**Branan Medical Corporation**

# Oratect® III Oral Fluid Drug Screen Device
## ME/TH/CO/AM/OP/PC or BZ
**Catalog No. HM11 and HM12**

**Intended Use**
The Oratect® III Oral Fluid Drug Screen Device is a one-step lateral flow immunoassay device for the qualitative detection of methamphetamine, MDMA, THC, cocaine, amphetamine, opiates, phencyclidine or benzodiazepines in human oral fluid. The Oratect® III Test detects these drugs at the following cut-off concentrations:

| | | |
|---|---|---|
| ME | d-Methamphetamine/MDMA | 25 ng/ml |
| TH | Delta-9-Tetrahydrocannabinol | 40 ng/ml |
| CO | Cocaine | 20 ng/ml |
| AM | d-Amphetamine | 25 ng/ml |
| OP | Morphine | 10 ng/ml |
| PC | Phencyclidine | 4 ng/ml |
| BZ | Diazepam | 5 ng/ml |

The test is intended to be administered by a trained professional. It should not be used without supervision. This product is intended for forensic use only and is not for use in diagnostic procedures.

**The Oratect® III Oral Fluid Drug Screen Device provides only preliminary drug test results. For a quantitative result or for a confirmation of a presumptive positive result obtained by the Oratect® III Oral Fluid Drug Screen Device, a more specific alternative method such as GC/MS or LC/MS must be used.**

**Summary and Explanation**
Illegal drug consumption contributes to many accidents, injuries and medical conditions. Screening individuals for drugs of abuse is an important method in identifying those who may cause harm to themselves and to others.

Oratect® III Oral Fluid Drug Screen Device is developed to detect active drugs-of-abuse present in saliva. Studies on methamphetamine, MDMA, cocaine, opiate, amphetamine, phencyclidine, benzodiazepine and cannabinoid show that all of these drugs are detectable in oral fluid. Oratect® III Oral Fluid Drug Screen Device is designed to integrate oral fluid collection and lateral flow immunoassay screen testing for drugs-of-abuse in one single device.

**Test Principle**
The Oratect® III Oral Fluid Drug Screen Device is based on a competitive immunoassay procedure in which drug derivatives immobilized on the membrane compete with the drug(s) which may be present in oral fluid for limited antibody binding sites on the colored colloidal gold antibody conjugate. During testing, oral fluid is collected at the collection pad and migrates across the membrane. If no drug is present in the oral fluid, the colored colloidal gold antibody conjugate will bind to the drug derivatives on the membrane to form visible bands at specific test regions. Therefore, the **presence of a purple-red band** at a specific test region indicates a **negative result**. If any drug(s) is (are) present in the oral fluid, it competes with the immobilized drug conjugate for limited antibody binding sites of the colored 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 derivative on the membrane. **Therefore, the absence of a purple-red band at the test region indicates a presumptive positive result for that particular test.**

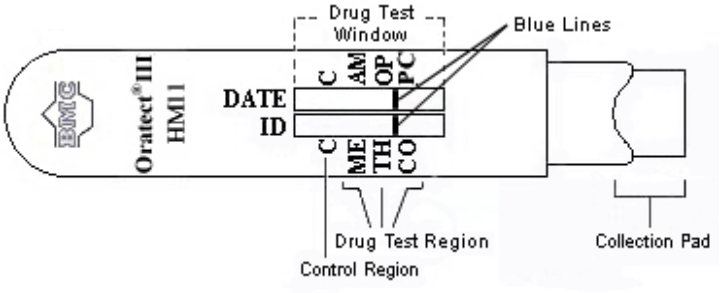


**Fig. a Detail regions of** Oratect® III Oral Fluid Drug Screen Device

The presence of a blue line in each window indicates that the device is unused. The flow of the blue lines indicates that a sufficient amount of oral fluid has been collected. A control band at the control region (C) indicates the test has performed properly. This control band should always appear regardless of the presence of drug or metabolite.

**Reagents**
The Oratect® III Oral Fluid Drug Screen Device contains two membrane strips and a collection pad. Each strip consists of a membrane, a colloidal gold conjugate pad, a sample pad and an absorbent pad.

*Membrane:* ME/TH/CO test strip: Methamphetamine, THC and Cocaine-protein conjugates are coated onto specific region on the membrane known as the "Test Region".

AM/OP/PC or AM/OP/BZ test strip: Amphetamine, Morphine, Phencyclidine or Amphetamine, Morphine, Benzodiazepine protein conjugates are coated onto the test region of the membrane.

*Colloidal Gold Conjugate Pad:* The colloidal gold conjugate pad for the ME/TH/CO test strip contains anti-methamphetamine, anti-THC and anti-cocaine antibody colloidal gold conjugates coated onto a fibrous pad. The colloidal gold conjugate pad for the AM/OP/PC or AM/OP/BZ test strip contains anti-amphetamine, anti-morphine, anti-phencyclidine or anti-amphetamine, anti-morphine, anti-benzodiazepine antibody colloidal gold conjugates.

*Collection Pad:* The collection pad consists of an absorbent material.

**Materials Provided**
Each Oratect® III Oral Fluid Drug Screen Device kit contains:
1. 1 Package Insert.
2. 1 Reference Guide.
3. 25 test devices. Each device consists of a plastic holder and a detachable cap. The devices are packaged individually in a foil pouch with a desiccant.
4. 1 plastic vial containing buffer for confirmation test.

**Materials Required but Not Provided**
- Timing device

**Warnings and Precautions**
- The Oratect® III Oral Fluid Drug Screen Device is intended for forensic use only and is not for use in diagnostic procedures.
- 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 kit.
- Handle all oral specimens as potentially infectious. Proper handling and disposal methods should be established.

**Product Storage**
The Oratect® III Oral Fluid Drug Screen Device pouch should be stored at room temperature (15°-30°C). Do not open pouch until ready to perform the assay.

**Specimen Collection and Handling**
IMPORTANT: At least 10 minutes prior to administering the test, instruct the donor not to eat, drink, smoke or chew tobacco products.

**Test Procedure**
1. Remove the test device from the sealed pouch.
2. Carefully remove the blue cap by holding the sides and pull gently. This will expose the collection pad.
3. Ensure that the blue line is present in each test window.
4. The oral fluid collection process must be observed. Instruct the donor to hold the top portion of the device (above the test windows).
5. When placing device into the mouth, **keep head level**.
   a. Open mouth and rub the collection pad inside mouth against one cheek gently in a circular motion several (approximately 15-20) times. **(Fig. b)**
   b. Still keeping head level, gently rub the collection pad against the opposite cheek in a circular motion (approximately 15-20) several times. **(Fig. b)**

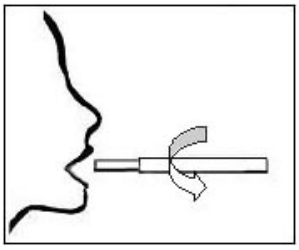

**Fig. b Gently rub the collection pad against each cheek several (approximately 15-20) times.**

**c.** Rub the collection pad on top of the tongue several times and then underneath the tongue several (approximately 15-20) times. **(Fig c. and Fig d.). Do not chew, suck, bite or bend the collection pad.**

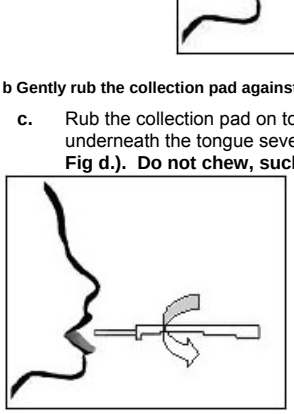

**Fig. c Gently rub the collection pad on top of the tongue several (approximately 15-20) times.**

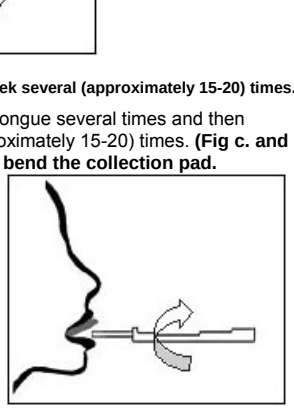

**Fig. d Gently rub the collection pad underneath the tongue several (approximately 15-20) times.**

6. Place the collection pad underneath the tongue for approximately 30 seconds to collect saliva. Instruct the donor to hold the device in place with their hand.
7. The flow of the blue lines indicates the collection of a sufficient amount of saliva. If blue lines are present after placing the collection pad underneath the tongue for 30 seconds, repeat the instructions in steps 5 and 6 until the blue lines flow.
8. Remove the device from mouth as soon as the blue lines start moving at both test windows.

   Note: The flow of the blue lines should appear in the test windows within 5 minutes. If no flow is observed after 5 minutes in the mouth, discard the device, review procedures 4-7 above with the donor and repeat the test using a new device.
9. Re-cap the device, lay it on a flat surface and **read results in 5 minutes after removing device from mouth. Do not read results after 30 minutes.**

**Interpreting Test Results**

**Negative Results**

For each of the test windows, purple-red colored bands should be observed; one band at the control region (C) and one band at the specific drug abbreviation (e.g. AM, OP, CO) in the test region. See example Fig e.

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 the **Fig. e** below, the oral fluid sample is negative for Amphetamine, Opiate and Cocaine **because bands are visible in the AM, OP, and CO test regions**.

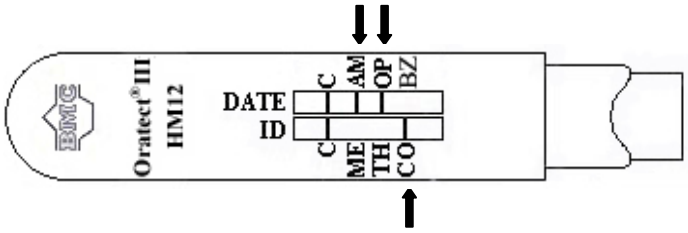


**Fig e. Example of Negative Test Results**

**Presumptive Positive Results**

When the control band is visible in the control region (C) and **no** band appears at the specific test region, the result is a **presumptive positive** for that particular drug. In **Fig. f** below, the oral fluid sample is presumptive positive for Phencyclidine, Methamphetamine (or MDMA) and THC **because no bands are visible in the test regions of PC, ME, and TH.**

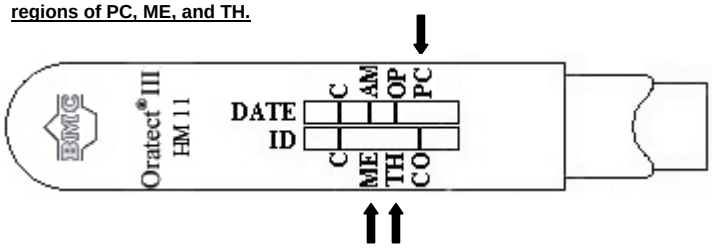


**Fig. f Example of Presumptive Positive Test Results**

**Invalid Results**

When **no** band appears in the control (C) region, **the test is invalid** regardless of the results in the test region. If the test is invalid, check testing procedures. **Repeat the test using a new device.** In **Fig. g** below, the test is invalid because there are **no bands in the control regions.**

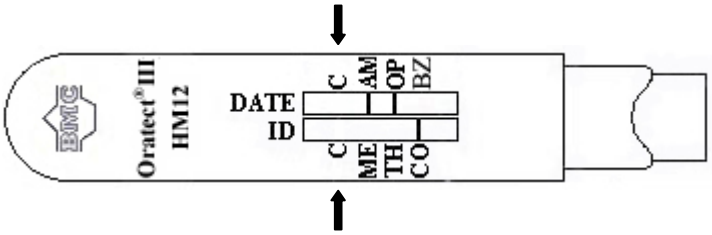


**Fig. g Example of Invalid Test Results**

**Important: Read each test independently. Do not compare color intensity of one test band to another. When a faint purple-red band for a specific test is obtained in the test region along with the presence of the control line (C), the sample should be considered negative. The Oratect® III Oral Fluid Drug Screen Device only provides qualitative results for the presence of drug(s) at specified cut-off concentration(s). For confirmation of a presumptive positive result, a more specific quantitative method (GC/MS or LC/MS) must be used.**

**Specimen Collection & Handling for Confirmation Testing**

- For device with any presumptive positive results, the collection pad should be removed and sent for confirmation test.
- Detach the collection pad with the blue cap by pulling. Be sure not to damage or distort the collection pad.
- Place the collection pad into the enclosed confirmation vial.
- Recap the vial and send it to a lab for confirmatory testing (Specimen should be stored at 15-30°C and tested within 2 weeks of collection).
- Follow standard chain of custody procedures.

**Quality Control**

The Oratect® III Oral Fluid Drug Screen Device provides two built-in control bands at the control regions (C) to indicate that the test has performed properly. These control bands should always appear regardless of the presence of drugs. The flow of the blue lines indicates that a sufficient amount of oral fluid has been collected. The presence of the purple-red bands in the control regions verifies that proper flow was obtained. If the control bands do not appear, the test device should be discarded.

**Limitations of Procedure**

- The assay is designed for human oral fluid use only.
- Positive results only indicate the presumptive presence of drugs and do not indicate or measure intoxication.
- Technical or procedural errors as well as substances in certain foods and certain medications may interfere with the test and cause false results.

**Performance Characteristics**

**Precision**

For each specific drug test, artificial oral fluid solution was spiked with a drug standard at various concentrations (0%, 50%, 200% and 300%). For each concentration, a total of 20 tests were performed to validate the test performance. The results for each drug of the Oratect® III Oral Fluid Drug Screen Device Tests are summarized below:

| Drug Test | Total # of Test/ Concentration | Concentration | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 0% | | 50% | | 200% | | 300% | |
| | | - | + | - | + | - | + | - | + |
| ME | 20 | 20 | 0 | 20 | 0 | 0 | 20 | 0 | 20 |
| MDMA | 20 | 20 | 0 | 20 | 0 | 0 | 20 | 0 | 20 |
| TH | 20 | 20 | 0 | 20 | 0 | 1 | 19 | 0 | 20 |
| CO | 20 | 20 | 0 | 20 | 0 | 0 | 20 | 0 | 20 |
| AM | 20 | 20 | 0 | 20 | 0 | 0 | 20 | 0 | 20 |
| OP | 20 | 20 | 0 | 20 | 0 | 0 | 20 | 0 | 20 |
| PC | 20 | 20 | 0 | 20 | 0 | 0 | 20 | 0 | 20 |
| BZ | 20 | 20 | 0 | 20 | 0 | 0 | 20 | 0 | 20 |

**Specificity**

The specificity study for each drug test was evaluated by adding structurally related compounds to artificial oral fluid solution. The results are expressed as the amount of the compound, in ng/ml, that produced a positive result.

| Drug Test | Approximate Concentration(ng/ml) | Approximate % Cross Reactivity |
|---|---|---|
| **ME/MDMA** | | |
| Desipramine | 10000 | 0.25% |
| d,l-Ephedrine | 1000 | 2.5% |
| 1R, 2S l-Ephedrine | 1000 | 2.5% |
| p-Hydroxymethamphetamine | 1000 | 2.5% |
| MDEA | 300 | 8.3% |
| MDMA | 25 | 100% |
| d,l-Methamphetamine | 30 | 83% |
| d-Methamphetamine | 25 | 100% |
| l-Methamphetamine | 500 | 5% |
| Methoxyphenamine | 2500 | 1% |
| Phenylephrine | 5000 | 0.5% |
| d-Pseudoephedrine HCl | 5000 | 0.5% |
| Trimethobenzamide | 4000 | 0.6% |
| **TH** | | |
| Cannabinol | 80 | 50% |
| Δ-8-tetrahydrocannabinol | 100 | 40% |
| Δ-9-tetrahydrocannabinol | 40 | 100% |
| 11-nor-Δ-8-THC-9-COOH | 10 | 400% |
| 11-nor-Δ-9-THC-9-COOH | 10 | 400% |
| 11-hydroxy-Δ9-THC | 400 | 10% |
| **CO** | | |
| Benzoylecgonine | 18 | 110% |
| Cocaine | 20 | 100% |
| Ecgonine | 5000 | 0.4% |

| Drug Test | Approximate Concentration (ng/ml) | Approximate % Cross Reactivity |
|---|---|---|
| **AM** | | |
| d-Amphetamine | 25 | 100% |
| d,l-Amphetamine | 40 | 62.5% |
| d,l-p-Chloramphetamine | 200 | 12.5% |
| MDA | 40 | 62.5% |
| MDEA | 100 | 25% |
| Phentermine | 100 | 25% |
| β-Phenylethylamine | 8000 | 0.3% |
| Tyramine | 8000 | 0.3% |
| **OP** | | |
| 6-Acetylcodeine | 20 | 50% |
| 6-Acetylmorphine | 12 | 83% |
| Codeine | 10 | 100% |
| Dihydrocodeine | 10 | 100% |
| Ethyl morphine | 60 | 17% |
| Heroin | 15 | 67% |
| Hydrocodone | 60 | 17% |
| Hydromophone | 70 | 14% |
| Morphine | 10 | 100% |
| Morphine-3-beta-D-Glucuronide | 25 | 40% |
| Nalorphine | 100 | 10% |
| **PC** | | |
| Phencyclidine | 4 | 100% |
| **BZ** | | |
| Alprazolam | 4 | 125% |
| Bromazepam | 4 | 125% |
| Chlordiazepoxide | 50 | 10% |
| Clobazam | 10 | 50% |
| Clonazepam | 20 | 25% |
| Delorazepam | 5 | 100% |
| Diazepam | 5 | 100% |
| Estazolam | 3 | 167% |
| Flunitrazepam | 8 | 63% |
| Flurazepam | 10 | 50% |
| Lorazepam | 10 | 50% |
| Lormetazepam | 15 | 33% |
| Nitrazepam | 4 | 25% |
| Nordiazepam | 3 | 67% |
| Oxazepam | 5 | 100% |
| Prazepam | 10 | 50% |
| Temazepam | 5 | 100% |
| Triazolam | 10 | 50% |

**Interference**

The following compounds were spiked into artificial oral fluid solution and found not to cross-react with the Oratect® III Oral Fluid Drug Screen Device when tested at concentration of 10μg/ml (10,000ng/ml)

Acetaminophen
Acetoacetic acid lithium salt
Acetone
Acetylsalicylic acid
6-Acetylcodeine *(except OP assay)*
6-Acetylmorphine *(except OP assay)*
Albumin
Allobarbital
Alphenal
Alprazolam *(except BZ assay)*
Amitriptyline
Amobarbital
Amoxapine
Amoxicillin
d-Amphetamine *(except AM assay)*
d,l-Amphetamine *(except AM assay)*
l-Amphetamine *(except AM assay)*
Ampicillin
Apomorphine
Aprobarbital
l-Ascorbic Acid
Aspartame
Atropine
Barbital
Benzillic acid
Benzocaine
Benzoylecgonine hydrate *(except CO assay)*
Benzoic acid
Bilirubin
Bromazepam *(except BZ assay)*
d-Brompheniramine
Buprenorphine
Butalbital
Butethal
Caffeine
Cannabinol *(except TH assay)*
Cannabidiol
Chloral Hydrate
Chlordiazepoxide *(except BZ assay)*
Chloroquine
d-Chlorpheniramine
Chlorpromazine
Chloroamphetamine (DL-p-) Hydrochloride *(except AM assay)*
Cholesterol
Clobazam *(except BZ assay)*
Clomipramine
Clonazepam *(except BZ assay)*
Cocaine *(except CO assay)*
Codeine *(except OP assay)*
Cortisone
l-Cotinine
Creatine
Creatinine
Cyclobenzaprine
Delorazepam *(except BZ assay)*
Deoxycortisone acetate
Desipramine *(except ME/MDMA assay)*
Dextromethorphan
Diazepam *(except BZ assay)*
Dihydrocodeine *(except OP assay)*
4-Dimethylaminoantipyrine
Diphenhydramine
Dopamine
Doxepin hydrochloride
Doxylamine
Ecgonine *(except CO assay)*
Ecgonine Methyl Ester
l-Ephedrine
d,l-Ephedrine *(except ME/MDMA assay)*
1R, 2S l- Ephedrine *(except ME/MDMA assay)*
1S, 2R d-Ephedrine
l-Epinephrine
Erythromycin
Estazolam *(except BZ assay)*
β-Estradiol
Estrone-3-sulfate potassium salt
Ethanol
Ethylidene-1,5-Dimethyl-1-3,3-Diphenylpyrrolindine Perchlorate salt
Ethyl Morphine *(except OP assay)*
Flunitrazepam *(except BZ assay)*
Flurazepam *(except BZ assay)*
Furosemide
Gentisic acid
Glucose
Glutethimide
Guaiacol Glyceryl Ether
Hemoglobin
Heroin *(except OP assay)*
Hippuric acid
Hydrochlorothizide
Hydrocodone *(except OP assay)*
Hydrocortisone
Hydromorphone *(except OP assay)*
11- Hydroxy-D-9-Tetrahydrocannabinol *(except TH assay)*
p-Hydroxymethamphetamine (Pholderin) *(except ME/MDMA assay)*
3-Hydroxytyramine
Ibuprofen
Imipramine
d,l-Isoproterenol
l-Isoproterenol HCl
Lidocaine
Lorazepam *(except BZ assay)*
Lormetazepam *(except BZ assay)*
MDMA *(except ME/MDMA assay)*
MDA *(except AM assay)*
MDEA *(except AM, ME/MDMA assays)*
Meperidine
d,l-Methadone
d-Methamphetamine *(except ME/MDMA assay)*
d,l-Methamphetamine *(except ME/MDMA assay)*
l-Methamphetamine *(except ME/MDMA assay)*
Methaqualone
Methoxyphenamine *(except ME/MDMA assay)*
2-Methylamine-Propiophenone HCl
Methylphenidate
Morphine (*except OP assay)*
Morphine-3-beta -D-Glucuronide *(except OP assay)*
Nalidixic acid
Nalorphine *(except OP assay)*
Naloxone
Naltrexone hydrochloride
d-Naproxen
Niacinamide
Nitrazepam *(except BZ assay)*
11-Nor-Delta 8-THC-9-COOH *(except TH assay)*
11-Nor-Delta 9-THC-9-COOH *(except TH assay)*
Nordiazepam *(except BZ assay)*
Nordoxepin hydrochloride
d,l-Norephedrine hydrochloride
Norethindrone
d-Norpropoxyphene
Nortriptyline hydrochloride
Oxalic Acid
Oxazepam *(except BZ assay)*
Oxolinic acid
Oxycodone
Papaverine
Penicillin-G (Benzylpenicillin)
Pentazocine
Pentobarbital
Perphenazine
Phencyclidine *(except PC assay)*
Pheniramine
Phenobarbital
Phenothiazine
Phentermine *(except AM assay)*
Phenylephrine *(except ME/MDMA assay)*
ß-Phenylethylamine *(except AM assay)*
d,l-Phenylpropanolamine hydrochloride
Prazepam *(except BZ assay)*
Prednisolone
Procaine
Promazine
Promethazine
d-Propoxyphene
Protriptyline
d-Pseudoephedrine HCl *(except ME/MDMA assay)*
Quinidine
Ranitidine
Riboflavin
Salicylic acid
Secobarbital
Serotonin
Sodium Chloride
Sulfamethazine
Sulindac
Temazepam *(except BZ assay)*
Tetracycline
Delta-8-Tetrahydrocannabinol *(except TH assay)*
Delta-9-Tetrahydrocannabinol *(except TH assay)*
Thiamine
Thioridazine
Triazolam *(except BZ assay)*
Trifluoperazine
Trimethobenzamide *(except ME/MDMA assay)*
Trimipramine Maleate
Tryptamine
d,l-Tryptophan
Tyramine *(except AM assay)*
d,l-Tyrosine
Uric Acid
Verapamil
Zomepirac

**Bibliography of Suggested Reading**


1. Wong, R. The Current Status of Drug Testing in the US Workforce, American Clinical Laboratory, vol. 21(1), page 21-23, 2002.
2. Caplan, Y. and Goldberger, B., Alternative Specimens for Workplace Drug Testing, J. Analytical Toxicology, vol. 25, p. 396-399, 2001.
3. Schramm, W., Smith, R. and Craig, P., Drugs of Abuse in Saliva: A Review, J. Analytical Toxicology, vol. 16, p. 1-9, 1992.
4. Mandatory Guidelines for Federal Workplace Drug Testing Programs, April 13, 2004 (69 FR 19644).
5. Wong, R. On-site Oral Fluid Drug Testing by Oratect, in Drugs of Abuse: Body Fluid Testing, Wong, R and Tse, H ed., Humana Press, p146-158, 2005.



Manufactured By:
Branan Medical Corporation
Irvine, CA 92618
USA
1-866-468-3287 (1-866-INTECT7) Domestic U.S. & Canada
1-949-598-7166 International
Part No.: PI-HM, Rev: B, 10/06