

FREQUENTLY ASKED QUESTIONS

Hair Testing

DRUGS & CUTOFFS – TECHNICAL EXPLANATIONS

Q What testing methodology is used for hair tests?

A A two-tiered testing process is used:

- 1) A portion of the hair sample is screened using an Enzyme Linked Immunosorbent Assay (ELISA) - a reliable and proven methodology for routine drug testing.
- 2) Any samples that are presumptively positive in the screening process are then confirmed, utilizing another portion of the hair sample, with either gas chromatography/mass spectrometry (GC/MS) or gas chromatography/mass spectrometry/mass spectrometry (GC/MS/MS).

Q What is ELISA?

A ELISA is an acronym for Enzyme-Linked Immunosorbent Assay. ELISA assays are heterogeneous non-isotopic assays that usually have an antibody immobilized onto a solid support. The ELISA assay uses a microtiter plate that has the antibody to the drug, drug metabolite or drug class coated to each well of the microtiter plate.

Q Is ELISA forensically defensible?

A Yes, the technology is well established and has been used in many formats for the analysis of drugs of abuse, therapeutic drug monitoring (TDM), serology (antibody tests) and blood banking procedures. Furthermore, ELISA technology is used extensively in the pharmaceutical industry for new drug screening and development.

Q What is the difference between EIA and ELISA?

A EIA is the more traditional enzyme immunoassay. The technology has been widely used for the analysis of drugs of abuse. It is homogenous in nature meaning that the analysis is performed without any physical separation during the analysis. ELISA is heterogeneous — the microtiter plate is washed before the reaction is allowed to go to completion. In general, ELISA assays may offer greater sensitivity than most EIA procedures.

Q What is the difference between RIA and ELISA?

A RIA is one of the earlier types of immunoassay utilizing radioisotopes for the detection of the target analyte. The technology had been widely used for the analysis of hormones in blood samples as well as drugs of abuse. Since RIA requires specialized disposal of the residual radioisotopes, it is not considered to be as environmentally friendly as the enzyme immunoassays (EIA or ELISA).

Q What is the difference between GC/MS and GC/MS/MS?

A GC/MS is the more traditional confirmation method for drugs of abuse testing. Both technologies produce a “molecular fingerprint” of the drug or compound being analyzed and provide definitive identification. GC/MS/MS is a newer technology that is also known as “tandem MS” and generally provides greater sensitivity which is often required for the analysis of alternative specimens.

Q What is “tandem” MS?

A. Tandem mass spectrometry (MS/MS) is an analytical technique that combines two mass spectrometers into one instrument, which provides greater sensitivity. As a compound is introduced into the MS/MS, usually by a chromatographic method such as gas chromatography (GC) or liquid chromatography (LC), the first MS ionizes the compound into a few, very specific pieces. These pieces or molecular fragments are characteristic of individual compounds. They are called parent ions. The parent ions produced by the first MS can be filtered so that only specific fragments are allowed entry into the second MS. The second MS takes the parent ions and fragments (ionizes, breaks) them into smaller, highly specific pieces called product ions. The product ions are used as the “molecular fingerprint” to identify the compound of interest.

Q What is the turnaround time?

A The laboratory receives the samples via overnight courier and US Mail. Preparation of the sample for testing is performed the day the samples arrive and the initial test is completed overnight. Negative results are reported within 24 hours of receipt. Positive results are confirmed, reviewed, and reported within 48-72 hours of receipt.

Q What drugs are tested with hair testing?

A Quest Diagnostics uses hair samples to test for the following drugs:

- Amphetamines (Amphetamine, Methamphetamine, MDMA and MDA)
- Opiates (Codeine, Morphine and 6-monoacetylmorphine)
- Cocaine (and cocaine metabolites)
- Marijuana metabolite (THC Carboxylic Acid metabolite)
- PCP

Q Can hair testing detect Ecstasy?

A Yes, Ecstasy is reported under the “Amphetamines” group.

Q Can hair testing detect oxycodone or other synthetic opiates?

A No. Currently our hair testing procedures do not target oxycodone or other synthetic opiates.

Q How long does the Laboratory retain positive (non-negative) specimens?

A Non-negative specimens are retained for a minimum of 12 months (the same as non-negative urine specimens.)

Q Will the test results really reflect drug use over the past 90 days?

A Yes. Hair follicles underneath the scalp are surrounded by a dense network of capillary blood vessels. Drugs in the bloodstream are able to incorporate and bind to the hair follicles underneath the scalp. It takes approximately 5-10 days for hair containing drug to reach the outer environment on top of the scalp to be collected based on the average rate of head hair growth. Head hair grows approximately 1.3 cm or a ½ inch per month. The standard length of hair tested by the laboratory is the first 3.9 cm or 1½ inches from the root end. Therefore, a hair analysis of 3.9 cm covers a time span of approximately 90 days and detects a pattern of drug use over this timeframe. Many employers find it useful to test both hair and urine for pre-employment purposes. Urine is useful for detecting recent or new drug use (the last 1-3 days except Marijuana, which is longer) and hair for providing an approximate three-month drug history of repetitive use.

Q What is the window of detection if hair from an alternate body location (e.g. chest, arm, etc.) is used?

A The growth rate and rates of incorporation of drugs into hair from locations other than the head has not been studied as extensively as that of head hair. Consequently, one cannot reliably determine the window of detection of drugs using hair from alternative body sites.

Q Is hair analysis appropriate for workplace drug testing other than pre-employment?

A Because hair testing detects drug use over a long period, usually around 90 days, it is not an appropriate method for post-accident or reasonable suspicion testing. In both of these situations, the drug testing procedure should detect the drug as closely as possible to the time of the incident. However, hair tests are appropriate for random testing protocols – especially if hair was used for the pre-employment test or the employee has been working for more than 90 days.

Q Is it appropriate to analyze segments of hair to identify specific time periods of drug use?

A No. While head hair grows at approximately ½ inches per month, the rate of growth is not constant between or within individuals. Consequently, we are of the opinion that segmental analysis should not be used to identify specific intervals of drug use in a forensically defensible manner.

Q Does Quest Diagnostics use “wash” procedures in hair analysis?

A Yes. All hair samples are washed prior to screening and confirmation analysis to remove external contamination. Please note that the “wash” procedures were reviewed by the FDA as a part of the 510(k) clearance.

Q How do we know that Quest Diagnostics hair testing procedures are accurate and reliable?

A Quest Diagnostics hair testing assays are all FDA-cleared. Also, our procedures have been presented in peer-reviewed journals and presented at scientific meetings

REPORTING

Q How are the results reported?

A As with all laboratory-based testing, results are logged into the laboratory information system and reported to the client by confidential fax, direct interface, printer or voice response.

ADULTERATION

Q Can a hair test be beaten/adulterated?

A We have not found any adulterants that can beat the test at this time. Moreover, the risk is minimized because every collection is directly and easily observed.

Q Some competitors are saying that the Quest Diagnostics hair testing procedures are susceptible to hair treatments while theirs are not?

A There are only two FDA cleared hair testing systems. Of these, only Quest Diagnostics reported the results of studies assessing the impact of various hair treatments on all five drug assays in the publicly available FDA summaries. The other system only reported results using an opiate assay. In the Quest Diagnostics studies, specimens were tested under worst-case conditions on hair that had been previously cut into smaller pieces and tested by the laboratory (it is not practical to perform controlled studies using intact human hair on the heads of drug users.) Even using these extreme conditions, most of the treatments had minimal or no impact for all drugs except for opiates and, to a certain extent, PCP.

SUPPLIES & COLLECTION

Q Can I use my urine Custody and Control Form?

A No. There is an alternative specimen Custody and Control Form that should be used which is intended for the lab-based testing of both hair and oral fluid specimens.

Q Can the test be run if I use the regular Custody and Control Form by mistake or I have run out of the alternate Custody and Control Form?

A Yes, however the tamper-evident tape on the urine Custody and Control Form is designed for the urine bottle and is too long for the hair envelope.

Q How do I order the Hair Collection Kits?

A You can order the Hair Collection Kits from Quest Diagnostics. Order these supplies using the same procedure you use to order routine Custody and Control Forms and the urine collection kits. Either call 1-800-877-7484, send us an e-mail at poct.es@questdiagnostics.com or use the fax line.

Q What do I receive when I order Hair Collection Kits?

A Each Hair Collection Kit contains a specimen transportation bag, a Hair Specimen Collection Envelope, an alcohol pad and aluminum foil. Additionally, you will receive air bills for shipping the specimens to either the Van Nuys or Atlanta laboratory. *Please note that Custody and Control Forms must be ordered separately.*

Q How are the hair samples collected?

A In order to be fair to the donor, we must have enough hair to repeat assays if necessary. Consequently, the requested amount of hair is approximately 100 mg made up of the first 1 ½ inches (from the root end) of the hair sample. Since hair weight varies by individual and since collectors do not have access to sensitive scales, it is easier to visualize in terms of the number of hairs in the sample size.

If the hair is over 4 inches long, we require approximately 120 strands. If placed in a bundle this quantity of hair would resemble the circumference of a pencil; or if laid flat, would be approximately 1 cm in width. It is critical that the root ends of the cut hair are aligned and placed with the root ends extending about ¼ inch beyond the pointed portion of the arrow formed by the foil in the collection kit. In order to approximate time of use (prior 90 days), the laboratory will cut and use about 1 ½ inches from the root end. If the hair is shorter than 4 inches, but longer than a ½ inch, more hair is required. If the hair is curly, root ends do not have to be kept aligned and the sample size should resemble the size of a standard cotton ball.

If the donor has no head hair or hair shorter than ½ inch long, the collector may use chest, underarm, leg, or facial hair — in that order of preference. Please note the source of the sample on the hair collection envelope. This will aid in a more accurate interpretation of the results. If body hair is collected, make sure to collect as much as possible. This hair is usually lighter in weight and therefore more is needed for testing.

Q Some competitors are saying that I cannot use Quest Diagnostics if I need to test hair from an alternative body site. Is this true?

A No. Quest Diagnostics will test hair from alternative body sites and clearly indicates on the laboratory report the hair source (e.g. head, underarm, chest, etc.) While the current Quest Diagnostics hair testing FDA-filings do not include data from alternative body sites, the competitive FDA cleared system only reported data from alternative body in three of its five assays. The “Precaution and Warnings” section of the competitive FDA cleared system reported that two of the assays were designed/evaluated using head samples and two other assays were evaluated using “primarily” head hair. Of the three assays that included data from alternative body sites, two included positive data from five and four participants, respectively, and the third assay included positive samples from 12 subjects.

Q What acceptance/rejection criteria does the laboratory use for proceeding with the analysis of a hair specimen?

A The following would be reasons for rejecting a hair specimen:

- No Chain of Custody Form
- No way to link specimen with the donor
- Quantity of hair insufficient for analysis
- Length of hair less than 1 cm
- Hair contaminated with lice

TRANSPORTATION

Q How do I get the specimen to the laboratory?

A Use one of the provided air bills to ship the specimen via overnight courier to our Van Nuys or Atlanta laboratories.

REGULATIONS

Q Can hair testing be used for Department of Transportation (DOT) testing?

A No, the Department of Transportation (DOT) has not approved hair testing at this time.

Q Is the HairCheck-DT® hair test FDA-cleared?

A Yes, it is FDA-cleared.

Q What does FDA Clearance mean?

A The FDA has evaluated both performance data and labeling. An FDA cleared assay meets current standards for accuracy and reliability, including the importance of confirmatory testing when the results of the screening test are positive. Manufacturers of tests with FDA approval or clearance have provided the FDA with data to assure that their tests generate reliable results for the specimens being tested. The evaluation of accuracy and reliability includes documentation that confirmed positives are not a result of external contamination.

Q Some competitors are saying that the Quest Diagnostics hair testing procedures are not effective in releasing drug from hair. Is this true?

A No. As a part of the FDA clearance process, Quest Diagnostics has shown that its hair testing protocols generate reliable results and are effective at detecting drug in hair.

Q Some competitors say that Quest Diagnostics' own FDA filing shows that its procedures may not be effective in releasing drug from hair. Why is that?

A Let us again restate that as a part of the FDA clearance process, Quest Diagnostics demonstrated that its hair testing protocols generate reliable results and are effective at detecting drugs in hair. The protocols used to determine the “recovery” data reported in the publicly available FDA summaries for the two different FDA cleared testing systems, were very different. The Quest Diagnostics studies were designed to test the recovery of drugs from the hair of positive specimens - i.e. comparison of screening extraction procedures versus a longer process designed to recover all drugs in the hair matrix. The competitor’s studies were designed to assess the stability or ‘recovery’ of the drug during their digestion process - i.e. spiked pre- and post-digestion – not the recovery of drug from hair.

Q Have Quest Diagnostics hair testing procedures withstood legal and/or administrative challenges?

A Yes. Quest Diagnostics hair testing procedures and results have successfully withstood legal challenges in workplace testing, military proceedings and other civil jurisdictions.