



Nicotine Testing – Common Questions

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What is cotinine?

Cotinine is an alkaloid found in tobacco and is also a metabolite of nicotine. In other words, cotinine is produced when the body metabolizes nicotine after ingestion. Cotinine is used as a biomarker for exposure to tobacco. Cotinine has an *in vivo* half-life of approximately 20 hours and is typically detectable for 1-2 days after the use of tobacco.

What type of cotinine tests exist?

Test type	Length of time	Benefits	Challenges	Who should administer
Blood	Up to 7 days after nicotine use	Can be collected during other biometric tests (e.g. lipids)	Must be collected intravenously (no finger stick). Invasive. No rapid tests - results take days.	Professional biometrics service provider onsite. Lab if done offsite.
Urine	4-7 days after last nicotine use, but dependent on urine pH	Can be combined with other tests. Rapid tests can provide results within 5 minutes. Generally considered the most sensitive specimen matrix.	Invasive. Specimen can be tampered with to yield a false negative result.	Professional biometrics service provider onsite. Lab if done offsite.
Saliva	1-2 days after last tobacco use	Inexpensive and non-invasive. Observed collections mean limited possibility for specimen tampering. Rapid tests can provide results within 10 min.	Specimen collection is test-specific, so it cannot be combined with others.	HR staff or internal designee.
Hair	Depends on hair length. Most tests are standardized to limit the window of detection to 30-90 days (0.5-1.5" of hair), but they can be expanded if the length of hair is sufficient.	Non-invasive; specimen tampering is almost impossible.	Most expensive test (requires use of professional lab equipment) and is not generally used to test employees. No rapid tests - results take days.	Professional biometrics service provider onsite. Lab if done offsite.

Do other forms of nicotine (e.g. the “patch,” gum) trigger a presumptive positive test?

Yes. Any form of ingested nicotine, even when used for medicinal purposes, will trigger a presumptive positive test if the concentration of cotinine in the bodily fluid is sufficient.

Are there other ways to test for tobacco use?

Yes. Carbon monoxide can more specifically test for tobacco use. Carbon monoxide (CO) is a gas that is created while smoking, and is present on one’s breath after tobacco use. It does not test for cotinine and would not trigger a “false positive” for someone using a nicotine replacement therapy. However, CO is only detectable for up to 24 hours after last use and requires a special machine to detect its existence in the respiratory system.

Further, one can test for another tobacco alkaloid, anabasine, which accurately reports tobacco use but does not test for cotinine (avoids false positives for those on NRT). However, tests for this substance only exist within research studies and are not commercially available.

How accurate are cotinine tests?

The saliva-based cotinine test developed by Alere has been registered with the U.S. FDA as an *in vitro* diagnostic test. Testing of known cotinine-positive and known cotinine-negative saliva samples with the saliva cotinine test showed 97.6% sensitivity (ability for the test to correctly identify positive specimens) and >99% specificity (ability for the test to correctly identify negative specimens). By comparison, the lab-based saliva test showed 90.5% sensitivity and 98.0% specificity.

Does Alere Wellbeing recommend cotinine testing?

Alere Wellbeing does not believe cotinine tests are necessary to prove tobacco abstinence. Self-reported quit rates are highly correlated with biochemical verification tests (e.g. cotinine) and misreporting rates are typically no greater than 5% (Velicer, et al., 1992).

However, an increasing number of employers are choosing to implement premium differentials or tobacco surcharges that may reach as high as 50% of the total health insurance premium (under new regulations associated with the Healthcare Reform Act). Given the dollar value of these differential/surcharges, we do see a place for cotinine testing being used in two ways:

- As a randomly administered test to employees who claim to be tobacco-free when premium differentials or incentives are offered. Used in this way, the test acts as a deterrent to employees who may otherwise be dishonest about their tobacco use in order to obtain the incentive or premium differential designed for non-tobacco users.
- As a way to test new employees who join companies that have a no-hire policy for tobacco users. NOTE: Several states have anti-discrimination laws in place around decisions to not hire or to fire individuals based on their choice to participate in a legal activity in their homes. As with any policy change, we recommend clients consult legal counsel when enacting such policies.

How does Alere Wellbeing recommend testing?

Alere Wellbeing takes no specific position on when or how to test. We believe the key components to creating a successful nicotine testing policy include:

- Randomly testing employees. The random nature of the test will encourage those who may be tempted to lie about their tobacco use to be more truthful or take advantage of the opportunity to quit.
- Clearly communicating why the tests are being done (e.g. in support of the larger premium differential) and what options are available if one tests positive.

- Not being punitive in response to a positive test; communicate the possibility of a false positive; provide the opportunity to test again; and encourage enrollment in the Quit For Life® Program for assistance with quitting.

What nicotine test does Alere Wellbeing recommend?

We recommend the Alere™ iScreen® OFD. Alere, one of the world's leading toxicology companies, has created an inexpensive, convenient, saliva-based test that can be used onsite and delivers results in as quickly as 10 minutes.

What happens if an employee tests positive for cotinine?

When an employee tests positive for cotinine, we refer to it as a “presumptive positive”. To verify the result, a confirmation test may be required by law when employment decisions are being made, and is recommended if the test is being used to determine eligibility for insurance premiums. Alere Wellbeing offers the Quantisal™ Collection Device for clients interested in confirmation testing. The Quantisal™ Collection Device can be ordered directly from Alere Wellbeing. The device costs \$3 (per device), comes with a chain of custody form, specimen transport pouch, FedEx shipping pouch, prepaid shipping, and can be ordered and paid for in advance.

Laboratory fees are separate and a Client Service Manager can assist clients with setting up an account with Alere Toxicology. Clients will only be billed for confirmation lab services when tests are sent in for confirmation. At that time, clients will be billed \$22 for each confirmation service.

The following information is needed to setup an account with Alere Toxicology Lab:

- Billing information
- Shipping information
- Secure fax number for reporting
- Point of contact and contact information

The following steps should be taken to perform confirmation testing:

- Complete chain of custody form
- Collect the sample with the Quantisal™ Collection Device
- Package for shipping
- Ship to laboratory

What does Alere Wellbeing recommend employers do if an employee tests positive, and nicotine testing is being used to determine incentive eligibility?

If an employee tests positive, we recommend providing them with two options:

1. Enroll in the Quit For Life® Program and complete required activities to receive the incentive/premium discount.
2. Employees can choose to continue using tobacco and not receive the incentive.

Is it possible to get a false positive?

All biochemical tests have some chance of triggering a false positive. While the sensitivity of most tests would likely not be triggered by small amounts of second hand smoke exposure, frequent exposure could trigger a positive outcome. Further, use of nicotine replacement therapy, which is a recommended part of any quitting process, would also trigger a positive test result even though the person may have quit smoking.

In cases where the employee continues to insist that he or she is not a tobacco user or claims to be using a nicotine replacement therapy, Alere Wellbeing recommends confirmation with a lab-based test or re-testing the individual at another time and suggesting that the individual avoid frequent exposure to second-hand smoke. We recommend clients seek legal guidance for any test program used for any hiring/firing purpose to ensure compliance with all statutes and laws.

Can Second Hand Smoke trigger a false positive?

The level of cotinine required to trigger a positive result (30ng/mL) would require significant exposure to Second Hand Smoke (SHS) and is high enough to eliminate most potential false positives from SHS.

What if an employee is using nicotine replacement therapy (NRT)?

As cotinine is a metabolite of nicotine, individuals using nicotine replacement therapy (such as the patch or gum) will test positive for cotinine and therefore should not be tested. We recommend adding a third option to your affidavit for “recently quit, currently using NRT.” For individuals claiming use of NRT we recommend the following options:

1. Advise them to enroll in the Quit For Life® Program and complete the required activities to receive the incentive.
2. Test employee using CO monitor which measures carbon monoxide, not cotinine, if there is no trace of Carbon Monoxide, employer awards employee the discount.
3. Retesting at a later date

Will e-cigarette users test positive for cotinine?

E-cigarettes do contain nicotine and therefore users will test positive for cotinine. E-cigarettes have not been approved by the FDA as a nicotine replacement therapy; however we recommend clients follow the same procedure for e-cigarette users as that for employees who claim to be recently quit and using NRT. Individuals who fall into this category and are randomly selected for nicotine testing should be considered a non-tobacco user and tested at a later date. Clients should develop their own policy for those rare instances where individuals are using e-cigarettes recreationally on a long-term basis (i.e. not as part of a tobacco cessation regime).

Do we need to have a healthcare professional administer the iScreen OFD test?

No, the saliva-based test is easy to administer and can be done by any designated staff member. Each test comes with detailed instructions for use.

What is the best way to communicate this program to employees?

We recommend using the customizable templates we provide to communicate this new policy to your employees. Alere Wellbeing has sample text available for introductory letters or email announcements about the implementation of nicotine testing.

Are there other tests on the market like the iScreen OFD?

The Nic Alert™ test is an example of another test that provides instant results. Nic Alert™ is more expensive than the iScreen OFD, it is not contained (requires a strip and collection cup), and it takes 30 minutes for results compared with 10 minutes for the iScreen OFD. Other instant result tests are more complex, more expensive and take longer to perform and interpret.

Why are some tests less expensive than the iScreen OFD?

There are point-of-care urine tests that are available inexpensively but require the handling and collection of urine as a specimen.

Other devices may appear less expensive and are sold online, but these are only the collection device and must be sent to a laboratory for screening and confirmation services.

Who can I call with questions about administering the test?

For any technical or service questions you can call: 1-800-340-4029

