



Saliva Alcohol Test Strip (Saliva)

Package Insert

Catalog No.	English
I-SA-25	

For Self Testing

PRINCIPLE AND INTENDED USE

The *iScreen*[®] Saliva Alcohol Test Strip (Saliva) is a screening test used to semi-quantitatively measuring alcohol in human saliva. The test strip indicates relative Blood Alcohol Concentration (BAC) at 0.0%, 0.02%, 0.04%, 0.08%, and 0.30% cut-off levels. Results are used in the diagnosis of alcohol intoxication. For *in vitro* diagnostic use only. The test is a firm plastic strip with a test pad attached at the tip. The test pad contains chemicals that are highly sensitive to alcohol. Alcohol in saliva reacts with the chemicals to produce a color change on the test pad. The color change depends on the amount of alcohol present. The results are read by comparing the color of the test pad with the color chart.

REAGENTS

The test strip contains Tetramethylbenzidine, Alcohol Oxidase (EC 1.1.3.13), Peroxidase (EC 1.11.1.7) and other additives.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- For diagnosing intoxication.
- Do not use after the expiration date printed on the sealed pouch.
- Keep out of reach of children.
- Treat all specimens and test materials as infectious.
- Dispose of properly.

STORAGE AND HANDLING

Store as packaged. Keep the test strip in the sealed pouch until use. Store in a dry place at 2-27°C or 36-81°F. **DO NOT FREEZE.** Do not use past the expiration date.

SPECIMEN COLLECTION

Collect enough saliva to completely saturate the test pad and perform the test immediately. Results may be inaccurate if the test pad is not completely saturated.

MATERIALS

Materials Provided

- Test strips
- Collection cups
- Package insert

Materials Required But Not Provided

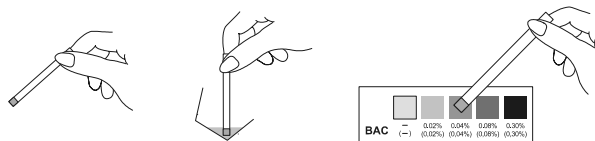
- Timer

DIRECTIONS FOR USE

Wait 15 minutes after the last alcohol intake or drink a glass of water before testing.

1. Bring all test items to room temperature for 15 minutes. Remove the test strip from the sealed pouch and use it as soon as possible. Ensure the test pad is a light cream color and is lighter than, or the same color as the negative color block printed on the pouch. Do not use if the test pad is blue or discolored.
2. Saturate the test pad completely for 5-10 seconds with saliva from the collection cup or directly apply saliva to completely saturate the test pad. Start the timer immediately.

Note: Do not place the test strip in the mouth. If the test pad is not completely saturated, results may be inaccurate.
3. **Read results at 2 minutes.** Compare the color of the test pad to the color blocks printed on the pouch. Do not read results after 3 minutes.



INTERPRETATION OF RESULTS

NEGATIVE: No color change appears on the test pad. There is no alcohol present if the color of the test pad matches the negative (-) color block on the pouch.

POSITIVE: A color change appears on the test pad. BAC ranges from 0.02% to 0.30% if the color of the test pad varies from light blue to dark blue.

NOTE: The test strip is very sensitive to alcohol.

INVALID: A slight color change appears on the edges of the test pad, but no color change appears on the center of the test pad. Repeat the test with a new test strip. Ensure the test pad is completely saturated with saliva.

QUALITY CONTROL

The quality of the Saliva Alcohol Test Strip (Saliva) should be confirmed by comparing the color of the unused test pad with the negative color block printed on the pouch. The color of the unused test pad should match the negative color block printed on the pouch, or be lighter than the negative color block.

LIMITATIONS

1. The Saliva Alcohol Test Strip (Saliva) is a screening test. It cannot detect exact BAC. Confirm results with an approved alcohol test before taking legal action. The test should not be used to determine if the user is capable of operating machinery or driving. Actions of any person, based on the outcome of the test, are at the person's own risk.
2. Alcohol impairs judgment. The test should be performed by someone who is not under the influence of alcohol.
3. Failure to wait 15 minutes after the last alcohol intake or to drink a glass of water, before testing may cause false results.
4. Wait 20 minutes after using over-the-counter products, eating, smoking, or chewing gum before testing. Such items may cause false positive results.
5. People who are color-blind or visually impaired should not read results.
6. Read the test under incandescent, fluorescent, or indirect sunlight. Do not read under streetlights. Sodium vapor from streetlights can cause colors to appear differently and cause false results.
7. The test strip should not be used to determine the presence of alcohol in beverages, in pure alcohol, or in other liquid solutions.

PERFORMANCE CHARACTERISTICS

The Saliva Alcohol Test Strip (Saliva) can detect relative BAC from 0.02% to 0.30%. Acceptable limits of BAC depend on local regulations. The Saliva Alcohol Test Strip (Saliva) will react with methyl, ethyl, propyl and butyl alcohols. The following substances have been tested and do not interfere with the Saliva Alcohol Test Strip (Saliva) at the concentration listed.

Substance	Concentration (% w/v)
Acetone	1.00%
2-Butanol	1.00%
1-Butanol (Butyl alcohol)	0.05%
Glycerol	1.00%
Isopropanol (Isopropyl Alcohol)	1.00%
Methanol	0.0001%

Distributed by:
Blue Grass Drug Screen, Inc. 1-866-323-7336

Manufactured for Alere Toxicology Services – Products Division

Printed in China

Number: xxxxxxxxxx
Effective date: 2012-xx-xx