

What about False Positive Results?

A screening test can give a false positive result. Certain cross reactive substances are known to occur. These can be present due to diet, prescription medicines, over-the-counter medications, etc. This is why it is important to send any sample not giving a negative result to the laboratory for further evaluation.

Analysis by the laboratory, which involves confirmation testing, will determine whether or not a drug is present in the urine. If the laboratory reports a positive result you may be assured that the drug was indeed present. However, it would be incorrect to assume the urine sample came from a drug abuser just because the result is positive. It is necessary to determine how contact with drug occurred.

Can False Negative Results Occur?

If you have observed behavioral changes which you feel could be caused by drug abuse, don't discard the suspicion just because the test result is reported negative. A false negative result can occur for a number of reasons. Certain products are being marketed as a means of defeating drug testing. These interfere with various methods used in either the screening or confirmation tests. Often, the concentration of the drugs in the urine sample is below the cut-off, or sensitivity, of the screening assay. When this occurs, the test is reported negative.

(The Following Technical Information and Additional Information for Health Care Professionals)

Performance Characteristics

The consumer study was conducted among 110 lay users who had no previous experience using drug testing products. The urine samples were prepared to contain strong negative (0% of cutoff), a very weak negative (50% of cutoff), a weak negative (75% of cutoff), a very weak positive (125% of cutoff), a weak positive (150% of cutoff) and high positive (300% of Cutoff). Pure drugs or drug metabolites were spiked into drug free human urine, the final drug concentrations in each urine sample were confirmed by GC/MS but TCA, TCA concentrations in the urine samples was confirmed by HPLC. All incorrect results were obtained at drug concentrations between 50% to 150% cutoff levels. The test results by the lay users are summarized as below:

Drug Names	Cutoff (ng/mL)	#Test	Result Interpretation		Total Agreement with GC/MS
			Correct	Incorrect	
AMP	1000	228	226	2	99.1%
BAR	300	228	223	5	97.8%
BZO	300	228	224	4	98.2%
COC	300	228	223	5	97.8%
MTD	300	228	226	2	99.1%
MET	1000	228	224	4	98.2%
MDMA	500	228	221	7	96.9%
OPI 300	300	228	222	6	97.4%
OXY	100	228	222	6	97.4%
OPI	2000	228	222	6	97.4%
PCP	25	228	225	3	98.7%
TCA	1000	228	224	4	98.2%
THC	50	228	224	4	98.2%

Quality Control

- Built-in Control: the test contains a built-in control feature, the C line. The presence of the C line indicates that the test is performed properly. If a C line does not form, the test is considered invalid. In this case, the testing should be repeated with a new device.
- External Quality Control: Control materials are not supplied with this kit. However, it is recommended that positive and negative controls should be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.
- Test each new lot and shipment by using external quality control materials (positive and negative), with each new untrained operator, monthly for storage, and as otherwise required by your lab internal quality system procedures.

Additional information and resources:

The following list of organizations may be helpful to you for counseling support and resources. These groups also have an Internet address which can be accessed for additional information.

1. National Clearinghouse for Alcohol and Drug Information
Web site: www.health.org Phone#: 1-800-729-6686

2. SAMHSA Health Information Network
Web site: www.health.org Phone# 1-877-SAMHSA-7

3. The national Council on Alcoholism and Drug Dependence
Web Site: www.ncadd.org Phone#: 1-800-NCA-CALL

4. The Parent's Resource Institute for Drug Education, Inc (PRIDE)
Web site: www.pride.org Phone#: 1-402-397-3309

5. American Council for Drug Education (ACDE)
Web site: www.acde.org Phone#: 1-800-488-DRUG

Manufactured for:
Express Diagnostics Int'l. Inc
1550 Industrial Drive
Blue Earth, MN 56013