

# AccuSign® Alcohol

## Rapid Saliva Test for Blood Alcohol

### Instructions for Use

**PBM**

For professional *in vitro* diagnostic use only  
Enzyme assay for the qualitative detection of blood alcohol from saliva

### Intended Use

AccuSign<sup>AE</sup> Alcohol test detects the presence of alcohol in saliva and provides semi-quantitative approximation of blood alcohol concentration. The test is intended for use as a rapid and sensitive indicator of blood alcohol level.

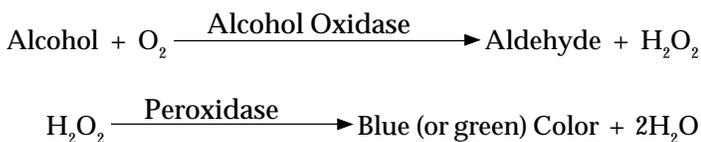
**AccuSign® Alcohol is intended for forensic use in screening individuals for alcohol use and potential impairment and not for use in medical diagnostic situations.**

### Summary and Principle of Procedure

It is well established that the concentration of alcohol in saliva is comparable to that in blood.<sup>3,4</sup>

AccuSign<sup>AE</sup> Alcohol test consists of a plastic strip with a reaction pad attached at the tip. On contact with solutions of alcohol, the reaction pad will rapidly turn shades of green to blue depending on the concentration of alcohol present.

The saliva sample is added to the surface of the reaction pad by placing it on the tongue and is allowed to soak in. If alcohol is present in the specimen, it will react with enzyme, which is embedded to the reaction pad, to generate a colored signal on pad.



### Reagent Composition

- Tetramethylbenzidine
- Alcohol Oxidase (EC 1.1.3.1.3)
- Peroxidase (EC 1.11.1.7)
- Other additives

### Precautions

- For *in vitro* diagnostic use only.
- The AccuSign<sup>AE</sup> Alcohol is visually interpreted test where color matching is used to provide an approximation of blood alcohol concentration.
- The AccuSign<sup>AE</sup> Alcohol device should remain in its sealed foil package until ready for use.
- Test materials that have been exposed to saliva should be treated as potentially infectious. These materials should be returned to the original foil package and disposed of properly.
- Do not use the AccuSign<sup>AE</sup> Alcohol test after the expiration date marked on the foil package.

### Stability and Storage

The AccuSign<sup>AE</sup> Alcohol test kit is to be stored at 2-27°C (36-80°F) in its sealed foil package. The expiration date was established under these storage conditions. If storage temperature exceeds 27°C, the test performance may degrade.

### Procedural Notes

The instructions below must be followed to achieve optimal test results. Follow the test procedure and always perform the test under carefully standardized conditions.

- If specimens, kit reagents or the AccuSign<sup>AE</sup> Alcohol devices have been stored in the refrigerator, allow them to reach room temperature before use.
- Do not open the foil package until you are ready to perform the test.
- Several tests may be run at one time.

### Test Protocol

1. Before testing, read the instructions. Strictly follow the test procedure.
2. Open the foil package and remove the test strip.
3. Place the test strip reaction pad on the tongue until the pad is saturated with saliva (Usually take 3-4 seconds to be saturated). If the specimen were already collected and stored, add 5 µl of the sample on reaction pad using pipette.
4. Wait 2 minutes. Compare the color of the reaction pad with the chart on the foil to determine the blood alcohol level.

### Interpretation of Results

**Positive:** The AccuSign<sup>AE</sup> Alcohol produces a color change in the presence of saliva alcohol. The color will range from a light-green color at 0.02% blood alcohol concentration to a dark blue color near 0.20% blood alcohol concentration.

**Note:** The test result can be read as soon as a distinct green color appears in the reaction pad. A green color that is lighter than the 0.02% color block should be interpreted as being positive to the presence of alcohol in saliva but less than 0.02% blood alcohol

**Negative:** A result where the reaction pad shows no color change should be interpreted as a negative result indicating that alcohol has not been detected.

A result where the outer edges of the reaction pad produces a slight color but the majority of the pad remains colorless should be repeated to ensure complete saturation of the reaction pad with saliva. If the second result is the same, the results should be interpreted as being negative result.

**Invalid:** If the reaction pad has a green color before applying saliva sample, do not use this test.

## Limitations

ii Failure to wait 15 minutes after placing food, drink, or other materials (including smoking) in the mouth before running the test can provide erroneous results due to possible contamination of the saliva by interfering substances.

- The AccuSign<sup>AE</sup> Alcohol test is designed and calibrated to be interpreted in two minutes. Longer times may result in erroneous results or false positive results. A proper sample must be obtained for a qualitatively good test.
- The AccuSign<sup>AE</sup> Alcohol test is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the AccuSign<sup>AE</sup> Alcohol test. Alcohol vapors are often present in many institutions and homes. Alcohol is a component in many household products such as disinfectant, deodorizers, perfumes and glass cleaners. If the presence of alcohol vapors is suspected, the test should be performed in an area known to be free of these vapors.

## Performance Characteristics

### Detection Limit

The detection limit of AccuSign<sup>AE</sup> Alcohol test is from 0.02 % to 0.20 % for approximate blood alcohol level. The cutoff level of AccuSign<sup>AE</sup> Alcohol can vary based on local regula-

tions and laws. Test results can be compared with color chart to reference levels.

### Assay Specificity

AccuSign<sup>AE</sup> Alcohol will react with the following substances.

- Methyl alcohol
- Ethyl alcohol
- Allyl alcohols

### Interfering Substances

The following substances may interfere with the AccuSign<sup>AE</sup> Alcohol test when using samples other than saliva:

Agents that enhance color development:

Peroxidases, Strong Oxidizers

Agents that inhibit color development:

- Reducing agents-Ascorbic acid, Tannic acid, Pyrogallol, Mercaptans and tosylates, Oxalic acid, Uric acid
- Bilirubin
- L-dopa
- L-methyl dopa
- Methampyrone

The normal quantity of the above substances in saliva is not enough to interfere with the test.

## References

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## Princeton BioMeditech Corporation

P.O. Box 7139, Princeton, New Jersey 08543-7139 U.S.A.  
4242 U.S. Route 1, Monmouth Junction, New Jersey 08852-1905 U.S.A.  
Tel: (732) 274-1000  
Fax: (732) 274-1010  
Internet E-mail: support@pbmc.com  
World Wide Web: <http://www.pbmc.com>

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