

# Clinical Reference Laboratory Stat QuikScreen® 5 Drug Test

One Step Onsite Drug Cup for COC/MET/OPI/PCP/THC

REF 60526-CRL

Instructions



## INTENDED USE

The Stat QuikScreen® 5 is a immunochromatographic assay for rapid, qualitative detection of drug combinations and their principal metabolites in urine at specified cut-off concentrations. This test is an in vitro diagnostic medical device for healthcare professional use only. This drug combination is composed from any the following drugs:

DRUG CLASS	SENSITIVITY
COCAINE/BENZOYLECGONINE	300 ng/ml
METHAMPHETAMINE	1000 ng/ml
OPIATES/MORPHINE	2000 ng/ml
PHENCYCLIDINE	25 ng/ml
MARIJUANA	50 ng/ml

*Note: The test provides only preliminary data which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.*

## SUMMARY AND EXPLANATION OF THE TEST

The Stat QuikScreen® 5 is an easy, fast, qualitative, visually read competitive binding immunoassay method for screening without the need of instrumentation. The method employs unique mixture of antibodies to selectively identify the drugs of abuse and their metabolites in test samples with a high degree of sensitivity.

Drug abuse remains a growing social and economical concern in many developed and developing countries throughout the world. The above stated drugs are among the most frequently abused illicit drugs, according to the U.S. Substance Abuse and Mental Health Services Administration.

The sensitivity of the Stat QuikScreen® 5 is set as required for the screening immunoassays of these drugs in the reference guidelines set by the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) and the U.S. Department of Health and Human Services.

## PRINCIPLE OF THE TEST

The Stat QuikScreen® 5 is a competitive binding immunoassay in which drug and drug metabolites in a urine sample compete with immobilized drug conjugate for limited labeled antibody binding sites. By utilizing antibodies that are specific to different drug classes, the test permits independent, simultaneous detection of any of the drug combinations from a single sample. The approximate run time is 5 minutes.

In the assay procedure, urine mixes with labeled antibody-dye conjugate and migrates along a porous membrane. When the concentration of a given drug is below the detection limit of the test, unbound antibody-dye conjugate binds to antigen conjugate immobilized on the membrane, producing a rose-pink color band in the appropriate Test Zone for that drug. Conversely, when the drug level is at or above the detection limit, free drug competes with the immobilized antigen conjugate on the membrane by binding to antibody-dye conjugate, forming an antigen- antibody complex, preventing the development of a rose-pink color band.

Regardless of the drug levels in the sample, a rose pink-color band is produced in each Control Zone (top bands) by a parallel immunochemical reaction. These bands serve as built-in quality control measures by demonstrating antibody recognition, verifying that the reagents are chemically active.



## REAGENTS AND MATERIALS PROVIDED

1. Test Devices. Contains dye-conjugated antibody and immobilized antigen in protein matrix with sodium azide.
2. Test Instructions. REF 60526-CRL

### Optional:

3. Negative Control I Contains buffered protein solution with sodium azide. REF 4010N
4. Cocaine Positive Control Contains BEG at 1000 ng/ml in a buffered protein solution with sodium azide. REF 12000-BP
5. Methamphetamine Positive Control Contains MET at 3000 ng/ml in a buffered protein solution with sodium azide. REF 11320-BP
6. Opiates Positive Control Contains MOR at 5000 ng/ml in a buffered protein solution with sodium azide. REF 11220-BP
7. Phencyclidine Positive Control Contains PCP at 100 ng/ml in a buffered protein solution with sodium azide. REF 14020P
8. Marijuana Positive Control Contains THC at 150 ng/ml in a buffered solution with sodium azide. REF 13020P

## WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic and professional use only.
2. Do not use the test device beyond the expiration date.
3. Urine specimens may be infectious; properly handle and dispose of all used reaction devices in a biohazard container.
4. Visually inspect the foil package to insure it is intact. If the package is not intact, the integrity of the test cup might be compromised.

## STORAGE AND STABILITY

Store test kit below 28°C; **do not freeze**. If stored at 2°-8°C, allow the test kit to reach room temperature (15°-28°) before performing the test. Refer to the expiration date for stability.

## SPECIMEN COLLECTION AND PREPARATION

Fresh urine specimens should be collected directly into the cup. The Stat QuikScreen® 5 device employs a **thermal strip which should be checked immediately** after collection to validate urine specimen. SAMHSA regulations specify that any temperature below 90.5° F must be considered adulterated. No additives or preservatives are required. *Note: Urine specimens can be transferred from a urine collection container into the Stat QuikScreen® test cup, if necessary.*

## TEST PROCEDURE

1. Do not break the seal of the pouch until ready to begin testing.
2. Remove the Test Cup from the foil pouch.
3. Collect urine specimen directly into the Test Cup. Insure that the sample amount meets the minimum level as indicated on the side of the Test Cup.
4. Read the results at 5 minutes.

**NOTE:** Negative results may be interpreted as soon as both lines have appeared. Positive results may be read from 5 to 30 minutes after test initiation. Do not use the test cup as a permanent record of test results.