

Siemens Healthcare Diagnostics, the leading clinical diagnostics company, is committed to providing clinicians with the vital information they need for the accurate diagnosis, treatment and monitoring of patients. Our comprehensive portfolio of performance-driven systems, unmatched menu offering and IT solutions, in conjunction with highly responsive service, is designed to streamline workflow, enhance operational efficiency and support improved patient care.

Syva, EMIT, and all associated marks are trademarks of Siemens Healthcare Diagnostics Inc. All other trademarks and brands are the property of their respective owners.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

#### **Global Division**

Siemens Healthcare  
Diagnostics Inc.  
1717 Deerfield Road  
Deerfield, IL 60015-0778  
USA  
[www.siemens.com/diagnostics](http://www.siemens.com/diagnostics)

#### **Siemens Global Headquarters**

Siemens AG  
Wittelsbacherplatz 2  
80333 Muenchen  
Germany

#### **Global Siemens Healthcare Headquarters**

Siemens AG  
Healthcare Sector  
Henkestrasse 127  
91052 Erlangen  
Germany  
Telephone: +49 9131 84 - 0  
[www.siemens.com/healthcare](http://www.siemens.com/healthcare)

[www.usa.siemens.com/diagnostics](http://www.usa.siemens.com/diagnostics)

Testing  
Processes

## Beginning the Process: A Guide for Developing a Drug-Testing Program

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.

## Introduction

Beginning the process—actually taking that first step—is often the hardest part of any new effort. But you've already completed that difficult first step by acknowledging that drug abuse may be a problem in your organization. And you've taken the second step by seeking a solution to the problem.

This brochure can help you continue your progress toward that solution by guiding you through the steps of developing a drug-testing program. Urine testing for drugs of abuse can be a valuable part of your efforts to eliminate drug abuse within your organization.

You probably have concerns and questions about starting a drug-testing program. Often an organization's first concern is the legality of drug testing. The courts have generally upheld business's right to test for drugs, if the testing is done carefully, and is based on a policy that is fairly applied and includes prior consent. However, the law in the area of drugs-of-abuse testing varies from state to state and is subject to frequent change. For this reason, employers should always obtain legal counsel when creating a drug testing program, and whenever questions arise regarding the program.

You may also be concerned about your employees' response to being tested for drugs. Although drug testing is an emotional issue, employees simply do not want to work side by side with drug abusers.

A December 1989 Gallup poll of 1,007 workers showed that, of those employees whose companies did not have a drug-testing program, 66% favored their company implementing drug testing. More than 97% of employees favored drug testing in the workplace under some circumstances.

Surveys consistently show that more and more companies are testing for drugs, and that more and more employees are supporting drug testing. Furthermore, the number of positive test results has been declining.

Clearly, momentum towards a drug-free workplace is building. With so many companies already testing, a company that does not test may find itself increasingly vulnerable to lawsuits, in the event of a drug related accident that might have otherwise been prevented by testing. This possibility, when combined with estimates that US companies lose between \$50 billion and \$100 billion annually because of drug abuse, should encourage your organization to institute a drug-testing program.

A drug-testing program that maintains the highest-quality standards should include (but need not be limited to) the following:

- comprehensive policies governing employee testing
- adequate notice to employees when a new program is initiated
- educational programs for supervisors and for all other employees
- sample handling and documentation procedures to ensure that the sample and the reported result were correctly matched
- proven test methods using stringent quality control measures
- strict adherence to confidentiality of test results
- program for counseling and rehabilitating the drug-abusing employee (usually referred to as an employee assistance program or EAP)

The Department of Health and Human Services (HHS) recommends that businesses evaluate drug-testing programs and laboratories according to the guidelines of the Substance Abuse and Mental Health Services Administration (SAMHSA). However, these guidelines were designed specifically for laboratories performing drug tests for the federal government, and cannot always be easily adapted to an industrial testing program. Therefore, SAMHSA requirements will be mentioned where appropriate in this brochure, but the discussion will not be limited to information contained in the SAMHSA guidelines.

### Developing a Policy

A well-thought-out policy is the key to a successful drug-testing program. A company should have a clear understanding of why it wants to start a testing program and what it expects to accomplish.

Because drug abuse can affect many different departments within the company, all existing company and departmental policies should be reviewed before formulating a policy. The drug-abuse policy must be consistent with other company policies, as well as existing union and other employee contracts.

A policy development committee should be drawn from the departments most directly affected. These might include the medical, human resources (personnel and benefits), safety, and security departments. Companies that have an employee counseling program should also include a program representative on the committee. The union should be represented if the policy will be part of union contract negotiations. In addition, legal counsel should be closely involved throughout the policy development process.

Some companies' policies take up only a single page, while others are quite detailed. At minimum, a drug abuse policy should contain the following elements:

- a position statement that reflects the company's views on drug abuse; that it is a risk to security; a liability to productivity; or a medical problem

- a statement of need, which usually either documents incidents that have already occurred within the company or expresses the company's desire to prevent such incidents
- a list of the company's responsibilities to its employees, and the departments that will carry out these responsibilities
- a list of employees' responsibilities or conditions of employment
- the procedures the company will implement to achieve the goals of the policy;
- the consequences of violating the policy either by testing positive for drugs, or by refusing to submit a sample

### Deciding Who Will Be Tested and When

The policy should specify who will be tested and when testing will take place. If all employees or applicants will not be tested, the policy must present a solid, nondiscriminatory reason for selecting those individuals who are tested. Management definitely should not be exempted from testing, both for nondiscriminatory, and for security reasons.

Testing is usually done at one or more of the following times:

- pre-employment
- as part of an employee's regularly scheduled physical
- whenever reasonable suspicion exists that the employee is under the influence of drugs
- following an accident
- on a random, neutral basis, without notice of when testing will occur
- as part of a program for monitoring employees undergoing rehabilitation for drug-abuse problems

Pre-employment testing is often the simplest choice for companies to implement because no union or employee bargaining is necessary to test prospective employees; only current employees are governed by existing contracts or employee agreements.

### Communicating the Drug-Testing Policy

An employee education program should not only help employees understand and accept the policy, but also increase employee awareness of the effects of substance abuse in the workplace.

Because the courts often use the company policy as an implied contract between employer and employee, companies must adhere strictly to the terms of the policy, and employees must understand these terms. A well-publicized company policy can help avoid complications in legal disputes. If employees can show they were not fully informed of a drug-abuse policy, courts and arbitrators may overturn disciplinary actions.

Employees must also be reminded of policy requirements when they are asked to produce a specimen. The requirements can be discussed at the time an employee gives written consent (required to assure due process) to both the testing, and to the release of test results to company management.

To effectively communicate and implement the drug abuse policy, managers and supervisors should be trained in the following:

- the rationale for having the policy
- how the policy was developed
- basic features of the policy
- procedures for implementing the policy
- basic drug-abuse terms and symptoms of drug use
- basic legal concerns

### Assuring a Reliable System of Drug Testing

A good testing program will both detect illegal drug use and protect those who are drug free. The following are important in assuring a totally reliable system of drug testing:

- collecting authentic, unadulterated specimens
- maintaining chain of custody (chain of custody is a legal term that refers to the ability to trace and safeguard the sample from the time it was donated by the employee or applicant through analysis to reporting of the result)

- using chemical analysis methods with proven accuracy
- monitoring the quality control of the laboratory performing the tests
- giving the applicant or employee an opportunity to explain the positive drug result

Even if a company contracts out the entire testing program (vendors can be hired to administer all aspects of sample collection and testing), the company is still responsible for ensuring that these conditions are met by the contracting agency.

### Methods of Testing

The usual approach in drug testing is to screen a batch of specimens by one test method to eliminate negative (drug-free) specimens. The samples that screen positive are then assayed by a second test method of equal or greater sensitivity to provide confirmation of the positive result. SAMHSA guidelines specify that the initial method must be an immunoassay (nearly all SAMHSA-certified labs use EMIT® Assays) and the confirmation method must be gas chromatography/mass spectrometry (GC/MS).

Companies can save both time and money by screening samples at their plant site and sending only the presumptive positive samples to an outside, commercial laboratory. GC/MS confirmation is virtually never done on site, because it requires relatively expensive and complicated equipment, thus demanding highly skilled and trained technicians. GC/MS is also not provided by all commercial laboratories.

Companies doing on-site testing should keep the following records:

- certification of instrument operator training
- instrument maintenance and service records
- daily quality-control records
- a log of the test results (often by code number).

Advantages of sending specimens to a reputable outside laboratory for both screening and confirmation include rapid confirmation of positive results; experienced drug-testing technologists; high-volume test equipment; availability of expert witnesses who can testify in legal proceedings, regarding both screening and confirmation methods; and advice on how to set up urine collection procedures.

### Choosing a Testing Laboratory

Not all laboratories are set up to perform drugs-of-abuse testing in a way that will stand up to legal challenge. The following criteria are important when evaluating drug-testing laboratories:

- Laboratory certification—laboratories certified under the SAMHSA guidelines can be counted on to provide accurate, reliable services. However, the number of SAMHSA-certified laboratories is limited. If not required by law to use a SAMHSA certified lab, a company may choose to use a laboratory certified by another accrediting body. The College of American Pathologists and the American Association of Clinical Chemists offer a Forensic Urine Drug Testing (FUDT) certification program similar to the SAMHSA program.
- Chain-of-custody procedures—laboratories should have special handling procedures for employee drug-testing specimens. These specimens should be carefully inspected, documented, and stored.
- Staff qualifications—the laboratory director should have an advanced degree in chemistry and be certified by one of the appropriate boards or societies. The technical staff should have formal training or comparable on-the-job training in laboratory technology, chemistry, or biochemistry.
- Quality-control procedures—the laboratory should include samples containing known drug concentrations with every batch of specimens that is analyzed. It should also regularly test specimens whose drug concentrations have been established by an outside source, but which are unknown to the testing staff.

- Technical assistance and expert testimony—laboratory personnel should be able to give advice about drug testing, and a staff member should be available to give expert testimony in legal hearings.
- Supplies—most laboratories provide specimen collection supplies.
- Result-reporting services—laboratories vary in the turnaround times they will guarantee. Reports relayed by telephone should be avoided because of the chance for error, the need for a permanent record, and for reasons of confidentiality.

### When the Test Result Is Positive

It is important to clarify that a positive test result shows recent use of a drug, but it does not necessarily indicate that a person's performance is impaired. Because fluid consumption and urine output vary greatly from one individual to another, urine drug concentrations cannot be consistently linked to specific levels of impairment.

A positive test indicates that the urine drug concentration is above a pre-determined cutoff level. A test is considered to be positive only when a positive screen is combined with a positive confirmation (usually by GC/MS). Requiring that the test results match virtually ensures that an error in performing or reporting either test will not cause a false positive result.

An employee should always have the opportunity to explain a positive drug test. Some of the commonly abused drugs do have legitimate medical uses. The employee may be able to supply proof, usually in the form of a doctor's prescription, that the drug was used under the care of a physician for medical purposes. However, prescription drugs can be abused by obtaining multiple prescriptions. For this reason, a medical review officer (MRO) should evaluate all information provided by the employee and determine the appropriate action to take following a positive drug test.

Employers sometimes feel that a drug abuser should be fired immediately. However, the courts look more favorably on a policy that tempers discipline with opportunities for rehabilitation.

Employee assistance programs (EAPs) that provide counseling and drug rehabilitation can be offered by the company directly or through a contract provider. If cost is a factor for a company, an effective EAP can be established that uses community alcohol and drug rehabilitation services as referral outlets for addicted employees.

In many situations, creating EAPs or allowing an employee with a drug-abuse problem to participate in a treatment program may be beneficial to the company, if it can help retain qualified and productive employees. After all, the ultimate goal of a drug testing program is to ensure that all employees are both competent to perform their jobs and productive.

The purpose of this booklet is to present a basic outline for developing a drug-testing program. If you find that you would like a more thorough discussion of the subject, we can arrange for one of our Substance Abuse Specialists to work directly with you. These consultants will analyze your particular needs and provide the right solutions for your substance-abuse program. This booklet addresses general legal issues related to employee drug analysis. It should not be used as a substitute for legal advice regarding specific programs or problems.