PROCESS AND PROCEDURES

LABORATORY TESTING

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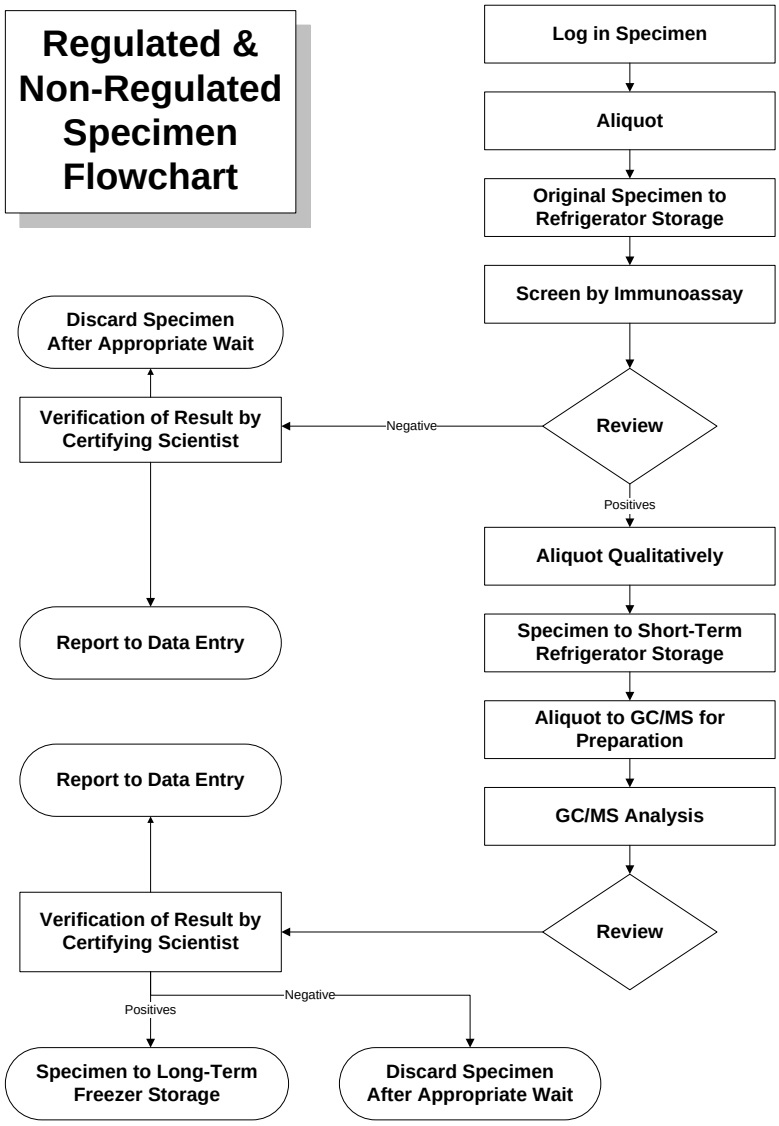
The next step in the process is the actual analysis of the sample. The lab will confirm that the sample is valid. Next, the lab will look for the different drugs of abuse specified by the federal regulations or by your company policy. This process takes place in the following manner and ends with a result being reported to the MRO.

Basic Laboratory Process Flow-Chart



What are the qualifications of the laboratory for testing the sample?

All DOT samples must be analyzed at a federally (SAMHSA) certified facility. This certification is a rigorous and on-going process administered by the National Laboratory Certification Program (NLCP) for the federal Department of Health and Human Services (DHHS). Currently, there are fewer than 40

SAMHSA-certified facilities in the country. Because of the substantial expense involved in this certification and due to the tremendous economies of scale necessary to remain cost, the number of certified labs continues to decrease each year.

Does WIN utilize a SAMHSA-certified laboratory for non-DOT samples?

Yes, WIN utilizes a certified laboratory for the analysis of all urine samples.

How do we know that we are testing a valid sample? What are validity tests?

The laboratory will perform Specimen Validity Testing (SVT) in order to determine if the sample is consistent with normal human urine. The purpose of validity testing is to determine whether certain adulterants or foreign substances were added to the urine, if the urine was diluted, or if the specimen was substituted.

Tests performed by the laboratory include Creatinine (if the Creatinine is low, also Specific Gravity), pH, and oxidizing adulterants. If there are abnormal physical characteristics, reactions or responses, or possible unidentified interfering substances, additional testing may be necessary.

What drugs will you test for?

Currently, DOT regulations limit testing to five (5) drug classes. Non-DOT testing is much more flexible and will be based on your company policy. A nine (9) panel test is frequently used for Non-DOT clients. The specific classes, cut-off and screening confirmation levels can be found in the table on the following page(s).

Expanded panels covering a wider range of narcotics, barbiturates, and benzodiazepines are also available. These typically involve a higher fee but can be appropriate to meet certain special employer needs. If you think you may need an expanded panel, please give us a call to discuss your specific situation.

What is a cut-off level and what levels are utilized in testing the samples?

The cut-off level is the point at which a sample is determined to be positive. If the drug or metabolite being tested for is present above this level, the sample is determined to be positive for that drug. While these levels can vary either by testing panel type or drug class, the DOT 5-panel and the Non-DOT 9-panel are by far the most common, and are exampled here:

DOT 5-Panel with Cut-Off Levels

Type of Drug or Metabolite	Initial Test	Confirmation Test
Marijuana Metabolites (THC Met.)	50 ng/ml	15 ng/ml
Cocaine Metabolites	150 ng/ml	100 ng/ml

Phencyclidine (PCP)	25 ng/ml	25 ng/ml
Amphetamines (Includes)	500 ng/ml	
Amphetamine		250 ng/ml
Methamphetamine		250 ng/ml *
MDA. MDMA,MDEA		250 ng/ml
Opiates	2000 ng/ml	
Codeine		2000ng/ml
Morphine		2000 ng/ml
6-acetylmorphine		10 ng/ml**

Non-DOT 9 Panel with Cut-Off Levels		
Type of Drug or Metabolite	**Initial Test**	**Confirmation Test**
Amphetamine (Includes)	1000 ng/ml	
Amphetamine		500 ng/ml
Methamphetamine		500 ng/ml
Barbiturates	300 ng/ml	300 ng/ml
Benzodiazepines	300 ng/ml	300 ng/ml
Cocaine	300 ng/ml	150 ng/ml
Marijuana Metabolites (THC Met.)	50 ng/ml	
		15 ng/ml
Methadone	300 ng/ml	300 ng/ml
Opiates (Includes)	2000 ng/ml	
Codeine		2000 ng/ml
Morphine		2000 ng/ml
Hydrocodone		2000 ng/ml
Hydromorphone		2000 ng/ml
Phencyclidine	25 ng/ml	25 ng/ml
Propoxyphene	300 ng/ml	300 ng/ml

What is the process that a sample goes through when being analyzed at the laboratory?

The testing process is made up of several steps: Accessioning / Data Entry, Screening (by immunoassay) and Validity Testing, and Certification / Verification. If the Screening test is presumptive positive, there will also be a Confirmation (by GC/MS) process. After certification and verification have taken place the result will be transmitted to the MRO.

Accessioning / Data Entry includes the initial receipt of the sample from the courier, opening of the packaging, inspection of the sample and Custody and Control Form (CCF) for fatal flaws, drawing off a

portion of the sample for the initial screening test, and placing the sample into short-term storage. At this time, the Chain of Custody Form is also reviewed by Data Entry with all applicable client, MRO and collection site information being entered into the system.

The initial screening of the sample takes place by immunoassay. Typically performed on instruments that can analyze hundreds of samples an hour, this process is fast, relatively inexpensive, and completely reliable in determining that a drug (or metabolite) is NOT present. Specimen validity testing also takes place at this time, as well.

If the initial screening test is presumptive positive for a particular drug, a second portion (aliquot) of the sample will be retrieved from the original bottle for confirmation testing. The aliquot must go through a preparation process before being analyzed by Gas Chromatography / Mass Spectroscopy (GC/MS) for the specific drug or drug metabolite. This process is much more labor intensive and time consuming. Due to the stringent requirements of accuracy and quality involved with this process, while not the norm, it is not uncommon to have this process repeated. Once completed the GC/MS result provides a completely reliable result confirming if the drug is present and, if so, in what quantity.

In order for a sample to be determined to be positive, the sample must both screen positive and confirm positive. The testing data for all results (screen negatives, samples that screen positive but do not confirm by GC/MS, as well as confirmed positives) are sent to "Certifying Scientists" for review and certification. These "certified" results are then given to data entry personnel to be transmitted to the MRO.

What problems would be considered a "Fatal Flaw" in the collection or chain of custody?

The following circumstances are considered fatal flaws and result in the termination of the testing process:

1. The specimen ID numbers on the specimen bottle and the CCF do not match;
2. The specimen bottle seal is broken or shows evidence of tampering, unless a split specimen can be redesignated;
3. The collector's printed name and signature are omitted from the CCF; and
4. There is an insufficient amount of urine for analysis.

What happens if the flaw is "correctable"?

There are several errors involving the Custody and Control Form (CCF) that can be corrected. In this case, the laboratory will attempt to contact the collector / collection site manager to obtain a Memorandum of Correction (MOC)—essentially an affidavit that will be added to the Chain of Custody.

The lab will retain the sample for a minimum of five (5) days from the time they initiate the attempt to obtain the MOC. While this delays the testing process, it provides a method to continue to analyze the

sample from this collection. If the lab is unable to obtain a MOC, they will be forced to report the sample as Rejected for Testing.

What are the possible results of the laboratory testing?

Possible results from the laboratory include:

- Negative
- Negative / Dilute
- Positive
- Positive / Dilute
- Rejected for Testing / Invalid Sample

"Rejected for Testing" include Invalid samples (i.e. non-human, oxidizing agent present, etc.) and samples with fatal flaws in the collection process.

DOT and DHHS also provide specific criteria that a laboratory must follow in determining the appropriate result of the sample.

Under DOT regulations, ALL results must go directly and only to the MRO for review. The MRO then perform their duties and submit a verified result to you as the employer.

How long should you expect for this testing process to take? What should the turnaround time be?

FROM THE TIME OF RECIEPT IN THE LABORATORY to the transmission to the MRO can vary substantially. If the sample screens negative and there are no flaws in the chain of custody form that require correcting, the process can take 24 hours or less. If the sample requires confirmation testing, you can expect this process to add an additional 24 to 48 hours. And, because of the stringent quality controls associated with these processes, that timeframe may be expanded another 24 to 48 hours. Samples requiring MOC's can, again, vary widely depending on the availability of the collector / collection site. This process can add hours or even several days to the turnaround time.

Additional FAQ's

Question: What laboratory will WIN utilize to process my test results, and is it SAMHSA certified?

WIN utilizes the laboratory services of Clinical Reference Laboratory (CRL), a SAMHSA certified laboratory that meets or exceeds all requirements for workplace or federally mandated testing programs, respectively.

Question: Once WIN receives a test result from the laboratory, is it immediately available for review and reporting?

No. Once results are received via a direct file transfer with the laboratory, the processing of that test result has only begun. Amongst many other things, we must match the CCF with the associated test result, verify its accuracy, enter the applicable information it contains, correct any discrepancies (if possible) which are found, before ultimately providing all of this information to the MRO for their review, disposition, and reporting.