

TESTCLEAR



We are your drug testing advisors.

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<http://www.testclear.com>

COCAINE ONE-STEP SCREEN HOME TEST PANEL

This cocaine one-step screen home test panel is a lateral flow chromatographic immunoassay for the qualitative detection of cocaine metabolite, benzoylecgonine, in human urine at a cutoff concentration 300 ng/mL. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is 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 used.

The Testclear Cocaine One-Step Screen Home Test Panel is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.

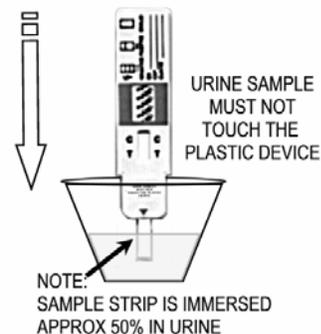
To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

DIRECTIONS FOR USE

Allow the test panel, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.



1. Bring the pouch to room temperature before opening it. Remove the test panel from the sealed pouch and use it as soon as possible.
2. Take off the cap outside of the test end. With arrows pointing toward the urine specimen, immerse the test panel vertically in the urine specimen for at least 10-15 seconds. Do not pass the arrows on the test panel when immersing the panel. See the illustration.
3. Place the test panel on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear. The results should be read at 5 minutes. Do not interpret results after 10 minutes.

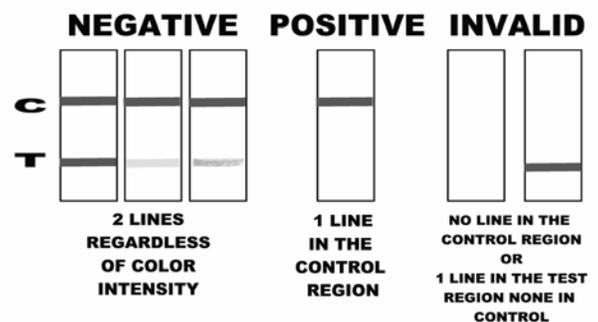


INTERPRETATION OF RESULTS

NEGATIVE: Two lines appear. One colored line should be in the control region (C), and another apparent colored or a faded color line adjacent should be in the test region (T). This negative result indicates that the drug concentration is below the detectable level. NOTE: The shade of the test line region (T) will vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: One colored line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the drug concentration is above the detectable level.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact your local distributor.



LIMITATIONS

1. The Testclear One-Step Cocaine Screen Home Test Panel provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography and mass spectrometry (GC/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A Positive result does not indicate level or intoxication, administration route or concentration in urine.
5. A Negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.