

PRODUCT INSTRUCTIONS



A150

Product Number 31150

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**QED A150 Employee Drug Testing Kits**



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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.<sup>1</sup>

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.<sup>2</sup> 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.

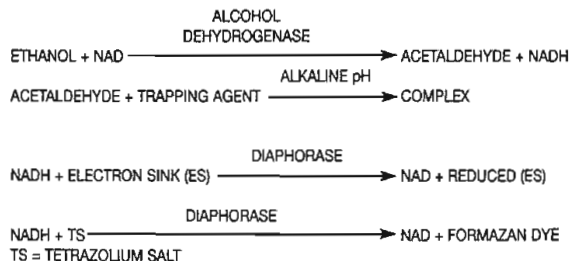
**PRINCIPLE**

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).<sup>3</sup> 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.<sup>4</sup>

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:**

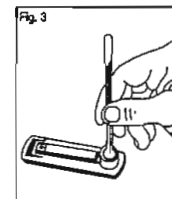
Note: It is recommended that all tests be run at room temperature 15-30°C (59-86°F).

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.



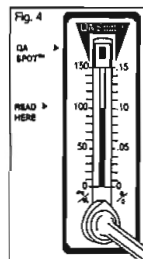
2. Actively swab around the cheeks, gums and under the tongue for 30-60 seconds or until the cotton swab is thoroughly wet.

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.

