

BRANAN MEDICAL CORPORATION

Product Training & Certification

WipetectTM Surface Drug Screen Device



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Wipetect™ Surface Drug Screen Device

Training and Certification for Test Administrators

The information provided is intended to educate test administrators in the use of the Wipetect™ Surface Drug Screen Device. Please read the following information carefully. A multiple-choice test will be administered once the material has been reviewed.

Intended Use

The Wipetect™ Drug Screen Device is a one-step lateral flow immunoassay device for the detection of drug residues on surfaces or drug solid. The Wipetect™ device is intended to detect opiate, methamphetamine, marijuana and cocaine.

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.

Specific Test Cut Off Concentration

Wipetect™ tests for the following drugs of abuse:

OPI	Opiate	10 ng/ml
ME	Methamphetamine	25 ng/ml
TH	Marijuana (Δ 9-tetrahydrocannabinol)	40 ng/ml
COC	Cocaine	20 ng/ml

The Wipetect™ 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 Wipetect™ Drug Screen Device, a more specific alternative method such as GC/MS or LC/MS/MS must be used.

Warnings and Precautions

- Wipetect™ is intended for forensic use.
- Wipetect™ device should remain in its original sealed pouch until ready for use.
- Discard the test device if pouch 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.
- The Wipetect™ pouch should be stored at room temperature (15°-30°C or 59°-86°F).

Test Device Regions

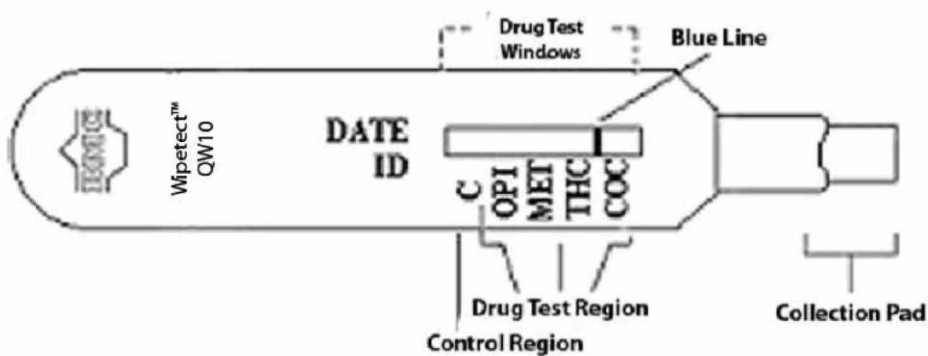


Fig. a Sections of Wipetect™

Test Principle

The Wipetect™ 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 for limited antibody binding sites on the colored colloidal gold antibody conjugate.

During testing, drug residue is collected by the collection pad, and migrates across the membrane when buffer is added.

If no drug is present on the surface, 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 on the surface, 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.

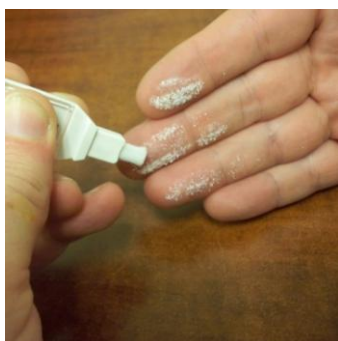
Therefore, the absence of a purple-red band at the test region indicates a presumptive positive result for that particular test.

Specimen Collection and Handling

Procedures

1. Remove the test device from its sealed pouch.
2. Carefully remove the blue cap by holding both sides and pulling gently. This will expose the collection pad.
3. Ensure the presence of a blue line in each test window.
4. A. For drug residue on suspected surface:
Wipe the suspected surfaces with collection pad (Fig. b & c), and then add 10 drops of buffer on the collection pad. (Fig d.)

B. For drug powder or tablet or plant:
Put small amount of suspected solid into the blue cap and then add 10 drops of buffer into the blue cap. Shake gently for approximately 1~2 minutes, insert the device. (Fig e.)
5. Once the blue lines begin to flow, re-cap the device, and lay on a flat surface. Read results in approximately 3 minutes. Do not read results after 30 minutes.
6. The flow of the blue lines indicates the collection of a sufficient amount buffer has been added. If the blue lines are still present after adding the buffer to the pad, have the operator repeat step 4 until the blue lines flow.



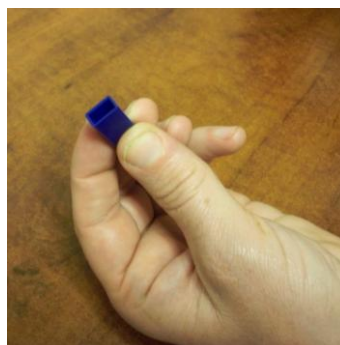
(Fig b.)



(Fig c.)



(Fig. d) Add 10 drops of buffer.



(Fig e.) Add solid material into blue cap. Add 10 drops of buffer into cap.

Note: The flow of the blue lines should appear in the test windows within 3 minutes. If no flow is observed after 3 minutes, discard the device, review the collection procedures and repeat the test using a new device.

The test results should be interpreted **3 minutes** after adding buffer to the device. See package insert.

Interpreting Test Results:

Negative Results

For each test, purple-red colored bands should be observed; one band at the control region (C) and one band at the specific drug abbreviation (e.g. OPI, MET, THC, COC) 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 is a **negative** result. Read each test independently. Do not compare color intensity of one test to another.

In the **Fig. f** below, the sample is negative for Opiate and THC because bands are visible in the OPI, and THC test regions

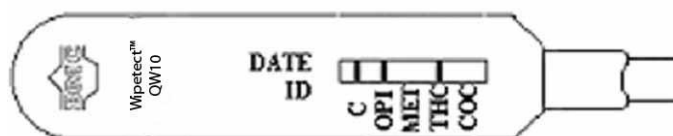


Fig. f Example of negative test results

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 sample is presumptive positive for Methamphetamine (or MDMA) and cocaine because no bands are visible in the test regions of MET and COC.

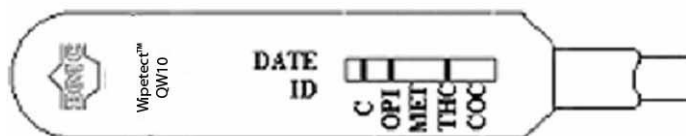


Fig. g Example of presumptive positive test results

Invalid Results

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

In **Fig. h** below, the test is invalid because there are no colored bands in the control regions.

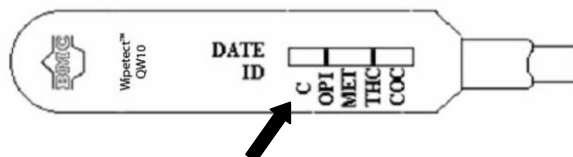


Fig. h Example of invalid test results

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 Wipetect™ 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/MMS) must be used.

Specimen Collection and Handling for Confirmation

1. If a user of this product obtains a presumptive positive test result, they should obtain confirmation testing using a more specific test method such as Gas Chromatography/Mass Spectrometry (GC/MS or Liquid Chromatography/Mass Spectrometry (LC/MS/MS). The test sample for this conformation testing should be collected immediately after obtaining the presumptive positive test result(s).
2. Use the enclosed sample collection tube (50 mL polypropylene tube). Note: if additional sample collection tubes are needed, please contact Branan customer service at 1-866-468-3287. Remove cap from collection tube and carefully spit into tube several times until half of the bottom cone (~2.5 mL is collected. Re-cap sample collection tube. Affixed label to the sample collection tube with the requested information. Store collected sample in a -20° C freezer or 2-8° C refrigerator pending shipment.
3. Send the sample to a licensed test laboratory for GC/MS or LC/MS/MS confirmation testing. The sample should be shipped by an overnight courier service using a small shipping box or padded envelope.

Limitations of the Procedure

- 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.
- Do not use the device past expiration date
- Read instructions before testing

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

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

Wipetect™ Certification Test

Instructions: This is a multiple-choice test. Read the questions completely before choosing the best answer. Write your answers on the sheet provided (p. 11).

1. The Wipetect™ Surface Drug Screen Device provides for the detection of
 - a. 5 drugs in oral fluid
 - b. 4 drugs in urine
 - c. 6 drugs in oral fluid
 - d. none of the above
2. Wipetect™ provides _____ drug test results.
 - a. preliminary
 - b. qualitative
 - c. quantitative
 - d. both a and b are correct
3. The absence of a colored band in the control (C) region of the Wipetect™ device means the test
 - a. result is negative
 - b. result is presumptive positive
 - c. result is invalid
 - d. none of the above
4. The presence of a colored band at a specific test region and a colored band at control (C) region means the test is
 - a. invalid
 - b. negative for that particular drug
 - c. presumptive positive
 - d. wrong
5. Interpret the following test. The test is
 - a. presumptive positive for OPI, COC, THC and MET
 - b. negative for OPI, COC, THC and MET
 - c. invalid
 - d. negative for ME and PC



6. Interpret the following test. The test is

- a. invalid
- b. negative for CO, OP, TH
- c. presumptive positive for ME
- d. both b and c are correct



7. When testing the device, the test administrator should do the following

- a. For drug residue on suspected surface:
Wipe the suspected surfaces with collection pad, and then add 10 drops of buffer.
- b. For drug powder or tablet or plant:
Put small amount of suspected solid into the blue cap and then add 10 drops of buffer into cap.
- c. For drug powder or tablet or plant:
Wipe the suspected powder or tablet or plant with the collection pad 10 times then wait for the blue line to flow.
- d. Both a & b.

8. The Wipetect™ Drug Screen Device pouch should be stored at room temperature _____.
Do not open pouch until ready to perform the assay.

- a. (15°-30°C)
- b. (10°-30°C)
- c. (150°-30°C)

9. Test results can be interpreted up to

- a. 1 hour
- b. See package insert for current read time for interpretation of test results
- c. In afternoon
- d. Next day

10. The test administrator should

- a. Open the pouch, remove the cap and touch the white collection pad with bare hands before wiping the surface.
- b. Discard the device if the pouch is torn.
- c. Heat the pouch in oven at 100°C before using.
- d. Store the pouch in freezer (at -20°C).

Wipetect™ Certification Test Result Sheet

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

Name _____

Organization _____

Address _____

City, State, Zip Code _____

Telephone _____

Fax _____

E-mail _____

Fax: 858-805-8604 Attn: Lois Jones

Mail: Branam Medical Corporation
140 Technology Drive, Suite 400
Irvine, California 92618
Attn: Lois Jones

E-mail: lois.jones@alere.com

Answers:

Question 1 _____

Question 6 _____

Question 2 _____

Question 7 _____

Question 3 _____

Question 8 _____

Question 4 _____

Question 9 _____

Question 5 _____

Question 10 _____