tr>
<td>TCA</td>
<td>1,000 ng/mL</td>
</tr>
</tbody>
</table>

**CONFIRMATION**

The Express Results™ Integrated Multi-Drug Screen Cup yields a positive result when the concentration of the drug in urine exceeds the cut-off concentration. Only trace amounts (less than 1%) of most benzodiazepines are excreted unaltered in the urine; most 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. The Express Results™ Integrated Multi-Drug Screen Cup yields a positive result when the concentration of methamphetamine in urine exceeds 1,000 ng/mL.

**METHYLENEDIOXYMETHAMPHETAMINE (MDMA)**

Methamphetamine is an amphetamine that was synthesized in 1914 by a German drug company for the treatment of obesity. Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamines, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of altered time perception and reduced sensory discrimination. MDMA can be used via capsule or tablet, with few effects on blood pressure or heart rate.

**BARBITURATES (BAR)**

Barbiturates are sedative-hypnotics and anesthetics that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors in a neurological pathway controlled by the GABA (gamma-aminobutyric acid) neurotransmitter. Barbiturates are toxic in overdose and are replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives on a wide range of medical procedures, and for the treatment of seizures disorders and alcohol withdrawal.

**CUT-OFF CONCENTRATION**

The effects of methamphetamine generally last 2-4 hours and the drug has a half-life of 8-24 hours in the urine. The urine screen test is negative for all drugs except for the stimulants, cocaine and amphetamines.

**METHADONE (MOP)**

Methadone is an opioid drug that strongly activates certain systems in the brain. Methadone is closely related chemically to heroin. In clinical practice, the effects of methadone are similar to those of heroin. Methadone is used in the treatment of opioid addiction. The side effects of methadone are similar to those of heroin. Methadone can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the CNS and a decrease in appetite. The effects of methadone are generally longer lasting than those of heroin.

**CANNABIS (COC)**

Cannabis is a potent central nervous system stimulant and a local anesthetic. Initially, it brings about anxiety and changes in perception. The effects of cannabis persist for several hours. Acute higher doses lead to enhanced stimulation of the CNS and a decrease in appetite. The effects of cannabis persist for several hours. Methadone is generally detectable in the urine for 3-5 days, depending on urine pH level. The Express Results™ Integrated Multi-Drug Screen Cup yields a positive result when the concentration of cannabis in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA) (USA). See OPIATE (MOP 300) for summary.

**PHENCYclidINE (PCP)**

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950s. Its effects are non-specific and include a range of symptoms that are similar to those of amphetamines and experienced hallucinations.

**BARBITURATES (BAR)**

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**PROPIONYL XEPHYPCIN (PPX)**

PPX is an analog of a non-opioid analgesic compound bearing structural similarity to methadone. As an analgesic, propionyl Xephymp can be from 50-75% as potent as oral codeine. Darvon®-Co, one of the most common brand names in the U.S., is an oral analgesic containing propionyl Xephymp and aspirin, and is used to relieve headaches and to reduce fever.

**WHAT IS ADULTERATION?**

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and thereby masking the drug or by raising the concentration in the urine sample to a level below the designated cut-off. Adulteration may also be employed in an attempt to produce a false positive result.

One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such as pH, specific gravity and to detect the presence of oxalates/PCC, specific gravity, pH and creatinine in urine.

- **Creatinine** (normal range: 0.21-0.29 mmol/L) is the end product of creatinine metabolism in the kidney. The concentration of creatinine in urine increases when blood creatinine levels increase. Oxalates/PCC levels of 0.25% or higher indicate a drug-free urine.
- **Specific gravity** (normal range: 1.001-1.010) is an indicator of urine concentration. A specific gravity below this range may be the result of drug dilution or adulteration.
- **pH** (normal range: 4.0-9.0) indicates the acidity or alkalinity of urine. Values outside of this range may indicate the specimen has been altered. If the pH is outside the normal range, the specimen may have been altered. A pH of 9 or above may indicate the use of urine from another individual or the use of a chemical agent to neutralize the urine or to make the urine alkaline.
A study was conducted at three physician offices by untrained operators using three different lots of product to demonstrate the within-run, between-run and between operator precision. An identical panel of coded specimens, containing drugs at concentrations of ± 50% and ± 25% cut-off level, was labeled as a blind and tested at each site. The results are given below:

**Drug Sensitivity**

| Method | Cut-off Range | n | AMP | BZO | OPI | MOP | AMP | BZO | OPI | MOP |
|--------|---------------|---|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| SUP    | ±25% Cut-off  | 30| 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   |
|        | 50% Cut-off   | 30| 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   |
|        | 75% Cut-off   | 30| 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   |
|        | 100% Cut-off  | 30| 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   |

**Materials**

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Forty (40) clinical samples for each drug were run using each of the Express Results™ Integrated Multi-Drug Screen Card at 5 minutes.

**Analytical Specificity**

The following table lists the concentrations of compounds (ng/mL), that are detected as positive in urine by the Express Results™ Integrated Multi-Drug Screen Card at 5 minutes:

**Analytical Sensitivity**

A drug-free urine pool was spiked with drugs at the listed concentrations. The results are summarized below:

**Drug Sensitivity**

A study was conducted at three physician offices for Barbiturates, Benzodiazepines, Methadone, Methylenedioxymethamphetamine, Morphine, and Tricyclic Antidepressants by untrained operators using three different lots of product to demonstrate the within-run, between-run and between operator precision. An identical panel of coded specimens, containing drugs at the concentration of ± 50% and ± 25% cut-off level, was labeled as a blind and tested at each site. The results are given below:
### Opiates

- Oxymorphone
- Hydromorphone
- Levorphanol
- Naloxone
- Thebaine
- Procaine

### Opiates (II)

- Oxycodone
- Morphine
- 3,4-Methylenedioxymethamphetamine
- Mephentermine
- Doxylamine
- Methadone
- Δ8-Cannabinol
- Marijuana (THC)
- Cocaethylene
- Cocaine
- Benzoylecgonine
- Norbuprenorphine

### Methadone and/or its Metabolites

- Methadone
- Methadone glucuronide

### Pharmacokinetics

<table>
<thead>
<tr>
<th>Drug</th>
<th>Concentration (µg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine</td>
<td>12,000</td>
</tr>
<tr>
<td>Thebaine</td>
<td>100,000</td>
</tr>
<tr>
<td>Naloxone</td>
<td>12,500</td>
</tr>
<tr>
<td>Procaine</td>
<td>25,000</td>
</tr>
</tbody>
</table>

### Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing Amphetamine, Barbiturates, Benzoazepines, Cocaine, Marjuana, Methadone, Methamphetamine, Methylideneisoxymethamphetamine, Opiate, Oxycodone, Phencyclidine, Propoxyphene or Tricyclic Antidepressants. The following compounds show no cross-reactivity when tested with the Express Results™ Integrated Multi-Drug Screen Cup at a concentration of 100 µg/mL:

1. Acetaminophen
2. Acetazolamide
3. Acetylphenylisopropylamine
4. Acylurea
5. Ascorbic acid
6. Atropine
7. Benzamidines
8. Benzodiazepines
9. Benzoisoxazolines
10. Benzylamines
11. Bromocriptine
12. Brompheniramine
13. Butyrophenones
14. Butynylisopropylamines
15. Carisoprodol
16. Captopril
17. Cimetidine
18. Chloramphenicol
19. Chlorpropamide
20. Chlorpromazine
21. Chlorothiazide
22. Cineole
23. Ciprofloxacin
24. Cisapride
25. Cisplatin
26. Colchicine
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**BIBLIOGRAPHY**

6. Distributed by: Quest Diagnostics Incorporated, 10101 Renner Blvd, Lenexa, KS 66219 USA.