

# ALCOOLTEST \*\*\* NARCOTEST

ALCOOLTEST MARKETING ITALIA di P. CAIMMI

CCIAA PG - REA n°234356 - P.IVA 02688070545 - CMMPT53P26G478C

tejas

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HDTc



Oratect®

Branan Medical Corporation

iScreen™

## Oratect® III Oral Fluid Drug Screen Device

CE



- Simultaneously tests oral fluid for 6 drugs
- Easy, rapid, non-invasive, on-site test
- Eliminates sample adulteration and contamination
- Rules out shy bladder and cross gender collection issues
- A true one-step procedure: specimen collection and testing in one simple step
- Results appear in minutes and stable for 30 minutes
- User-friendly blue line indicates sufficient flow of saliva
- A preliminary screen test, must be confirmed by a specific method

| CAT # | Description                                | Tests/ box |
|-------|--|------------|
| HM11  | THC40/MET25(MDMA25)/COC20/AMP25/OPI10/PCP4 | 25         |
| HM12  | THC40/MET25(MDMA25)/COC20/AMP25/OPI10/BZO5 | 25         |

## OratectPlus™ Oral Fluid Drug and Alcohol Screen Device

CE

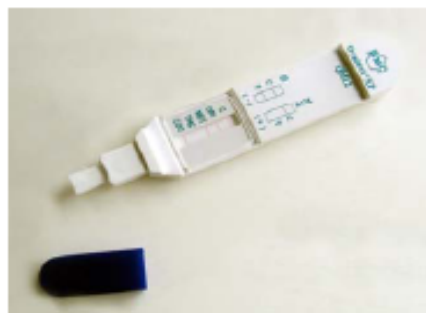


- One-step collection and testing in the same device
- Combines drugs of abuse and alcohol testing
- Blue line indicates sufficient flow of saliva
- Rapid collection and testing; results in 5 minutes
- Eliminates cross-gender collection issues and need for restroom facilities
- A preliminary screen test, must be confirmed by a specific method

| CAT # | Description  | Tests/ box |
|-------|--|------------|
| HMA11 | THC40/MET25(MDMA25)/COC20/AMP25/OPI10/PCP4 + ALCOHOL | 25         |
| HMA12 | THC40/MET25(MDMA25)/COC20/AMP25/OPI10/BZO5 + ALCOHOL | 25         |

## OratectXP™ Oral Fluid Drug Screen Device

CE



- One-step collection and testing
- Fast collection time in one to two minutes
- Reduced saliva sample size makes for easier specimen collection
- Eliminates transfer of specimen to a separate device
- Indicator for sufficient saliva collection
- Quick results (available within 5 minutes)
- User friendly & no need for restroom facilities
- Eliminates cross-gender collection issues
- Prevents sample adulteration or contamination
- A preliminary screen test, must be confirmed by a specific method

| CAT #  | Description                     | Tests/ box |
|--------|---------------------------------|------------|
| QM12** | OPI10/MET25(MDMA)25/THC40/COC10 | 25         |

\*Available March 2008



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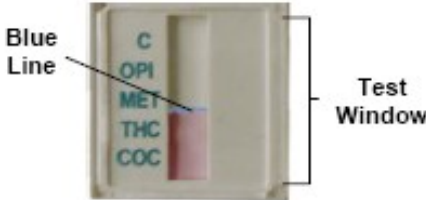

Oratect® Branan Medical Corporation iScreen<sup>TM</sup> OFD






## OratectXP<sup>TM</sup> Reference Guide

The OratectXP<sup>TM</sup> Oral Fluid Drug Screen Device is a simple one-step test for the detection of drugs of abuse in oral fluid.

OratectXP<sup>TM</sup> Procedures -- Refer to package insert for detailed instructions and technical information.

|   |   |  |
|---|---|--|
| <p>1. Remove the blue cap by holding the sides and pulling gently. This will expose the collection pad. Make sure there is a blue line present in the window area indicating an unused device.</p>   | <p>2. Open mouth and gently rub the collection pad inside mouth against cheek in a circular motion several (approximately 15-20) times. Make sure to keep head level.</p>    | <p>3. Gently rub the collection pad against the opposite cheek in circular motion several (approximately 15-20) times.</p>    |
| <p>4. Gently rub the collection pad on top of the tongue several (approximately 15-20) times. Do not chew, suck, bite or bend the collection pad.</p>  <p>5. Rub the collection pad underneath the tongue several (approximately 15-20) times.</p> | <p>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 hand. Sufficient amount of saliva collected is indicated by the flow of the blue line. Repeat steps 2-6 until the blue line flow.</p>  | <p>7. Remove from mouth as soon as the blue line flow at the test window. Re-cap the device.</p>  <p>8. Lay the device on a flat surface and read results in 5 minutes after removing the device from mouth. Do not read results after 30 minutes.</p> |

### Interpreting OratectXP<sup>TM</sup> Test Results

|   |   |  |
|---|---|--|
| <p><b>Invalid Result</b></p> <p>When no colored band appears in the CONTROL (C) region, the test is invalid even if there is a band in the test region. Repeat the test with a new device.</p> <p><b>Example Interpretation:</b></p>  <p>OPI: Invalid<br/>MET: Invalid<br/>THC: Invalid<br/>COC: Invalid</p> | <p><b>Negative Result</b></p> <p>Colored bands should be observed:</p> <ul style="list-style-type: none"> <li>• One in the CONTROL (C) region</li> <li>• One in the specific TEST region</li> </ul> <p>The color of the test band may be slightly darker or lighter than the control band. Any visible band that can be seen is a negative result.</p> <p><b>Example Interpretation:</b></p>  <p>OPI: Negative<br/>MET: Negative<br/>THC: Negative<br/>COC: Negative</p> | <p><b>Presumptive Positive Result</b></p> <p>A colored band at the CONTROL (C) region should be observed. When there is no colored band at the specific TEST region, the test is presumptive positive for that particular drug.</p> <p><b>Example Interpretation:</b></p>  <p>OPI: Negative<br/>MET: Presumptive Positive<br/>THC: Negative<br/>COC: Negative</p> |
|---|---|--|



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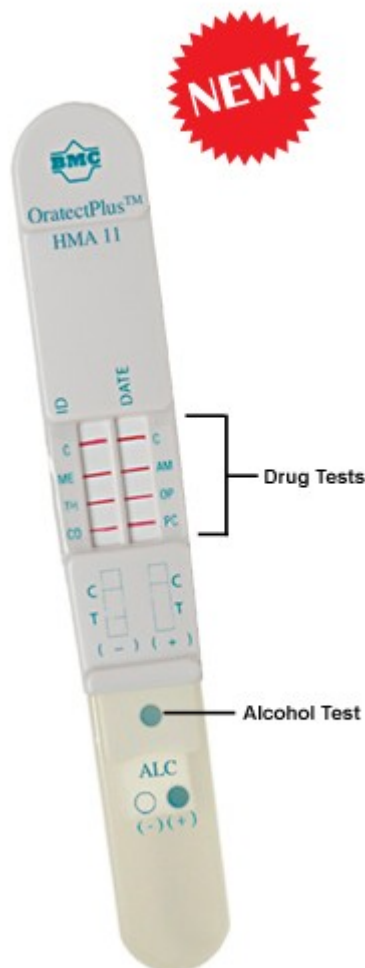
Branan Medical Corporation

iScreen<sup>TM</sup>  
OFD

## OratectPlus<sup>TM</sup>

Newly available is the OratectPlus<sup>TM</sup> Oral Fluid Drug & Alcohol Screen Device. Never before has there been a test that can detect drugs plus alcohol on the same device. The OratectPlus device simultaneously tests for 6 drugs which include marijuana, cocaine, opiates, amphetamine, methamphetamine and either PCP or Benzodiazepines plus Alcohol. The alcohol test correlates with 0.02% blood alcohol concentration.

### THE FACTS



- One-step collection & testing in the same device
- Combines drugs of abuse & alcohol testing
- No transfer of specimen to a separate test is required
- Flow of blue lines indicate sufficient collection of saliva
- Rapid collection and testing: results in 5 minutes
- User-friendly and eliminates need for restroom facilities
- Eliminates cross-gender collection issues
- Avoids gender observation
- Reduces sample adulteration or contamination
- Two test configuration of 6 drugs plus alcohol
- Includes transport vial for confirmation testing

### AVAILABLE DRUGS-OF-ABUSE TESTS

- **Alcohol**
- Amphetamines
- Benzodiazepines
- Cocaine
- Marijuana (THC)
- Methamphetamines includes MDMA (Ecstasy)
- Opiates
- Phencyclidine (PCP)

\*OratectPlus<sup>TM</sup> is for forensic use only

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## OratectPlus<sup>TM</sup> Oral Fluid Drug and Alcohol Screen Device ME/TH/CO/AM/OP/PC or BZ and Alcohol Catalog No. HMA11 & HMA12

### Intended Use

The OratectPlus<sup>TM</sup> Oral Fluid Drug and Alcohol Screen Device is designed for the qualitative detection of drugs of abuse and alcohol simultaneously in human saliva. It 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. In addition, it is an one step enzymatic color test for the qualitative detection of alcohol in human oral fluid. The OratectPlus<sup>TM</sup> Oral Fluid Drug and Alcohol Screen Device detects these drugs and alcohol at the following cut-off concentrations:

|    |                         |                |
|----|-------------------------|----------------|
| ME | d-Methamphetamine/MDMA  | 25 ng/ml       |
| TH | Δ9-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        |
| AL | Alcohol                 | ≥ 0.02 % B.A.C |

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 OratectPlus<sup>TM</sup> Oral Fluid Drug and Alcohol Screen Device provides only preliminary drug/alcohol test results. For quantitative results or for a confirmation of a presumptive positive result obtained by OratectPlus<sup>TM</sup> Oral Fluid Drug and Alcohol Screen Device, a more specific alternative method must be used.

### Summary and Explanation

Illegal drug and/or excessive alcohol consumption contribute to many accidents, injuries and medical conditions. Screening individuals for drugs of abuse and alcohol is an important method in identifying those who may cause harm to themselves and to others.

Studies on methamphetamine, MDMA, cocaine, opiate, amphetamine, phencyclidine, benzodiazepine, cannabinoid and alcohol show that all of them are detectable in oral fluid. OratectPlus<sup>TM</sup> Oral Fluid Drug and Alcohol Screen Device is designed to integrate oral fluid collection and simultaneous testing for drugs-of-abuse and alcohol in one single device.

### Test Principle

The OratectPlus<sup>TM</sup> Oral Fluid Drug and Alcohol Screen Device is based on:

(1) Drug tests: A competitive lateral flow immunoassay 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 colored band** at a specific test region indicates a **negative result**. If any drug is 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 color band at the test region indicates a presumptive positive result for that particular test.**

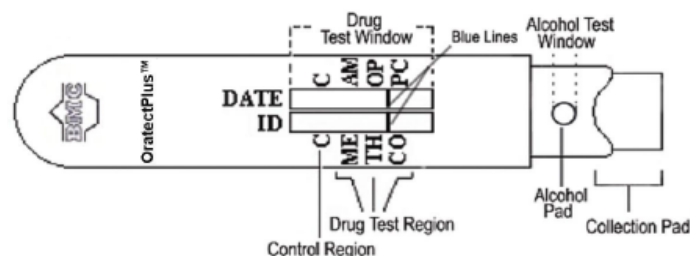
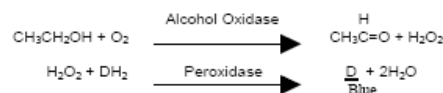


Fig. A Detailed regions of OratectPlus<sup>TM</sup> Oral Fluid Drug and Alcohol Screen Device

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.

(2) Alcohol Test: A pad coated with enzymes, turns to color shades of green and blue on contact with alcohol in the oral fluids. The alcohol pad employs a solid phase chemistry which uses the following highly specific enzymatic reaction:



During testing, oral fluid is collected on the alcohol pad and saturates the alcohol pad. If no alcohol is present in the oral fluid, the alcohol pad remains colorless (remains white or cream color) because there is no alcohol in the oral fluid to react with enzymes to start the color reaction. If alcohol is present in the oral fluid, the alcohol pad changes to green or blue color because the alcohol reacts with alcohol oxidase to produce aldehyde and peroxide. The peroxide reacts with peroxidase in the presence of hydrogen donor to produce a blue color. Therefore, the presence of green to blue color at the alcohol pad window indicates a presumptive positive result for alcohol.

### Reagents

The OratectPlus<sup>TM</sup> Oral Fluid Drug and Alcohol Screen Device contains:

(1) Drug Tests: The drug tests consist of 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 regions on the membrane known as the "Test Region".

AM/OP/PC or AM/OP/BZ test strip: Amphetamine, Morphine and Phencyclidine or Amphetamine, Morphine and 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 and anti-phencyclidine or anti-amphetamine, anti-morphine and anti-benzodiazepine antibody colloidal gold conjugates.

(2) Alcohol Test: The alcohol pad contains

Tetramethylbenzidine,  
Alcohol Oxidase,  
Peroxidase,  
Buffer and  
Stabilizing Proteins

### Materials Provided

Each OratectPlus<sup>TM</sup> Oral Fluid Drug and Alcohol Screen Device kit contains;

- 1 Package Insert.
- 1 Reference Guide.
- 25 test devices. Each device consists of a plastic holder and a detachable cap. The devices are packaged individually in a foil pouch with an oxygen absorber-dessicant.
- 1 plastic vial, containing buffer for confirmation test.

### Materials Required but Not Provided

- Timing device

### Warnings and Precautions

- The OratectPlus<sup>TM</sup> Oral Fluid Drug and Alcohol 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.
- Persons who are color blind or visually impaired should not interpret test results.

The alcohol test is designed and calibrated to be interpreted 5 minutes after starting the saliva collection procedure. Waiting longer than 10 minutes may result in erroneous results or false positive results. The alcohol test is highly sensitive to the presence of alcohol. The alcohol vapors in air are sometimes detected by the OratectPlus<sup>TM</sup> Oral Fluid Drug and Alcohol Screen Device. Alcohol vapors are often present in many institutions and homes. Alcohol is a component in many household products such as disinfectants, deodorizers, and glass cleaners. If the presence of alcohol vapors is suspected, the test should be performed in an area known to be free of these vapors.

The alcohol test is a visually interpreted test where any color change to green or blue is considered a presumptive positive result with the alcohol concentration of 0.02% Blood Alcohol Concentration or higher in the saliva.



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## Product Storage

The OratectPlus™ Oral Fluid Drug and Alcohol Screen Device pouch should be stored at room temperature, 15°-30°C (59°F-86°F) and **not to exceed 30°C (86°F)**. Under this condition, the alcohol test will perform according to specification until the expiration date.

If storage temperature exceeds 30°C (86°F), degradation of the product and performance may occur.

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 subject not to eat, drink, smoke or chew gum or tobacco products because it can provide erroneous results due to possible contamination of the saliva by interfering substances.

## Test Procedure

- Remove the test device from the sealed pouch.
- Carefully remove the clear cap by holding the sides and pull gently. This will expose the collection pad and a round alcohol pad beneath the alcohol window.
- Ensure that the blue line is present in each test window.
- Observe the alcohol pad. The pad should be a light cream color. If it is dark tan in color or otherwise discolored, the device should not be used.
- The oral fluid collection process must be observed. Instruct the subject to hold the top portion of the device (above the test windows).
- When placing device into the mouth, **keep head level**.
  - Open mouth and rub the collection pad inside mouth against one cheek gently in a circular motion several (approximately 15-20) times. (Fig. B)
  - Still keeping head level, rub the collection pad against the opposite cheek in a circular motion several (approximately 15-20) times. (Fig. B)

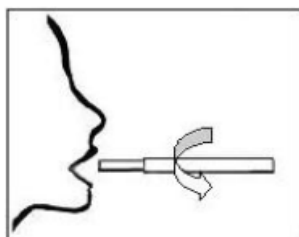


Fig. B Rub the collection pad against each cheek several (approximately 15-20) times.

- Rub the collection pad on top of the tongue several (approximately 15-20) 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.

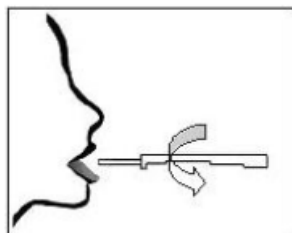


Fig. C Rub the collection pad on top of the tongue several (approximately 15-20) times.

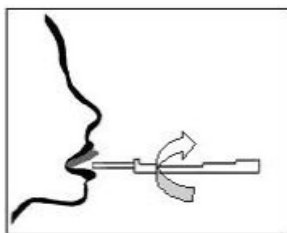


Fig. D Rub the collection pad underneath the tongue several (approximately 15-20) times.

- 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.
- 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 7 until the blue lines flow.  
Note: The flow of the blue lines should appear in the test windows within 5 minutes. If no flow patterns are 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.
- Re-cap the device, lay it on a flat surface and read results:
  - Alcohol test should be read at 5 minutes after removing device from the mouth. Do not read results after 10 minutes.
  - Drug tests should be read at 5 minutes after removing device from mouth. Do not read results after 30 minutes.

## Interpreting Test Results

### (1) Alcohol Test Results

**(A) Alcohol Negative Result:** The alcohol pad shows no color change (remain white or cream colored); it should be interpreted as a negative result (no alcohol present). See Fig. E for an example of alcohol Negative Test result.

The Fig. E below, the oral fluid sample is negative for Alcohol because there is no color change from the alcohol pad.

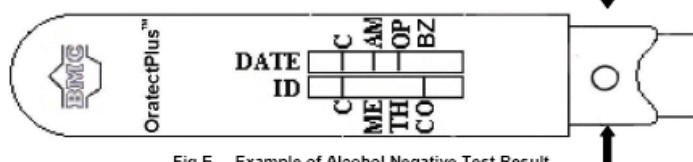


Fig E. Example of Alcohol Negative Test Result

A result where the outer edges of the alcohol pad produces a slight color but the majority of the pad remains colorless should be repeated to ensure complete saturation of the alcohol pad with oral fluid. If the second result is the same, the results should be interpreted as being negative (no alcohol present).

**(B) Alcohol Presumptive Positive Result:** The Alcohol test produces a color change to green to blue in the presence of salivary alcohol 0.02 % B.A.C. or higher. At higher alcohol concentration near 0.30% B.A.C., the color may change to a dark blue-gray.

The Fig. F below, the oral fluid sample is positive for Alcohol because there is color change (green / blue to dark gray) from the alcohol pad.

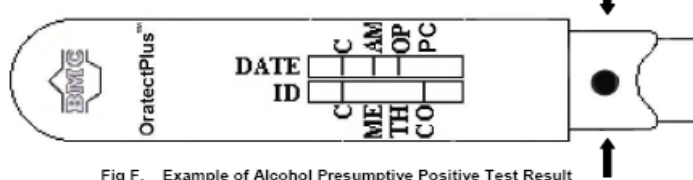


Fig F. Example of Alcohol Presumptive Positive Test Result

### (2) Drug Test Results

**(A) Drug Negative Results:** For each of the drug test windows, 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 G.

The color of the test band may be slightly darker or lighter than the control band. A 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. G below, the oral fluid sample is negative for Amphetamine, Opiate or Cocaine because bands are visible in the AM, OP, and CO test regions.

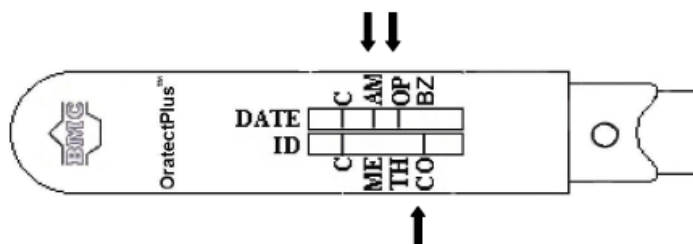


Fig. G Example of Drug Negative Test Results

**(B) Drug 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 presumptive positive for that particular drug. In Fig. H below, the oral fluid sample presumptive positive for Phencyclidine, Methamphetamine and THC because no bands are visible in the test regions of PC, ME, and TH.

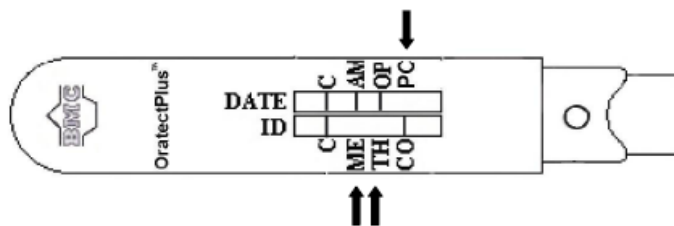


Fig. H Example of Drug Presumptive Positive Test Results



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## 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, and samples. Repeat the test using a new device. In Fig. 1 below, the test is invalid because there are **no bands in the control regions**.

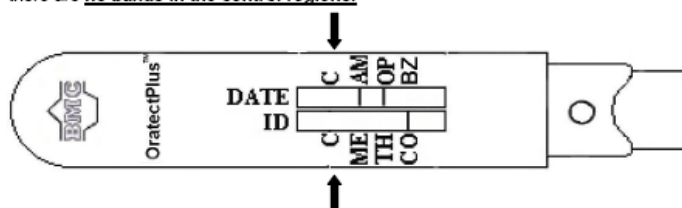


Fig. 1 Example of Invalid Test Results

**Important:** Read each test independently. Do not compare color intensity of one test band to another. When a faint color band for a specific test is obtained in the test region, the sample should be considered negative. The OratectPlus<sup>TM</sup> Oral Fluid Drug and Alcohol Screen Device provides qualitative results for the presence of drug(s) and alcohol at specified cut-off concentration(s). For confirmation of a presumptive positive drugs-of-abuse result, a more specific quantitative method (GC/MS or LC/MS) must be used.

## Specimen Collection & Handling for Confirmation Testing

- For devices with any presumptive positive results, the collection pad should be removed and sent for confirmation test.
- Squeeze the clear cap over the collection pad and detach both the clear cap and the collection pad. 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 as soon as possible from collection).
- Follow standard chain of custody procedures.
- To confirm presumptive positive alcohol test results a breathalyzer or blood test should be used.

## Quality Control

The OratectPlus<sup>TM</sup> Oral Fluid Drug and Alcohol Screen Device provides built-in control bands at the control regions (C) to indicate that the test performed properly. These control bands should always appear regardless of the presence of drugs. The presence of the colored bands in the control regions verifies that,

- Adequate sample volumes have been used and
- 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/or alcohol. However, it does 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 – Drugs-of-Abuse Tests

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 OratectPlus<sup>TM</sup> Oral Fluid Drug and Alcohol Screen Device are summarized below:

| Drug Test | Total # of Test/ Concentration | Concentration |   |     |   |      |    |      |    |
|-----------|--------------------------------|---------------|---|-----|---|------|----|------|----|
|           |                                | 0%            |   | 50% |   | 200% |    | 300% |    |
|           |                                | -             | + | -   | + | -    | +  | -    | +  |
| MET       | 20                             | 20            | 0 | 20  | 0 | 0    | 20 | 0    | 20 |
| MDMA      | 20                             | 20            | 0 | 20  | 0 | 0    | 20 | 0    | 20 |
| THC       | 20                             | 20            | 0 | 20  | 0 | 1    | 19 | 0    | 20 |
| COC       | 20                             | 20            | 0 | 20  | 0 | 0    | 20 | 0    | 20 |
| AMP       | 20                             | 20            | 0 | 20  | 0 | 0    | 20 | 0    | 20 |
| OPI       | 20                             | 20            | 0 | 20  | 0 | 0    | 20 | 0    | 20 |
| PCP       | 20                             | 20            | 0 | 20  | 0 | 0    | 20 | 0    | 20 |
| BZ        | 20                             | 20            | 0 | 20  | 0 | 0    | 20 | 0    | 20 |

### Precision – Alcohol Test

For the alcohol test, saliva was obtained by rinsing with positive ethanol control solutions at various B.A.C. (0.02%, 0.04% and 0.06%). Negative saliva was used to test at 0% concentration. For each concentration, a total of 15 tests were performed

to validate the test performance. The results of the OratectPlus<sup>TM</sup> Oral Fluid Drug and Alcohol Screen Device are summarized below:

| Test    | Total # of Test/ Concentration | B.A.C. |   |       |    |       |    |       |    |
|---------|--------------------------------|--------|---|-------|----|-------|----|-------|----|
|         |                                | 0.00%  |   | 0.02% |    | 0.04% |    | 0.06% |    |
|         |                                | -      | + | -     | +  | -     | +  | -     | +  |
| Alcohol | 15                             | 15     | 0 | 1     | 14 | 0     | 15 | 0     | 15 |

## 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 |
|-------------------------------|-----------------------------------|--------------------------------|
| <b>ME/MDMA</b>                |                                   |                                |
| 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%                           |
| <b>TH</b>                     |                                   |                                |
| 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-Δ-9-THC            | 400                               | 10%                            |
| <b>CO</b>                     |                                   |                                |
| Benzoylcegonine               | 18                                | 110%                           |
| Cocaine                       | 20                                | 100%                           |
| Ecgonine                      | 5000                              | 0.4%                           |
| <b>AM</b>                     |                                   |                                |
| d-Amphetamine                 | 25                                | 100%                           |
| d,l-Amphetamine               | 40                                | 62.5%                          |
| l-Amphetamine                 | 800                               | 3.2%                           |
| 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%                           |
| <b>OP</b>                     |                                   |                                |
| 6-Acetylcodeine               | 20                                | 50%                            |
| 6-Acetylmorphine              | 12                                | 83%                            |
| Codeine                       | 10                                | 100%                           |
| Dihydrocodeine                | 10                                | 100%                           |
| Ethyl morphine                | 60                                | 17%                            |
| Heroin                        | 15                                | 67%                            |
| Hydrocodone                   | 60                                | 17%                            |
| Hydromorphone                 | 70                                | 14%                            |
| Morphine                      | 10                                | 100%                           |
| Morphine-3-beta-D-Glucuronide | 25                                | 40%                            |
| Nalorphine                    | 100                               | 10%                            |
| <b>PC</b>                     |                                   |                                |
| Phencyclidine                 | 4                                 | 100%                           |
| <b>BZ</b>                     |                                   |                                |
| 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%                           |
| Przepam                       | 10                                | 50%                            |
| Temazepam                     | 5                                 | 100%                           |
| Triazolam                     | 10                                | 50%                            |

# ALCOOLTEST \*\*\* NARCOTEST

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Oratect® Branan Medical Corporation iScreen<sup>TM</sup> OFD

## Alcohol Test

The Alcohol test will react with methyl, ethyl, and allyl alcohols, but it will not react with alcohols having 5 or more carbons, glycine, glycerol, and serine. This property is a result of specificity of the alcohol oxidase enzyme extracted from yeast.

## Interference

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

|                                    |                                       |
|------------------------------------|---------------------------------------|
| Acetaminophen                      | Ethylidene-1,5-Dimethyl-1-3,3-        |
| Acetoacetic acid lithium salt      | Diphenylpyrrolidine Perchlorate salt  |
| Acetone                            | Ethyl Morphine (except OP assay)      |
| 6-Acetylcodeine (except OP assay)  | Flunitrazepam (except BZ assay)       |
| 6-Acetylmorphine (except OP assay) | Flurazepam (except BZ assay)          |
| Acetylsalicylic acid               | Furosemide                            |
| Albumin                            | Gentisic acid                         |
| Allobarbitol                       | Glucose                               |
| Alphenal                           | Glutethimide                          |
| Alprazolam (except BZ assay)       | Guaiacol Glyceryl Ether               |
| Amitriptyline                      | Hemoglobin                            |
| Amobarbital                        | Heroin (except OP assay)              |
| Amoxapine                          | Hippuric acid                         |
| Amoxicillin                        | Hydrochlorothiazide                   |
| d-Amphetamine (except AM assay)    | Hydrocodone (except OP assay)         |
| d,l-Amphetamine (except AM assay)  | Hydrocortisone                        |
| l-Amphetamine (except AM assay)    | Hydromorphone (except OP assay)       |
| Ampicillin                         | 11- Hydroxy-Δ-9-Tetrahydrocannabinol  |
| Apomorphine                        | (except TH assay)                     |
| Aprobarbital                       | p-Hydroxymethamphetamine (Pholderin)  |
| l-Ascorbic Acid                    | (except ME assay)                     |
| Aspartame                          | 3-Hydroxytyramine                     |
| Atropine                           | Ibuprofen                             |
| Barbital                           | Imipramine                            |
| Benzillic acid                     | d,l-Isoproterenol                     |
| Benzocaine                         | l-Isoproterenol HCl                   |
| Benzoic acid                       | Lidocaine                             |
| Benzoylcegonine hydrate            | Lorazepam (except BZ assay)           |
| (except CO assay)                  | Lormetazepam (except BZ assay)        |
| Bilirubin                          | Meperidine                            |
| Bromazepam (except BZ assay)       | d,l-Methadone                         |
| d-Brompheniramine                  | d-Methamphetamine (except ME assay)   |
| BuprenorphineButalbital            | d,l-Methamphetamine (except ME assay) |
| Butethal                           | l-Methamphetamine (except ME assay)   |
| Caffeine                           | Methaqualone                          |
| Cannabidiol                        | Methoxyphenamine (except ME assay)    |
| Cannabinol (except TH assay)       | 2-Methylamine-Propiophenone HCl       |
| Chloral Hydrate                    | MDA (except AM assay)                 |
| Chlordiazepoxide (except BZ assay) | MDEA (except AM, ME assays)           |
| Chloroamphetamine (DL-p-)          | MDMA (except ME assay)                |
| Hydrochloride (except AM assay)    | Methylphenidate                       |
| Chloroquine                        | Morphine (except OP assay)            |
| d-Chlorpheniramine                 | Morphine-3-beta -D-Glucuronide        |
| Chlorpromazine                     | (except OP assay)                     |

Prazepam (except BZ assay)

Prednisolone

Procaine

Promazine

Promethazine

d-Propoxyphene

Protriptyline

d-Pseudoephedrine HCl

(except ME assay)

Quinidine

Ranitidine

Riboflavin

Salicylic acid

Secobarbital

Serotonin

Sodium Chloride

Sulfamethazine

Sulindac

Temazepam (except BZ assay)

Tetracycline

Δ-8-Tetrahydrocannabinol

(except TH assay)

Δ-9-Tetrahydrocannabinol

(except TH assay)

Thiamine

Thioridazine

Triazolam (except BZ assay)

Trifluoperazine

Trimethobenzamide (except ME assay)

Trimipramine Maleate

Tryptamine

d,l-Tryptophan

Tyramine (except AM assay)

d,l-Tyrosine

Uric Acid

Verapamil

Zomepirac

## Alcohol Test

The following substances may interfere with the OratectPlus<sup>TM</sup> Oral Fluid Drug and Alcohol Screen Device when using samples other than oral fluid:

(1) Agents which enhance color development: Peroxides and strong oxidizers

(2) Agents which inhibit color development:

Reducing Agents: Ascorbic acid, Tannic Acid, Pyrogallol, Mercaptans and tosylates, Oxalic acid, and Uric acid.

Bilirubin, L-dopa, L-methyldopa, and Methampyrone

The above-named substances do not normally appear in sufficient quantity in oral fluid to interfere with the test. However, care must be taken that they are not introduced into the mouth during the 10 minutes period preceding the test.

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Oratect®

Branan Medical Corporation

iScreen<sup>TM</sup> OFD

## URINE DRUG TEST

### Fastect® II Drug Screen Dipstick Tests

CE



- Single and multiple CLIA-WAIVED drugs-of-abuse dipstick tests for use with urine
- Tests up to four drug combinations simultaneously
- User-friendly at reasonable cost
- Customize according to your needs with a minimum volume order
- A preliminary screen test, must be confirmed by a specific method

### Single Drug Screen Dipstick Tests

| CAT # | Description | Tests/Box |
|-------|-------------|-----------|
| MF10  | THC50       | 50        |
| MF11  | COC300      | 50        |
| MF13  | OPI300      | 50        |
| MF14  | AMP1000     | 50        |
| MF16  | MET500      | 50        |
| MF17  | PCP25       | 50        |
| MF18  | BZO300      | 50        |
| MF19  | BAR300      | 50        |
| MF20  | MTD300      | 50        |
| MF21  | TCA1000     | 50        |
| MF22  | MDMA500     | 50        |
| MF23  | OXY100      | 50        |

### Multiple Drug Screen Dipstick Tests

| CAT # | Description                 | Tests/ box |
|-------|-----------------------------|------------|
| BF10  | THC50/COC300                | 50         |
| BF13  | THC50/MET500                | 50         |
| BF16  | THC50/OPI300                | 50         |
| TF12  | THC50/MET500/OPI300         | 50         |
| TF13  | THC50/COC300/OPI300         | 50         |
| TF15  | COC300/OPI300/MET500        | 50         |
| TF16  | THC50/COC300/MET500         | 50         |
| TF23  | THC50/COC300/OXY100         | 50         |
| QF08  | BAR300/BZO300/MTD300/OXY100 | 50         |
| QF09  | THC50/COC300/OPI300/BZO300  | 50         |
| QF12  | THC50/COC300/OPI300/MET500  | 50         |
| QF13  | BZO300/COC300/OPI300/MTD300 | 50         |

### Intect® 7 Urine Adulteration Test Strips

CE



- Ensures the integrity of your urine samples
- Meets the specimen validity testing (SVT) requirement
- Tests for 7 parameters:
  - ✓ Creatinine
  - ✓ Nitrite
  - ✓ Glutaraldehyde
  - ✓ pH
  - ✓ Specific Gravity
  - ✓ Bleach
  - ✓ Pyridinium Chlorochromate
- User-friendly and cost-effective
- A preliminary screen test, must be confirmed by a specific method

| CAT # | Description   | Vials/ box |
|-------|---|------------|
| AD007 | Urine Adulteration Test Strips, 7-parameters (25 strips/vial) | 50         |



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## ToxCup® Drug Screen Cup

CE



- CLIA-WAIVED multiple drugs-of-abuse test cup with or without adulteration tests
- Urine collection, testing and shipping in one device
- Tests five drugs and four adulteration tests simultaneously or up to 7 drugs without adulteration tests
- Customize according to your needs with a minimum volume order
- A preliminary screen test, must be confirmed by a specific method

## Multiple Drug Screen Cup Tests

| CAT #  | Description                                     | Tests/ box |
|--------|---|------------|
| PT08** | THC50/COC300/OPI300/MET500                      | 25         |
| PT11   | THC50/COC300/OPI2000/PCP25/AMP1000              | 25         |
| PT12   | THC50/COC300/OPI2000/PCP25/MET500               | 25         |
| PT15   | THC50/COC300/OPI300/MET500/AMP1000              | 25         |
| PT24** | THC50/COC300/OPI300/MET500/OXY100               | 25         |
| HT20** | THC50/COC300/OPI300/MET500/AMP1000/MTD300/PCP25 | 25         |
| HT21   | THC50/COC300/OPI300/MET500/BZO300/BAR300/OXY100 | 25         |

\*\*Requires 6 weeks lead time

## Multiple Drug Screen Cup Tests with Adulteration Tests (CR/NI/PH/OX)

| CAT # | Description                                       | Tests/ box |
|-------|---|------------|
| PT11A | THC50/COC300/OPI2000/PCP25/AMP1000 + CR/NI/PH/OX  | 25         |
| PT12A | THC50/COC300/ OPI2000/MET500/PCP25 + CR/NI/PH/OX  | 25         |
| PT15A | THC50/COC300/ OPI300/MET500/AMP1000 + CR/NI/PH/OX | 25         |
| PT23A | THC50/COC300/OPI300/MET500/BZO300 + CR/NI/PH/OX   | 25         |

The ToxCup® Drug Screen Cup is a one-step test for the rapid detection of up to seven drugs of abuse or five drugs and four adulteration tests. Its design integrates sample collection, drug/adulteration testing and shipment for confirmation in one device.

## THE FACTS

- **CLIA-Waived** device
- Simultaneously tests for drugs and adulterants
- Rapid one-step procedure
- No sample exposure
- Integrates sample collection, testing and shipment for confirmation in a single container
- Easy to interpret visual results
- Room temperature storage - Built-in temperature strip



Oratect® Branan Medical Corporation iScreen<sup>TM</sup> OFD

## Monitect® Drug Screen Cassette Test

CE



- Single or multiple drugs-of-abuse cassette tests available with or without adulteration tests for use with urine
- Tests up to five drug combinations and four adulteration tests simultaneously
- Customize according to your needs with a minimum volume order
- A preliminary screen test, must be confirmed by a specific method

### Single Drug Screen Cassette Tests

| CAT #  | Description | Tests/ box |
|--------|-------------|------------|
| MC10   | THC50       | 25         |
| MC11   | COC300      | 25         |
| MC13   | OPI300      | 25         |
| MC14   | AMP1000     | 25         |
| MC15   | MET1000     | 25         |
| MC16   | MET500      | 25         |
| MC17   | PCP25       | 25         |
| MC18   | BZO300      | 25         |
| MC19   | BAR300      | 25         |
| MC20   | MTD300      | 25         |
| MC21** | TCA1000     | 25         |
| MC22   | MDMA500     | 25         |
| MC23   | OXY100      | 25         |
| MC24** | BUP5        | 25         |

\*\*Requires 6 weeks lead time

### Multiple Drug Screen Cassette Tests

| CAT #  | Description                        | Tests/ box |
|--------|------------------------------------|------------|
| BC10   | THC50/COC300                       | 25         |
| BC17   | BAR300/BZO300                      | 25         |
| TC11   | THC50/COC300/MET500                | 25         |
| TC13   | THC50/COC300/OPI300                | 25         |
| TC19   | THC50/COC300/AMP1000               | 25         |
| QC12   | THC50/COC300/OPI2000/MET1000       | 25         |
| QC14** | OPI300/MET300/THC50/COC300         | 25         |
| PC11   | THC50/COC300/PCP25/OPI2000/AMP1000 | 25         |
| PC12** | THC50/COC300/PCP25/OPI2000/MET1000 | 25         |

### Multiple Drug Screen Cassette Tests with Adulteration Tests (OX/PH/CR/NI)

| CAT #   | Description                                      | Tests/ box |
|---------|--|------------|
| BC10A** | THC50/COC300 + OX/PH/CR/NI                       | 25         |
| TC11A** | THC50/COC300/MET500 + OX/PH/CR/NI                | 25         |
| QC12A   | THC50/COC300/OPI2000/MET1000 + OX/PH/CR/NI       | 25         |
| PC11A   | THC50/COC300/PCP25/OPI2000/AMP1000 + OX/PH/CR    | 25         |
| PC12A   | THC50/COC300/PCP25/OPI2000/MET1000 + OX/PH/CR/NI | 25         |

\*\*Requires 6 weeks lead time

Simply collect sample, pipette into testing wells and read results. Monitect® is a FDA 510K cleared multiple drug screen cassette that can simultaneously test for both drugs and adulterants. It can test from one (1) to five (5) drugs and can be accompanied with four (4) adulterant tests.

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## QuickTox® Drug Screen Dipcard

CE



- Multiple CLIA-WAIVED drugs-of-abuse dipcard tests for use with urine
- Tests up to twelve drugs simultaneously or nine drugs with four adulteration tests
- Eliminates pipetting and minimizes sample handling
- Results can be easily photocopied for permanent record
- Customize your drug selection according to your needs with a minimum volume order
- A preliminary screen test, must be confirmed by a specific method

## Multiple Drug Screen Dipcard Tests

| CAT #  | Description  | Tests/ box |
|--------|--|------------|
| QT13   | THC50/COC300/OPI300/MET500/BZO300  | 25         |
| QT19   | THC50/COC300/OPI300/MET500/AMP1000   | 25         |
| QT33** | THC50/COC300/OPI300/MET500/PCP25/BZO300/BAR300                                       | 25         |
| QT44   | THC50/COC300/OPI300/MET500/AMP1000/BZO300/BAR300/OXY100                              | 25         |
| QT51** | THC50/COC300/OPI2000/MET1000/AMP1000/PCP25/BZO300/BAR300/MTD300                      | 25         |
| QT52   | THC50/COC300/OPI300/MET500/AMP1000/BZO300/BAR300/MTD300/OXY100                       | 25         |
| QT70   | THC50/COC300/OPI300/MET500/AMP1000/PCP25/BZO300/BAR300/MTD300/OXY100/MDMA500         | 25         |
| QT80f  | COC300/OPI300/MET300/THC50/AMP1000/PCP25/BZO300/BAR300/MTD300/TCA1000/OXY100/MDMA500 | 25         |

\*\*Requires 6 weeks lead time

## Multiple Drug Screen Dipcard Tests with Adulteration Tests (CR/NI/PH/OX)

| CAT # | Description   | Tests/ box |
|-------|---|------------|
| QT51A | THC50/COC300/OPI2000/MET1000/AMP1000/PCP25/BZO300/BAR300/MTD300 + CR/NI/PH/OX | 25         |
| QT52A | THC50/COC300/OPI300/MET500/AMP1000/BZO300/BAR300/MTD300/OXY100 + CR/NI/PH/OX  | 25         |

FDA cleared - One-Step to quicker results. QuickTox® is a multiple drugs of abuse dip card that allows for easy mix and match of tests. It is capable of testing up to 11 drugs or 9 drugs and 4 adulterants simultaneously. With its flat design and clear cap, QuickTox® can be photographed without fear of contamination of the tester's desk or bench.

THE FACTS - **CLIA-Waived** device Simultaneous detection of multiple drugs -Configurations can be chosen from 5-11 drugs - Built-in adulterant testing available - Rapid results - Tests activate in 10 seconds - Results are ready in 5 minutes - 1 hour result stability - Eliminates pipetting - Minimizes sample handling - Procedural control - 14-month shelf life

### ADULTERANTS:

- Creatinine
- Nitrite
- pH
- Oxidizing Agents
- **Detects:** Stealth, Urine Luck, Whizzes, Klear, Clear Choice, Drano, Bleach

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## Controls

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## MoniCheck® Urine Controls

## IntectCheck® Controls

| CAT #  | Description   | Vials/kit |
|--------|---|-----------|
| AU-000 | Negative, 20ml  | 1         |
| AU-004 | Positive (THC50/COC300/OPI2000/MET1000/AMP1000/PCP25/BZO300/BAR300/MTD300), 20 ml | 1         |
| AU-007 | Positive (THC50/COC300/OPI300/MET500/AMP1000/PCP25/BZO300/BAR300/MTD300), 20 ml   | 1         |
| AU-010 | Positive (OXY100/MDMA500), 10ml   | 1         |

| CAT # | Description  | Vials/kit |
|-------|--|-----------|
| IC007 | IntectCheck® Normal & Abnormal Controls for Intect® 7 Urine Adulteration Test Strips | 5         |

## Urine Collection Cups\*\*\*

CE



| CAT # | Description                  | Cups/bag |
|-------|------------------------------|----------|
| BC075 | Plastic Urine Collection Cup | 50       |

\*\*\* Not CE Marked



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30175 Hannover, Germany



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