
Verify®
Accurato
Facile da usare
Risultato rapido
Self Test Alcool
Cassetta Per Test Rapido Alcool
(Saliva)
contiene 1 test
RISULTATO IN 3-5 MINUTI

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 095123 0008 Rev. 04

Manufacturer:

Hangzhou AllTest Biotech Co., Ltd.
550#, Yinhai Street
Hangzhou Economic and Technological Development Area
310018 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Products for determination of infection markers tumor markers and products for self testing**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V1 095123 0008 Rev. 04

Report no.: SH221064A02

Valid from: 2022-04-05
Valid until: 2025-05-26

Date, 2022-04-05

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 095123 0008 Rev. 04

Model(s):

Toxo IgG/IgM Rapid Test,
Rubella IgM Rapid Test,
CMV IgM Rapid Test,
ToRCH IgM Combo Rapid Test,
PSA Rapid Test,
PSA Qualitative Rapid Test,
Chlamydia Rapid Test,
Sperm Concentration Rapid Test,
SP-10 Male Fertility Rapid Test,
hCG Rapid Test,
Digital hCG Pregnancy Test
LH Rapid Test,
FSH Rapid Test,
Vaginal pH Rapid Test,
Ferritin Rapid Test,
TSH Rapid Test,
H.pylori Rapid Test,
Urinary Tract Infections Test,
FOB Rapid Test,
Vitamin D Rapid Test

Facility(ies):

Hangzhou AllTest Biotech Co., Ltd.
550#, Yinhai Street, Hangzhou Economic and Technological Development Area, 310018 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

.

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Dichiarazione di Conformità CE

Produttore: Nome: HANGZHOU ALLTEST BIOTECH CO., LTD.
Indirizzo: #550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou - 31

Nome del Prodotto: Test Rapido per Alcol
Codice Articolo: DAL-802H

Noi, HANGZHOU ALLTEST BIOTECH CO., LTD., dichiariamo di essere i soli responsabili di questa dichiarazione. Dichiariamo inoltre che il prodotto sopra menzionato soddisfa le disposizioni del GPSR (UE) 2023/988, e del Regolamento (EC) n. 1907/2006, e del regolamento (EC) n. 1272/200.
Come trasposti nelle leggi nazionali. Tutta la documentazione di supporto è conservata presso i locali del produttore.

DIRETTIVE E REGOLAMENTI

Direttive generali e regolamenti applicabili:
REGOLAMENTO CLP (EC) n. 1272/2008 del Parlamento Europeo e del Consiglio del 16 dicembre 2008
REGOLAMENTO REACH (EC) n. 1907/2006 del Parlamento Europeo e del Consiglio del 18 dicembre 2006
GPSR (UE) 2023/988 del PARLAMENTO EUROPEO E DEL CONSIGLIO DEL 10 MAGGIO 2023

Norme applicate: EN ISO 13485:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-1:201, EN ISO 18113-4:2011, EN 13612:2002/AC:2002, EN ISO 23640:2015 -EN 13641:2002, EN 13532:2002, EN ISO 15223-1:2016

Luogo e data di emissione della dichiarazione di conformità: Hangzhou, 2024.12.20

Firma: _____

Nome: Gao Fei (Ruolo: Direttore Generale)

HANGZHOU ALLTEST BIOTECH CO.,LTD. 3301180084165

Hangzhou AllTest Biotech Co.,Ltd.
#550, Yinhai Street,
Hangzhou Economic & Technological Development Area,
Hangzhou -310018, P.R. China

杭州奥泰生物技术股份有限公司
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网 址：www.alltests.com.cn

EC Declaration of Conformity

Manufacturer:
Name：HANGZHOU ALLTEST BIOTECH CO.,LTD.
Address：#550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou -310018, P.R. China

Product Name: Alcohol Rapid Test
Cat. No.: DAL-802H

We, HANGZHOU ALLTEST BIOTECH CO., LTD., herewith declare that we are exclusively responsible for this declaration of conformity. We herewith declare that the above mentioned product meet the transposition into national law, the provisions of the following GPSR (EU) 2023/988, Regulation (EC) No 1907/2006 and Regulation (EC) No 1272/200.
All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES AND REGULATIONS

General applicable directives and regulations Applied:
CLP REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008
REACH REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006
GPSR (EU) 2023/988 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 10 May 2023

Standard Applied: EN ISO 13485:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-4:2011, EN 13612:2002/AC:2002, EN ISO 23640:2015, EN 13641:2002, EN 13532:2002, EN ISO 15223-1:2016

Place, Date of issue of DOC: in Hangzhou on 2024.12.20

Signature:
Name: Gao Fei (Position: General Manager)

HANGZHOU ALLTEST BIOTECH CO.,LTD. 3301180084165

Hangzhou AllTest Biotech Co.,Ltd.
#550, Yinhai Street,
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Technical File

Alcohol Rapid Test (Saliva)

Prepared by:

Approved by:

Version: 01

Issued Date:2024.12.10

HANGZHOU ALLTEST BIOTECH CO., LTD.

Address: #550, Yinhai Street, Hangzhou Economic and Technological Development Area,

310018 Hangzhou, PEOPLE'S REPUBLIC OF CHIN

1.1 Product Name：
Alcohol (ALC) Rapid Test (Saliva)

1.2 Brand Name: AllTest

1.3 General description

1.3.1 Intended Use
The Alcohol Rapid Test (Saliva) is a rapid, highly sensitive method to detect the presence of alcohol in saliva and provide an approximation of relative blood alcohol concentration.
This test provides a preliminary screen only. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Clinical consideration and professional judgment should be applied to any test screen result, particularly when preliminary positive screens are indicated.

1.3.2 Summary
Two-thirds of all adults drink alcohol. The blood alcohol concentration at which a person becomes impaired is variable dependent upon the individual. Each individual has specific parameters that affect the level of impairment such as size, weight, eating habits and alcohol tolerance. Inappropriate consumption of alcohol can be a contributing factor to many accidents, injuries, and medical conditions.

1.3.3 Principle
It is well established that the concentration of alcohol in saliva is comparable to that of blood. The Alcohol Rapid Test (Saliva) consists of a plastic dipstick with a reaction pad attached at the tip. On contact with solutions of alcohol, the reaction pad will rapidly turn colors depending on the concentration of alcohol present. The pad employs a solid-phase chemistry which uses a highly specific enzyme reaction.

1.3.4 Precautions
The Alcohol Rapid Test (Saliva) is a visually interpreted test where color matching is used to provide an approximation of relative blood alcohol concentration. Test materials that have been exposed to saliva should be treated as potentially infectious. Do not use the Alcohol Rapid Test (Saliva) after the expiration date marked on the foil package.

1.3.5 Storage and Stability
The Alcohol Rapid Test (Saliva) is to be stored at 2-30°C (36-86°F) in its sealed foil package. If storage temperatures exceed 30°C, the test performance may degrade. If the product is refrigerated, The Alcohol Rapid Test (Saliva) must be brought to room temperature prior to opening the pouch.

1.3.6 Controls

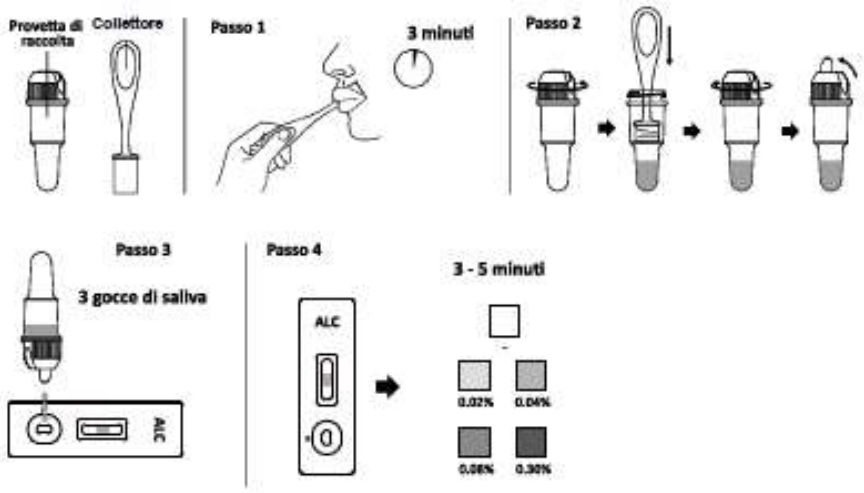
The Alcohol Rapid Test (Saliva) may be qualitatively verified by using a test solution prepared by adding 5 drops of 80 proof distilled spirits to 8 oz. (1 cup) of water. This solution should produce a color reaction on the pad. The color reaction with alcohol in saliva is somewhat slower and less intense than with alcohol in an aqueous solution

1.4 Standard testing procedure

Allow the pouched cassette to equilibrate to room temperature (15-30°C) prior to testing. Instruct the donor to not place anything in the mouth including food, drink, gum or tobacco products for at least 10 minutes prior to collection.

1.4.1 Alcohol Rapid Test (Saliva)

1 Avoid from placing anything in the mouth for fifteen (15) minutes prior to beginning of the test. This includes non-alcoholic drinks, tobacco products, coffee, breath mints and food, etc.
2 Spit the saliva into the collection cup.
3 Open the foil package and remove the test cassette. Observe the reactive pad on the end of the test cassette. If the reaction pad has a blue color before applying saliva sample, do not use.
4 Saturate the reactive pad with saliva from collection cup or by applying saliva directly to the pad. (It usually takes 6-8 seconds to be saturated.) Start timer immediately after saliva application.
5 Read result at two (2) minutes. Compare the color of the reaction pad with the color chart to determine the relative blood alcohol level.



1.5 Interpretation of results

Positive: The Alcohol Rapid Test (Saliva) will produce a color change in the presence of saliva alcohol. The color will range from light blue color at 0.02% relative blood alcohol concentration to a dark blue color near 0.30% relative blood alcohol concentration. Color pads are provided within this range to allow an approximation of relative blood alcohol concentration. The test may produce colors that appear to be between adjacent color pads.

NOTE: The Alcohol Rapid Test (Saliva) is very sensitive to the presence of alcohol. A blue color that is lighter than the 0.02% color pad should be interpreted as being positive to the presence of alcohol in saliva but less than 0.02% relative blood alcohol.

Negative: When The Alcohol Rapid Test (Saliva) shows no color change this should be interpreted as a negative result indicating that alcohol has not been detected.

Invalid: If the color pad has a blue color before applying saliva sample, do not use the test.

NOTE: A result where the outer edges of the color pad produces a slight color but the majority of the pad remains colorless the test should be repeated to ensure complete saturation of the pad with saliva. The test is not reusable.

1.6 Limitations

1. Failure to wait 15 minutes after placing food, drink, or other materials (including smoking) in the mouth before running the test can produce erroneous results due to possible contamination of the saliva by interfering substances.
2. The Alcohol Rapid Test (Saliva) is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by The Alcohol Rapid Test (Saliva). Alcohol vapors are present in many institutions and homes. Alcohol is a component in many household products such as disinfectant, deodorizers, perfumes, and glass cleaners. If the presence of alcohol vapors is suspected, the test should be performed in an area known to be free of vapors.
3. Ingestion or general use of over-the-counter medications and products containing alcohol can produce positive results.

1.7 Performance Characteristics

The detection limit on The Alcohol Rapid Test (Saliva) is from 0.02% to 0.30% for approximate relative blood alcohol level. The cutoff level of The Alcohol Rapid Test (Saliva) can vary based on local regulations and laws. Test results can be compared to reference levels with color chart on the foil package.

1.8 Reagents

Tetramethylbenzidine
Alcohol Oxidase
Peroxidase
Other additives

1.9 BIBLIOGRAPHY

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2. Tsai, S.C. et.al. *Determination of Five Abused Drugs in Nitrite-Adulterated Urine by Immunoassays and Gas Chromatography–Mass Spectrometry.* J. Anal. Toxicol. 1998; 22 (6): 474
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2.1 Clinical study

A side-by-side comparison was conducted using the Alcohol Rapid Test (Saliva) and a commercially available Alcohol (Saliva). Testing was performed on 180 clinical specimens previously collected from the volunteers of drinking different quantity of wine. Compare the reagent areas to the corresponding color blocks on the color chart at the specified times. Hold the strip close to the color blocks and match carefully. The test results are shown in table below.

Table: Clinical study

Method		Commercially Alcohol Rapid Test (Saliva)		Total Result
AllTest ALC Rapid Test (Saliva) ALC25110004-T	Results	Positive	Negative	
	Positive	80	1	81
	Negative	1	98	99
Total Result		81	99	180

Positive Agreement=80/81×100% = 98.8%
Negative Agreement =98/99×100% = 99.0%
Total Agreement=（80+98）/（81+99）×100% = 98.9%

Conclusion:
Clinical test has been conducted on altogether 180 specimens. Alltest tests were parallel comparison studied with comparison device, and after consistency test on the Kappa value of the result, the total conformity rate of the test result of Alltest test and ACON ALC saliva product for comparison is 98.9%, the consistency test result of Kappa is 0.95, and this indicate that the two has got high conformity in the respect of ALC test.

2.2 Analytical Sensitivity

Study to validate the sensitivity of the reagent pads on the Alltest Alcohol Rapid Test (Saliva) was conducted. The analytical sensitivity was determined by spiking water specimens with intact alcohol standard at 0, 0.01%, 0.02%, 0.04%, 0.08%, 0.15% and 0.3%. The alcohol standards were randomized and coded. The results were confirmed by commercial Alcohol Strip. A total of 30 replicates for each standard were tested. The specimens were visual compare the color of the reaction pad with the color chart at 2 minutes after specimen application. Results are presented in table below:

Sensitivity Claim for each Analyte
The minimum sensitivity level for each analyte of the Alltest Alcohol Rapid Test is defined as the lowest level at which over 80% of the test results are positive when the diluted positive samples for an analyte of known concentrations were tested.

Results:
Test results are listed in the following tables. Gray blocks identify the low range (sensitivity) of each analyte.

Table: Analytical Sensitivity

Alcohol Rapid Test (Saliva)
ALC25110004-T

Alcohol Conc.	n	Negative	Positive	% Positive
0%	30	30	0	0%
0.01%	30	29	1	3.45%

0.02%*	30	5	25	83.3%
0.04%	30	0	30	100%
0.08%	30	0	30	100%
0.15%	30	0	30	100%
0.30%	30	0	30	100%

* Lowest Positive Concentration

ALC25110005-T

Alcohol Conc.	n	Negative	Positive	% Positive
0%	30	30	0	0%
0.01%	30	29	1	3.45%
0.02%*	30	4	26	86.7%
0.04%	30	0	30	100%
0.08%	30	0	30	100%
0.15%	30	0	30	100%
0.30%	30	0	30	100%

* Lowest Positive Concentration

ALC25110006-T

Alcohol Conc.	n	Negative	Positive	% Positive
0%	30	30	0	0%
0.01%	30	29	1	3.45%
0.02%*	30	6	24	80.0%
0.04%	30	0	30	100%
0.08%	30	0	30	100%
0.15%	30	0	30	100%
0.30%	30	0	30	100%

* Lowest Positive Concentration

Conclusions:

From data listed in the above tables, the minimum sensitivity level of Alltest Alcohol Rapid Test was identified at 0.02%.

2.3 Variability (Inter/Intra/Day to assay)

Drop the sample onto the pad and then remove the excess sample with the pad and tested according to the package inset. Five replicates of each level were tested each day for 3 consecutive days using all the 3 lots. Compare the reagent areas to the corresponding color blocks on the color chart at the specified times. Hold the strip close to the color blocks and match carefully. Results were presented in Table below

Table: Variability

Alcohol Rapid Test (Saliva)

Alcohol: Purified water

Day	Lot#:	1	2	3	4	5
Day 1	ALC25110004-T	N*	N	N	N	N
	ALC25110005-T	N	N	N	N	N
	ALC25110006-T	N	N	N	N	N
Day 2	ALC25110004-T	N	N	N	N	N
	ALC25110005-T	N	N	N	N	N

	ALC25110006-T	N	N	N	N	N
Day 3	ALC25110004-T	N	N	N	N	N
	ALC25110005-T	N	N	N	N	N
	ALC25110006-T	N	N	N	N	N

Note: “N*” mean Negative

Alcohol Conc.	n	Negative	Positive	% Positive
0%	30	30	0	0%
0.01%	30	29	1	3.45%
0.02%*	30	5	25	83.3%
0.04%	30	0	30	100%
0.08%	30	0	30	100%
0.15%	30	0	30	100%
0.30%	30	0	30	100%

* Lowest Positive Concentration

ALC25110005-T

Alcohol Conc.	n	Negative	Positive	% Positive
0%	30	30	0	0%
0.01%	30	29	1	3.45%
0.02%*	30	4	26	86.7%
0.04%	30	0	30	100%
0.08%	30	0	30	100%
0.15%	30	0	30	100%
0.30%	30	0	30	100%

* Lowest Positive Concentration

ALC25110006-T

Alcohol Conc.	n	Negative	Positive	% Positive
0%	30	30	0	0%
0.01%	30	29	1	3.45%
0.02%*	30	6	24	80.0%
0.04%	30	0	30	100%
0.08%	30	0	30	100%
0.15%	30	0	30	100%
0.30%	30	0	30	100%

* Lowest Positive Concentration

Conclusions:

From data listed in the above tables, the minimum sensitivity level of Alltest Alcohol Rapid Test was identified at 0.02%.

2.4 Variability (Inter/Intra/Day to assay)

Drop the sample onto the pad and then remove the excess sample with the pad and tested according to the package inset. Five replicates of each level were tested each day for 3 consecutive days using all the 3 lots. Compare the reagent areas to the corresponding color blocks on the color chart at the specified times. Hold the strip close to the color blocks and match carefully. Results were presented in Table below

Table: Variability

Alcohol Rapid Test (Saliva)

Alcohol: Purified water

Day	Lot#:	1	2	3	4	5
Day 1	ALC25110004-T	N*	N	N	N	N
	ALC25110005-T	N	N	N	N	N
	ALC25110006-T	N	N	N	N	N
Day 2	ALC25110004-T	N	N	N	N	N
	ALC25110005-T	N	N	N	N	N
	ALC25110006-T	N	N	N	N	N
Day 3	ALC25110004-T	N	N	N	N	N
	ALC25110005-T	N	N	N	N	N
	ALC25110006-T	N	N	N	N	N

Note: “N*” mean Negative

Alcohol: 0.02%

Day	Lot#:	1	2	3	4	5
Day 1	ALC25110004-T	P*	P	P	P	P
	ALC25110005-T	P	P	P	P	P
	ALC25110006-T	P	P	P	P	P
Day 2	ALC25110004-T	P	P	P	P	P
	ALC25110005-T	P	P	P	P	P
	ALC25110006-T	P	P	P	P	P
Day 3	ALC25110004-T	P	P	P	P	P
	ALC25110005-T	P	P	P	P	P
	ALC25110006-T	P	P	P	P	P

Note: “P*” mean Positive

Conclusion: Test results were consistent between the 3 lots of test、 cassette and cup.

2.5 Interference Substances and Specificity Study

1）Saliva samples were spiked with different analytes, which were then confirmed as positive saliva samples by available Alcohol (Saliva). These positive saliva samples were then spiked with possible interfering substances. Each saliva sample was tested with 5 replicates of the ALC rapid test. Results were read by comparing color reaction to the color chart according to the Instructions on the package insert.

2）Saliva samples were spiked with different analytes, which were then confirmed as negative saliva samples by available Alcohol (Saliva). These negative saliva samples were then spiked with possible interfering substances. Each saliva sample was tested with 5 replicates of the ALC rapid test. Results were read by comparing color reaction to the color chart according to the Instructions on the package insert.

Interfering Substances:

The following potentially interfering substances at concentrations indicated were added to the saliva:

Interfering Substances Tested	**Concentration Level**

Peroxidases	0.5mg/dl
hydrogen peroxide	10ppm
Creatinine	200mg/dL
Ascorbic acid	5mg/dl
Tannic acid	10mg/dl
Calcium Chloride	100mg/dL
Mercaptans	10mg/dl
NaCl	1,000mg/dL
Oxalic acid	15mg/dl
Uric Acid	15mg/dl
L-dopa	10mg/dl
L-methyldopa	10mg/dl
Methampyrone	8mg/dl
KCl	1,000mg/dL
Methyl alcohol	1%
Sodium hypochlorite	80ppm
Pyrogallol	15mg/dl
Ethyl alcohol	0.3%
Glucose	1,000mg/dL
Tosylates	10mg/dl
Urea	1,000mg/dL
Allyl alcohols	1%
Bilirubin	4mg/dl

Result:

Interfering Substances Tested	**Concentration Level**	**Testing Results**	
		Negative urine with spiked interference substance	**Alcohol urine with spiked interference substance**
Peroxidases	0.5mg/dl	Negative	ALC pad color enhances
hydrogen peroxide	10ppm	Negative	ALC pad color enhances
Creatinine	200mg/dL	Negative	Positive, no interference
Ascorbic acid	5mg/dl	Negative	ALC pad color lower
Tannic acid	10mg/dl	Negative	ALC pad color lower
Calcium Chloride	100mg/dL	Negative	Positive, no interference
Mercaptans	10mg/dl	Negative	ALC pad color lower
NaCl	1,000mg/dL	Negative	Positive, no interference
Oxalic acid	15mg/dl	Negative	ALC pad color lower
Uric Acid	15mg/dl	Negative	ALC pad color lower
L-dopa	10mg/dl	Negative	ALC pad color lower
L-methyldopa	10mg/dl	Negative	ALC pad color lower
Methampyrone	8mg/dl	Negative	ALC pad color lower
KCl	1,000mg/dL	Negative	Positive, no interference
Methyl alcohol	1%	Positive	ALC pad color enhances
Sodium hypochlorite	80ppm	Negative	ALC pad color enhances.

Pyrogallol	15mg/dl	Negative	ALC pad color lower
Ethyl alcohol	0.3%	Positive	ALC pad color enhances
Glucose	1,000mg/dL	Negative	Positive, no interference
Tosylates	10mg/dl	Negative	ALC pad color lower
Urea	1,000mg/dL	Negative	Positive, no interference
Allyl alcohols	1%	Positive	ALC pad color enhances
Bilirubin	4mg/dl	Negative	ALC pad color lower

Conclusion:

From the above data, some the substances at the concentration levels tested interfered with the ability for the Alltest alcohol test (Saliva) to obtain correct results, list see below:

Agents which enhance color development

- Peroxidases
- Strong oxidizers

Agents which inhibit color development

- Reducing agents:
  Ascorbic acid, Tannic acid, Pyrogallol, Mercaptans and Tosylates, Oxalic acid, Uric Acid.
- Bilirubin
- L-dopa
- L-methyldopa
- Methampyrone

The Alcohol Rapid Test (Saliva) will react with methyl, ethyl and allyl alcohols.

2.6 Accelerate Stability

Accelerated Stability of The Alcohol Rapid Test (Saliva) was evaluated using samples from three different batches. These were placed in an incubator with the temperature calibrated at 37℃. Relative humidity (RH) calibrated at about 60%. A series of stability tests were performed at0, 7, 14, 21, 28, 43, 58, 73, 103,133, 148,163,178,185,192 days for 37℃according to Arrhenius Plot. See Table in below. Test dipsticks were assayed using each test concentration at ethanol negative Saliva, 0.02% and 0.3% ethanol standard solution specimens. Testing at each specific time interval consisted of quintuplicate for each specimen and read the result at read time according to color chart. Results are presented in tables below.

Following table illustrate the designated time points when the stability test will be performed. Results are presented in tables below.

Arrhenius Formula:

In K=-Ea/RT + In A

“K” mean Rate constant

“A” mean Arrhenius constant

“Ea” mean Activation energy

“R” mean Gas constant

“T” mean Temperature in Kelvin

Table: Time line for Accelerate Stability Study

Day	0	7	14	21	28	43	58	73	103	133	148	163	178	185	192

Temp.	day	days	days	days	days	days	days	days	days	days	days	days	days	days	days
37℃	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*

Acceptance Criteria：

The Alcohol Rapid Test (Saliva) must be exceed 80% given same as color chart results when with test all the samples.

Remark:

N=Negative

P=Positive

F= Fail

I=Invalid

Results:

Alcohol Rapid Test (Saliva)

Store at 37℃

Days	Specimen	Lot No.															
		Lot 1: ALC25110004-T					Lot 1: ALC25110005-T					Lot 1: ALC25110006-T					
0	Negative Saliva	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
	0.02% Alcohol	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	
	0.3% Alcohol	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	
7	Negative Saliva	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
	0.02% Alcohol	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	
	0.3% Alcohol	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	
14	Negative Saliva	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
	0.02% Alcohol	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	
	0.3% Alcohol	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	
21	Negative Saliva	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
	0.02% Alcohol	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	
	0.3% Alcohol	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	
28	Negative Saliva	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
	0.02% Alcohol	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	
	0.3% Alcohol	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	
43	Negative Saliva	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
	0.02% Alcohol	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	
	0.3% Alcohol	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	
58	Negative Saliva	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
	0.02% Alcohol	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	
	0.3% Alcohol	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	
73	Negative Saliva	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
	0.02% Alcohol	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	
	0.3% Alcohol	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	
103	Negative Saliva	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
	0.02% Alcohol	P	P	F	P	P	P	P	P	P	P	P	P	P	P	P	
	0.3% Alcohol	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	
133	Negative Saliva	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	

	0.02% Alcohol	P	P	P	P	F	P	P	P	P	P	P	P	F	P	P
	0.3% Alcohol	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
148	Negative Saliva	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	0.02% Alcohol	P	P	P	P	F	P	P	P	P	P	P	P	F	P	P
	0.3% Alcohol	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
163	Negative Saliva	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	0.02% Alcohol	P	P	P	P	F	P	P	P	P	P	P	P	F	P	P
	0.3% Alcohol	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
178	Negative Saliva	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	0.02% Alcohol	P	P	P	P	F	P	P	P	P	P	P	P	F	P	P
	0.3% Alcohol	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
185	Negative Saliva	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	0.02% Alcohol	P	P	P	P	F	P	P	P	P	P	P	P	F	P	P
	0.3% Alcohol	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
192	Negative Saliva	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	0.02% Alcohol	P	P	P	P	F	P	P	P	P	P	P	P	F	P	P
	0.3% Alcohol	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P

Conclusion: The Alcohol Rapid Test (Saliva) was stable at 37℃ for 192 days. These data were plotted on an Arrhenius Plot and the shelf life of this product was determined to be at least 24 months from the data of manufacture.