INTENDED USE

The ALCO-Screen™ saliva alcohol test is intended for use as a rapid, highly sensitive method to detect the presence of alcohol in saliva and to provide a semi-quantitative approximation of blood alcohol concentration. For applications where a quantitative determination of blood alcohol concentration is required, a positive ALCO-Screen™ result must be verified using an acceptable quantitative alcohol analysis procedure. ALCO-Screen™ requires no special training provided that instructions are followed carefully. However, quantitative follow-up testing should be performed by a qualified professional. The ALCO-Screen™ may also be used to non-quantitatively detect the presence of alcohol in many other fluids, such as blood serum, soft drinks, water and other beverages that may be used to camouflage the consumption of alcohol.
SUMMARY AND DISCUSSION

Excessive or inappropriate consumption of alcohol is one of the most common and pervasive social problems in our society. It is a contributory factor to many accidents, injuries and medical conditions. Screening of individuals for alcohol consumption is an important method for the identification of individuals who might be at risk due to alcohol intoxication, use or abuse. Screening also provides additional benefit as a deterrent against inappropriate alcohol consumption. The blood alcohol concentration at which a person becomes impaired is variable dependent upon the individual. Individual specific parameters such as physical size, weight, metabolic level, eating habits and alcohol tolerance all affect the level of impairment of the individual. ALCO-Screen™ is not intended as a measurement of mental or physical impairment but rather a screening test for the presence of alcohol in semi-quantitative amounts.

TEST PROCEDURE

- Abstain from placing anything in the mouth for fifteen (15) minutes prior to beginning the test. This includes non-alcoholic drinks, tobacco products, coffee, breath mints, food, etc.

- Open the foil package and remove the test strip. Observe the reactive pad on the end of the test strip. The pad should be a light cream color. A test strip with a reagent pad which is dark tan in color or otherwise discolored should be discarded.

- Saturate the reactive pad with saliva from the test individual's mouth or sputum cup. Immediately start a reliable timing device.

- At exactly two (2) minutes observe the color change (if any) in the reactive pad. A color change of green or blue indicates the presence of alcohol and a positive result. Results obtained after more than 2 minutes and 30 seconds (2.5 minutes) may be erroneous and should not be used.

- Estimate the approximate blood alcohol concentration by comparing the color of the reactive pad to the color chart on the back of the test package.

TEST RESULT INTERPRETATION

ALCO-Screen™ produces a color change in the presence of saliva alcohol ranging from a light green-gray color at 0.02% blood alcohol concentration to a dark blue-gray color near 0.30% blood alcohol concentration. This color change is simulated by the graphic on the left. Color blocks are provided within this range to allow an approximation of blood alcohol concentration to be made. ALCO-Screen™ may produce colors that appear to be between adjacent color blocks. ALCO-Screen™ is very sensitive to the presence
of alcohol. 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 content. A result where the reagent pad shows no color change (remains white or cream colored) should be interpreted as a negative result (no alcohol present). A result where the outer edges of the reagent pad produce a slight color but the majority of the pad remains colorless should be repeated to ensure complete saturation of the reagent pad with saliva. If the second result is the same, the results should be interpreted as being negative (no alcohol present).

See Technical Specifications Below:

TEST LIMITATIONS

- 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.

- ALCO-Screen™ is designed and calibrated be interpreted two minutes after saturation of the reactive pad. Waiting longer than two minutes to interpret the test can result in erroneous or false positive results.

- ALCO-Screen™ may be used to detect the presence of alcohol in fluids other than saliva. However, when used in this manner, the color chart on the package does not apply. If alcohol is present in the fluid, a color change ranging from a light green-gray to black to cocoa brown will occur as the alcohol concentration increases. Little or no color change may occur with pure alcohol (99%) due to the absence of water which is required for the color change reaction. When testing beverages, a result should not be considered positive unless the pad changes to a very dark brown or black.

- ALCO-Screen™ is highly sensitive to the presence of alcohol. Alcohol vapors in the air can sometimes be detected by the ALCO-Screen™ Alcohol vapors are often present in many institutions and homes. 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). See See Technical Specifications Below

PRECAUTIONS

- ALCO-Screen™ is a visually interpreted test where color matching is used to provide an approximation of blood alcohol concentration. As such, exact interpretation of results is not required in most cases. However, persons who are color blind or visually impaired may experience difficulty when a more specific interpretation is required. Furthermore, where test interpretation may be biased for whatever reason, it is suggested that an another person’s opinion of test results or color matching be obtained.
• 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.

• Never use ALCO-Screen™ after the expiration date marked on the outside of each test package.

ALCOSCREEN-02 DOT APPROVED VERSION

The Alco-Screen 02 is the simplest, most cost effective method of monitoring for alcohol consumption in a DOT Zero Tolerance testing program. The zero tolerance level for federally mandated DOT testing programs is .02% blood alcohol content (BAC). The Alco-Screen 02 uses this zero tolerance level (.02% BAC) as the detection level set point for the test strip resulting in the simplest method of test administration and interpretation. Alcohol detection using a saliva sample can be more sensitive and accurate compared to breath tests because the relationship between the amount of saliva alcohol content and blood alcohol content is 1:1 while with equivalent breath alcohol content it is .000048:1. Extremely versatile, the ALCO-Screen 02™ strip test can detect the presence of alcohol in other fluids or beverages in addition to testing saliva alcohol.

Test administration is the same utilized for the standard ALCO-Screen outlined in detail above except for the test duration time being 4 minutes instead of 2 minutes. Test interpretation however, is solely based on whether a single test line develops on the reactive test pad. Development of a test line indicates a positive test for alcohol equal to or greater than .02% BAC. If a test line fails to develop on the pad the test is negative indicating BAC percentage is less than .02%. Any line, no matter how faint, developing on the reactive test pad at 4 minutes is a positive test. Typical actual test results are shown below:
*No conclusion should be drawn from the color or intensity of the test line beyond that of a positive test result.

The Alco-Screen 02 is highly sensitive and can be used for evidentiary purposes. The Alco-Screen 02 has been tested and approved by the US Department of Transportation (DOT) for required testing of all transportation and safety sensitive employees for blood alcohol concentrations above the federally mandated zero tolerance level of 0.02%. Alco-Screen-02 is a simple one-step saliva screening test that works in a clean, non-invasive manner and provides results in 4 minutes. Completed test results can be photocopied for permanent filing.

AVAILABILITY AND ORDERING

The ALCO-Screen™ and ALCO-Screen™-02 saliva alcohol tests are available at wholesale in packs of twenty-four (24), seventy-two (72) and in cases of two hundred and eighty eight (288) tests. Each ALCO-Screen™ saliva alcohol test strip is individually and hermetically sealed in a foil package with desiccant. Expiration dates are approximately one (1) year. Test instructions and test result interpretation charts are incorporated into each test package.
PRINCIPLE
It is well established that the concentration of alcohol in saliva is comparable to that of blood. The following figure shows the correlation between saliva and blood alcohol. The regression line equation was:
\[ Y = 0.003 + 1.075X \]  
\[ r = 0.992, p < 0.001 \]

The ALCO-SCREEN test consists of a plastic strip with a reactive pad applied at the tip. The tip, on contact with solutions of alcohol, will rapidly turn shades of green to blue depending on the amount of alcohol present. The reactive pad employs a solid phase chemistry which uses the following highly specific enzyme reaction:

\[
\begin{align*}
\text{CH}_3\text{CH}_2\text{OH} + \text{O}_2 & \xrightarrow{\text{Alcohol Oxidase}} \text{H} \quad \text{CH}_3\text{C} = \text{O} + \text{H}_2\text{O} \\
\text{H}_2\text{O}_2 + \text{DH}_2 & \xrightarrow{\text{Peroxidase}} \text{D} \quad \text{Blue} + 2\text{H}_2\text{O}
\end{align*}
\]

SPECIFICITY
The ALCO-SCREEN will react with methyl, ethyl, and allyl alcohols. ALCO-SCREEN will not react with alcohols having 5 or more carbons, nor with glycerol, glyceral, or serum. This property is a result of the specificity of the alcohol oxidase enzyme extracted from yeast.

REAGENT COMPOSITION: (per test unit)
- Tetramethylbenzidine: 0.176 mg
- Alcohol Oxidase (EC 1.1.3.1.3): 0.5 IU
- Peroxidase (EC 1.11.1.7): 30 IU
- Buffer: 0.747 mg
- Stabilizing Proteins: 0.19 mg

INTERFERENCES
The following substances may interfere with the ALCO-SCREEN stick when using samples other than saliva:
- Agents which enhance color development:
  - Peroxides
  - Strong oxidizers
- Agents which inhibit color development:
  - Reducing Agents:
    - Ascorbic acid
    - Tannic Acid
    - Pyrogallol
    - Mercaptans and tosylates
    - Oxalic acid
    - Uric acid
    - Bilirubin
    - L-dopa
    - L-methylisopropylamine