

## Saliva Alcohol Test Strip (Saliva)

### Package Insert

REF C031-021	English
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#### PRINCIPLE AND INTENDED USE

The Saliva Alcohol Test Strip (Saliva) is a rapid screening test used for measuring alcohol in human saliva. Results are used in the diagnosis of alcohol intoxication. 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. The test gives relative Blood Alcohol Concentration (BAC) from 0.02% to 0.30%.

#### 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 36-80°F. **DO NOT FREEZE.** Do not use past the expiration date.

#### SPECIMEN COLLECTION AND PREPARATION

Store specimens in a sealed container. Store for up to 4 hours at room temperature (15-30°C or 59-86°F). Store for up to 8 hours refrigerated at 2-8°C or 36-46°F. Do not freeze. Bring to room temperature before testing.

#### MATERIALS

##### Materials Provided

- Test strips
- Collection cups
- Package insert
- Timer

##### Materials Required But Not Provided

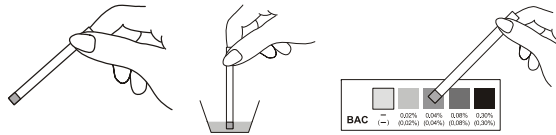
#### DIRECTIONS FOR USE

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

1. Bring all test items to room temperature. Remove the test strip from the sealed pouch and use it as soon as possible. Ensure the test pad is a light cream color. Do not use if the test pad is blue or discolored.
2. **Saturate the test pad with saliva** from the collection cup or directly apply saliva to the test pad. Start the timer immediately.

**Note:** Do not place the test strip in the mouth.

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. Alcohol is present if the color of the test pad is a lighter blue than 0.02% color block. The test is positive for BAC below 0.02%.

**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. Contact your local distributor if the problem continues.

#### QUALITY CONTROL

The quality of the Saliva Alcohol Test Strip (Saliva) should be confirmed with a test solution. Use 5 drops of 80

proof distilled spirits in 30 mL of water to make the solution. The test solution will produce a color change on the test pad of 0.02% or greater BAC. Saliva produces a slower, less intense color change than with the test solution. Do not pure alcohol in the test solution. It will not produce a positive result.

#### 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 test results in good lighting to avoid false results. Read the test under incandescent, fluorescent, indirect sunlight, or mercury vapor lighting. Do not read under streetlights. Sodium vapor from streetlights can cause colors from positive samples to appear differently and cause higher test 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.
8. The test is highly sensitive to alcohol and alcohol vapors in the air. Perform the test in an area free of these vapors.

#### 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 and allyl alcohols.

CLIA Category: Waived

#### Index of Symbols

	Attention, see instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-27°C		Lot Number		Catalog #

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