

INTENDED USE

ALCO-SCREEN 02[®] is a qualitative screening test used to detect the presence of ethyl alcohol in human saliva. The test detects relative blood alcohol concentrations (BAC) greater than or equal to 0.02%. Results are used for the diagnosis of alcohol intoxication. For in-vitro diagnostic use. The assay is a disposable test for one-time use.

PRINCIPLE

ALCO-SCREEN 02[®] consists of a plastic strip with a test pad attached at the tip. The test pad is treated to react with alcohol in saliva. A distinct colored line will develop across the test pad if alcohol is detected at greater than or equal to 0.02%BAC.

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 package. Do not use if the package is unsealed or damaged.
- Do not open test package until ready to use.
- Do not use if you see a blue line across the test pad upon opening the test package.
- Read test under incandescent, fluorescent or indirect sunlight.
- Do not read under sodium vapor light.
- Persons who are visually impaired should not interpret this test.
- ALCO-SCREEN 02[®] 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. You can test for alcohol vapors by first performing the test using tap water in place of saliva. If you get a positive result using tap water, move testing to an alcohol free area.
- Do not re-use the test.
- Dispose of properly
- This test provides an estimate of blood alcohol concentration. It should not be used to determine if it is safe to operate machinery or a motor vehicle.
- Results from this test may not be used as evidence in 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 02[®] test strip per package.
- Instruction sheet.

Materials needed but not included:

- Timer
- Clean collection cup: Solo[®] P100 (1 oz).

LIMITATIONS

1. Confirm positive results using an acceptable evidentiary alcohol test method.
2. Do not use ALCO-SCREEN 02[®] 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 use 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.

DIRECTIONS FOR USE

Before you begin:

- DO NOT place anything in mouth for 15 minutes before testing.
- Remove test package from the box and let it reach room temperature.
- Open package immediately before testing.
- Inspect test pad. The test pad should be a cream color.
- A faint shadow may be seen across the test pad where it has been treated to detect alcohol.
- Do not use the test if a blue line can be seen across the test pad.

For U.S. Department of Transportation mandatory testing ONLY:

- Saturate the reactive pad by applying saliva directly to the pad.
- Immediately start timer and proceed to Procedure below.

For Non-U.S. Department of Transportation mandatory testing:

1. Use 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 the procedure below.

Procedure:

1. Wet test pad with saliva for 5 seconds, then remove. Start the timer immediately.
2. At 4 minutes, read the results.
3. If a distinct colored line appears (see below), relative blood alcohol concentration (BAC) is greater than or equal to 0.02%.
Note: Results read after 5 minutes may not be accurate.

TEST RESULTS

INTERPRETATION



Positive result greater than or equal to 0.02% B.A.C.



Negative Result

Positive: Distinct colored line appears on the test pad. BAC greater than or equal to 0.02%.

Negative: No colored line appears on the test pad. BAC is below 0.02%.

For questions, please call customer service at 1 (800) 348-5174

QUALITY CHECK

Chematics offers third party control solutions that can be used to comply with CLIA regulations and/or to test the viability of the ALCO-SCREEN 02[®] test device. The controls are formulated as a POSITIVE CONTROL and a NEGATIVE CONTROL. Contact your ALCO-SCREEN 02[®] supplier or Chematics at (574) 834-2406 or (800) 348-5174 for additional information, pricing and availability.

INTERFERENCES

ALCO-SCREEN 02[®] will react with methyl, ethyl and other short-chain alcohols. The following substances may interfere with ALCO-SCREEN 02[®] if present above the listed concentrations:

Substance	Concentration (%v/v)
1-butanol (butyl alcohol)	0.0005%
2-butanol	1.0%
Methanol (methyl alcohol)	0.0002%
acetone	1.0%
glycerol	1.0%
isopropanol	0.5%

TECHNICAL ASSISTANCE

For technical assistance or further information, contact Chematics, Inc. Technical Assistance at 1-800-348-5174. Hours of operation: 8:00 AM to 5:00 PM EST.