

QuickTox™ Drug/Adulteration Test COC/MOR/MET/THC/PCP with Nitrite, Creatinine, pH and Oxidizing Agent Adulteration Test Pads

Catalog No. QT12A

Intended Use

The QuickTox™ Drug Test is an *in vitro* screen test for the rapid detection of cocaine, morphine, methamphetamine, THC and phencyclidine in human urine. The cutoff concentrations are as follows:

COC	Benzoyllecgonine	300 ng/ml
MOR	Morphine	2000 ng/ml
MET	Methamphetamine	1000 ng/ml
THC	11-nor- Δ^9 -Tetrahydrocannabinol-9-carboxylic acid	50 ng/ml
PCP	Phencyclidine	25 ng/ml

Additionally QuickTox™ can assess the validity of the urine sample simultaneous to drug-of-abuse testing. The adulteration pads of the QuickTox™ Test are chemical indicator assays that provide visual qualitative results for nitrite, creatinine, pH and oxidizing agents. The QuickTox™ Drug/Adulteration Test is intended for the professionals *in vitro* diagnostic use only, and is not intended for over-the-counter sale.

The QuickTox™ Drug Test provides only preliminary analytical test results for drugs-of-abuse. For a quantitative analytical result or to confirm positive results obtained by QuickTox™, a more specific alternative chemical method must be used. The Substance Abuse Mental Health Sources Administration (SAMHSA) and the National Institute on Drug Abuse (NIDA) have established Gas Chromatography/Mass Spectrometry (GC/MS) as 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 indicated.

Summary and Explanation

The QuickTox™ Drug/Adulteration Test combines two essential technologies: the simple, one-step, chromatographic immunoassay and the visual, chemical indicator assay to provide a unique and convenient urine screening method for both drugs-of-abuse and urine adulteration testing.

Drugs-of-Abuse Tests:

COC: Cocaine is derived from the leaves of the coca plant. It 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 especially likely to lead to dependence since the effect is more rapid and heightened. Cocaine is primarily excreted as benzoyllecgonine and can generally be detected for 24–60 hours after cocaine use or exposure.¹

MOR: Heroin, morphine, and codeine are opiates that are derived from the resin of the opium poppy. Heroin is quickly metabolized to morphine. The body also converts codeine to morphine. Thus, the presence of morphine (or morphine metabolite) in the urine indicates heroin, morphine, and/or codeine use. Morphine is detectable in the urine for several days after an opiate dose.

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 the urine within 4–6 hours after use and for 3–5 days, depending on urine pH level.¹⁻²

THC: THC (11-nor- Δ^9 -Tetrahydrocannabinol-9-carboxylic acid) is the primary active ingredient in marijuana (cannabinoids). 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 psychotropic effects can occur. Long-term THC use may be associated with behavioral disorders. Withdrawal from marijuana use may produce restlessness, insomnia, anorexia, and nausea.

PCP: Phencyclidine is an arylcyclohexylamine that is used as a veterinary anesthetic. It is used illegally as a hallucinogen, and is commonly referred to as PCP, angel dust, crystal cyclone, love boat, hog, or killer weed. PCP can produce lethargy, disorientation, and loss of coordination, visual distortion, euphoria, ataxia, and even coma. PCP can be taken orally, by nasal ingestion, smoking, or intravenous injection. It is metabolized in the liver and excreted through the kidneys. The half-life of phencyclidine is about three days.

Adulteration Tests:

The validity of 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 insure that the samples are intact and unadulterated prior to DAU testing.

Cr: Creatinine is a normal urine constituent. Although these ranges are affected by age, sex, diet, muscle mass and local population distribution². The DOT guideline³ states that urine specimens with creatinine levels less than 20 mg/dl are indicative of dilution or substitution.

Ni: Although nitrite is not a normal component of urine, nitrite levels of up to 3.6 mg/dl may be found in some urine specimens due to urinary tract infections, bacterial contamination or improper storage. Nitrite level above 50 mg/dl is above the clinical level and is considered abnormal.³

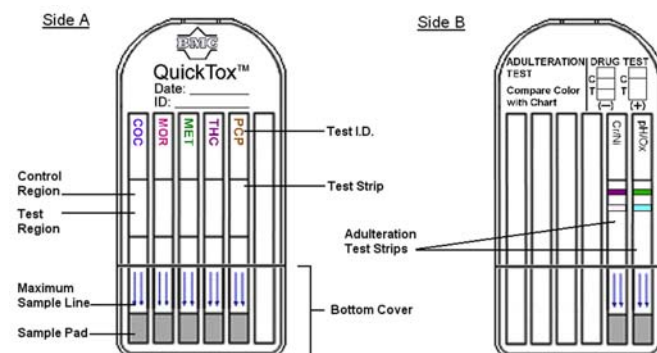
Ox: Normal urine specimen should be free of any oxidizing (Ox) agents. A positive 'Ox' detection in the urine suggests adulteration. Bleach and other oxidizing compounds are found in commercially available adulterant products.

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.

Test Principle – Drugs-of-Abuse Tests

Urine based screening tests for drugs of abuse are available from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method for screening urine for drugs of abuse. The QuickTox™ line of drug screen tests is based on the principle of the highly specific immunochemical reactions between antigens and antibodies, which are used for the analysis of specific substances in urine. The QuickTox™ Drug Test is based on a competitive immunoassay procedure in which 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 an 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. In the test procedure, the QuickTox™ Test is dipped into a urine sample. This allows the urine to come into contact with the sample pads of the QuickTox™ test strips. 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 drug(s) is(are) present in the urine, it competes with the drug conjugate, which is immobilized on the membrane, for the limited binding sites of the colored antibody colloidal gold conjugate. When a sufficient amount of drug is present, the drug will saturate the antibodies, and the colored colloidal gold conjugate cannot bind to the drug conjugate on the membrane. **Therefore, the absence of a color band at the test region indicates a positive 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 line at the test region on the membrane. **Therefore, the presence of a color band at the test region indicates a negative result for that particular test.**

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



Test Principle—Adulteration Tests

Cr: The 'Cr' pad detects creatinine. The creatinine in the urine sample reacts with a creatinine indicator in an alkaline medium to form a purple color complex. The color intensity of the tested pad is directly proportional to the concentration of creatinine in the sample.

Ni: The 'Ni' pad detects nitrite. This test is based on the reaction of aromatic amine to yield a diazonium salt, which then couples with an indicator to form a color complex ranging from pink to dark red depending on the concentration of nitrite in the sample.

pH: The 'pH' pad is based on a double indicator principle that gives a broad range of colors ranging from orange for low pH (<4), to yellow and green (pH4 to 9), to brown for high pH (pH >11).

Ox: The 'Ox' pad forms a color complex from blue to brownish black when an oxidizing agent is present.

Reagents and Materials Provided

Each QuickTox™ Drug Test Kit contains:

1. Package Insert containing directions for use.
2. 25 QuickTox™ test devices. Each with test strips for cocaine, morphine, methamphetamine, THC and phencyclidine. Each test strip consists of a sample pad, a colloidal gold conjugate pad, a membrane and an absorbent pad.

Membrane Test Region: Morphine monoclonal antibody, protein conjugates for benzoylcegonine, methamphetamine, THC and phencyclidine are coated onto the test regions of the membrane. The control region of each test strip contains goat anti-rabbit antibody.

Conjugate Pad: The colored conjugate pad contains morphine-protein gold complex, monoclonal antibodies for benzoylcegonine, methamphetamine, THC and phencyclidine.

Each QuickTox™ test device also contains two test strips with adulteration pads for creatinine (Cr)/Nitrite (Ni) and pH (pH)/Oxidizing Agent (Ox).

Cr: 2.05% creatinine reactive indicator, 97.95% buffer and non-reactive ingredients.

Ni: 0.81% nitrite reactive indicators and 99.19% buffer and non-reactive ingredients.

pH: 0.10% reactive indicator and 99.9% non-reactive ingredients.

Ox: 0.22% indicator and 99.78% non-reactive ingredients.

3. The QuickTox™ Drug/Adulteration test device is packaged with a desiccant and sealed in a foil pouch.

Materials Required But Not Provided

1. Timing device (i.e. timer, clock, watch, etc.)
2. Collection Cup
3. Positive and negative drug controls as well as normal and abnormal adulteration controls are available separately from Branan Medical Corporation.

Warnings and Precautions

- Drug tests are for professionals *in vitro* diagnostic use only.
- The adulteration tests are for professional forensic/toxicology use only, and not intended for use in the diagnosis of diseases or illness.
- 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 potentially infectious. Proper handling and disposal methods should be established.

Product Storage

The QuickTox™ Drug/Adulteration Test should be stored at room temperature (15°–30°C) with normal humidity until the expiration date stated on the label. The product is humidity-sensitive and should be used immediately after opening.

Specimen Collection and Handling

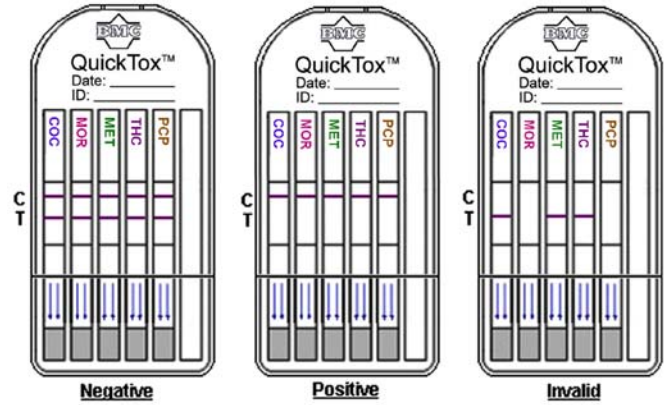
QuickTox™ Drug Tests are formulated for use with urine specimens. Use only freshly voided, untreated urine. Do not centrifuge or add preservatives to urine. Urine samples should be collected so that testing may be performed as soon as possible after collection, preferably during the same day. Specimens 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 DAU testing. Frozen samples are not recommended for adulteration testing.

Test Procedure

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

1. Collect urine in a collection cup.
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™ test device straight into the sample. **(Do not introduce the urine sample beyond the maximum sample line as indicated by the arrows).**
4. Dip for a minimum of 30 seconds.
5. Start the timer immediately after dipping the device into the sample.
6. Remove the QuickTox™ test device from the sample and re-attach the bottom cover.
7. **Adulteration Tests:** Read the results within 1–2 minutes. Do not read test results after 2 minutes. Refer to the color chart provided for color matching and interpretation of results.
8. **Drugs-of-Abuse Tests:** Read results after 5 minutes. Do not read results after 8 minutes. If the test is left standing for longer than 8 minutes, the intensity of the colored lines may change.

Interpretation of Results – Drugs-of-Abuse Tests



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

Negative: The appearance of a colored line at the test region (T) and the appearance of a colored line at the control region (C) indicate that the result is negative for that particular test. The color of the test line may be slightly darker or lighter than the control line.

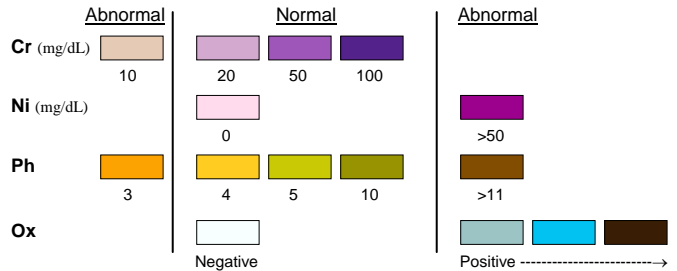
Positive: Only one colored line appears at the control region (C). No line observed at the test region indicates a positive result for that particular test.

Invalid: No line appears in the control (C) region. The test is inconclusive even if there is a line in the test region. If the test device does not produce a line at the control region, check testing procedures, samples, and/or control materials, and repeat the testing with a new device.

Important: Read each test independently. Do not compare color intensity of one test to another. Samples with faint test lines on the test regions should be considered negative. However, because of the uncertainty, tests with faint lines as well as tests with positive results should also be confirmed with a more specific method (such as GC/MS) before a positive determination is made.

Interpretation of Results: Adulteration Tests

Qualitative results are obtained by visually comparing the color of each test pad with the corresponding color blocks below. No equipment is required.



Quality Control

Drugs-of-Abuse: Good laboratory practice recommends the use of control materials to ensure proper kit performance. SAMHSA recommends that positive quality control specimens be at or near the cut-off concentration for the test. Quality control standards are available from commercial sources and are recommended to be used daily. The same assay procedure should be followed with control standards as with a urine specimen. If control values do not fall within established limits, assay results are invalid.

The QuickTox™ Drug Test provides built-in control bands with different antigen/antibody reaction at the control regions (C). The control line at each test strip should always appear regardless of the presence of drugs or metabolites. If the control lines do not appear, the test device should be discarded. The presence of these colored bands at the control regions also serve as 1) verification that adequate sample volumes are used, and 2) that proper flow is obtained.

Adulteration Tests: Control products are available for the adulteration tests. Contact Branan Medical Corporation for assistance.

Limitations of Procedure

- The assay is designed for use with human urine only.
- Positive drug test results indicate possible presence of drug/metabolites but do not indicate or measure intoxication.
- There is a possibility that technical or procedural errors as well other substances in certain foods and medication may interfere with the drug tests and cause false results. See Specificity section for the lists of substances that will produce positive results.

- 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 specimen may have been mislabeled, a new specimen should be collected and the test repeated.
- 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 device has not been tested at point of care locations.

Performance Characteristics – Accuracy

Drugs-of-Abuse Tests: Each test of the QuickTox™ Drug Test was evaluated in comparison to Branan Medical Corporation's Monitect™ single drug dipstick test. In this study, 40 presumed negative urine samples were tested with the QuickTox™ Drug Tests and the Monitect™ single drug dipstick tests. Of the 40 presumed negative urine samples tested, all were found negative by both methods (100% agreement).

Additionally, each test strips of the QuickTox™ Test was evaluated separately. For each drug test, a minimum of 40 clinical urine samples with known GC/MS values were used. The clinical samples were blind-labeled and tested. The results of the Comparison Studies are summarized below:

Benzoyllecgonine GC/MS samples

Cocaine Test Strip	GC/MS Neg. (below C/O)	GC/MS Near Pos. (between +25% to C/O)	GC/MS Pos. (> +25%)	% Agreement w/ GC/MS
Positive	0	26	13	97.5%
Negative	21	1	0	100%

Morphine GC/MS samples

Morphine Test Strip	GC/MS Neg. (below C/O)	GC/MS Near Pos. (between +25% to C/O)	GC/MS Pos. (> +25%)	% Agreement w/ GC/MS
Positive	0	12	54	100%
Negative	9	0	0	100%

D-Methamphetamine GC/MS samples

MET Test Strip	GC/MS Neg. (below C/O)	GC/MS Near Pos. (between +25% to C/O)	GC/MS Pos. (> +25%)	% Agreement w/ GC/MS
Positive	0	4	33	93%
Negative	10	2	1	100%

Δ-9-THC-COOH GC/MS samples

THC Test Strip	GC/MS Neg. (below C/O)	GC/MS Near Pos. (between +25% to C/O)	GC/MS Pos. (> +25%)	% Agreement w/ GC/MS
Positive	0	3	22	92.6%
Negative	13	2	0	100%

Phencyclidine GC/MS samples

PCP Test Strip	GC/MS Neg. (below C/O)	GC/MS Near Pos. (between +25% to C/O)	GC/MS Pos. (> +25%)	% Agreement w/ GC/MS
Positive	0	4	22	92.8%
Negative	12	2	0	100%

Adulteration tests: The accuracy of the adulterant tests was verified by an independent laboratory analyzing ten each of the normal and the various adulterated urine specimens. Low creatinine samples were obtained by diluting normal urine with water at a 1:4 ratio. HCl or NaOH was added to urine to obtain acidic or basic specimens. Ultra Bleach, pyridinium chlorochromate (PCC) and sodium nitrite were added to produce the respective adulterated samples. Results were as follows:

Adulterant Test	Normal Samples			Adulterated Samples		
	# of Samples	Conc./ Level	Results	# of Samples	Conc./ Level	Results
Creatinine	10	50 mg/dl	All normal	10	<10 mg/dl	All abnormal
pH	10	pH = 7	All normal	10	pH = 2.5	All abnormal
				10	pH = 12	All abnormal
Nitrite	10	<5 mg/dl	All normal	10	>50 mg/dl	All abnormal
Oxidizing Agent	10	None	All normal	10	1% v/v Bleach	All abnormal
				10	1% v/v PCC	All abnormal

Performance Characteristics — Precision

Drugs-of-Abuse Tests: For each drug test, drug-free normal urine was spiked with the corresponding drug standards to various concentrations (-50%, -25%, cut-off, +25% and +50%). For each concentration, a total 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 Test are summarized below:

Drug Test	Total # of Test / Conc.	Concentration														
		-50%			-25%			Cut-Off			+25%			+50%		
		-	+	+/-	-	+	+/-	-	+	+/-	-	+	+/-	-	+	+/-
COC	25	25	0	0	19	0	6	2	2	20	0	20	5	0	24	1
MOR	25	25	0	0	21	0	4	0	3	22	0	22	3	0	25	0
MET	25	25	0	0	23	0	2	0	2	23	0	19	6	0	23	2
THC	25	25	0	0	20	0	5	0	6	19	0	23	2	0	25	0
PCP	25	25	0	0	23	0	2	2	1	22	0	19	6	0	23	2

Specificity – Drugs-of-Abuse Tests

The specificity study for each of the drug test of the QuickTox™ Test 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, which was observed to produce a positive result.

COC	ng/ml
Benzoyllecgonine	300
Cocaine	300
Ecgonine	>100,000
Ecgonine Methyl Ester	>100,000
MOR	ng/ml
Codeine	2000
Ethyl morphine	2000
Hydromorphone	2500
MET	ng/ml
d-Methamphetamine	1,000
(+/-)-3,4-methylenedioxymethamphetamine	2,000
L-Methamphetamine	5,000
Procaine	10,000
d-Amphetamine	50,000
Chloroquine	50,000
(+/-)-Ephedrine	50,000
β-Phenylethylamine	50,000
Ranitidine	50,000
THC	ng/ml
11-nor-Δ-8-tetrahydrocannabinol-9-carboxylic acid	50
11-hydroxy-Δ ⁹ -tetrahydrocannabinol	2,500
Δ-9-tetrahydrocannabinol	10,500
Δ-8-tetrahydrocannabinol	7,000
Cannabinol	10,000
Cannabidiol	100,000
PCP	ng/ml
Thienylcyclohexypiperidine	2,000

The effects of pH and specific gravity of the specimen on the performance of the drugs-of-abuse tests were conducted on the predicate kit (Monitect™ single drug dipstick test). Results obtained are acceptable and demonstrate that performance at test cutoff levels are not affected when the pH range is 4.5 to 8.5 and the specific gravity range is 1.005 to 1.030.

Expected Results—Adulteration Pads

Cr: Daily creatinine excretion, related to the muscle mass of the human body is usually constant.⁶ DOT guidelines state that creatinine levels of less than 20 mg/dL are indicative of dilution.⁷

Ni: Although nitrite is not a normal component of urine, nitrite levels of up to 3.6 mg/dl may be found in some urine specimens due to urinary tract infections, bacterial contamination or improper storage. Nitrite level above 50mg/dl is above the clinical level and is considered abnormal.

pH: Urine pH may range from 4 to 10. Values below pH 4.0 or above pH 10 are abnormal and indicative of adulteration.

Ox: The presence of oxidizing agents in the urine is abnormal and indicative of adulteration.

Interferences – Drugs-of-Abuse Tests

Various drugs, drug metabolites, and other constituents commonly found in urine were evaluated for interferences and cross-reactivity. Concentrations up to 100 µg/ml did not interfere or cross-react with the drug tests of the QuickTox™ device.

Acetaminophen (4-Acetamidophenol; APAP; N-Acetyl-p-aminophenol)

Acetone
Albumin
Allobarbitol
Alprazolam
Alphenal
Aprobarbital
Amitriptyline
Amobarbital
Ampicillin
Aspartamine
Aspirin (Acetylsalicylic Acid)
Atropine
Barbital
Benzocaine (Ethyl p-Aminobenzoate)
Bilirubin
Bromazepam
Butabarbital
Butalbital
Butethal
Caffeine
Chlordiazepoxide
(+/-)-Chlorpheniramine
Clobazam
Clonazepam
Clorazepam
Creatine
Delorazepam
Dextromethorphan
Diazepam
4-methylaminoantipyrine
Dopamine (3-Hydroxytyramine)
(+)-Epinephrine
Erythromycin
Estazolam
Ethanol

Flurazepam
Flunitrazepam
Furosemide
Guaiacol Glyceryl Ether
Glucose
Hemoglobin
(+/-)-Isoproterenol
Lormetazepam
Lorazepam
Lidocaine
Medazepam
(-) Nicotine
N-Methyl-Ephedrine
(+)-Naproxen ([S]-6-Methoxy- α -Methyl-2-Naphthaleneacetic Acid)
Nordiazepam
Nitozepam
Oxalic Acid
Oxazepam
Penicillin-G (Benzylpenicillin)
Pentobarbital
Pheniramine
Phenobarbital
Phenothiazine (Thiodiphenylamine)
L-Phenylephrine
Prazepam
Riboflavin
Secobarbital
Sodium Chloride
Sulindac
Temazepam
Thienylcyclohexypiperidine
Thioridazine
Thimethobenzamide
Trizolan
Tyramine
Vitamin C (L-Ascorbic Acid)

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Manufactured by:
Branan Medical Corporation
10015 Muirlands Road, Suites E&F
Irvine, CA 92618

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