

PRODUCT INSTRUCTIONS



A150

Product Number 31150

FOR THE QUANTITATIVE DETERMINATION OF ALCOHOL IN SALIVA FOR *IN VITRO* DIAGNOSTIC USE

INTENDED USE

The OraSure Technologies' Q.E.D.® Saliva Alcohol Test is intended for the rapid, accurate quantitative determination of alcohol in saliva.

These products are recommended for professional use in the evaluation of persons suspected of being intoxicated and as an aid in the management of alcoholism.

SUMMARY

Ethanol is the most common toxic substance encountered in medical cases. Not only is it lethal in its own right, but is commonly a contributory factor in accidents of all types. In the case of a patient brought to the hospital in a coma, the effect of alcohol, if any, must be ruled out in a differential diagnosis of the cause of coma.¹

The distribution of alcohol in saliva and blood is well established with the concentration of ethanol in saliva being approximately 1.07 times higher than the corresponding blood alcohol level.^{1,2} While there is good correlation between blood and saliva alcohol levels, normal physiological variability in these levels does exist. In situations where exact blood alcohol concentrations must be known, follow-up testing of patients with positive Q.E.D.® test readings should be performed. Appropriate follow-up tests include whole blood alcohol determinations using gas chromatography.

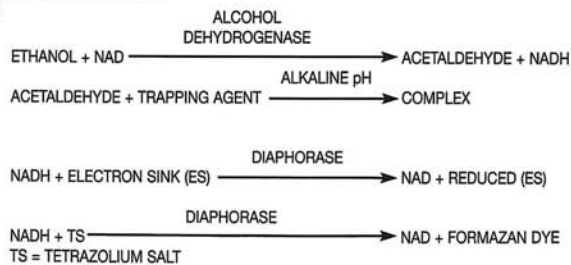
PRINCIPLE

The Q.E.D.® Saliva Alcohol Test uses alcohol dehydrogenase to catalyze the oxidation of ethanol to acetaldehyde, with the simultaneous reduction of nicotinamide adenine dinucleotide (NAD).³ An alkaline pH and an acetaldehyde trapping agent force the reaction to generate one mole of NADH for each mole of alcohol present.

In the presence of an oxidizing agent (the Electron Sink), diaphorase and a tetrazolium salt, all of which are incorporated into the solid phase, NADH is oxidized and a colored end product is formed. The length of the resulting colored bar is directly proportional to the concentration of ethanol in the specimen.

Chemical Reaction Sequence

Fig. 1



REAGENTS

Each Q.E.D.® Saliva Alcohol Test contains alcohol dehydrogenase, diaphorase, NAD, an oxidizing reagent and a tetrazolium salt, all of which are immobilized on a solid substrate.

PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Patient specimens and used tests contain potentially infectious, human saliva; handle with appropriate care.
3. Because this test is visually read, it should not be interpreted by readers who are color-blind or visually impaired.

REAGENT PREPARATION AND STORAGE

Q.E.D.® Saliva Alcohol Tests are ready-to-use. No additional preparation is required. The storage and usage of Q.E.D.® tests at room temperature 15-30°C (59-86°F) is recommended.

An unopened Q.E.D.® test is stable until the date printed on the pouch when stored as recommended. Once the pouch has been opened, the Q.E.D.® test must be used immediately.

SPECIMEN COLLECTION

NOTE: Accurate alcohol level determination requires that samples be collected at least 10 minutes after eating or drinking anything—especially alcohol-containing substances.⁴

1. Open the foil pouch immediately prior to use and remove the Q.E.D.® Saliva Alcohol Test and desiccant packet.
2. Discard the desiccant packet. The central stripe of the device and QA Spot™ at the closed end of the Q.E.D.® device should not be purple. Discard any device in which these areas are purple.
3. Place the cotton-tipped end of the collector in the mouth and swab around the cheeks, gums, and under the tongue for 30-60 seconds or until cotton is thoroughly wet (Fig. 2).
4. Complete the remainder of the test at once.

CALIBRATION

The Q.E.D.® Saliva Alcohol Tests are precalibrated. No additional calibration is required.

TEST PROCEDURE

Materials Provided:

- Q.E.D.® A150 Saliva Alcohol Test (Product Number 31150)
10 Ready-to-use Q.E.D.® A150 Tests (0-145 mg/dL) and Specimen Collection Swabs
1 Product Instructions

Materials Not Provided:

Quality Control Material: Q.E.D.® Ethanol Controls (Product Numbers 31050S, 31150S)
Timing device capable of accurately measuring 2, 5, and 10 minutes

Test Procedure:

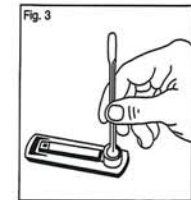
Note: It is recommended that all tests be run at room temperature 15-30°C (59-86°F).

1. Open the foil pouch and remove the Q.E.D.® test immediately prior to use. Discard any test in which the desiccant pack indicator has turned pink. Discard any test in which the central stripe of the device or QA Spot™ is purple.



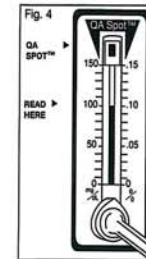
2. Actively swab around the cheeks, gums and under the tongue for 30-60 seconds or until the cotton swab is thoroughly wet.

The cotton must be saturated.



3. Place the Q.E.D.® test on a flat surface. Insert the collector into the entry port; then apply gentle, steady pressure until the pink fluid flows past the QA Spot™ at the end of the device.

With the filling method, the key is to apply gentle, steady pressure and to watch the capillary fill. The background color should appear pink after the capillary is filled.



After the test is complete, examine the QA Spot™ located at the closed end of the device. The QA Spot™ should be purple. Any purple color across the QA Spot™ area is considered acceptable. Read the alcohol concentration from point on the scale where the purple bar stops. If bubbles appear in the device, read the alcohol concentration from the highest point on the scale where the purple bar stops.

The test is invalid if the QA Spot™ is not purple after 5 minutes.

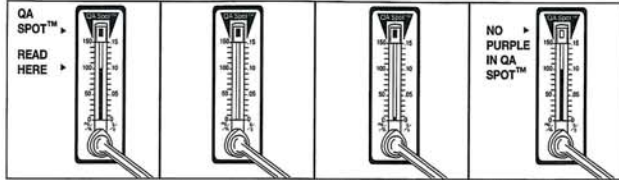
4. Do not pick up the Q.E.D.® device until the test is complete. The Q.E.D.® A150 test is complete in 2 minutes.

NOTE: Do not remove the swab after it has been inserted. Removal and reinsertion of the swab may cause bubbles to form in the device and may make the test result difficult to read.

IMPORTANT TEST PROCEDURE TIPS

1. Be sure to actively swab around the mouth until the cotton is **thoroughly wet**. The QA Spot™ will not turn purple unless activated by the sample. Repeat any test in which the QA Spot™ does not turn purple.
2. The red dye in the filter colors the saliva pink to aid in visualization of the capillary filling. The background color should appear pink after the capillary has been filled. The QA Spot™ will turn purple to indicate that the test procedure was performed correctly.

Interpreting Q.E.D.[®] A150 Test Results



Valid Test - Positive Reading: 100 mg/dL (.1%)
 Valid Test - Negative Reading: 0 mg/dL (0%)
 Valid Test - Negative Reading: Less than 10 mg/dL (.01%)
 Invalid Test - QA Spot™ did not turn purple. Repeat Test.

QUALITY CONTROL

The functionality and stability of the Q.E.D.[®] test can be determined by examination of the QA Spot™ located at the closed end of the device. The QA Spot™ will turn purple **within 5 minutes** after the device has been completely filled with saliva. The purple color indicates that the device has been properly filled and that the chemical reagents contained in the device are fully functional.

Normal and Ethanol Controls

Quality Control materials are useful in determining assay reliability and performance. OraSure Technologies recommends that both normal and ethanol controls be run upon receipt of each new lot. Because ethanol is not normally present in the body in measurable quantities, normal saliva contains essentially no ethanol. Use distilled or deionized water for the normal control. Use the Q.E.D.[®] Ethanol Control for the positive control.

Substitute control materials for the patient sample. For ethanol controls, compare the Q.E.D.[®] test result to the range of expected values published in the OraSure Technologies' Q.E.D.[®] Ethanol Control product instructions.

Failure to achieve expected control values may be an indication of problems with user technique or assay reliability. Contact OraSure Technical Service if you require assistance 800-869-3538.

RESULTS

Test results are read directly from the Q.E.D.[®] test device designated by the end of the colored bar. The length of the bar is directly proportional to the concentration of ethanol in the sample. The Q.E.D.[®] test device has concentration scales in both mg/dL and %.

The Q.E.D.[®] Saliva Alcohol Test results are directly correlated to whole blood alcohol concentrations. There is no need to correct the Q.E.D.[®] test result to account for the 1.075:1 distribution between alcohol levels in saliva and blood.

Alcohol levels of less than 0.01% (10 mg/dL) should be reported as negative for alcohol.*

The Q.E.D.[®] Saliva Alcohol Test is a precise and accurate means of measuring whole blood alcohol levels through saliva alcohol determinations. However, in situations where exact blood alcohol concentrations must be known, follow-up testing of patients with positive Q.E.D.[®] readings should be performed. Appropriate follow-up testing includes whole blood alcohol determinations using gas chromatography.

LIMITATIONS

Accurate alcohol level determination requires that samples be collected at least 10 minutes after eating or drinking anything - especially alcohol-containing substances.

DYNAMIC RANGE

The Q.E.D.[®] A150 Saliva Alcohol Test is accurate from 10 - 145 mg/dL (0.01 - 0.145%).

Should quantitation of alcohol levels in excess of 0.145% (145 mg/dL) be necessary, another method should be employed.

EXPECTED VALUES

Alcohol is not normally present in saliva in measurable quantities, i.e., less than 10 mg/dL.*

PERFORMANCE CHARACTERISTICS[†]

Precision

Using the procedure outlined above, repetitive analysis with OraSure Technologies' Q.E.D.[®] Saliva Alcohol Test resulted in the following precision:

Q.E.D.[®] A150 Test

Level	Replicates	Mean mg/dL	S.D. mg/dL	C.V. %
Moderate	n=20	66.1	2.2	3.4
Elevated	n=20	107.6	4.0	3.7

Day-to-Day (5 day Period)

Level	Replicates	Mean mg/dL	S.D. mg/dL	C.V. %
Moderate	n=20/day	65.6	2.1	3.2
Elevated	n=20/day	109.4	3.6	3.3

Accuracy

The accuracy of OraSure Technologies' Q.E.D.[®] product was evaluated by comparison to another enzymatic method. The Q.E.D.[®] test was also compared to gas chromatography using whole blood.[‡]

A summary of the results of these comparisons appears below:

Q.E.D. [®] A150 Test		Correlation Coefficient	Regression Equation
Method	Sample		
GC	whole blood	n=168 r=0.98	y=1.03x - 2.4
enzymatic	saliva	n=71 r=0.98	y=0.94x - 2.0
enzymatic	serum*	n=54 r=0.97	y=0.83x + 5.0

*Serum alcohol levels are reported to be approximately 1.2 times (1/0.83) higher than blood levels.[‡]

The correlation between saliva and blood alcohol levels is reported to be 0.96-0.97.^{‡‡}

Specificity

The following substances have been evaluated and do not interfere with the Q.E.D.[®] Saliva Alcohol Test at the concentration indicated.

Compound	Concentration (mg/dL)	Compound	Concentration(mg/dL)
Ethylene Glycol	17.5	1-Propanol	7
Acetone	70	2-Propanol	35
Methanol	70	1-Pentanol	7
1-Butanol	7	Ascorbic Acid	3.5
2-Butanol	35		

Using alcohol-containing products such as mouthwash, cough syrup, breath spray, or chewing tobacco may cause elevated results. Refer to limitations section.

REFERENCES

1. Tietz, R.W., Fundamentals of Clinical Chemistry, W.B. Saunders Company, Philadelphia, PA, 1976.
2. Jones, A.W., Inter- and Intra-Individual Variations in the Saliva/Blood Alcohol during Ethanol Metabolism in Man, J. Clinical Chemistry, (1979) 25, pp. 1394-1398.
3. Bergmeyer, H.U., Methods of Enzymatic Analysis, Academic Press, New York, (1965), p. 285.
4. Dubowski, K.M., Alcohol Analysis: Clinical Laboratory Aspects, Part II, Laboratory Management, April, 1982, p. 27.
5. Data on file, OraSure Technologies, Inc., Bethlehem, PA.
6. Jones, A.W., Distribution of Ethanol Between Saliva and Blood in Man, Clinical, and Experimental Physiology, 6, (1979), pp. 53-59.

PRODUCT AVAILABILITY

Product #	Description
31150B	Q.E.D. [®] A150, case of 30 tests
31150C	Q.E.D. [®] A150, case of 100 tests
31050S	Q.E.D. [®] DoT Ethanol Control
31150S	Q.E.D. [®] A150 Ethanol Control
31000V	Q.E.D. [®] Alcohol Procedure Video
31150T	DoT STT Training Kit
31150X	DoT STT Extra Student Kits

The Q.E.D.[®] Test is a single use alcohol screening device to be administered by a certified Screening Test Technician or trained professional. IN NO EVENT SHALL ORASURE BE LIABLE FOR ANY DIRECT OR INDIRECT CONSEQUENTIAL, INCIDENTAL OR SPECIAL DAMAGES.

TECHNICAL ASSISTANCE

For further information and technical assistance, contact OraSure Technical Service: 1-800-869-3538

Manufactured by:



OraSure Technologies, Inc.

diagnostic solutions for the new millennium

1745 Eaton Avenue, Bethlehem, PA 18018
 Phone 610-882-1820 • Fax 610-882-1830
 www.orasure.com

ECREP European Representative:

OraSure Technologies, Inc.
 Fokkerstraat 11
 2811 EN Reeuwijk
 The Netherlands



QED SALIVA ALCOHOL TEST

The On-The-Spot Leader in Alcohol Testing



The **QED A150 Saliva Alcohol Test** is easy to operate and provides quantitative results that are as accurate as a blood test. This self-contained test serves customers anywhere, any time. Uses include home, workplace, criminal justice, hospital emergency, psychiatric and occupational health departments to name just a few.

QED Saliva Alcohol Test Advantages

- Q.E.D.? A150 Saliva Alcohol Test has a quantitative range of 0 - 145 mg/dL (0.0% - 0.145% BAC).
- Q.E.D.? Quality Controls
- Quantitative results in 2-5 minutes
- Reads like a thermometer
- Long shelf life
- Built-in quality control spot
- CLIA waived High correlation to blood analysis
- Non-invasive
- No instrumentation required
- DOT-approved Screening Test Technician (STT) video training kit available .
- In clinical trials, saliva alcohol levels measured by the Q.E.D.? demonstrated high correlation to blood analyzed by gas chromatography ($r=0.98$).



How It Works



Collecting saliva: Actively swab around the cheeks, gums, and under the tongue for 30-60 seconds until the cotton swab is thoroughly saturated.

Filling the capillary: Place the Q.E.D.? test on a flat surface. Gently twist the collector into the entry port. Apply gentle steady pressure until the pink fluid passes the QA Spot at the end of the device.

Interpreting test results: Allow two (2) minutes for the Q.E.D. A150 test to develop. The QA spot must be dark purple to indicate a valid test. If the same color forms a bar within the measurement scale, read the highest point. Ignore bubbles.

FAQ

1. What does a positive reading look like with the Q.E.D. test?

When a QED test result is positive a dark purple color bar forms within the measurement scale. This color is distinctly darker than the pink or orange color seen as the sample fills the device. The color bar on a positive test - the same color seen in the QA spot develops in 2 minutes.

2. How hard should I press down with the QED applicator?

Gently apply slow and even pressure when placing the swab in the entry port. Too much pressure can jam the test. For best results, gently twist the collector into the entry port until the cotton touches the red filter pad and then begin pressing.

3. What does the Clinical Laboratory Improvement Act (CLIA) waiver mean for workplace testing?

Because work site testing is considered forensic testing, CLIA regulations do not apply. The waived status for the QED? Saliva Alcohol Test under CLIA '88 makes testing easier in hospitals, rehabilitation centers and treatment facilities where our test is used as an in-vitro diagnostic tool.

4. Does the QED? test measure residual alcohol in the mouth or is it measuring the alcohol within the entire body (blood stream)?

Beverage alcohol (ethyl alcohol) is absorbed directly and unchanged into a person's body and is evenly distributed throughout the blood stream and other bodily fluids, including saliva. The QED? test measures the amount of alcohol in bodily fluids, commonly called blood-alcohol concentration, or BAC. Residual alcohol in the mouth just after a person takes a drink is quickly absorbed, swallowed, or evaporated, and a person's mouth is "clear" of residuals 10 minutes after eating or drinking.

5. Do you have a Screening Test Technician (STT) training video for non-Department of Transportation (DOT) settings?

While the STT Training Video is DOT-approved and covers the DOT regulations, it should not be viewed as a "DOT only" product. Companies with alcohol testing policies would do well to use the DOT program as a model, in case their program was ever challenged. Similarly, test technicians should consider DOT-certification as a way to further validate their ability to do the testing.

6. How can a company use the Screening Test Technician (STT) training video to certify an STT if no one at the company is already certified?

Think of the STT training video as a high-tech version of the DOT's model course for STTs, published by the Government Printing Office. A company always had the option to order the DOT model course, have someone read the entire document, and then let that person certify an STT. The video simplifies the process. A company's "facilitator" can now watch the video and read through a special guide, then show the video to a student and use the training aids to certify that person as an STT.

7. Can a "facilitator" become certified while taking a student through the video course?

No. The DOT ruled that STTs cannot certify themselves. However, once a student is certified, the student can be the facilitator, and the facilitator becomes the student.

8. How will planned revisions to the DOT Regulations affect my certification?

The DOT has released its proposed new rule, the comment period on which closed April 7, 2000. The DOT is advocating re-certification for all STTs every two years. OraSure Technologies, Inc. will continue its "train the trainer" program for STTs to help people comply with current and future regulations.

9. Will the QED? test react with ketone often found in the saliva of diabetic patients?

No. Unlike breath analyzers and other saliva tests, the QED? test is specific to ethyl alcohol and will not cross-react with acetone and ketone produced by diabetic patients.

10. Will the QED? device work if it is stored at temperatures outside the range on the packaging?

Storing and using QED? tests at room temperature (15-30°C, 59-86°F) insures optimal performance and a full shelf life. However, the QED? test will work fine if exposed to temperatures outside that range for limited periods. The QED? device has been tested under a wide range of temperatures and storage conditions -- simulating the inside of a vehicle glove box on a hot summer day (about 120°F) and the lonely cold of North Dakota in January (about 0°F). In all cases, the test performed as it should. Before using a QED? Saliva Alcohol Test exposed to extreme heat, allow the device to cool to room temperature; if the QED? device is exposed to extreme cold, put it into a pocket to warm it up.

11. How can companies using the QED? test in very remote areas comply with the DOT's requirement that confirmation tests on positive screening tests must be conducted within 30 minutes?

The DOT will accept results of confirmation tests conducted more than 30 minutes after a positive screening test. Look to 49 CFR Part 40 section 40.65, paragraph (b). The DOT added a sentence which directs the Breath Alcohol Technician (BAT) to simply explain "why?" if a confirmation test is done more than 30 minutes after a screening test. This is not a fatal flaw.

12. Why should I buy the QED? Saliva Alcohol Test if I need an Evidential Breath Testing (EBT) to confirm positive test results?

The QED? test is much less expensive to operate than a breath test, unless you conduct a very high volume of tests in a central location. By and large, each test done on saliva instead of breath saves money. Plus, performing two independent tests is more legally defensible on the rare occasion an employee does test positive for alcohol.

13. What are the quality control (QC) requirements for the QED? test?

Control checks, using OraSure Technologies' QED? ethanol control solution should be run once per lot number of QED? tests. CLIA waived status eliminated the need for daily control checks.