

BRANAN MEDICAL CORPORATION

Product Training & Certification

Fastect[®] II Drug Screen Dipstick



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Fastect® II Drug Screen Dipstick Test

Training and Certification for Test Administrators

The information provided is intended to educate test administrators on the use of the Fastect® II Drug Screen Dipstick Test. Please read the following information carefully. A multiple-choice test will be administered once the material has been reviewed.

Intended Use

Fastect® II is a one-step dip test for the rapid detection of multiple drugs of abuse and their metabolites in human urine at or above the following cutoff concentrations:

AMP	Amphetamines	1000 ng/ml
BAR	Barbiturates	300 ng/ml
BZO	Benzodiazepines	300 ng/ml
COC	Cocaine	300 ng/ml
OPI	Opiates	300 ng/ml
MET	Methamphetamine	500 ng/ml
MDMA	Ecstasy	500 ng/ml
MTD	Methadone	300 ng/ml
OXY	Oxycodone	100 ng/ml
PCP	Phencyclidine (PCP)	25 ng/ml
THC	Marijuana	50 ng/ml
TCA	Tricyclic antidepressants	1000 ng/ml
BUP	Buprenorphine	10 ng/ml
K2	Synthetic marijuana (For Forensic Use only)	10 ng/ml

Fastect® II provides preliminary qualitative results and is intended for prescription use only.

Fastect® II provides only a preliminary screening test result. For a quantitative result or to confirm positive results obtained by Fastect® II, a more specific alternative method must be used. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method.

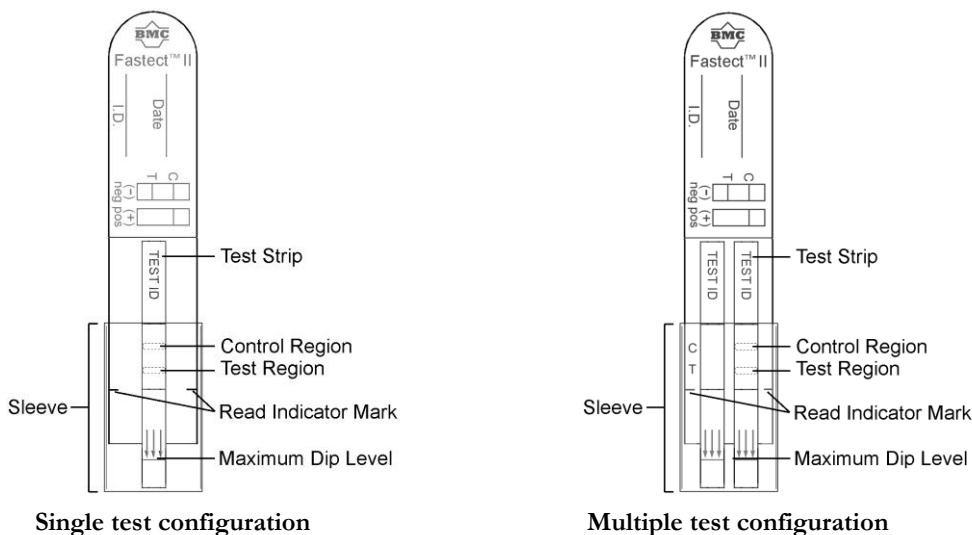
Warnings and Precautions

- The Fastect® II is intended for *in vitro* diagnostic use only.
- The Fastect® II 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 after its date of expiration (indicated on the drug test pouch).
- Handle all specimens as potentially infectious. Proper handling and disposal methods of testing device and fluids should be established.
- Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample.

- The Fastect[®] II kit should be stored at room temperature (15–30 °C or 59–86 °F).

Fastect[®] II Drug Screen Dipstick Test

Fastect[®] II Drug Screen Dipstick Test is available in one, two, three or four panel formats. The three and four panel kits display results on both sides of the test device.



Test Principle

The Fastect[®] II Drug Screen Dipstick Test is based on the principal of highly specific immunochemical reactions between antigens and antibodies. These immunochemical reactions are used for the analysis of specific substances in urine.

The dipstick device contains membrane strips onto which drug conjugates are pre-coated at specific regions known as test regions.

Colored antibody-colloidal gold conjugates are coated onto a pad and placed on one end of each membrane. In the test procedure, a sample of urine is added to the sample well and allowed to migrate across the membrane by capillary action.

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

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

The absence of a color band at the test region indicates a presumptive positive result for that particular test. For a presumptive positive or negative result, a color band must appear in the control region (C) of the test. The color band indicates that the test has performed

properly. If the control band does not appear, the test results are invalid. Invalid tests must be repeated with a new device.

Specimen Collection and Handling

Fastect II[®] is formulated for use with human urine specimens. Use only freshly voided untreated urine. Do not centrifuge or add preservatives to the urine. Urine samples should be collected so testing can be performed as soon as possible after collection, preferably the same day. Specimens that have been refrigerated or frozen must be brought up to room temperature prior to testing.

Procedures

IMPORTANT: Donor sample (urine specimen) should be brought to room temperature (15-30 °C) prior to testing. Do not open pouch until ready to perform the assay.

1. Remove the test device from its sealed pouch.
2. Push the sleeve all the way up, so that the test strip(s) are exposed.
3. Dip the test strip(s) of the test device into the urine specimen for at least 10 seconds. **Ensure that you do not submerge the test strips past the indicator arrows.** (See Fig. 1)

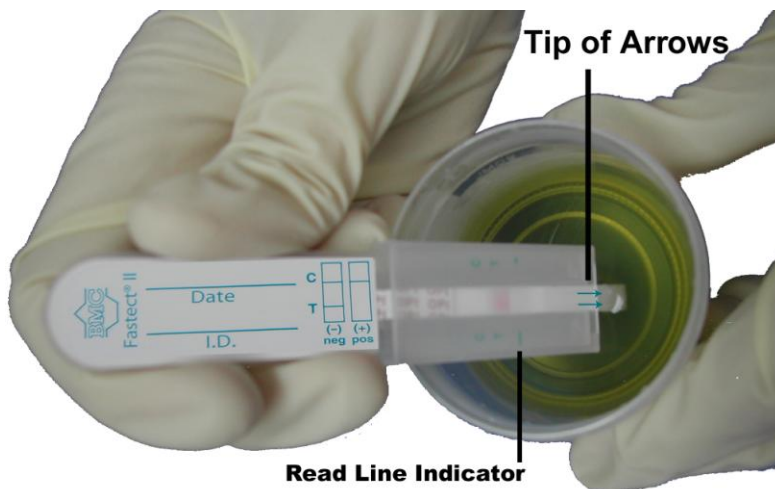


Fig. 1

4. Slide the sleeve down to the **Read Indicator Mark** (See Fig. 1) and lay the device on a level surface.
5. Once the control bands (C) appear (in 5 minutes or less) the results are ready to interpret. See package insert.

Interpretation of Results

Negative Results

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

In **Fig. 2** below, the sample shown is **negative** for both THC and COC tests:



Fig. 2 Example of Negative Test Results

Positive Results

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

In **Fig. 3** below, the sample is a **presumptive positive** for COC because **no bands are visible in the test region.**

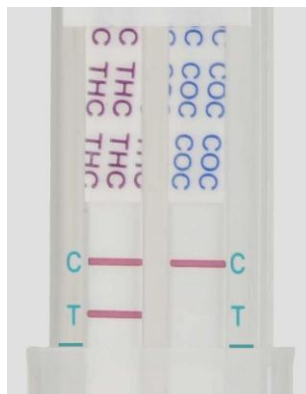


Fig. 3 Example of Positive Test Results

Invalid Results

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

In **Fig. 4** below, all tests are **invalid** because there are **no colored bands in the control region**.



Fig. 4 Example of Invalid Test Results

IMPORTANT: Read each test independently. Do not compare color intensity of one test to another. Samples with faint test bands at the test regions should be considered negative. Fastect[®] II provides qualitative results for the presence of drug(s) at specified cut-off concentration(s). It is recommended that samples with questionable test band and positive result be confirmed with a more specific method (Gas Chromatography/Mass Spectrometry).

Limitations of the Procedure

- The assay is designed for use with human urine only.
- Positive results only indicate the presence of drugs and/or metabolites and do not indicate or measure intoxication
- There is a possibility of technical or procedural errors as well as other substances in certain foods and/or medications that may interfere with the test(s) and cause false 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 sample may have been mislabeled, a new specimen should be collected and the test repeated.
- If it is suspected that the sample may have been tampered with, a new specimen should be collected and the test repeated.

THIS COMPLETES THE FASTECT® II 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.

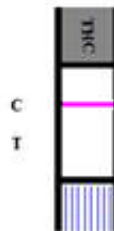
Fastect[®] II Certification Test

Instructions: This is a multiple-choice test. Read the questions completely before choosing the best answer. Write answers on the sheet provided (p. 10).

- Fastect[®] II provides
 - preliminary drug test results
 - quantitative drug test results
 - qualitative drug test results
 - confirmed test results
 - both a and c are correct
- The absence of a colored band in the control region (C) means
 - the test result is negative
 - the test result is presumptive positive
 - the test result is invalid
 - the test should be repeated using a new device
 - both c and d are correct
- The presence of a colored band in the control region (C) and a colored band at a specific test means
 - the test is invalid
 - the test is negative for that particular drug
 - the test is presumptive positive for that particular drug
- The Fastect[®] II device should be stored at
 - 25-35° C
 - 35-77° F
 - 15-30° C
 - 59-86° F
 - both c and d

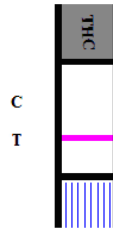
- Interpret the following test

- Negative for THC
- Presumptive positive for THC
- Invalid



6. Interpret the following test

- a. Invalid
- b. Negative for THC
- c. Presumptive positive for THC



7. The device should be dipped into the urine sample for at least

- a. 10 seconds
- b. 1 minute
- c. 30 seconds
- d. 3 minutes

8. Once the control band forms in ____ or less, the results are ready to be read.

- a. 5 minutes
- b. 4 hours
- c. 8 days
- d. 1 hour

9. Fastect[®] II should be dipped into the urine up to the level

- a. indicated by the tips of the arrows
- b. marked "T"
- c. marked "C"

10. Which of the following are true?

- a. The presence of a band at the test region (T) indicates a presumptive positive result.
- b. Do not compare band intensity of one test to another.
- c. No band at the test region (T) indicates a negative result.
- d. The presence of a colored band at the control region (C) and a colored band at a specific test (T) region indicate that the results are negative for that particular drug.
- e. Both b and d.

Fastect® II Certification Test Result Sheet

Please enter your answers in the spaces below. Print your name and organization **clearly**. Provide your organizations address, telephone number, fax, and your work 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 _____

Answers:

Question 1 _____

Question 6 _____

Question 2 _____

Question 7 _____

Question 3 _____

Question 8 _____

Question 4 _____

Question 9 _____

Question 5 _____

Question 10 _____

Please return to:

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