PROMILLESS

PROMILLESS INSTRUCTIONS FOR USE

Promilless Alcohol Test Strip instructions for use

Note: The Promilless product family consist of several variants which differ by the threshold limit only. This instructions for use is compatible with all threshold limits.

Manufactured by:

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INTRODUCTION

This instructions for use is designed for users of the Promilless alcohol test strip.

Promilless alcohol test strip gives the end user a highly reliable test result for even the slightest amount of ethanol present in saliva. product concept is meant to be affordable, easy-to-use and portable.

Latest version of the manual can be read in electric form in address: https://promilless.com/ you can also contact the manufacturer to order the latest version of the manual.

Promilless alcohon test strip gives the end user a highly reliable test result for even the slightest amount of ethanol present in saliva. Product concept is meant to be affordable, easy-to-use and portable.
Time for color indication: ≤ 2 minutes. Indication limit depends on the product variant and can be 0 ‰, 0,2 ‰ or 0,5 ‰ (0%, 0,02% or 0,05% respectively).

The device is indicated for use by consumers and healthcare personnel.

INTENDED USE

Promilless alcohol test is fast and easy-to-use quick test designed to be used for detecting alcohol content from human saliva. The test is suitable for assessing blood alcohol content and can be used by consumers, healthcare professionals and authorities

DISCLAIMER

The manufacturer is responsible for safety, reliability and performance of this production only in the following condition:

- The product is operated under observance of this manual
- Testi Technologies does not accept any liability for the use or misuse whether direct or indirect of the products, or for damages arising out of the use of or inability to use the product
- All clinical conclusions and decisions that are based on the use of this product are the responsibility of the medical specialist

COMPLAINTS AND ADVERSE EVENT REPORTING

Any serious incident that has occurred in relation to this system should be reported to Testi Technologies and the competent authority of the member state in which the user and/or patient is established.

Any complaint that has occurred in relation to this system should be reported to Testi Technologies immediately.

PRODUCT SAFETY AND CONTRAINDICATIONS

The design and materials of the product have been chosen having safety of the user as first priority. Product safety information provided by the producers of the component materials have been utilized, and chemical safety data sheets collected and used to recognize risks connected to it. Used standards or similar have been mentioned.

Also, possible allergens have been avoided, but rare allergic reactions and/or possible situations caused by interactions with medication or similar cannot be totally precluded. On the other hand, the exposure to any harmful components is negligible, since the amounts of possibly harmful chemicals are very small and the use of the product is only occasional.

Contra-indications are not known but it is possible that some medications or severe metabolic illnesses affect the biochemistry of the product.

DEVICE DESCRIPTION

Promilless alcohol test strip uses novel proprietary technology, and it is equipped with a control pad which confirms the functionality of the test. Test is sensitive even to the slightest amount of alcohol and the product is optimised to avoid the occurrence of false positives.

Product comprises a base support and substrate material with defined test zone and control zone. Colour change in the test zone indicates that the concentration of ethanol in saliva exceeds the predetermined limit, while colour change in Control zone shows that the test is functional. Technically the indication is two valued, either there is alcohol in saliva, which is indicated by change in color, or no alcohol and no color change.

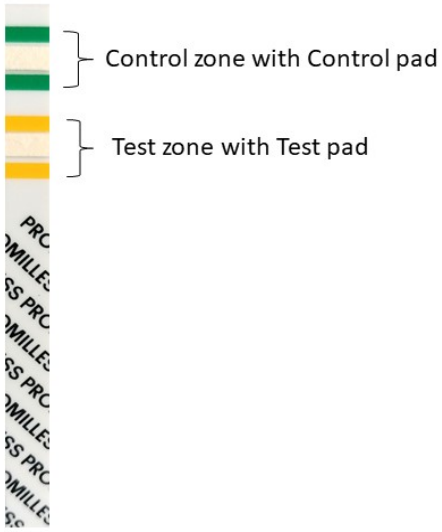
UNPACKING AND SYSTEM OVERVIEW

Product consist of the test strip that is packed with a desiccant pillow in a foil pouch which is heat sealed and shields the strip. The dimensions of the strip are 6mm x 70mm.

The foil pouches are packed in envelopes which include the instructions for use on the inside.

Promilless test strip, foil pouch and envelopes:

Promilless Test strip:



Quick guide for use of Promilless test strip on the envelope. (Note: (Each product variant has it's own version of the quick guide according to the threshold limit):

INSTRUCTIONS

DO NOT EAT, DRINK, SMOKE OR CHEW GUM 15 MINUTES BEFORE USING THE TEST. Prior to the test, ensure that you have saliva in your mouth. The test indicates the blood alcohol content from you saliva.

① Remove the test strip from the foil packaging.

② Dip the test strip in saliva for 2 seconds so that the green-yellow test area is against your tongue.

RESULT WITHIN 2 MINS

The test can be interpreted within two minutes. Do not interpret the test result after two minutes have passed. The green control area may darken earlier than the yellow area. Even the slightest darkening of the yellow test area means there is alcohol in the blood.

Ⓐ Only the green control area has darkened: Your blood alcohol content is less than 0.00 %.

Ⓑ Both the green control area and the yellow test area have darkened: your blood alcohol content is over 0.00 %.

NOTE! The green control area must always darken – it ensures that the test is functioning correctly. If the green control area of the strip does not darken, repeat the test with a new strip.

NON-COMPLIANCE WITH THE INSTRUCTIONS MAY WEAKEN THE FUNCTIONALITY AND RELIABILITY OF THE TEST.

PRINCIPLE OF THE EXAMINATION METHOD

The measurement of ethanol concentration in the saliva is done by placing the product indication area on the tongue of the user for 2 seconds. Within 2 minutes from wetting the pads the result is shown. To get reliable results, both the Test and Control pads must get properly wet with saliva. Product is not presenting the actual alcohol per mille level but indicates qualitatively if nominal saliva alcohol content exceeds the given limit (0‰, 0,2‰ or 0,5‰).

When the Test pad absorbs enough saliva, the enzymatic reaction the test is based on, is realized in the product. In this reaction ethanol in saliva sample is catalytically oxidized by Alcohol Oxidase releasing hydrogen peroxide, which then in turn oxidize ABTS to its colored form. The result of this reaction gives information of the BAC to the user.

When the Control pad absorbs enough saliva, the control reaction gives the user a guarantee that the chemical substances are performing adequately in the product, and that the indicated result can be trusted. Control pad is used to exclude substances, which might prevent the reaction and create false or invalid results.

The color formation and final shade of greyish green of a positive result can vary due to metabolic differences between individuals.

PRECAUTIONS AND LIMITATIONS

- Don’t eat or drink (or smoke) anything during 15 minutes before testing to avoid false positive
- Open the foil pouch just before testing
- Take care there is enough saliva on the tongue, the strip needs to get properly wet
- Read the result at 2 minutes. Do not interpret the results after 2 min have passed
- Don’t compare. The results are individual, they should not be compared to anyone else’s result (colour, intensity or speed)

The device should not be usaed since the results cannot be relied on, if:

- Either of the pads is missing or couloured when the foil pouch is opened
- Temperature is either below or above the use range (+2 °C to +30 °C)
- The product has expired

In the case of malfunctioning product inform the manufacturer.

CAUTION: The test helps the user make a decision based on the result, for which they are nonetheless responsible.

DETAILED INSTRUCTIONS FOR USE	
Remove the test strip from the foil package.  	⚠ NOTE! Use the strip immediately.
Dip the test strip into saliva about 2 seconds, with the green and yellow areas against the tongue.  	⚠ NOTE! Ensure that both test pads are moistened
Result will be visible within 2 minutes.  	⚠ NOTE! Interpret the test result within two minutes. Do not read or rely on the result **after** two minutes have passed. The green control area may darken before the yellow test area. ***Even a slight darkening of the yellow area indicates the presence of alcohol in the blood.***

INTERPRETATION OF RESULTS

Indication area is the actual reactive area detecting the alcohol content and showing the result.

The indication area includes two zones: Control zone and Test zone, both containing one pad (Control pad and Test pad respectively) on which the active parts of the product are printed.

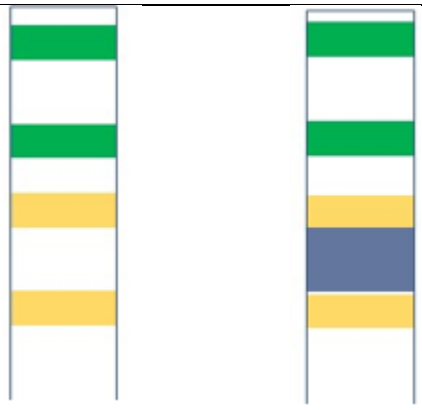
The test result should be read within 2 minutes from wetting the test strip with saliva.
The figure below presents the indication area and shows all four different possible test results.

Test pad (T) between the yellow lines is used to detect if there is any alcohol present in user saliva.
Control pad (C) between the green lines indicates if the test has succeeded.

If there is no color change in the Control pad, the test result that Test pad indicates is not valid.

Possible test results:

1.	both pads change colour **= Positive test result**	Control pad colored → test succeeded Test pad colored → alcohol content in saliva exceeds the given limit
2.	Only Control pad changes colour **= Negative test result**	Control pad colored → test succeeded Test pad no color change → alcohol content in saliva below the given limit
3.	No colour reaction on test or control pads = **Invalid result**	Test failed
4.	Colour reaction only on Test pad, Control indication not detected = **Invalid result**	Test failed; Test indication cannot be relied on

Option 1: Positive result	**Option 2**: Negative result	**option 3 & 4**: Invalid result
		

- Control pad is used to exclude substances, which might prevent the reaction and create false or invalid results. (option 3) above).
- When product shelf-life is exceeded, or it is not used or stored according to instructions the option 3 may result.
- If saliva is absorbed poorly or only in one of the pads options 4) or 3) may result.

DISPOSAL INSTRUCTIONS	
	NOTE! Dispose of the Promilless strip immediately after use
Promilless alcohol test strips can be disposed with normal general waste.	

TECHNICAL SPESIFICATION	
Technical parameters	
Type classification	Medical Device, EU MDR 2017/749 Class I
Size (W x H x D)	Device thickness: 1.5mm Width: 6mm Length:70mm
Weight	340g
Shelf life	15 months (The lot number and expiry date are indicated on the foil pouch and on the closing sticker of the envelope.)
Use	Device is single-use only
Disposable	Yes
Environmental Conditions	
Operating Temperature	+2 °C - +30 °C
Transport & Storage Temperature	+2 °C - +30 °C

SYMBOLS	
	SINGLE USE Do not attempt to re-use the item.
	KEEP DRY! Do not use in wet conditions. Keep away from moisture and areas of humidity.
	CE MARK Indicates that the product complies with applicable EU legislation
	MANUFACTURER Name and address of the manufacturer.
	MEDICAL DEVICE Indicates that the product is a medical device
	POLYPROPYLENE Indicates that the material used is polypropylene
	RECYCLABLE Indicates that the packaging or product is recyclable
	TEMPERATURE RANGE Indicates temperature conditions
	UDI CODE Indicates the presence of a Unique Device Identification (UDI) in human- and/or machine-readable form.
	READ INSTRUCTIOND FOR USE Indicates that the user should consult the instructions for use (IFU) for important information prior to using the device

LITERATURE REFERENCES

Several publications confirm that alcohol concentration in saliva is comparable to the blood alcohol concentration (McColl *et al.* 1979, Jones 1979a, Jones 1979b, Haeckel & Bucklitsch 1987, Jones 1993, Gubala & Zuba 2003), and therefore easily accessible saliva sample can be used as a specimen demonstrating the alcohol concentration in the blood. The developed test is based on well-recognized chemistry (Honchar 1978, Prencipe 1987), where enzymes alcohol oxidase and peroxidase are utilized. Wargh *et al.* (2023) showed that sensitive Promilless products serve their intended purpose well.

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Haeckel, R. & Bucklitsch, I. (1987) The comparability of ethanol concentrations in peripheral blood and saliva. The phenomenon of variation in saliva to blood concentration ratios. *J. Clin. Chem. Clin. Biochem.* 25(4): 199-204.

Honchar, M.V. (1978) A sensitive method for quantitative analysis of hydrogen peroxide and oxidase substrates in biological samples. *Ukr. Biokhim. Zh.* 70(5): 157-163.

Jones, A.W. (1979a) Inter- and intra-individual variations in the saliva/blood alcohol ratio during ethanol metabolism in man. *Clin. Chem.* 25(8): 1394-1398.

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McColl, K.E., Whiting, B., Moore, M.R. & Goldberg, A. (1979) Correlation of ethanol concentrations in blood and saliva. *Clin. Sci. (Lond)* 56(3): 283-286.

Prencipe, L., Iaccheri, E. & Manzati, C. (1987) Enzymatic ethanol assay: a new colorimetric method based on measurement of hydrogen peroxide. *Clin. Chem.* 33(4): 486-489.

Wargh, N, Piltti, J. & Hedberg, P. (2023) The performance of saliva test strips for determining ethanol levels, as compared to gas chromatography and breathalyser methods. Scandinavian Journal of Clinical and Laboratory Investigation, DOI: 10.1080/00365513.2023.2255970