



One Step Alcohol Saliva Test Strip

Cat. No. W53-S

INTENDED USE AND SUMMARY

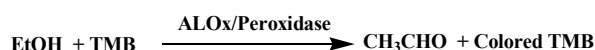
One Step Alcohol Saliva Test Strip is intended for use as a rapid method to detect the presence of alcohol in saliva for alcohol concentration (BAC) greater than 0.02%. It has been published that the concentration of alcohol in saliva is almost equal to that in blood.

The rapid test is intended for the semi-quantitative detection of ethyl alcohol in human saliva. To confirm the concentration of positive specimens, an alternate, non-enzymatic technology such as headspace gas chromatography should be used.

For *in vitro* use only. For professional use only.

PRINCIPLE

One Step Alcohol Saliva Test Strip is based on the high specificity of alcohol oxidase (ALOX) for ethyl alcohol in the presence of peroxidase and enzyme substrate such as tetramethylbenzidine (TMB) as shown in the following:



The distinct color on reactive pad could be observed in less than 20 seconds after the tip was contacted with saliva samples with the ethyl alcohol concentration greater than 0.02%. It should be pointed out that other alcohols such as methyl, propanyl and allyl alcohol would develop the similar color on the reactive pad. However, these alcohols are not normally present in saliva.

PRECAUTIONS

1. For *in vitro* use only.
2. Discard after first use. The test strip cannot be used more than once.
3. Do not use the product beyond expiration date.
4. The product is sensitive to the presence of alcohol and moisture. After open the package, the test device should be used immediately.
5. Do not use the kit if the pouch is punctured or not well sealed.

CONTENTS OF THE KIT

1. One pouch containing a one step Alcohol saliva test strip and desiccant. The desiccant is for storage purposes only, and is not used in the test procedures.
2. Leaflet with instructions for use.
3. This kit contains 100 individually wrapped pouches.

MATERIALS NOT PROVIDED

1. Timer (watch or clock)

STORAGE AND STABILITY

1. Store 2° C to 30° C in the sealed pouch up to the expiration date.
2. Keep away from direct sunlight, moisture and heat.

3. DO NOT FREEZE.
4. Preferably open the pouch only shortly before the test.

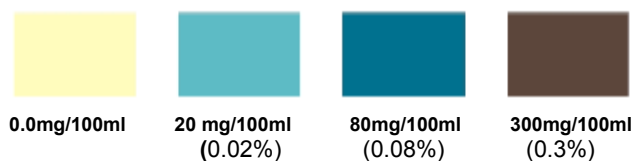
SPECIMEN COLLECTION AND PREPARATION

1. Nothing should be placed into the mouth of the subject for at least 10 minutes prior to saliva collection. This includes food, drink, tobacco products or other materials.
2. Saliva specimen can be collected in a sputum cup or a clean container, or directly applied to the reaction pad of the test strip.

TEST PROCEDURE

1. Remove a strip from the foil pouch by tearing at the notch and place it on a level surface.
2. Saturate the reactive pad by dipping the reaction pad into the saliva specimen collected in a sputum cup, or by applying saliva directly to the reaction pad. After 10 seconds, shake off the excess saliva.
3. Immediately start timer and at 2 minutes, compare the reactive pad with the provided colored chart below.

Blood Alcohol Concentration



NOTE: Results after more than 2 minutes may be not accurate

INTERPRETATION OF RESULTS

Positive(+):

A distinct color developed all over the pad. The positive result indicates that the BAC is 0.02% or higher. The alcohol concentration are related to the colored chart above.

Negative (-):

Almost no color change by comparing with the background. The negative result indicates that the BAC is less than 0.02%.

Invalid:

The test should be considered invalid if only the edge of the reactive pad turned color that might be ascribed to insufficient sampling. The subject should be re-tested.

QUALITY CONTROL

Good laboratory Practice recommends the daily use of control material to validate the reliability of device. Commercially available controls that contain sodium azide or other preservatives that will inhibit the enzyme activity cannot be used with One step Alcohol Saliva Test Strip.

One Step Alcohol Saliva Test Strip may be qualitatively verified by using a test solution prepared by adding 10 drops of ethanol

CONFIRMBIOSCIENCES

Confirm BioSciences Inc, 9520 Chesapeake Drive, #604, San Diego, CA 92123
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alcohol into 8 oz of distill water. This solution should show a distinct positive result.

LIMITATIONS

One step Alcohol Saliva Test Strip is designed for use on human saliva only. A positive result indicates only the presence of alcohol and does not indicate or measure intoxication.

There is a possibility that technical or procedure error as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer to "Interference" section for list of substances that will interfere the test results.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The following data were obtained based on 108 clinical saliva samples.

- Sensitivity 99%
- Specificity 93.1%
- Accuracy 95%

B. Sensitivity

Detection limit is 10mg/dL (0.01g/dL)

C. Interference

The following substances may interfere with Wondfo One Step Alcohol Saliva Test

- | | |
|------------------|-------------------------|
| Strong oxidizers | Ascorbic acid |
| Tannic acid | Polyphenolic compopunds |
| Mercaptans | Uric acid |
| Bilirubin | Oxalic acid |












These compounds are not normally present in sufficient amount in saliva to interfere with the test. However, the precautions step must be taken so that these materials are not introduced into the mouth during the 10 minutes period proceeding to the test

BIBLIOGRAPHY OF SUGGESTED READING

1. **A. W. Jones.** Inter- and intra-individual Components of Variation in the Saliva/Blood Alcohol Ratio during the Metabolism in Man. CUN. CHEM. 25/8, 1394-1398(1979), 1394 CLINICAL CHEMISTRY, Vol. 25, No. 8, 1979.
2. **S. A. Savchuk, V. N. Vlasov, et al.** Application of Chromatography and Spectrometry to the Authentication of Alcoholic Beverages. Journal of Analytical Chemistry, Vol. 56, No. 3, 2001, pp. 214–231. Translated from Zhurnal Analiticheskoi Khimii, Vol. 56, No. 3, 2001, pp. 246–264.
3. **K.-H.Smolle, G.Hofmann,P.Kaufmann, et al.** Alcohol Test: a simple and quick method to detect ethanol in saliva of patients in emergency departments. Intensive Care Med (1999) 25: 492-495
4. **Donald M. Truxillo,Talya N. Bauer,Matthew E. Paronto.** Reactions to organizational alcohol testing and treatment

programs. Journal of Business and Psychology, Vol. 17, No. 1, Fall 2002.

INDEX OF SYMBOLS

	See instruction for use		Tests per kit		Manufacturing date
	For in vitro diagnostic use only		Expiry date		Do not reuse
	Store between 2 ~ 30 °C		Batch number		Catalog #
	Keep away from sunlight		Keep dry		