

Fastect[®] II Drug Screen Dipstick Test

Training and Certification Program

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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

The Fastect[®] II Drug Screen Dipstick Test is a one-step, lateral flow chromatographic immunoassay dip test for the rapid detection of various drugs-of-abuse and their metabolites in human urine. The assay is used to obtain a visual, qualitative result and is intended for professional use only.

The Fastect[®] II Drug Screen Dipstick Test provides only a preliminary qualitative analytical test result. For a quantitative analytical result or to confirm presumptive positive results obtained by Fastect[®] II, a more specific alternative chemical method must be used. The Substance Abuse Mental Health Sources (SAMHSA) and the National Institute on Drug of Abuse (NIDA) have established Gas Chromatography/Mass Spectrometry (GC/MS) as the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

Specific Test Cut Off Concentration

| | | |
|------|--|------------------|
| AMP | Amphetamine | 1000 ng/ml |
| BAR | Barbituates (Secobarbital) | 300 ng/ml |
| BZO | Benzodiazepines (Oxazepam) | 300 ng/ml |
| COC | Cocaine (Benzoylecgonine) | 300 ng/ml |
| OPI | Opiates (Morphine) | 300 & 2000 ng/ml |
| MET | Methamphetamine | 500 & 1000 ng/ml |
| MDMA | Methylenedioxymethamphetamine | 500 ng/ml |
| MTD | Methadone | 300 ng/ml |
| OXY | Oxycodone | 100 ng/ml |
| PCP | Phencyclidine (PCP) | 25 ng/ml |
| THC | Tetrahydrocannabinol (11-nor- Δ^9 -tetrahydrocannabinol-9-carboxylic acid) | 50 ng/ml |
| TCA | Tricyclic antidepressants | 1000 ng/ml |

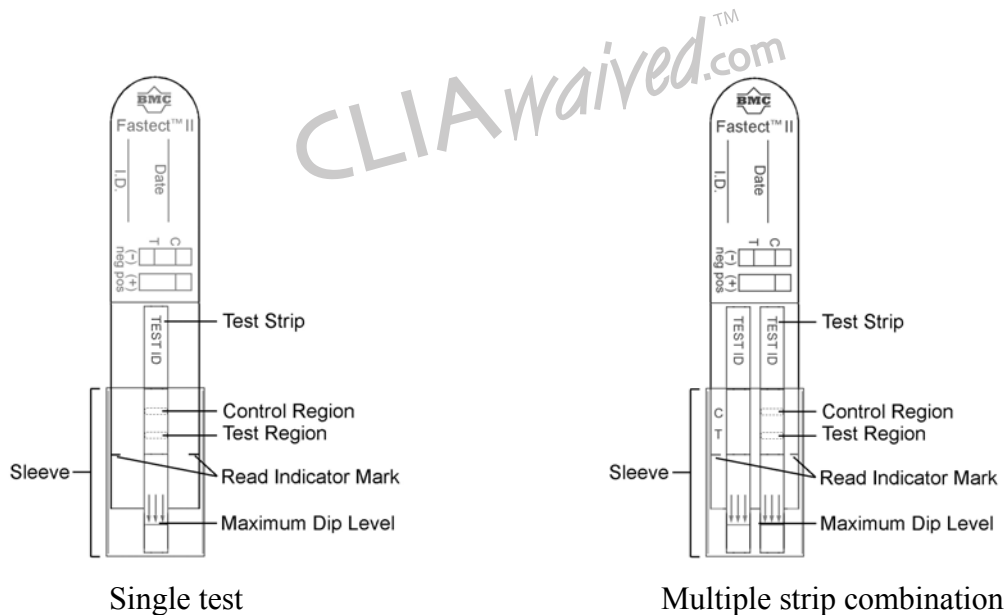
Warnings and Precautions

- For *in vitro* diagnostic use only.
- 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 specimens as potentially infectious. Proper handling and disposal methods should be established.
- Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample.
- The Fastect® II Drug Screen Dipstick Test 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 test devices include the use of both sides.

The graphic display illustrates the single and multiple test confirmation.



Test Principle

The Fastect® II Drug Screen Dipstick Test is based on the principal of highly specific immunochemical reactions between antigens and antibodies that 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. In either case, the control band must be present for the test to be valid. It is important to read each test independently. Do not compare the color intensity of one test to another.**

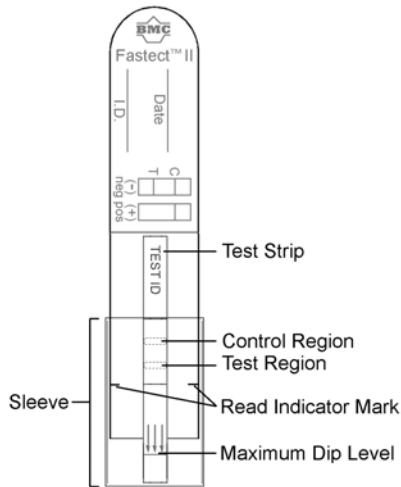
Specimen Collection and Handling

The Fastect II[®] Drug Screen Dipstick Test is formulated for use with 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 must be brought up to room temperature prior to testing. Previously frozen specimens must be thawed, brought to room temperature and mixed prior to use. Frozen samples are not recommended for adulteration testing.

Fastect II[®] Drug Screen Dipstick Test Procedure

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

1. Remove the test device from the sealed pouch.
2. Push the sleeve all the way up.
3. Dip the sample pad of the test device into the urine specimen to the maximum dip level for at least 10 seconds. **Dip up to and not beyond the tips of the arrows.**
4. Slide the sleeve down to the **Read Indicator Mark** and lay the device on a level surface.
5. Negative results are ready to interpret once the control bands (C) form. Presumptive positive results can be interpreted once the control bands (C) form and the membrane background clears (in 5 minutes or less). Results are stable and may be interpreted up to 1 hour after the control bands (C) form.



6. If results are to be confirmed, follow standard chain of custody procedures.

Interpreting Test 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. a** below, the sample shown is negative for both THC and COC tests:

Negative

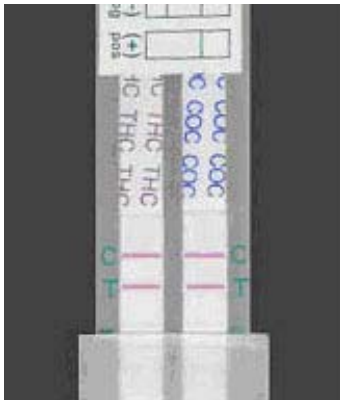


Fig. a Example of Negative Test Results

Presumptive 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 **presumptive positive** for that particular drug.

In **Fig. b** below, the sample is presumptive positive for both THC and COC **because no bands are visible in the test region.**

Presumptive Positive

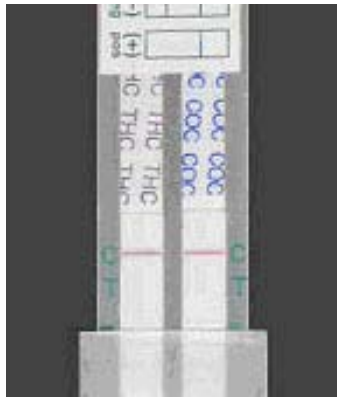


Fig. b Example of Presumptive Positive Test Results

Invalid Results

When **no** band appears in the control (C) region, **the test is invalid** regardless of the test results. 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. c** below, all tests are invalid because there are no colored bands in the control region.

Invalid



Fig. c 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. The Fastect® II Drug Screen Dipstick Test 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 presumptive positive result be confirmed with a more specific quantitative method (Gas Chromatography/Mass Spectrometry).

Limitations of the Procedure

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

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 1-888-882-7739 OR E-MAIL INFO@CLIAwaived.com or FAX:(801) 720-7568

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