Fastect® II Drug Screen Dipstick Test

Step-by-Step Testing Instructions

The Fastect® II Drug Screen Dipstick Test is a preliminary screening test that detects drugs-of-abuse in urine at specified detection levels. For a quantitative analytical result or to confirm preliminary positive results, a more specific method must be used. The Substance Abuse Mental Health Sources Administration (SAMHSA) has established Gas Chromatography/Mass Spectrometry (GC/MS) as the preferred confirmatory method.

This is a CLIA-Waived Test. A CLIA Certificate of Waiver is needed to perform testing in waived settings. Read this entire Instruction Sheet carefully before use. If a laboratory modifies the following test instructions including QC, the test will be considered high complexity and no longer considered CLIA Waived. This Instruction Sheet provides a brief summary of the testing procedure. For more information see the Product Insert that is provided with the product.

Warnings and Precautions

- For in vitro diagnostic use only (not for internal use).
- Store the Fastect® II Drug Screen Dipstick Test at room temperature 59˚F to 86˚F (15˚C to 30˚C).
- Keep the Fastect® II Drug Screen Dipstick Test in its original sealed pouch until ready for use. Do not use the test if the pouch is ripped or torn.
- Do not use the Fastect® II Drug Screen Dipstick Test after the expiration date printed on the pouch.
- Be careful with urine because it may contain infectious diseases. Always wear gloves and wash hands with soap and water after handling urine.
- To ensure that the test will work properly the testing instructions must be followed. Failure to do so may result in inaccurate screening results.
- Do not use this test if you are color-blind.

Limitations of the Test

- Use the test with human urine only.
- The test is for one use only; it is not reusable.
- This test is a screening device; it does not detect the actual concentration of a drug.
- Contaminated or tainted urine sample may give false results.
- Certain foods or medications may cause the test to give false results.
- Send preliminary positive or uncertain results to a laboratory to confirm results.
- The colors of human urine usually range from amber yellow to very light yellow. Dark urine or urine with a brown or abnormal color should not be tested using this test. Dark urines should be sent to a laboratory for testing.

Detection Levels

The Fastect® II Drug Screen Dipstick Test may not detect drug amounts lower than the detection levels.

<table>
<thead>
<tr>
<th>Drug Test</th>
<th>Detection Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>THC</td>
<td>50 ng/mL</td>
</tr>
<tr>
<td>Cocaine</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>Opiates</td>
<td>300 ng/mL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug Test</th>
<th>Detection Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methamphetamine</td>
<td>500 ng/mL</td>
</tr>
<tr>
<td>Amphetamine</td>
<td>1000 ng/mL</td>
</tr>
<tr>
<td>Barbiturates</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>Benzodiazepine</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>100 ng/mL</td>
</tr>
<tr>
<td>PCP</td>
<td>25 ng/mL</td>
</tr>
<tr>
<td>Methadone</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>TCA</td>
<td>1000 ng/mL</td>
</tr>
<tr>
<td>MDMA</td>
<td>500 ng/mL</td>
</tr>
</tbody>
</table>

Quality Control

An internal procedural control has been built into the test to ensure that the test performs properly. The appearance of a line in the control region (C) serves as the internal procedural control to verify that the reagents in the test are still working, and that the test is valid. The manufacturer’s recommendation for daily quality control is to document the appearance of the control line for the first sample tested each day.

The use of external controls is recommended to verify proper kit performance. Quality Control samples should be tested with each new lot, each new shipment and according to the quality control requirements of the testing facility, and/or applicable federal, state or local guidelines. When testing quality control samples, follow the same testing procedure as for testing urine samples.

Contact the Customer Service Department at Branan Medical Corporation at 1-866-468-3287 or email to info@brananmedical.com for the appropriate external controls. Do not use commercially available urine controls since these products may not be compatible with the Fastect® II Drug Screen Dipstick Test.

Expected Results

The Fastect® II Drug Screen Dipstick Test should give a negative result when testing the urine of a normal healthy person. The Fastect® II device will give a preliminary positive result when the drug or drug metabolite is present in the urine at or above the detection level. The Fastect® II Drug Screen Dipstick Test is only the first step in a two-step process for detecting drugs of abuse in urine. Any urine specimen that produced a questionable or preliminary positive result should be sent to a laboratory for confirmation testing with a more specific method.
Step-by-Step Testing Instructions

1. Open the pouch and remove the device from the pouch.
2. Write the urine sample ID number on the device.
3. Push the sleeve all the way up.
4. Dip the device into the urine sample for 10 seconds. Do not dip above the tip of the arrows.
5. Push the sleeve down to the Read Indicator Mark. Place the device on a flat surface.

Interpretation of Results

6. Read test result after 5 minutes. Do not read results after 1 hour.
7. The device may have two sides. Read test results on one side then turn the device over and read the test results on the other side.

Look at each test strip separately

Negative (–)

The result is negative when there are two red lines, one in the control region (C) and one in the test region (T).

The picture above indicates that both the THC and COC tests are negative.

Note: Any test line, even a very faint test line, is considered a negative result.

Preliminary Positive (+)

The result is preliminary positive when there is a red line in the control region (C) and no line in the test region (T).

The picture above indicates that both the THC and COC tests are preliminary positive since there are no red lines at the test region (T).

Invalid

The result is invalid when no line appears at the control region (C). The test is invalid even if there is a line in the test region (T). Do not use this result. Repeat the test using a new device. Contact Branan Medical Corporation if you have any question.

The picture above indicates that both the THC and COC tests are invalid.