INTRODUCTION
The one step saliva alcohol screening test is a simple, accurate and convenient chemical assay for the rapid and qualitative detection of human blood alcohol levels. The Biotechnostix, Inc. one-step saliva alcohol screening test is fast and easy to use. The results are read visually without the need for instrumentation. It shows a high degree of sensitivity and can detect up to 0.02% alcohol concentration in saliva.

Note: This test shall not be used to determine one’s ability to legally operate a motor vehicle or heavy equipment. Any decision based on the results of this test will be the sole responsibility of the user.

PRINCIPLE OF PROCEDURE
BTNX strips are disposable plastic strips, which consist of a single reagent pad. The test is designed to provide a qualitative measurement of alcohol in a saliva specimen by comparing the color developed at the end of the reaction period with the color chart provided. The test strips employ alcohol oxidase, peroxidase and a hydrogen donor indicator in a carrier matrix supported on the strip with the alcohol oxidase functioning as a catalyst to convert any ethanol present along with ambient oxygen to acetaldehyde and hydrogen peroxide. The peroxidase functions as catalyst to induce a color change in the hydrogen donor and convert the hydrogen peroxide to water.

The reactions are as follows:
\[ \text{ETOH} + \text{O}_2 \rightarrow \text{CH}_2\text{CHO} \]
\[ \text{H}_2\text{O}_2 + \text{TMB.2OH} \rightarrow \text{Colored substrate} + 2\text{H}_2\text{O} \]

REAGENTS
Each reagent pad contains the following reagents in a homogenous dried format:
1. Alcohol Oxidase
2. Horseradish Peroxidase
3. Substrate tetramethylbenzidine (TMB)
4. Buffer with protein stabilizer

COLLECTION OF THE SAMPLE
Collect the saliva to a clean tube.

ASSAY PROCEDURE
1. Remove the test device from its foil pouch by tearing along the notch and use it as soon as possible.
2. Saturate pad end of stick with saliva in clean tub.
3. After complete saturation of pad, remove stick from saliva and read at the end of 2 minutes.
4. Compare reactive pad to color blocks.

Quality Control
For each run, both negative and positive controls should be used to ensure proper user technique and determine assay reliability and performance. Normal saliva sample can be used for the negative control. If the expected results are not achieved with the controls, do not proceed with testing.

INTERPRETATION OF RESULTS
Negative: No color change on reactive pad
Positive: Reactive pad changes color in 2 minutes.

PRECAUTION
1. In vitro diagnostic use only.
2. Do not use beyond expiration day.
3. The test device should not be reused.
4. The test strip is moisture sensitive and should be used immediately after taking out of the pouch.

STORAGE AND STABILITY
The test kit can be stored at temperatures between 2 to 30°C in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

LIMITATIONS
1. Failure to wait 15 minutes after placing food, drink, or other materials in the mouth before running the test can provide erroneous results due to possible contamination of the saliva by interfering substances.
2. Waiting longer than four minutes to interpret the test can result in erroneous or false positive results.
3. The test is highly sensitive to the presence of alcohol. Alcohol vapors in the air can sometimes be detected by the test. Alcohol is a component in many household products such as disinfectants, deodorizers, 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 (such as outside).