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:

\[
\text{EtOH} + \text{TMB} \rightarrow \text{CH}_3\text{CHO} + \text{Colored TMB}
\]

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.
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.
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 with 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 compounds
- 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**


4. Donald M. Truxillo, Talya N. Bauer, Matthew E. Paronto. Reactions to organizational alcohol testing and treatment