QuickTox® Drug Screen Dipcard
Quick Reference Guide

This is a CLIA-Waived Test. A CLIA Certificate of Waiver is needed to perform testing in waived settings. Read this entire Instruction Sheet carefully before use. If a laboratory modifies the following test instructions including QC, the test will be considered high complexity and no longer considered CLIA-Waived and subject to all CLIA regulations. The QuickTox® Drug Screen Dipcard is for use with human urine only. This Instruction Sheet and the manufacturer’s package insert that is provided with the product must be followed.

This is a preliminary screening test that detects drug-of-abuse in urine at specified detection levels. To confirm preliminary positive results, a more specific method such as Gas Chromatography/Mass Spectrometry (GC/MS) must be used.

Warnings and Precautions
- For in vitro diagnostic use only (not for internal use).
- Store QuickTox® Drug Screen Dipcard at room temperature 59˚F to 86˚F (15˚C to 30˚C).
- Keep the QuickTox® Drug Screen Dipcard in its original sealed pouch until ready for use. Do not use the test if the pouch is ripped or torn.
- Do not use the QuickTox® Drug Screen Dipcard after the expiration date printed on the pouch.
- Be careful when handling urine because it may contain infectious agents. Always wear gloves and wash hands with soap and water after handling urine.
- To ensure that the test will work properly the testing instructions must be followed. Failure to do so may result in inaccurate screening results.
- Do not use this test if you are color-blind.

Limitations of the Test
- Use the test with human urine only.
- The test is for one time use only; it is not reusable.
- This test is a screening device; it does not detect the actual concentration of a drug.
- Contaminated or tainted urine sample may give false results.
- Certain foods or medications may cause the test to give false results.
- Send preliminary positive or uncertain results to a laboratory to confirm results.
- The colors of human urine usually range from amber yellow to very light yellow. Dark urine or urine with a brown or abnormal color should not be tested using this test. Dark urines should be sent to a laboratory for testing.
- The QuickTox® Drug Screen Dipcard should give negative results when testing the urine of a normal healthy person. The QuickTox® device will give a preliminary positive result when the drug or drug metabolite is present in the urine at or above the detection level. See the Expected Results section of the enclosed Package Insert.

Detection Levels
The QuickTox® Drug Screen Dipcard may not detect drug amounts lower than the detection levels.

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Drug/Metabolite</th>
<th>Detection Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>COC</td>
<td>Benzoylecgonine</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>OPI</td>
<td>Morphine</td>
<td>1000 ng/mL</td>
</tr>
<tr>
<td>OPI</td>
<td>Morphine</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>MET</td>
<td>d-Methamphetamine</td>
<td>1000 ng/mL</td>
</tr>
<tr>
<td>MET</td>
<td>d-Methamphetamine</td>
<td>500 ng/mL</td>
</tr>
<tr>
<td>THC</td>
<td>11-nor-Δ9-Tetrahydrocannabinol-9-carboxylic acid</td>
<td>50 ng/mL</td>
</tr>
<tr>
<td>AMP</td>
<td>d-Amphetamine</td>
<td>1000 ng/mL</td>
</tr>
<tr>
<td>PCP</td>
<td>Phencyclidine</td>
<td>25 ng/mL</td>
</tr>
<tr>
<td>BZO</td>
<td>Oxazepam</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>BAR</td>
<td>Secobarbital</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>MTD</td>
<td>Methadone</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>TCA</td>
<td>Nortriptyline</td>
<td>1000 ng/mL</td>
</tr>
<tr>
<td>MDMA</td>
<td>3,4-Methylenedioxyamphetamine</td>
<td>500 ng/mL</td>
</tr>
<tr>
<td>OXY</td>
<td>Oxycodone</td>
<td>100 ng/mL</td>
</tr>
<tr>
<td>BUP</td>
<td>Buprenorphine</td>
<td>10 ng/mL</td>
</tr>
</tbody>
</table>

Quality Control
An internal procedural control has been built into the test to ensure that the test performs properly. The appearance of a line in the control region (C) serves as the internal procedural control to verify that the reagents in the test are still working, and that the test is valid.

The use of external controls is recommended to verify proper test kit performance. Quality Control samples should be tested with each new lot according to the quality control requirements of the testing facility. It is also recommended to test the products in storage monthly. When testing quality control samples, follow the same testing procedure as for testing urine samples. CLIA waived laboratories should follow the manufacturer’s quality control recommendations.

To obtain the appropriate external controls, contact the Customer Service Department at Branan Medical Corporation by emailing to info@brananmedical.com. Do not use commercially available urine controls since these products may not be compatible with the QuickTox® Drug Screen Dipcard.

Refer to Quality Control section in the package insert for troubleshooting instructions.
Step-by-Step Testing Instructions

1. Remove the QuickTox® Drug Screen Dipcard from the pouch by tearing at the notch.

2. Detach the bottom cover by pulling gently.

3. Dip the QuickTox® Drug Screen Dipcard straight into the urine for a minimum of 10 seconds. **DO NOT** dip beyond the tip of the arrows.

4. Remove the QuickTox® Drug Screen Dipcard from the urine. Re-attach the bottom cover and lay the device on a flat surface.

Interpretation of Results

**Interpretation of Result.**

Look at each test strip separately. Read the test results on one side, then turn the device over and read results on the other side.

Read test results at 5 minutes.

**Negative (−)** Look at each test strip separately

- The result is negative when there are two red lines, one in the control region (C) and one in the test region (T).
- This means that the urine sample does not contain that particular drug, or that the drug level is lower than the detection level.
- In the above example, OPI, MET and BAR tests are negatives.

**Note:** Any visible test line (T), even a very faint test line, is considered a negative result.

**Preliminary Positive (+)** Look at each test strip separately

- The result is preliminary positive when there is a red line in the control region (C) and no line in the test region (T).
- This means that the urine sample is preliminary positive for that particular drug.
- In the above example, COC, THC and PCP tests are preliminary positives.

**Invalid** Look at each test strip separately

- The result is invalid when no line appears at the control region (C). When there is no line in the control region (C), the test is invalid even if there is a line in the test region (T).
- Do not use this result.
- In the above example, MET and BAR tests are invalid.
- If no line appears at the control region (C), the test may not have performed properly. Check testing procedure and repeat the test using a new QuickTox® Drug Screen Dipcard.
COC/OPI/MET/THC/AMP/PCP/BZO/BAR/MDT/TCA/MDMA/OXY/BUP

This package insert covers combination test of cocaine, opiates, methamphetamine, THC, amphetamine, phencyclidine, benzodiazepines, barbiturates, methadone, tricyclic antidepressants, MDMA, oxycodone, or buprenorphine in QuickTox® devices.

Intended Use

The QuickTox® Drug Screen Dipcard Test is an in vitro screen test for the rapid detection of multiple drugs and drug metabolites in human urine at or above the following cutoff concentrations:

- **COC**: Benzoylecgonine (300 ng/ml)
- **OPI**: Morphine (300 ng/ml)
- **OP1**: Morphine (2000 ng/ml)
- **MET**: Methamphetamine (500 ng/ml)
- **MET**: Methamphetamine (1000 ng/ml)
- **THC**: 11-nor-Δ9-Tetrahydrocannabinol-9-carboxylic acid (50 ng/ml)
- **AMP**: Amphetamine (1000 ng/ml)
- **PCP**: Phencyclidine (25 ng/ml)
- **BZO**: Oxazepam (300 ng/ml)
- **BAR**: Secobarbital (300 ng/ml)
- **MDA**: Methadone (300 ng/ml)
- **MDMA**: 3,4-methylenedioxymethamphetamine (1000 ng/ml)
- **OXY**: Oxycodone (100 ng/ml)
- **BUP**: Buprenorphine (10 ng/ml)

The QuickTox® Drug Screen Dipcard Test provides visual qualitative results and is intended for professional in vitro diagnostic use only. It is not intended for over-the-counter sale to non-professionals.

The QuickTox® Drug Screen Dipcard Test provides only preliminary test results for drug-of-abuse. For a quantitative result or to confirm positive results obtained by the QuickTox® Drug Screen Dipcard Test, a more specific alternative method must be used. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method.

Summary and Explanation

**COC**: Cocaine derived from the leaves of the coca plant, is a potent central nervous system stimulant, and has been used as a local anesthetic. Cocaine use induces euphoria, confidence, and a sense of increased energy; these psychological effects are accompanied by increased heart rate, pupil dilation, fever, tremors, and sweating. Cocaine is generally smoked or administered intravenously or orally. Cocaine base can be smoked in the form commonly known as “crack”, which is likely to lead to dependence since the effect is more rapid and intensified. Cocaine is primarily excreted as benzoylecgonine and can generally be detected for 24–60 hours after cocaine use or exposure.

**OPI**: Heroin, morphine and codeine are opiates that are derived from the resin of the opium poppy. Heroin is quickly metabolized to morphine. Thus, morphine and morphine glucuronide may both be found in the urine of a person who has taken only heroin. The body also converts codeine to morphine, and generally, morphine and other opiates can be detected in the urine within 2 to 6 hours after use and remains detectable up to 3 days. However, the length of time following drug use for which a positive result may occur is dependent upon several factors including the frequency and amount of usage, metabolic rate, excretion rate, drug half-life, and the drug user's age, weight, activity and diet.

**MET**: Methamphetamine is a potent sympathomimetic agent with therapeutic applications. Methamphetamine use in acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, and a sense of increased energy and power. Methamphetamine is excreted in the urine as amphetamine and oxidized as deaminated derivatives. However, 40% of methamphetamine is excreted unchanged. Thus the presence of the parent compound in the urine indicates methamphetamine use. Methamphetamine can be detected in urine within 4-6 hours after use and for 3-5 days, depending on urine pH level.

**THC**: THC use may impair short-term memory and inhibit learning capacity. It may also alter mood and sensory perceptions, cause loss of coordination, induce anxiety, paranoia, hallucinations, depression, confusion, and increased heart rate. A tolerance to the cardiac and psychotrophic effects can occur. Long-term THC use may be associated with behavioral disorders. Withdrawal from marijuana use may produce restlessness, irritability, and anxiety. It is metabolized in the liver and excreted through the kidneys. The half-life of phencyclidine is about three days.

**BZO**: Barbiturates are a class of central nervous system depressants. Phenobarbital has been used as a daytime sedative and extensively as an anticonvulsant. Phenobarbital is an example of long acting barbiturate derivative while pentobarbital and secobarbital are examples of short acting barbiturate sedatives. Barbiturate abuse can lead not only to impaired motor coordination and mental disorder, but also to respiratory collapse, coma and eventual death. Short acting barbiturates will generally be excreted in urine as metabolites, while long acting barbiturates will primarily appear unchanged. Barbiturates normally remain detectable in urine for 4 to 6 days after use (up to 30 days for Phenobarbital).

**MDA**: Methadone is a synthetic analgesic drug that is originally used for the treatment of narcotic addiction. Methadone use induced psychological effects such as analgesia, sedation and respiratory depression. Overdose of methadone may cause coma or even death. Methadone is taken orally or intravenously and is metabolized in the liver. The major route of methadone excretion is in the urine. The effects of methadone last up to 24 hours after use and can be detected in the urine up to 14 days. The length of time following drug use for which a positive result may occur is dependent upon several factors including the frequency and amount of drug, metabolic rate, excretion rate, drug half-life, and the user’s age, weight, activity and diet.

**MDMA**: 3,4-methylenedioxymethamphetamine (MDMA) is a synthetic drug that is chemically related to the amphetamine family of compounds. MDMA has been available as a street drug since the 1980s, however, since the 1990s its use has increased, particularly among teenagers and young adults. The drug has street names that include "Ecstasy, XTC, Clarity, Essence and Adam". MDMA is typically available in tablet form containing approximately 60-150 milligrams of MDMA. The common method of use is oral ingestion, although the powder form can be snorted and occasionally smoked. MDMA has properties of both stimulants and hallucinogens. The effects of the drug last up to 6 hours after oral ingestion. The adverse effects include elevated blood pressure, increased heart rate, hyperthermia, dehydration, anxiety, paranoia and insomnia. The detection period of MDMA in urine is 1-3 days for single use and up to 5 days for heavy use.

**OXY**: Oxycodone is a synthetic analgesic drug administered orally for the relief of pain. The major route of oxycodone excretion is in the urine. The effects of oxycodone last up to 4 hours after use. The length of time following drug use for which a positive result may occur is dependent upon several factors including the frequency and amount of usage, metabolic rate, excretion rate, drug half-life, and the drug user’s age, weight, activity, and diet.

**BUP**: Buprenorphine is a synthetic derivative of thebaine with partial agonist and antagonist actions. It is 25 to 40 times more potent than morphine as an analgesic. It has been used for the treatment of narcotic addiction as an alternative to methadone. Buprenorphine has a half-life of 2-4 hours in plasma and complete elimination of a single dose can take up to 6 days.
Warnings and Precautions

Each QuickTox® family of urine drug screen tests is based on the principle of the highly specific immunochromatographic reactions between antigens and antibodies. The QuickTox® Drug Screen Dipcard Test is based on a competitive immunochromatographic procedure in which immobilized drug conjugates compete with the drug(s) present in urine for limited antibody binding sites. The test device consists of individual test strips assembled into separate chambers of a plastic insert. On each membrane strip, a drug conjugate is pre-coated at a specific region known as the test region. A colored antibody-colloidal gold conjugate is coated onto a pad and placed at one end of the membrane strip. In the test procedure, the QuickTox® Drug Screen Dipcard test device is dipped into a urine sample. This allows the urine to contact with the sample pads of the QuickTox® Drug Screen Dipcard test device. The urine then migrates across the membrane by capillary action. If any drug is present in the urine, it competes with the drug conjugate, which is immobilized on the membrane for the limited binding sites on the colored antibody colloidal gold conjugate. When a sufficient amount of drug is present, the drug will saturate the antibody binding sites and the colored colloidal gold conjugate cannot bind to the drug conjugate on the membrane. The absence of a color band at a specific test region indicates a negative result for that particular test. If there is no drug or drug metabolite present to compete for the binding sites of the colored colloidal gold conjugate, it binds to the immobilized drug conjugate to form a visible band at the specific test region of the membrane. The presence of a color band at a specific test region indicates a negative result for that particular test.

A control band with a different antigen/antibody reaction is added to the immuno-chromatographic membrane strip at the control region (C) to indicate that the test performed properly. This control band should always appear regardless of the presence of drug or metabolite.

Figure A: The above illustration depicts QuickTox® Drug Screen Dipcard with 12 drug tests.

Reagents

Protein conjugate for benzoylecgonine, morphine, methamphetamine, THC, amphetamine, phenylclidine, benzodiazepine, barbiturate, methadone, nor triptyline, MDMA, oxycodone, or buprenorphine is coated onto the test region of the membrane. The colored conjugate pad for each strip contains antibodies for benzoylcegonine, morphine, methamphetamine, THC, amphetamine, phenylclidine, benzodiazepine, barbiturate, methadone, tricyclic antidepressant, MDMA, oxycodone, or buprenorphine.

Materials Provided

Each QuickTox® Drug Screen Dipcard Test Kit contains:

1. 1 Package Insert (directions for use).
2. 25 QuickTox® test devices. Each test device is packaged with a desiccant and sealed in a foil pouch.

Warnings and Precautions

- FOR IN VITRO DIAGNOSTIC USE ONLY
- For professional use only.
- The test device should remain in its original sealed pouch until ready for use.
- Discard the test device if package is ripped or torn.
- Handle all urine specimens as if potentially infectious. Proper handling and disposal methods should be established.
- Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample.
- Dip device up to, but not beyond the tip of the arrows.
- Do not drop device into sample collection cup.

Figure B

Sample level must meet the tip of the arrows.
Dipping the device beyond the tip of the arrows may cause invalid results.

Product Storage

The QuickTox® Drug Screen Dipcard Test should be stored at room temperature (15°–30°C) until the expiration date on the label. Do not open pouch until ready to perform the assay.

Specimen Collection and Handling

QuickTox® Drug Screen Dipcard Tests are formulated for use with urine specimens. Use only freshly voided, untreated urine. Do not centrifuge or add preservatives to urine. Urine samples should be collected so that testing may be performed as soon as possible, preferably during the same day. Specimens that have been refrigerated must be brought to room temperature prior to testing. Previously frozen specimens must be thawed, brought to room temperature, and mixed thoroughly prior to testing.

Note: All materials coming in contact with urine specimens should be handled and disposed of as if potentially infectious. Avoid contact and follow good laboratory practice.

Test Procedure

IMPORTANT: Donor sample (urine specimen) should be brought to room temperature (15°-30°C) prior to testing. Do not open pouch until ready to perform the assay.

2. Remove the test device from the sealed pouch by tearing at the notch.
3. Detach the bottom cover and dip the sample pads of the QuickTox® Drug Screen Dipcard Test device straight into the urine. Dip for a minimum of 10 seconds. Dip up to, but not beyond the tip of the arrows. Please refer to Fig. B in Warnings and Precautions.
4. Remove the QuickTox® Drug Screen Dipcard Test device from the sample and re-attach the bottom cover.
5. Once the control band (C) appears (in 5 minutes or less) results are ready to interpret. Read results at 5 minutes.

Interpretation of Results

Figure C

Negative Positive Invalid

*Note: The above results are for illustration purposes only; see the explanations below for interpretation of results.

Negative: The presence of a colored band at the control region (C) and a colored band at a specific test region regardless of the intensity indicate that the result is negative for that particular test.

Positive: The presence of a colored band at the control region (C) and the absence of a colored band at the test region indicate a positive result for that particular test.

Invalid: No band appears at the control region (C). The test is inconclusive even if there is a band in the test region. If the test device does not produce a band at the control region, check testing procedures, samples, and/or control materials, and repeat the test using a new device.
Important: Read each test independently. Do not compare color intensity of one test to another. Samples with faint test bands at the test regions should be discarded. The QuickTox Drug Screen Dipcard Test provides qualitative results for the presence of drug(s) at specified cut-off concentrations. It is recommended that samples with questionable test bands and positive results be confirmed with a more specific quantitative method (Gas Chromatography/Mass Spectrometry).

Quality Control

Non-CLIA Waived Laboratories:
An internal procedural control has been built into the test to ensure that the test performs properly. The appearance of a line in the control region (C) serves as the internal procedural control to verify that the reagents in the test are still working, and that the test is valid. The manufacturer’s recommendation for daily quality control is to document the appearance of the control line for the first sample tested each day.

The use of external controls is recommended to verify proper kit performance. Quality Control samples should be tested with each new lot, each new shipment and according to the quality control requirements of the testing facility. It is also recommended to test the products in storage monthly. When testing quality control samples, follow the same testing procedure as for testing urine samples.

CLIA-Waived Laboratories:
An internal procedural control has been built into the test to ensure that the test performs properly. The appearance of a line in the control region (C) serves as the internal procedural control to verify that the reagents in the test are still working, and that the test is valid. The manufacturer’s recommendation for daily quality control is to document the appearance of the control line for the first sample tested each day.

The use of external controls is recommended to verify proper kit performance. Quality Control samples should be tested with each new lot, each new shipment and according to the quality control requirements of the testing facility. It is also recommended to test the products in storage monthly. When testing quality control samples, follow the same testing procedure as for testing urine samples.

Contact the Customer Service Department at Branan Medical Corporation at 1-888-468-3287 or by e-mailing to info@brananmedical.com with any questions regarding quality control or to order the appropriate external controls. Do not use commercially available urine controls since these products may not be compatible with the QuickTox Drug Screen Dipcard.

Limitations of Procedure
• The assay is designed for use with human urine only.
• Positive results only indicate the presence of drug metabolites and do not indicate or measure intoxication.
• There is a possibility that technical or procedural error as well other substances in certain food and medication may interfere with the test and cause false results. See Specificity section for the list of substances that will produce either positive results, and Interference section for the list of components that do not interfere with test performance.
• If a drug metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drugs of abuse and certain food and/or medication.
• If it is suspected that the sample may have been mishandled a new specimen should be collected.
• If it is suspected that the sample may have been tampered, a new specimen should be collected.

Performance Characteristics

Precision
For each specific drug test, drug-free normal urine was spiked with drug standards to various concentrations (-50%, -25%, +25% and +50%). For each concentration, a minimum of 25 tests were performed to validate the test performance around the cut-off concentration. The results for each drug test in the QuickTox Drug Screen Dipcard are summarized below:

<table>
<thead>
<tr>
<th>Drug Test</th>
<th>Total # of Test / Conc.</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-50%</td>
<td>-25%</td>
</tr>
<tr>
<td>COC300</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>OPI300</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>OPI2000</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>MET500</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>MET1000</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>THC50</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>AMP1000</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>PCP25</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>BZO300</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>BAR500</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>MDA500</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>OXY100</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>BUP10</td>
<td>30</td>
<td>30</td>
</tr>
</tbody>
</table>

Accuracy
The accuracy of the QuickTox Drug Screen Dipcard Test device was evaluated in comparison to the results from GC/MS analysis or other commercially available confirmatory methods. A minimum of thirty-six (36) negative urine samples were collected from volunteer donors and tested with each drug strip. Of the negative urine samples tested, all were found negative by both methods (100% agreement).

Additionally, for each drug test a minimum of 40 clinical urine samples previously analyzed by GC/MS method with known concentration(s) of drug(s) were blinded labeled and evaluated. The results are summarized below:

<table>
<thead>
<tr>
<th>Drug Test</th>
<th>GC/MS Pos.</th>
<th>GC/MS Neg.</th>
<th>GC/MS ≥ 50%</th>
<th>GC/MS &gt; O/C</th>
<th>GC/MS &gt; C/O</th>
</tr>
</thead>
<tbody>
<tr>
<td>COC300</td>
<td>30</td>
<td>30</td>
<td>0</td>
<td>26</td>
<td>4</td>
</tr>
<tr>
<td>OPI300</td>
<td>30</td>
<td>30</td>
<td>0</td>
<td>24</td>
<td>6</td>
</tr>
<tr>
<td>OPI2000</td>
<td>30</td>
<td>30</td>
<td>0</td>
<td>26</td>
<td>6</td>
</tr>
<tr>
<td>MET500</td>
<td>30</td>
<td>30</td>
<td>0</td>
<td>24</td>
<td>6</td>
</tr>
<tr>
<td>MET1000</td>
<td>30</td>
<td>30</td>
<td>0</td>
<td>24</td>
<td>6</td>
</tr>
<tr>
<td>THC50</td>
<td>30</td>
<td>30</td>
<td>0</td>
<td>24</td>
<td>6</td>
</tr>
<tr>
<td>AMP1000</td>
<td>30</td>
<td>30</td>
<td>0</td>
<td>24</td>
<td>6</td>
</tr>
<tr>
<td>PCP25</td>
<td>30</td>
<td>30</td>
<td>0</td>
<td>24</td>
<td>6</td>
</tr>
<tr>
<td>BZO300</td>
<td>30</td>
<td>30</td>
<td>0</td>
<td>24</td>
<td>6</td>
</tr>
<tr>
<td>BAR500</td>
<td>30</td>
<td>30</td>
<td>0</td>
<td>24</td>
<td>6</td>
</tr>
<tr>
<td>MDA500</td>
<td>30</td>
<td>30</td>
<td>0</td>
<td>24</td>
<td>6</td>
</tr>
<tr>
<td>OXY100</td>
<td>30</td>
<td>30</td>
<td>0</td>
<td>24</td>
<td>6</td>
</tr>
<tr>
<td>BUP10</td>
<td>25</td>
<td>25</td>
<td>0</td>
<td>25</td>
<td>0</td>
</tr>
</tbody>
</table>

CLIA Waiver Performance

Accuracy and Precision
To demonstrate that the QuickTox Drug Screen Dipcard test device is a simple test and can be used by untrained users to obtain accurate test results, site studies were conducted at three (3) non-laboratory sites. The participants (untrained users) at these sites are non-laboratory professionals with no training or previous experience with drugs-of-abuse tests or the QuickTox Drug Screen Dipcard device. The participants are a demographically diverse population that includes a range of ages, educational and regional background and are representative of the users of a CLIA Waived test.

For each specific drug test contained in the QuickTox Drug Screen Dipcard device, drug-free normal urine was spiked with drug standards to various concentrations (-50%, -20%, +20% and +50%). Each of the concentration was divided into 20 aliquots and each aliquot was blind-labeled with a unique code. A total of 30 tests per concentration were performed at each of the three sites to validate the test performance around the cut-off concentration. The results are summarized below:

<table>
<thead>
<tr>
<th>Site Conc.</th>
<th># of sample per conc. Per test</th>
<th>COC</th>
<th>OPI</th>
<th>MET</th>
<th>THC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>50%</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>-20%</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>+20%</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>+50%</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>50%</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>-20%</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>+20%</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>+50%</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>50%</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>-20%</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>+20%</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>+50%</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
The percent of correct results among all the drug tests for the strong negative (-50%) and strong positive (+50%) was 100% (95% CI: 93% to 100.0%). The percent correct results for the weak negative (-20%) was from 90% (95% CI: 80% to 96%) for the MET500, BAR and MTD tests to 100% (95% CI: 93% to 100.0%) for the BUP test. The percent correct results for the weak positive (+20%) was from 93% (95% CI: 84% to 98%) for the COC, PCP and MDMA tests to 100% (95% CI: 94% to 100%) for the AMP test.

The data demonstrated that there was no statistically significant difference in the percent of correct results among the three sites for strong negative, weak negative, weak positive, and strong positive concentrations for all above-mentioned drug tests.

### Specificity

The specificity study for each of the drug test of the QuickTox® Drug Screen Dipcard Test device was evaluated separately by adding structurally related compounds to normal human urine. The results are expressed as the amount in ng/ml of the compound that was observed to produce a positive result.

### COC 300 ng/ml

<table>
<thead>
<tr>
<th>Compound</th>
<th>ng/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzylecgonine</td>
<td>300</td>
</tr>
</tbody>
</table>

### OPI 2000 ng/ml

<table>
<thead>
<tr>
<th>Compound</th>
<th>ng/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-Acetylmorphine</td>
<td>2,000</td>
</tr>
<tr>
<td>Codeine</td>
<td>2,000</td>
</tr>
<tr>
<td>Dihydrocodeine</td>
<td>2,000</td>
</tr>
<tr>
<td>Ethylmorphine</td>
<td>2,000</td>
</tr>
<tr>
<td>Heroin</td>
<td>2,000</td>
</tr>
</tbody>
</table>

### OPI 300 ng/ml

<table>
<thead>
<tr>
<th>Compound</th>
<th>ng/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-Acetylmorphine</td>
<td>500</td>
</tr>
<tr>
<td>Codeine</td>
<td>300</td>
</tr>
<tr>
<td>Dihydrocodeine</td>
<td>500</td>
</tr>
<tr>
<td>Ethylmorphine</td>
<td>300</td>
</tr>
<tr>
<td>Heroin</td>
<td>100</td>
</tr>
</tbody>
</table>

### MET 1000 ng/ml

<table>
<thead>
<tr>
<th>Compound</th>
<th>ng/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ephedrine</td>
<td>50,000</td>
</tr>
<tr>
<td>p-Hydroxymethamphetamine</td>
<td>10,000</td>
</tr>
<tr>
<td>d,l-3,4-MDMA</td>
<td>1,000</td>
</tr>
</tbody>
</table>

### MET 500 ng/ml

<table>
<thead>
<tr>
<th>Compound</th>
<th>ng/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ephedrine</td>
<td>10,000</td>
</tr>
<tr>
<td>p-Hydroxymethamphetamine</td>
<td>1,750</td>
</tr>
<tr>
<td>d,l-3,4-MDMA</td>
<td>1,000</td>
</tr>
<tr>
<td>d-Methamphetamine</td>
<td>500</td>
</tr>
</tbody>
</table>

### AMP 1000 ng/ml

<table>
<thead>
<tr>
<th>Compound</th>
<th>ng/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>d-Amphetamine</td>
<td>1,000</td>
</tr>
<tr>
<td>f-Methamphetamine</td>
<td>25,000</td>
</tr>
<tr>
<td>d,l-3,4-MDA</td>
<td>5,000</td>
</tr>
</tbody>
</table>

### PCP 25 ng/ml

<table>
<thead>
<tr>
<th>Compound</th>
<th>ng/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenylcyclidine</td>
<td>25</td>
</tr>
</tbody>
</table>

### BZO 300 ng/ml

<table>
<thead>
<tr>
<th>Compound</th>
<th>ng/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alprazolam</td>
<td>150</td>
</tr>
<tr>
<td>Lorazepam</td>
<td>1,500</td>
</tr>
<tr>
<td>Bromazepam</td>
<td>800</td>
</tr>
<tr>
<td>Medazepam</td>
<td>1,000</td>
</tr>
<tr>
<td>Clonazepam</td>
<td>4,000</td>
</tr>
<tr>
<td>Oxazepam</td>
<td>1,000</td>
</tr>
<tr>
<td>Diazepam</td>
<td>150</td>
</tr>
<tr>
<td>Temazepam</td>
<td>1,000</td>
</tr>
<tr>
<td>Flunitrazepam</td>
<td>1,000</td>
</tr>
<tr>
<td>Trazolam</td>
<td>1,500</td>
</tr>
<tr>
<td>Flurazepam</td>
<td>300</td>
</tr>
</tbody>
</table>

### MTD 300 ng/ml

<table>
<thead>
<tr>
<th>Compound</th>
<th>ng/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>MTD</td>
<td>300</td>
</tr>
</tbody>
</table>

### THC 50 ng/ml

<table>
<thead>
<tr>
<th>Compound</th>
<th>ng/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norbuprenorphine Glucuronide</td>
<td>50</td>
</tr>
</tbody>
</table>

The effects of pH and specific gravity of the specimens on the performance of the drugs-of-abuse tests at cutoff level were tested. Results obtained were acceptable and not affected by any urine samples with pH range of 4.5 to 8.5 and specific gravity range of 1.005 to 1.030.

### Interferences

Various drugs, drug metabolites, and other constituents commonly found in urine were evaluated for interferences and cross-reactivity. The following compounds were found not to cross-react with the QuickTox® Dipard Dipcard Test device when tested at concentrations of 10 μg/ml (100,000 ng/ml):**
Benzilic acid
Benzoic acid (Ethyl p-Aminobenzoate)
Benzolic acid
Benzyloecgonine (except COC assay)
Benztphanate
Bilirubin
Bromazepam (except BZO assay)
d-Brompheniramine
Buprenorphine (except BUP assay)
Buprenorphine Glucuronide (except BUP assay)
Butalbital (except BAR assay)
Butalbital (except BAR assay)
Butalh (except BAR assay)
Caffeine
Cannabidiol
Cannabidiol (except THC assay)
Cannabidiol (except THC assay)
Chloralhydrate (except BZO assay)
Chloralhydrate (except BZO assay)
d-Chlorpheniramine
Chlorpromazine
Cholesterol
Cllozabam (except BZO assay)
Clomipramine (except TCA assay)
Clonazepam (except BZO assay)
Cocaine
Codeine (except OPI & OXY assays)
Coristone
I-Cotinine
Creatine
Creatinine
Cyclobenzaprine (except TCA assay)
Delorazepam (except BZO assay)
Deoxycorticosterone
Desipramine (except TCA assay)
Dextromethorphan
Diazepam (except BZO assay)
Dihydrocodeine (except OPI assay)
4-Dimethylnalinoantipyrine
Diphenhydramine
Dopamine (3-Hydroxytyramine)
Doxepin (except TCA assay)
Doxylamine (except MTD assays)
Egonine (except COC assay)
Egonine Methyl Ester
d,l-Ephedrine (except MET assay)
L-Epinephrine
Erythromycin
Estazolam (except BZO assay)
ß-Estradiol
Estrone-3-Sulfate
Ethanol
Ethyl Morphine (except OPI assay)
Ethyl-p-aminobenzoate
2-Ethylidene-1,5-Dimethyl-1,3,5-
Diphenylpyrrolidone (except MTD assay)
Flunitrazepam (except BZO assay)
Flurazepam (except BZO assay)
Furosemide
Gentisic acid
Glucose
Glutethimide
Gualiacol Glycerin Ether
Hemoglobin
Heroin (except OPI assay)
Hippuric acid
Hydrochlorothiazide
Hydrocodeine (except OPI & OXY assays)
Hydorcholine
Hydromorphone (except OPI & OXY assays)
p-Hydroxymethamphetamine (except MET assay)
11-Hydroxy-∆-9-THC (except THC assay)
Ibuprofen
Imipramine (except TCA assay)
l-Isoproterenol
d,l-Isoproterenol
Ketamine HCl
Lisdacaine
Lorazepam (except BZO assay)
Lorazepam Glucuronide (except BZO assay)
Medezepam (except BZO assay)
Mephenidine
Methadone (except MTD assay)
d-Methamphetamine (except MET & MDA assays)
I-Methamphetamine (except MET assay)
Methalouline
Methoxphenamine (1R,2S)-N-Methyl-Ephedrine
2-Methalamine-Proprionphenone
d,l-3,4-Methylenedioxyamphetamine (except AMP & MDA assays)
d,l-3,4-Methylenedioxyethylamphetamine (except MDMA assay)
d,l-3,4-Methylenedioxyethylamphetamine (except MDA assay)
Nalidixic acid
Nalorphine
Naloxone
d-Naproxen
Nicotinamide
Nirazepam (except BZO assay)
Nalbuphine (except BUP assay)
Nalbuphine Glucuronide (except BUP assay)
Nordiazepam (except BZO assay)
Nordoxepin (except TCA assay)
d,l-Norpethidine
Nortriptyline (except TCA assay)
Oxalic Acid
Oxazepam (except BZO assay)
Oxalic acid
Oxycodone (except OXY assay)
Oxaparine
Penicillin
Pentazocine
Pentobarbital (except BAR assay)
Perphenazine (except TCA assay)
Phencyclidine (except PCP assay)
Phenifline (except MTD assay)
Phenobarbital (except BAR assay)
Phentiazine (Thiopentalamine)
Phenterline (except AMP assay)
Phenylephrine
β-Phenylethylamine (except AMP assay)
Prednisolone
Pracepam (except BZO assay)
Procaine (except MET assay)
Promazine (except TCA assay)
Promethazine
d-Propanoic acid
Prototypical line (except TCA assay)
d-Pseudoephedrine
Pyridoxine
Quinidine
Quinine
Ranitidine
Riboflavin
Salicylic acid
Secobarbital (except BAR assay)
Serotonin
Sodium Chloride
Sumifentazine
Sulindac
Temazepam (except BZO assay)
Tetrazycline
Δ-THC (except THC assay)
Δ-THC (except THC assay)
11-nor-Δ-8-THC-9-Carboxylic Acid (except THC assay)
11-nor-Δ-9-THC-9-Carboxylic Acid (except THC assay)
Thiamine
Thioridazine
Triazolam (except BZO assay)
Triflurorazam
Trimethobenzamidex (except MET500 assay)
Trimepramine Maleate (except TCA assay)
Tryptamine
Tyramine
Tyramine
Tyramine
Tyramine
Verapamil
Zomepirac

Bibliography of Suggested Reading

Manufactured by:
Branan Medical Corporation
140 Technology Dr., Suite 400
Irvine, CA 92618
1-866-468-3287 (1-866-INTECT7) Domestic U.S. & Canada
1-949-598-7166 International

Part No.: PI-QT-CLIA Rev: J, 03/2013