



New Device Clearance

Psychemedics Corporation Opiate Assay

This is a brief overview of information related to FDA's clearance to market this product.

Product Name: Psychemedics Corporation Opiate Assay
Manufacturer: Psychemedics Corporation
Address: 1280 Massachusetts Avenue, Suite 200, Cambridge, MA 02138
Clearance Date: December 11, 2000

What is it? Psychemedics Corporation Opiate Assay is a laboratory test that uses hair from the back of the head to detect heroin use.

How does it work? A hair sample is taken from the back of the head. It is then treated with chemicals to release drugs trapped in the hair. If the test detects the possible presence of any drugs made from an opium plant (for example, heroin, morphine, and codeine), another portion of the hair sample is further tested (using a method called liquid chromatography/mass spectrometry) to check for 6-Monoacetyl morphine, a metabolite of heroin.

When is it used? The test is used to determine if there has been repeated heroin use over the previous three months.

What will it accomplish? Current urine testing methods can only determine if heroin has been used within a few days of testing. This test increases the window of detection to three months.

When should it not be used? This test should not be used to determine if heroin has been used within the last week or to determine if someone is currently impaired. This test should not be used with hair from any other part of the body. Positive results from this test should not be interpreted without confirmation with mass spectrometry. Positive results of this test do not show morphine or codeine abuse. A negative result should not be interpreted as proof that a person has never used heroin over the prior three months.

Additional information: Summary of Safety and Effectiveness Data and Labeling can be found at:
<http://www.fda.gov/cdrh/pdf/k000851.pdf>