



CLIA Waived

2-Minute Saliva Test for Blood Alcohol

INTENDED USE

ALCO-SCREEN® is a semi-quantitative screening test used to estimate the Blood Alcohol Concentration (BAC) using human saliva. The test strip estimates BAC at the 0.00%, 0.02%, 0.04%, 0.08% and 0.3% levels. Results are used in the diagnosis of alcohol use or intoxication.

For in vitro diagnostic use.

PRINCIPLE

The ALCO-SCREEN® consists of a plastic strip with a test pad attached at the tip. The test pad is treated to react with alcohol in saliva and will change to shades of green-gray to blue depending on the presence of and amount of alcohol detected.

REAGENTS

The test pad contains tetramethylbenzidine, alcohol oxidase (EC 1.1.3.13), peroxidase (EC 1.11.1.7) and other non-active ingredients.

PRECAUTIONS

- For in vitro diagnostic use.
- Keep out of reach of children.
- Do not use past the expiration date printed on the foil package.
- Do not use if the package is unsealed or damaged.
- Do not open test package until ready to use.
- Before testing saliva sample compare the color of the unused test strip to the negative (0.0%) color block. If the unused test strip is darker than the negative color block, this may indicate that the device has deteriorated during storage and should not be used.
- Read the test under incandescent, fluorescent, or indirect sunlight.
- Do not read the test under mercury or sodium vapor light.
- This test should not be interpreted by persons who are color-blind or are visually impaired.
- The test pad is very sensitive to alcohol and will react if there are alcohol vapors present in the air. Safeguards must be taken regarding the use of hand sanitizers containing ethyl alcohol (i.e. ethanol) by persons performing the test. Perform the test in an area free of alcohol vapors.
- Do not re-use the test.
- Dispose of properly.
- The test only provides an estimate of the Blood Alcohol Concentration (BAC). It should not be used as a tool to determine if it is safe for the user to operate machinery or a motor vehicle.
- Results from this test may not be used for legal proceedings.

STORAGE AND HANDLING

- Do not store at temperature above 80°F (27°C) or below 50°F (10°C).
- Do not freeze.

MATERIALS

Materials Provided:

- Twenty-four (24) individually packaged tests per box
- One ALCO-SCREEN® test strip per foil package
- One instruction sheet

Materials Needed But Not Included:

- Timer
- Clean Collection Cup: Solo® Cup P100 (1oz.)

DIRECTIONS FOR USE

Before you begin

- DO NOT place anything into mouth for 15 minutes before testing.
- Remove test package from the box and let it reach room temperature.
- Open package immediately before testing.
- Inspect the test pad. The test pad should be a cream color. If the test pad is tan or otherwise discolored, do not use the test.

Specimen Collection and Handling

1. Using a clean dry Solo® Cup (P100, 1oz, clear polystyrene), simply spit into the cup.
2. Make sure you collect enough saliva to completely wet the test pad.
3. Do not place anything in the saliva sample.
4. Immediately start procedure.

Procedure

1. Wet test pad with saliva for 5 seconds then remove. Start the timer immediately.
2. At 2 minutes compare color of test pad to the color chart on the test package.
3. Estimate the BAC by reading the number printed below the color block that best matches the color of the test pad.

Note: Results read after 2 minutes, 30 seconds may not be accurate.

TEST RESULTS

Negative: The test pad shows no color change and matches the Negative color block on the foil package.

Positive: The test pad shows a color change from light green-gray color at 0.02% BAC to a dark blue-gray color near 0.30% BAC.

QUALITY CHECK

ASC offers third party control solutions that can be used to comply with CLIA regulations and/or to test the viability of the ALCO-SCREEN® test device. The controls are formulated as a POSITIVE CONTROL and a NEGATIVE CONTROL. Contact your ALCO-SCREEN

LIMITATIONS

1. Confirm positive results using an acceptable evidentiary alcohol test.
2. Do not use the test to determine one's ability to legally operate a motor vehicle or other heavy equipment. Any decisions based on the results of this test are the sole responsibility of the user.
3. Alcohol impairs judgment. Someone sober should perform the test.
4. You must wait 15 minutes after placing food, drink, or other materials in your mouth before running the test.
5. The effects of blood in the mouth on test performance were not evaluated. If there is visible blood in the mouth or sores, this test should not be conducted.

INTERFERENCES

ALCO-SCREEN® will react with methyl, ethyl, and other short-chain alcohols.

The following substances may interfere with the ALCO-SCREEN® if present above the listed concentrations.

<u>Substance</u>	<u>Concentration (% v/v)</u>
1-Butanol (Butyl Alcohol)	0.0006%
2-Butanol	1.0%
Methanol	0.0003%
Acetone	1.2%
Glycerol	1.2%
Isopropanol	0.6%



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