

Branan Medical Corporation

Product Training & Certificate

QuickTox[®]
Drug Screen Dipcard
(with and without Adulteration Tests)



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QuickTox[®] Drug Screen Dipcard

QuickTox[®] Drug Screen Dipcard with Adulteration Tests

Training and Certification for Test Administrators

The information provided is intended to educate test administrators in the use of the QuickTox[®] Drug Screen Dipcard. The information will include both QuickTox[®] with and without adulteration tests. Please read the following information carefully. A multiple-choice test will be administered once the material has been reviewed.

Intended Use

The QuickTox[®] Drug Screen Dipcard is a one-step, lateral flow chromatographic immunoassay for the rapid detection of various drugs of abuse and drug metabolites in human urine. The assay is used to obtain a visual, qualitative result and is intended for prescription use only.

The QuickTox[®] Drug Screen Dipcard provides only preliminary qualitative test results. For a quantitative result or to confirm presumptive positive results obtained by QuickTox[®], a more specific alternative method must be used. Gas Chromatography/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 presumptive positive results are indicated.

Specific Test Cut Off Concentrations

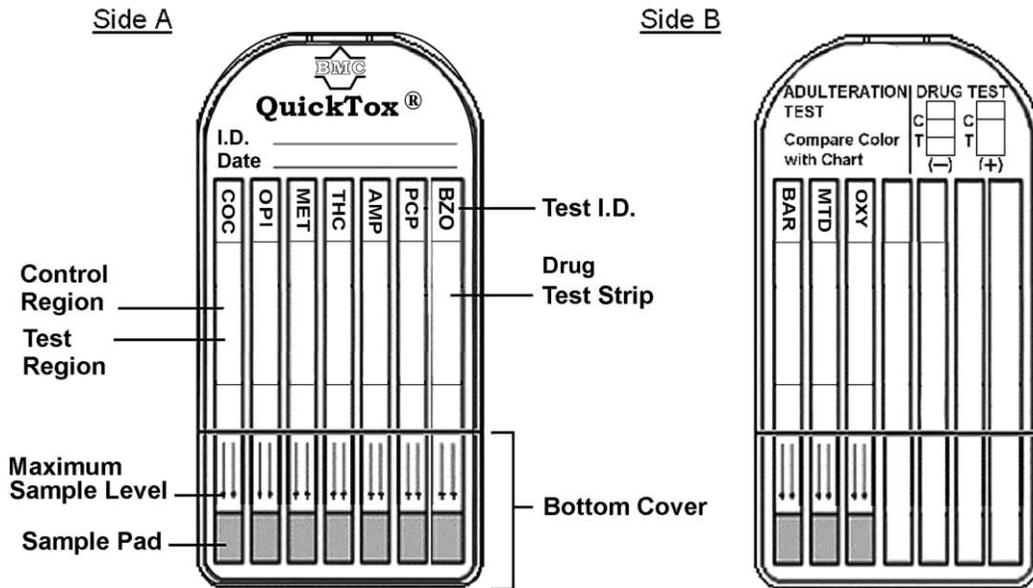
AMP	Amphetamine	1000 ng/ml
BAR	Barbiturates (Secobarbital)	300 ng/ml
BZO	Benzodiazepine (Oxazepam)	300 ng/ml
COC	Cocaine (Benzoylecgonine)	300 ng/ml
MDMA	3,4-methylenedioxymethamphetamine	500 ng/ml
MTD	Methadone	300 ng/ml
MET	Methamphetamine	500 & 1000 ng/ml
OPI	Opiates (Morphine)	300 & 2000 ng/ml
OXY	Oxycodone	100 ng/ml
PCP	Phencyclidine (PCP)	25 ng/ml
THC	Tetrahydrocannabinol (11-nor- Δ^9 -Tetrahydrocannabinol-9-carboxylic acid)	50 ng/ml
BUP	Buprenorphine	10 ng/ml
TCA	Tricyclic antidepressants	1000 ng/ml

Warnings and Precautions

- For *in vitro* diagnostic 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.
- Do not use the test device beyond the expiration date indicated on the pouch.
- Handle all specimens as 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.
- The QuickTox[®] Multiple Drug Dipcard should be stored at room temperature (15°-30° C or 59°-86° F).

QuickTox[®] Drug Screen Dipcard

Depending upon the test configuration, both sides of the device may be used.



Test Principle

The QuickTox[®] Drug Screen Dipcard is based on the principal of the highly specific immunochemical reactions between antigens and antibodies that are used for the analysis of specific substances in urine.

Depending on the test(s) chosen, the test device contains multiple test strips onto which drug conjugates are pre-coated at specific regions known as test regions.

Colored antibody-colloidal gold conjugates are coated onto a pad and placed on one end of each membrane. In the test procedure, the QuickTox[®] Drug Screen Dipcard is dipped into a urine sample. The urine is carried by the sample pad to the colloidal gold conjugate pad and then migrates across the membrane by capillary action.

If any drugs are present in the urine, it will compete with the drug conjugate for the limited binding sites of the color colloidal gold conjugate. When a sufficient amount of drug is present, the drug will saturate the binding sites and the colored colloidal gold cannot bind to the drug conjugate on the membrane.

If no drug is present, the colored colloidal gold conjugates will bind to the binding sites on the membrane to form colored bands at specific test regions. Any **presence of a colored band** at a specific test region indicates a **negative result**.

The absence of a color band at the test region indicates a **presumptive positive result for the particular test. In either case, the control band must be present for the test to be valid.**

QuickTox[®] Drug Screen Dipcard with Adulteration Tests

The validity of Drugs-of-Abuse (DAU) screening depends on the integrity of the urine samples. Contaminated or adulterated samples may cause erroneous results leading to significant consequences. Hence, it is important to ensure that the samples are intact and unadulterated prior to DAU testing.

CR (Creatinine)	Creatinine is a normal urine constituent. Although the ranges are affected by age, sex, diet, muscle mass and local population distribution, the Department of Transportation (DOT) guideline states that urine specimens with creatinine levels less than 20mg/dl may be indications of dilution or substitution.
OX (Oxidizing Agents)	Normal urine specimen should be free of any oxidizing (Ox) agents. A positive 'Ox' detection in the urine suggests adulteration. Bleach and/or other oxidizing compounds are found in commercially available adulterant products. When present in the urine, oxidizing agents such as bleach and pyridinium chlorochromate will form a blue to brown-black color on the OX test pad.
PH	The normal urine pH ranges from 4-9. An abnormal 'pH' result (below pH 4 or above 10) indicates adulteration with acidic or alkaline adulterants added to the urine.
NI (Nitrite)	Although nitrite is not a normal component of urine, nitrite levels of up to 10 mg/dl may be found in some urine specimens. A nitrite level of greater than 50 mg/dl is considered beyond the clinical level and is suspiciously abnormal. Nitrite pad changes from no color to pink (normal) to dark purple (abnormal) above 50 mg/dl (≥ 50 mg/dl)
SG	If a urine specimen exhibits a creatinine concentration of <10 mg/dl, then specific gravity should be 1.003 or less which is suspicious of dilution while if specific gravity should be >1.020, this is indicative of substitution.
GL	Glutaraldehyde is not a normal component of urine and its detection is an indication that the urine may have been adulterated. However, in ketoacidosis, starvation, other metabolic abnormalities, ketone and acetone in urine cause an atypical color formation; the color, typical color of brown, as indicated on the color chart is highly suspicious of glutaraldehyde adulteration.

Adulterant testing is a screening method; any abnormal results should be confirmed by an alternate method.

Specimen Collection and Handling

The QuickTox[®] Drug Screen Dipcard is formulated for use with urine specimens. Use only freshly voided untreated urine. Do not centrifuge or add preservatives to the urine. Urine samples should be collected so testing can be performed as soon as possible after collection, preferably the same day. Specimens that have been refrigerated must be brought up to room temperature prior to testing. Previously frozen specimens must be thawed, brought to room temperature and mixed prior to use. Frozen samples are not recommended for adulteration testing.

IMPORTANT: Test device and donor sample (urine specimen) should be brought to room temperature prior to testing. Do not open pouch until ready to perform the assay.

Test Procedure: QuickTox[®] Drug Screen Dipcard

1. Remove the test device from the sealed pouch by tearing at the notch. Discard the desiccant.
2. Remove the bottom cover and dip the test strips of the QuickTox[®] test device straight into the urine sample for a minimum of 10 seconds. **Dip up to but not beyond the tips of the arrows.**
3. Remove the QuickTox[®] Drug Screen Dipcard from the sample and re-attach the bottom cover.
4. Place the device on a level surface.
5. **Drugs of Abuse Tests:** Negative results are ready to interpret once the control bands (C) form. Presumptive positive results can be interpreted once the control bands (C) form and the membrane background clears (in 5 minutes or less). See package insert.

Test Procedure: QuickTox[®] Drug Screen Dipcard with Adulteration Tests

1. Remove the test device from the sealed pouch by tearing at the notch. Discard the desiccant.
2. Remove the bottom cover and dip the test strips of the QuickTox[®] test device straight into the urine sample for a minimum of 10 seconds. **Dip up to but not beyond the tips of the arrows.**
3. Remove the QuickTox[®] Drug Screen Dipcard from the sample and re-attach the cover.
4. Place the device on a level surface.
Adulteration Tests: Read results in 1 minute. Do not read after 2 minutes as reaction colors may fade. Refer to the color chart provided for color matching and interpretation of results.
6. **Drugs of Abuse Tests:** Negative results are ready to interpret once the control bands (C) form. Presumptive positive results can be interpreted once the control bands (C) form and the membrane background clears (in 5 minutes or less). The results are ready to interpret. See package insert.

Interpreting Test Results

Negative Results

For each drug test, two (2) colored bands should be observed in the result window, one band at the control region (C) and a band at the specific test region (T). The color of the test band may be slightly darker or lighter than the control band. Any band that can be seen visually, no matter how faint, is a **negative** result. Read each test independently. Do not compare color intensity of one test to another.

In **Fig. a**, the results are negative because the control band and the test bands are visible.

Negative Results

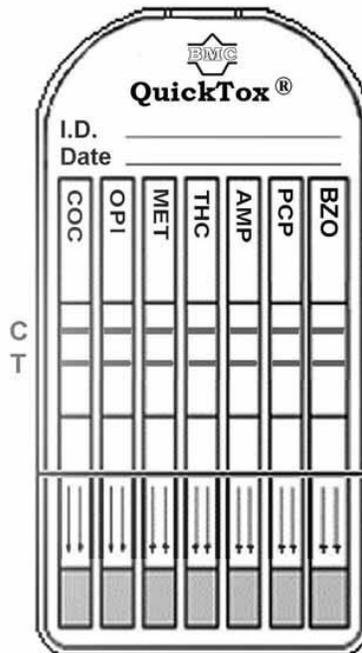


Fig. a

Presumptive Positive Results

When the control band is visible in the control region (C) and no visible bands in the test region (T), the result is presumptive positive for that particular drug.

In the figure below, the sample is presumptive positive for COC, OPI, THC, AMP, PCP and BZO because **no bands are visible in the test region**. Refer to **Fig. b**.

Presumptive positive Results

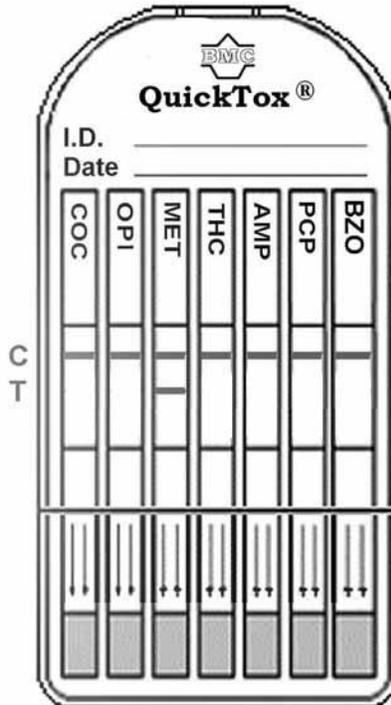


Fig. b

Invalid Results

When **no** band appears in the control (C) region, **the test is invalid** regardless of the test results. There must be a control band in the control region. If the test is invalid, check testing procedures, and samples. **Repeat the test using a new device.**

In **Fig c.** below, OPI, THC, AMP, PCP and BZO tests are invalid because there are no colored bands in the control region.

Invalid Results

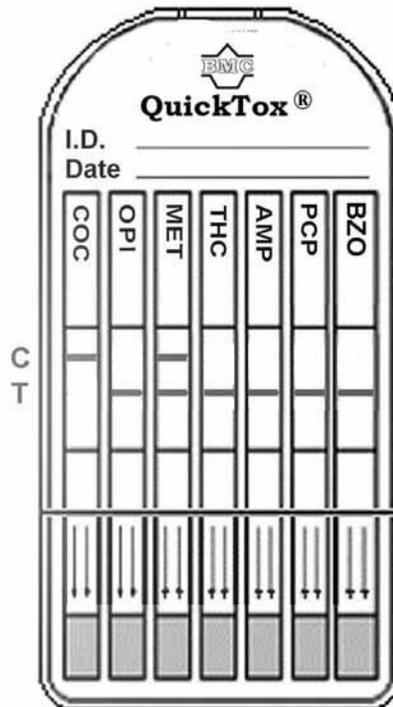


Fig. c

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 considered negative. The QuickTox[®] Drug Screen Dipcard provides qualitative results for the presence of drug(s) at specified cut-off concentrations. It is recommended that samples with a questionable test band and presumptive positive results be confirmed with a more specific method (Gas Chromatography/Mass Spectrometry).

Limitations of the Procedure

- The assay is designed for use with human urine only.
- Presumptive positive results only indicate possible presence of drug/metabolites but do not indicate or measure intoxication.
- There is a possibility of procedural errors as well as other substances in certain foods and medications that may interfere with the drug tests and cause a cross-reaction.
- If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drug of abuse and certain foods and/or medication.
- If it is suspected that the sample may have been mislabeled, a new specimen should be collected.
- If it is suspected that the sample may have been tampered with, the test should be repeated, and a new specimen should be collected.
- Abnormal adulteration test results do not indicate the use of a specific adulterant.
- If abnormal results are obtained with any adulteration test, the specimen should be retested and sent to a laboratory for confirmatory analysis.

THIS COMPLETES THE QUICKTOX[®] TRAINING PROGRAM. TO BECOME CERTIFIED AS A TEST ADMINISTRATOR FOR THE DEVICE, YOU MUST COMPLETE THE FOLLOWING QUIZ WITH A MINIMUM SCORE OF 80%.

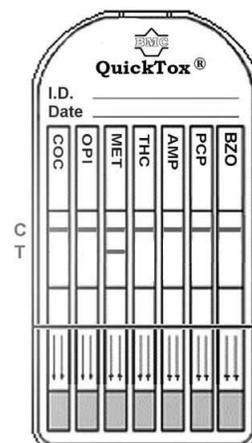
IF YOU HAVE ANY QUESTIONS OR WOULD LIKE TO SPEAK TO CUSTOMER SUPPORT, CALL US AT 1-866-468-3287/949-598-7166 OR E-MAIL INFO@BRANANMEDICAL.COM.

QuickTox[®] Multiple Drug Dipcard

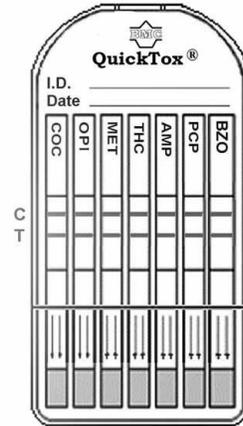
CERTIFICATION TEST

Instructions: This is a multiple-choice test. Read the questions completely before choosing the best answer. Write answers on the sheet provided (p. 13).

1. The QuickTox[®] provides for the detection of
 - a. 1 drug in oral fluid.
 - b. 6 drugs in urine and oral fluid.
 - c. Up to 13 drugs or 12 drugs and 6 adulterant tests in urine.
2. QuickTox[®] provides _____ drug test results.
 - a. Preliminary
 - b. Quantitative
 - c. Qualitative
 - d. Confirmed
 - e. Both a and c are correct
3. The absence of a colored band in the control region (C) means the test result is
 - a. Negative
 - b. Presumptive positive
 - c. Invalid
4. The presence of a colored band at the control (C) region and a colored band at a specific test means the test is
 - a. Invalid
 - b. Negative
 - c. Presumptive positive
5. Interpret the following test:
 - a. Negative for COC, THC and MET
 - b. Presumptive positive for COC, OPI, THC, AMP, PCP and BZO
 - c. Invalid
 - d. Both A & B



6. Interpret the following test:
- Invalid
 - Presumptive positive for AMP and OPI
 - Negative for Drugs of Abuse



7. The QuickTox[®] device should be dipped into the urine sample for a minimum of
- 10 seconds
 - 1 minute
 - 30 days
 - 3 hours
8. Once the control band forms in _____ or less, the results are ready to be read.
- 2 days
 - 1 hour
 - 8 hours
 - 5 minutes
9. The arrows indicate the level at which the strips must be dipped in the urine. Dip the QuickTox[®] device
- Until the urine covers the arrows entirely.
 - To the tips of the arrows.
 - To the edge of the clear plastic case.
10. Which is false pertaining to adulteration tests?
- They ensure the integrity of the urine samples in DAU testing.
 - Creatinine, Nitrite, Oxidizing Agents, pH, Specific Gravity and Glutaraldehyde are adulterant pads included in the QuickTox[®] Drug Screen Dipcard.
 - Adulteration pad results may be read in 1 minute.
 - After 2 minutes, reaction colors may fade.
 - None of the above.

QuickTox[®] Certification Test Result Sheet

Please enter your answers in the spaces below. Print your name, organization, address, telephone, fax, and e-mail address. A certificate will be sent to you if you achieve a score of 80% or higher. Good Luck!

Name _____

Organization _____

Address _____

City, State, Zip Code _____

Telephone _____

Fax _____

E-mail _____

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ANSWERS:

Question 1 _____

Question 6 _____

Question 2 _____

Question 7 _____

Question 3 _____

Question 8 _____

Question 4 _____

Question 9 _____

Question 5 _____

Question 10 _____