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Test Result  
Interpretation

## Frequently Asked Questions About Syva's EMIT Drug-Abuse Tests

Answers for life.

**SIEMENS**

# Syva has been a leading developer and manufacturer of drugs-of-abuse tests for more than 30 years.

Now part of Siemens Healthcare Diagnostics, Syva® boasts a long and successful track record in drugs-of-abuse testing, and leads the industry in the production of enzyme immunoassays. In addition to drugs-of-abuse assays, Syva has been a key player in the development and manufacture of therapeutic drug monitoring assays.

Syva products are sold in more than 45 countries worldwide.

This booklet contains information on the reliability and accuracy of drug testing and provides answers to some frequently asked questions.

## Testing and Results

### A. What is an immunoassay?

An immunoassay is a test that uses antibodies to detect the presence of drugs and other substances in urine or blood. Each immunoassay uses antibodies that react only with that particular drug or drug class\* for which the sample is being tested. In the test mixture, these antibodies attach themselves to the drug if it is present in the sample.

### B. Who uses the drugs-of-abuse immunoassays and why?

A full menu of EMIT® urine assays is available to detect the drugs most commonly abused in our society today. Major users of EMIT drugs-of-abuse assays include hospital laboratories and emergency departments, drug and alcohol treatment programs, parole and probation agencies, prisons, work-release programs, the US military, and medical or security departments of public institutions and private industry.

\*Including drug metabolites, which are compounds resulting from the breakdown of a drug by the body.

### C. How does an EMIT drug test work?

Step by step, an EMIT drug test works as follows:

1. An EMIT drug test contains antibodies that attach themselves to a drug in a person's urine sample.
2. All the antibodies that have not become attached to a drug in the sample attach themselves to achemically-tagged drug from the EMIT test reagent.
3. A chemically-tagged drug without any attached antibody produces a chemical reaction that changes the light-absorbing properties of the test mixture. A tagged-drug that has an attached antibody is inhibited from producing the chemical reaction.
4. EMIT test instruments measure changes in the amount of light the sample absorbs, which is related to the amount of drug the sample contains. The more drug present in the person's urine, the greater the response produced. If there is no drug present in the sample, the response is lower.
5. To determine the presence or absence of a detectable drug, the sample's response is compared to the response of a calibrator, which contains a known amount of the drug. If the sample's response is less than that of the calibrator, the sample is considered to be negative. Conversely, if the sample's response is higher than or equal to the calibrator's, the sample is considered to be positive for the drug.

### D. Does an EMIT drugs-of-abuse test measure the amount of drug present in the urine?

Concentrations of compounds in urine may vary widely because of individualized excretion patterns, fluid intake, diet, and the effect of physiological and psychological stresses on kidney function. Therefore, EMIT drugs-of-abuse assays are not designed to measure the amount

of drug present in urine samples. They provide either positive or negative results, indicating the presence or absence of a detectable drug.

EMIT® d.a.u.® and EMIT II® drugs-of-abuse assays can give, in addition to positive/negative results, data that can be used to estimate the approximate concentrations of drug and drug metabolites present in a sample.

### E. What do the test results mean?

A positive result means that the drug is present in the urine sample at a level above or equal to the amount of drug in the calibrator. It does not necessarily mean that the individual is intoxicated, since there is no established relationship between the amount of drug in urine and intoxication. A negative result means that either there is no drug present in the urine sample, or the level is below that of the calibrator.

### F. How long after taking a drug can it be detected in the urine by an EMIT test?

Drugs vary considerably in how quickly they pass through the body. This variation depends on the drug; the individual's metabolism; the frequency of drug use; and the amount of drug ingested. Depending on these factors, most drugs can be detected in the urine for up to three days after being taken. Some drugs, such as methaqualone and phenobarbital, however, may be detected for as long as two to three weeks. Other drugs, such as some amphetamines and secobarbital, pass through the body so quickly that a negative result may be obtained from someone who has recently used the drug. Studies have shown that due to highly individualized excretory patterns of cannabinoids, consistently negative results may not be seen for several days to more than a month after marijuana use, particularly in the case of heavy use.<sup>1</sup>

The following table shows approximate retention times of drugs in urine.

Drug	Approximate Retention Time
Amphetamines	48 hours <sup>2,3</sup>
Barbiturates	Short acting (eg, secobarbital) 24 hours <sup>4</sup> Long acting (eg, phenobarbital) 2–3 weeks <sup>5,6,7</sup>
Benzodiazepines	3 days if therapeutic dose is ingested <sup>8</sup> Up to 6 weeks after extended dosage (ie, 1 or more years) <sup>9</sup>
Benzoylcegonine Cocaine Metabolite)	2–4 days <sup>2,10,11</sup>
Ethanol	2–14 hours <sup>12</sup>
Methadone	Approximately 3 days <sup>2,13</sup>
Opiates	2 days <sup>2</sup>
Propoxyphene	6–48 hours <sup>14</sup>
Cannabinoids	Moderate smoker (4 times/week) 5 days <sup>15</sup> Heavy smoker (smoking daily) 10 days <sup>15</sup> Retention time for chronic smokers may be 20 days <sup>16</sup>
Methaqualone	2 weeks <sup>17</sup>
Phencyclidine	Approximately 8 days <sup>18</sup> Up to 30 days in chronic users (mean value=14 days) <sup>19</sup>

Note: Interpretation of retention time must take into account variability of urine specimens, drug metabolism and half-life, patient's physical condition, fluid intake, and method and frequency of ingestion. These are general guidelines only.

### G. Can EMIT drugs-of-abuse tests determine the mode of administration?

No, the EMIT tests detect only the presence of drug in the sample.

## Test Reliability

### A. How accurate are EMIT drugs-of-abuse tests?

EMIT drugs-of-abuse tests have been shown to be among the most consistently accurate drug-testing methods in current use.

In 1988, the American Association for Clinical Chemistry (AACC) conducted a study of 31 laboratories and their accuracy in testing for drugs of abuse. This study was conducted under blind conditions, using cutoff concentrations very close to the guidelines of the Substance Abuse and Mental Health Services Administration (SAMHSA). There were no false positive results. There were a small number of false negative results (2–4%) on samples with drug concentrations close to the cutoff. Their overall accuracy rate was 97%. The EMIT Assay was the most commonly used initial test, being used 87–90% of the time, depending on the particular drug class being tested for.<sup>20</sup>

Many studies have been conducted comparing EMIT assays with other commonly used methods including radioimmunoassay (RIA), thin-layer chromatography (TLC), gas chromatography/mass spectrometry (GC/MS), gas-liquid chromatography (GLC), high-performance liquid chromatography (HPLC), bonded phase adsorption (BPA), and gas chromatography with flame ionization detector (GC/FID).<sup>21</sup> Researchers cited the ease of use, speed of performance, and excellent sensitivity of EMIT assays. One of these studies (Frederick et al) yielded a 97–98% confirmation of the EMIT assays.<sup>22</sup> Another (Jones et al) resulted in a 96% confirmation by a less sensitive method, then a 100% confirmation by GC/MS.<sup>23</sup> Kogan et al reported a 100% confirmation of 100 samples analyzed by EMIT d.a.u. drugs-of-abuse assays;<sup>24</sup> followed-up by Vereby et al, in 1986, which resulted in a 100% confirmation of EMIT assays by using BPA/TLC, RIA, and GC/MS.<sup>25</sup>

**B. Can any medications cause false positive test results?**

Medications with very similar chemical structures may sometimes produce positive results in certain tests. The levels at which tested medications may interfere are listed in the product literature accompanying each test, or in notifications mailed directly to customers.

For more detailed information, customers are invited to call the Siemens Technical Solutions Center toll free at 800-277-8994.

**C. Is it necessary to confirm a positive result? How should this be done?**

The EMIT drugs-of-abuse test provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry (GC/MS) is the preferred confirmatory method.<sup>26</sup> Other chemical confirmation methods are available.

**Cannabinoid (Marijuana) Tests**

**A. Can merely being in close contact with others who are smoking marijuana cause a non-smoker to test positive by an EMIT cannabinoid test?**

Research to study the effects of passive inhalation of marijuana has been conducted under widely varying experimental conditions. Variants include ventilation, enclosure size, length and frequency of exposure, and concentrations of THC (delta-9-tetrahydrocannabinol).

In early studies, a few positive results were obtained using the more sensitive EMIT d.a.u. Cannabinoid 20 ng Assay. However, not a single urine specimen from a passive inhaler produced a positive result using the EMIT d.a.u. 100 ng Assay with its higher cutoff level.<sup>27</sup>

It is important to keep in mind that these studies investigated the effects of passive inhalation under extreme conditions. However, it would obviously be difficult to encounter such extreme passive inhalation exposure levels in a real-life situation, without at least the tacit consent of the person exposed.<sup>28</sup> A New York study using more realistic environmental conditions showed levels insufficient to test positive, even at the 20 ng/mL level. The study concluded that under ordinary environmental conditions, detection of marijuana use is unaffected by passive inhalation.<sup>29</sup>

**B. How long after smoking marijuana can the drug be detected in the urine?**

Excretory patterns are highly individualized, but in general, consistently negative test results may not be seen for several days to several weeks after ingesting or inhaling marijuana. Heavy, chronic use will extend that period.<sup>1</sup> As seen in recent studies, the EMIT d.a.u. Cannabinoid 100 ng Assay will detect drugs in light users for 2–8 days, and in heavy users for 6–19 days.<sup>1,27</sup>

**C. If someone gives a negative result one day and a positive result the next day, does it mean they have smoked marijuana again?**

Not necessarily. Marijuana is stored in the body and is broken down into compounds that are released in an erratic pattern over a period of days or weeks. Thus, a person could produce a negative result several days after discontinuing smoking, followed the next day by a positive result. Depending on the person's frequency of marijuana use, it may take days to weeks before test results become consistently negative.

**D. How can a test for marijuana work when there are so many different types of marijuana?**

Although there are many different types of marijuana, all contain the same active ingredient; delta-9-tetrahydrocannabinol (THC), which is thought to be responsible for the “high.” This substance is broken down in the body to form a number of compounds, or metabolites. These breakdown compounds are excreted in the urine and are detectable by the tests. Because all types of marijuana are broken down to the same metabolites, they are all detected by EMIT tests.

**E. Can the EMIT cannabinoid tests be used to determine intoxication?**

No, nor can any urine test for marijuana use. No clinical or legal definition of marijuana intoxication has been established.

**Use of EMIT Drugs-of-Abuse Test Results in Court**

**A. Can EMIT drugs-of-abuse tests be used as evidence in court?**

EMIT drugs-of-abuse test results can and have been admitted as evidence in a variety of legal proceedings.<sup>30</sup> The EMIT test method is well recognized by experts as a valid method of testing for drugs of abuse.

As of this writing, the US Supreme Court has upheld the legality of mandatory drug-testing programs in three separate cases.<sup>31,32,33</sup>

Although the accuracy of the tests was never in question in any of the cases, it is interesting that in all three cases the court affirmed the accuracy of the drug-testing technology used in the programs.

Justice Anthony Kennedy, writing for the majority, stated in one of these cases, “the combination of EMIT and GC/MS (gas chromatography/mass spectrometry) tests required by the [US Customs] service is highly accurate, assuming proper storage, handling, and measurement techniques.”<sup>32</sup>

Syva Company, now part of Siemens Healthcare Diagnostics, believes that these decisions clearly validate and reinforce opinions expressed by a number of lower courts. The use of an initial EMIT test in combination with a confirmatory GC/MS test has been widely recognized by the federal courts as an accurate and reliable procedure for detecting the presence of illegal drugs in urine.

**B. In what types of court proceedings have EMIT urine drug tests been used as evidence?**

EMIT drugs-of-abuse test results have been used as evidence in the revocation of parole and probation privileges; in prison disciplinary action; and in sanctions against employees. In many such cases, EMIT test results have been used in conjunction with other evidentiary information.

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Notes: