



## ***Q.E.D.® Saliva Alcohol Test***

*A Quantitative Test for the Determination of Equivalent Blood Alcohol Content (BAC) Using a Saliva Sample. Approved by the Federal Department of Transportation (DOT) for Commercial Alcohol Testing Programs. Simple as Reading a Thermometer.*

### **PRINCIPLE**

The Q.E.D.® Saliva Alcohol test is a techno-logical breakthrough that can be used as an accurate, quantitative measurement device for

- Non Invasive, Quantitative Results in 2-4 Minutes
- Interpretation like Reading a Thermometer
- Long Shelf Life of 1 Year Plus
- Individually Sealed in Foil Envelope with Cotton Swabs
- Built-in Quality Control and Calibration
- U.S. DOT Approved for Testing and Evidence
- High Correlation ( $r=.098$ ) to Blood Analysis results
- No Special Equipment or Training Required

obtaining blood alcohol levels using a saliva sample. The test can reliably be used in place of blood, urine, or breath testing methods which require expensive equipment and operator training. Through a preset chemical reactive process that requires no user intervention, a color bar rises to the level of alcohol present in the system in much the same way as a mercury thermometer. In extensive clinical trials, saliva alcohol levels measured by the Q.E.D.® Saliva Alcohol test demonstrated a high correlation rate of 98% ( $r=0.98$ ) to blood analyzed by sophisticated laboratory gas chromatography methods.

## TEST PROCEDURE

The Q.E.D.® Saliva Alcohol Test is an easy to use diagnostic procedure with everything required contained in a sealed foil package. Total time required for the test is between 3 and 5 minutes. The three basic steps are as follows:



1. Using the cotton swab included, actively swab around the cheeks, gums, and tongue for 30-60 seconds or until the cotton swab is completely saturated with saliva.

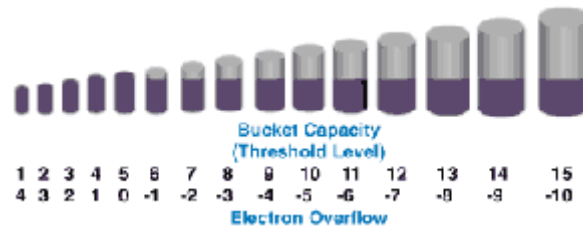
2. Place the test device on a flat surface. Gently twist the swab with the collected saliva sample into the entry port and apply steady pressure to activate the capillary action until the pink fluid passes the QA Spot™ located at the top of the test device.

3. Read the test results. Allow the test device to develop for two minutes. A distinct purple bar will form within the marked scale region. The highest point of the purple bar represents the level of Alcohol expressed as either a percentage (.0x%) or milligrams (mg/dL) concentration.

The Q.E.D.® Saliva Alcohol Test will accurately measure a range of blood alcohol concentration of 0-145mg/dL or 0.0%-0.145%, the top range being almost twice that of the legal limit of 0.08

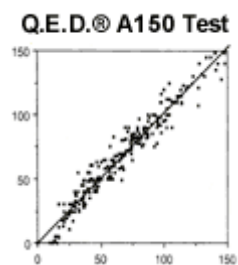


## Diagram of Enzyme Chemistry Used by the Q.E.D.® Test



Available electrons fall into the electron acceptor buckets.

Color forms only when the buckets are filled or overflow.



Q.E.D.® (Saliva) vs. G.C. (Whole Blood) Study done at Thomas Jefferson Hospital, Philadelphia, PA

**On-Site Simplicity with Clinical Lab Accuracy** The Q.E.D.® test can be used as an accurate screen in place of blood or breath tests. In clinical trials, saliva alcohol levels measured by the Q.E.D.® demonstrated high correlation to blood analyzed by gas chromatography ( $r=0.98$ ).

The Q.E.D.® A150 test has a quantitative range of 0 - 145 mg/dL (0.0% - 0.145% BAC).

DOT-approved Screening Test Technician (STT) video training kit available from a national network of factory-certified trainers and distributors.

## FAQs on Q.E.D.® Saliva Alcohol Test

### 1. What does a positive reading look like with the QED® 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 work site 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. One customer asked if "using the QED® Saliva Alcohol Test was just a matter of spitting on to those little thermometers?"

The QED® test does provide laboratory accuracy with on-site simplicity, but spitting is not polite and we wouldn't want to support bad manners.

### 6. When are you going to make 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.

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

The DOT requires that the STT Training Video Facilitator be someone with at least one year's experience working as an STT or training STTs. Without that experience, a Facilitator must complete a "train the trainer" STT course offered by OraSure Technologies or an authorized QED Distributor or STT Trainer.

### 8. 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.

### 9. 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.

### 10. Can books in the (Screening Test Technician) STT video kit be copied?

No. The materials are copyrighted and therefore cannot be reproduced. It is for that reason we have produced additional student kits. QED® distributors price extra student kits inexpensively to encourage additional certification under the law.

### 11. 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.

**12. 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. We tested the QED® device 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.

**13. 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.

**14. 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.

**15. 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.