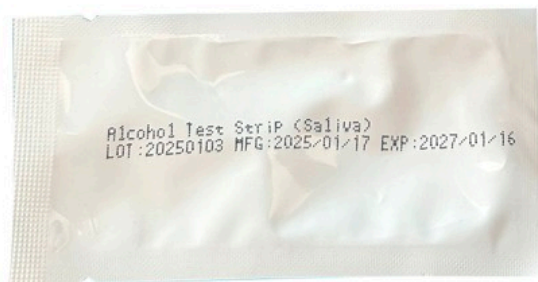
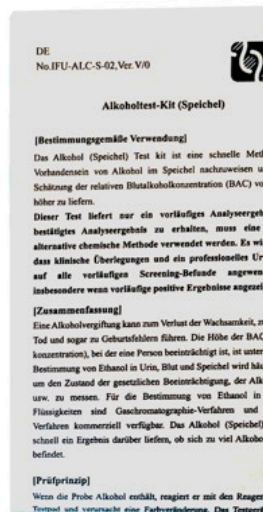


Ficha Técnica IU-DRUG-ALC

Referencia	Descripción
IU-DRUG-ALC	Test de Alcohol de Detección Rápida en Saliva Formato Tira - 1 Prueba



ESPECIFICACIONES	
Indicada para	Detectar la presencia de alcohol.
Muestra	En saliva
Referencia del fabricante	CAL2S-1

Empaque	Empaque individual de 1 kit de prueba Caja de transporte de 480 unidades / 24 cajas de 20 unidades
EAN	6952062779698

Kit de prueba de alcohol (saliva)

[Uso previsto]

El kit de prueba de alcohol (saliva) es un método rápido para detectar la presencia de alcohol en la saliva y proporcionar una estimación aproximada de la concentración relativa de alcohol en la sangre (BAC) de 0.02% o más.

Esta prueba proporciona solo un resultado analítico preliminar. Para obtener un resultado analítico confirmado, se debe utilizar un método químico alternativo más específico. Se recomienda que se apliquen las consideraciones clínicas y el juicio profesional a cualquier hallazgo preliminar de detección, especialmente cuando se indican resultados positivos preliminares.

[Resumen]

La intoxicación por alcohol puede provocar la pérdida del estado de alerta, el coma, la muerte e incluso defectos congénitos. El nivel de BAC (concentración de alcohol en la sangre) en el que una persona se ve afectada es variable. La determinación de etanol en orina, sangre y saliva se usa comúnmente para medir el estado de deterioro legal, intoxicación por alcohol, etc.

Las técnicas de cromatografía de gases y los métodos enzimáticos están disponibles comercialmente para la determinación de etanol en fluidos humanos. El kit de prueba de alcohol (saliva) puede proporcionar rápidamente un resultado sobre si hay demasiado alcohol en la muestra.

[Principio de prueba]

Si la muestra contiene alcohol, reaccionará con los reactivos de la almohadilla de prueba y provocará un cambio de color. El dispositivo de prueba consiste en una tira con un hisopo reactivo.

Al entrar en contacto con muestras que contienen alcohol, la almohadilla de prueba cambiará rápidamente de color de acuerdo con la concentración de alcohol presente. Este cambio de color es proporcional a la concentración de alcohol en la muestra.

Al comparar el color con los bloques de color en la escala de colores, la concentración de alcohol se puede determinar aproximadamente.

[Advertencias y precauciones]

1. La operación debe realizarse en estricta conformidad con las instrucciones; No utilice productos caducados o dañados.
2. No mezcle componentes de diferentes lotes.
3. No mezcle ni intercambie diferentes muestras.
4. No coma, beba ni fume en el área donde se manipulan muestras o kits.
5. No realice la prueba en una habitación con un flujo de aire fuerte, como cerca de un ventilador o aire acondicionado.



[Materiales y componentes]

Materiales proporcionados

1. Dispositivo de prueba
2. Instrucción
3. Copa de colección

Materiales requeridos pero no proporcionados

- Temporizador

[Condiciones de almacenamiento y período de validez]

1. El kit debe almacenarse a una temperatura entre 2 y 30°C hasta la fecha de caducidad indicada en el paquete sellado.
2. Después de abrir el paquete sellado, el dispositivo de prueba debe usarse lo antes posible, dentro de una hora.
3. El dispositivo de prueba debe mantenerse alejado de la luz solar directa, la humedad y el calor.
4. No congele el kit de prueba.

[Recolección y preparación de muestras]

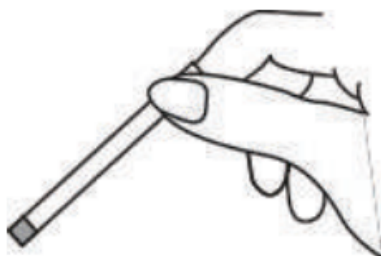
1. Las muestras de saliva deben recogerse en recipientes limpios y secos. Asegúrese de que el volumen de la muestra recolectada sea suficiente para sumergir el área de inmersión de la tira.
2. Evite llevarse cualquier cosa a la boca durante 15 minutos antes de comenzar la prueba, incluidos refrescos, productos de tabaco, café, dulces y alimentos.
3. Realice la prueba inmediatamente después de la recolección de la muestra. Si el ensayo no puede realizarse inmediatamente, las muestras pueden almacenarse en las condiciones especificadas.

[Procedimiento de prueba]

Lea atentamente las instrucciones antes de usar y lleve el dispositivo de prueba y las muestras a temperatura ambiente 15-30°C (59-86°F).

Mantenga la temperatura entre 15 y 30°C y la humedad entre el 20% y el 80% durante toda la prueba. Si la almohadilla reactiva está azul antes de aplicar la saliva, no use el dispositivo.

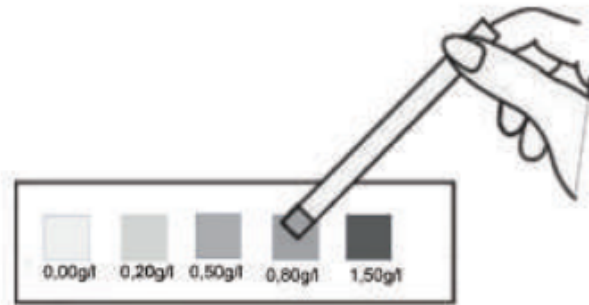
1. Para comenzar la prueba, abra el paquete sellado rasgando la muesca. Retire la tira reactiva del embalaje y utilícela lo antes posible.



2. Sature el hisopo reactivo con saliva, ya sea del recipiente de recolección o aplicada directamente al hisopo. (Por lo general, tarda de 6 a 8 segundos en saturarse). Inicie el temporizador inmediatamente después de aplicar la saliva.



3. Lea los resultados después de 2 minutos comparando visualmente el color de la almohadilla reactiva con la escala de colores correspondiente para determinar la concentración relativa de alcohol. No interprete el resultado después de 5 minutos.



[Interpretación de los resultados de las pruebas]

- **Resultado negativo:** No aparece ningún cambio de color en el panel de prueba. El color debe coincidir con el bloque de color indicado como negativo (-). Esto indica que no se detectó alcohol.
- **Resultado positivo:** Se produce un cambio de color en la almohadilla de prueba. El color varía de un azul claro a un azul oscuro, cayendo dentro de los bloques de color correspondientes.
- **Resultado no válido:** Los bordes exteriores de la almohadilla de reactivo muestran una ligera mancha, pero la mayor parte del hisopo permanece incoloro. Repita la prueba con una tira nueva, asegurándose de que el hisopo esté completamente saturado con la muestra. Si el problema persiste, detenga la prueba y póngase en contacto con su distribuidor local.

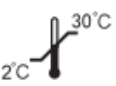
[Limitaciones de los métodos de inspección]

1. El dispositivo de prueba solo proporciona un resultado preliminar para detectar la concentración de alcohol en muestras de saliva humana. Se debe utilizar un método analítico secundario para obtener un resultado confirmado. La cromatografía de gases (GC) es el método preferido de confirmación.
2. No esperar 15 minutos después de ingerir alimentos, bebidas u otros materiales (incluido el humo) antes de realizar la prueba puede producir resultados incorrectos debido a la posible contaminación de la saliva con sustancias que interfieren.
3. La interpretación de los resultados visuales depende de varios factores: la variabilidad en la percepción

del color, la presencia o ausencia de factores inhibidores y las condiciones de iluminación durante la lectura de la tira. Se recomienda precaución al interpretar los resultados de la prueba debido a la naturaleza subjetiva de la prueba.

4. El dispositivo de prueba no debe usarse para determinar la presencia de alcohol en bebidas, alcohol sin diluir u otras soluciones líquidas.
5. La ingestión o el uso general de medicamentos de venta libre y productos que contienen alcohol pueden producir resultados positivos.
6. La ingestión o el uso general de medicamentos de venta libre y productos que contienen alcohol, como medicamentos para el resfriado, aerosoles para el aliento y enjuagues bucales, pueden producir resultados positivos. Espere al menos 20 minutos después de ingerir dichos productos antes de usar la tira.
7. La concentración de alcohol en el cuerpo humano aumenta lentamente después de la ingestión de alcohol. Después de alcanzar el máximo, la concentración de alcohol en el cuerpo humano disminuye. El tiempo que tarda la concentración de alcohol en reducirse a cero depende de la cantidad de alcohol ingerido.

[Instrucciones de símbolos]

	Fecha de caducidad		Número de lote
	Número de catálogo		Mantener seco
	Rango de temperatura almacenamiento del producto		Evite la exposición excesiva al sol
	No reutilizar		Fecha de fabricación
	Lea atentamente las instrucciones de uso antes de usar		No use el producto cuando el paquete esté dañado
	Fabricante		Contener cantidad suficiente para <n> pruebas

CERTIFICADOS



EC Declaration of Conformity

Manufacturer:

Name: ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.

Address: No. 777 Jimingshan Road, High-Tech Development Zone, 230088 Hefei,
Anhui, PEOPLE'S REPUBLIC OF CHINA

Product Name: Alcohol Test Kit (Saliva)

Ref. No.: CAL2S-1

We, ANHUI DEEPBLUE MEDICAL TECHNOLOGY 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 1272/2008.

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 Hefei on 2025.01.06

Signature:

Name: Chen Fengling (Position: General Manager)

Certificate of Analysis

Report NO: ALCOHOL Rapid-CP-20250101

Product name	Alcohol Test Kit (Saliva)		Specification	Strip,1pc/foil pouch
LOT	20250101		Quantities	20000pcs
Manufacturing date	2025/01/07		Expiring date	2027/01/06
Applying date	2025/01/07		Test date	2025/01/07
Report time	2025/01/07			
NO	Test Item		Standard code	Test results
1	Physical character	Appearance	Should be neat and complete, no burr, no damage, no pollution.	Pass
		Strip width	Should be not less than 2.5mm	Pass
2	Functional Performance		0.02%	Pass
			0.3%	Pass
			0.5%	Pass
			Negative Sample	Pass
3	Repeatability		With the same positive reference substance, the reaction results should be consistent and the color development should be uniform.	Pass
Inspection standard	According to SLSCQJ-ZL-225 inspection			
Inspect the conclusion	This product has been tested, it is suitable for SLSCQJ-ZL-225			

Quality director: Hong Yue

Checker: Luping Chen

Inspector: Chang jing Yu

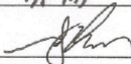




ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.

Website: <http://www.dbluemedical.com/>

Alcohol Test Kit (Saliva) Performance Evaluation Report

Prepared by:	郭传翔	Date:	2024 ¹² 年12月30日
Checked by:	徐莉	Date:	2024 ¹² 年12月30日
Approved by:		Date:	2024 ¹² 年12月30日



1.1. Product Name:

Alcohol Test Kit (Saliva)

1.2. General description

1.2.1. Background

The Alcohol Test Kit (Saliva) is a rapid method to detect the presence of alcohol in saliva and provide an approximation of relative blood alcohol concentration (BAC) at 0.02% or greater.

This assay provides only a preliminary analytical test result. 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.

1.2.2. Summary

Alcohol intoxication can lead to loss of alertness, coma, death and as well as birth defects. The BAC at which a person becomes impaired is variable. Determination of ethyl alcohol in urine, blood and saliva is commonly used for measuring legal impairment, alcohol poisoning, etc. Gas chromatography techniques and enzymatic methods are commercially available for the determination of ethyl alcohol in human fluids. The Alcohol Test Kit (Saliva) can provide a quick result of whether there is excessive alcohol in the sample.

1.2.3. Principle

If the sample contains alcohol, the alcohol will react with chemicals on the reaction pad and causes a color change. The test device consists of a strip with a reaction pad. On contact with specimens of alcohol, the reaction pad will rapidly change colors depending on the concentration of alcohol present. This color change is proportional to the concentration of alcohol in the specimen. By comparing with the color blocks on color chart, an approximate alcohol concentration can be determined.

1.2.4. Warnings and Precautions

- 1) Operation should be carried out in strict accordance with the instructions, do not use expired or damaged products.
- 2) Do not mix components from different kit lots.
- 3) Do not mix and interchange different specimens.
- 4) Do not eat, drink or smoke in the area where the specimens or kits are handled.
- 5) Do not perform the test in a room with strong air flow, ie. an electric fan or strong air-conditioning.



1.2.5. Storage and Stability

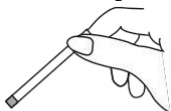
- 1) The kit should be stored at 2-30 °C until the expiry date printed on the sealed pouch.
- 2) After the foil pouch is unsealed, the test device should be used as soon as possible within one hour.
- 3) The test device should be kept away from direct sunlight, moisture and heat.
- 4) Do not freeze the test kit.

1.3. Standard testing procedure

Read the instructions carefully before use and bring test device and specimens were restored to room temperature 15-30°C (59-86°F) .

Please keep the temperature at 15-30 °C and the humidity at 20%-80% during the whole test.If the reaction pad has a blue color before applying saliva sample, do not use.

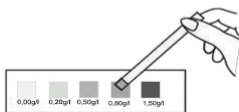
1. To begin testing, open the sealed pouch by tearing along the notch. Remove the test strip from the pouch and use it as soon as possible.



2. Saturate the reactive pad with saliva from specimen collection container or by applying saliva directly to the pad. (It usually takes 6-8 seconds to be saturated.) Start timer immediately after saliva application.



3. Read results at 2 minutes by visually comparing the color of the reaction pad to the corresponding color chart to determine the relative alcohol concentration. Do not interpret the result after 5 minutes.



1.4. Interpretation of Test results

Negative result: No color change appears on the reaction pad. The color should match the color block corresponding to a negative (-) result. This indicates that alcohol has not been detected.



Positive result: A color change appears on the reaction pad. The color on the reaction pad varying from a light blue to a dark blue, falling on or between the corresponding color blocks.

Invalid result: The outer edges of the reaction pad produce a slight color but the majority of the reaction pad remains colorless. Repeat the test with a new test strip, ensuring complete saturation of the reaction pad with the specimen. If the problem persists, do not continue the test and contact your local distributor.

1.5. Limitations

- 1) The test device provides only a preliminary result for detection alcohol concentration in human saliva samples. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography (GC) is the preferred confirmatory method.
- 2) 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.
- 3) Interpretation of visual results is dependent on several factors: the variability of color perception, the presence or absence of inhibitory factors, and the lighting conditions when the strip is read. Caution should be taken when interpreting test results due to the subjective nature of the test.
- 4) The test device should not be used to determine the presence of alcohol in beverages, in undiluted alcohol, or in other liquid solutions.
- 5) Ingestion or general use of over-the-counter medications and products containing alcohol can produce positive results.
- 6) Ingestion or general use of over-the-counter medications and products containing alcohol such as cold medicines, breath sprays and mouthwashes can produce positive results. Wait at least 20 minutes after ingesting any such products before using the test strip.
- 7) Alcohol concentration in human body slowly increases after the alcohol ingestion. After the maximum appearance, the alcohol concentration in human body reduces. How long the alcohol concentration reduces to zero depends on how much alcohol ingested.

2.1. Clinical study

A side-by-side comparison was conducted using the Alcohol Test Kit (Saliva) and the Contrast Reagent. A total of 178 samples were collected in this study. 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.

Method		Contrast Reagent		Total Results
Result		Positive	Negative	
DEEPBLUE Test Kit	Positive	71	1	72
	Negative	2	104	106
Total Results		73	105	178

Test result analysis:

Relative Sensitivity (%) = 97.26% (95%CI: 90.55%~99.25%)

Relative Specificity (%) = 99.05% (95%CI: 94.80%~99.83%)

Total Coincidence Rate(%) = 98.31%(95%CI: 95.16%~99.43%)

Conclusions:

Comparing with the Contrast Reagent, the consistent ratio of saliva alcohol test strips within same grad was >90% and the consistent ratio for negative and positive is more than 95%. The test results meet the requirements. The relative sensitivity is 97.26% (95%CI:90.55% to 99.25%), the relative specificity is 99.05% (95%CI:94.80% to 99.83%) and the total coincidence rate is 98.317% (95%CI: 95.16% to 99.43%).

The results of study show that the Alcohol Test Kit (Saliva) developed by ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD. has comparable clinical performance to similar products already on the market.

2.2. Analytical Sensitivity

Study to validate the sensitivity of the reagent pads on the Alcohol Test Kit (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%, 0.3% and 0.5%. 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:

Lot number:

20220201, 20220202, 20220203

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

20220201

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%
0.50%	30	0	30	100%

* Lowest Positive Concentration

20220202

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%
0.50%	30	0	30	100%

* Lowest Positive Concentration

20220203

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%
0.50%	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: Purified water

Day	Lot	1	2	3	4	5
Day 1	20220201	N	N	N	N	N
	20220202	N	N	N	N	N
	20220203	N	N	N	N	N
Day 2	20220201	N	N	N	N	N
	20220202	N	N	N	N	N
	20220203	N	N	N	N	N
Day 3	20220201	N	N	N	N	N
	20220202	N	N	N	N	N
	20220203	N	N	N	N	N

Note: "N" mean Negative

Alcohol: 0.02%

Day	Lot	1	2	3	4	5
Day 1	20220201	P	P	P	P	P
	20220202	P	P	P	P	P
	20220203	P	P	P	P	P
Day 2	20220201	P	P	P	P	P
	20220202	P	P	P	P	P
	20220203	P	P	P	P	P
Day 3	20220201	P	P	P	P	P
	20220202	P	P	P	P	P
	20220203	P	P	P	P	P

Note: "P" mean Positive

Conclusion:

The above results showed the test results of the three batches were consistent, indicating that the reagents have good repeatability and high precision.

2.4. Interference Substances and Specificity Study

1) Saliva samples were spiked with different analytes, which were then confirmed as positive saliva samples by available Alcohol Test Kit (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 Test Kit (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	1000mg/dL
Oxalic acid	15mg/dl
Uric Acid	15mg/dl
L-dopa	10mg/dl
L-methyldopa	10mg/dl
Methampyrone	8mg/dl
KCl	1000mg/dL
Methyl alcohol	1%
Sodium hypochlorite	80ppm
Pyrogallol	15mg/dl
Ethyl alcohol	0.3%
Glucose	1000mg/dL
Tosylates	10mg/dl
Urea	1000mg/dL
Allyl alcohols	1%
Bilirubin	4mg/dl

Result:

Interfering Substances Tested	Concentration Level	Testing Results	
		Negative urine with spiked	Alcohol urine with spiked interference



		interference substance	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	1000mg/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	1000mg/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	1000mg/dL	Negative	Positive, no interference
Tosylates	10mg/dl	Negative	ALC pad color lower
Urea	1000mg/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.

2.5. Accelerate Stability



2.5.1. Physical test

Appearance

Pick 1 product randomly, observe with naked eye, the product should be clean and integrated without being burr, damaged and polluted.

Width

The width of the strip should not be less than 2.5 mm.

2.5.2. Repeatability

Take the same batch test papers. Use positive control to test 10 times. The results of 10 replicates should be consistent and all positive.

2.5.3. Accelerated stability study

With reference to ASTM F1980:2016, products are tested after being stored at different temperatures for a period of time. Calculate the accelerated aging factor and estimate the expiration date of the product.

The test kits are stored at 37°C, 45°C, and 60°C, and tested once a week, and the test results are recorded. When the measured product performance does not meet the requirements, record the maximum time that can be stored at this temperature. Then calculate the estimated expiration date of this product according to the formula.

2.5.4. Accelerate Stability

Accelerated stability of reagents stored at 37°C

Table Accelerated stability test study results table of Lot 20220201 (37 °C)

Weeks		1	2	3	4	5	6	7	8	9	10
Performance	Physical Detection	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
	Width	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Limit of detection	0.02% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	0.3% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	0.5% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	Negative Saliva	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-
Repeatability	Positive control	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+

Note: “-” means negative; “+” means positive



Table Accelerated stability test study results table of Lot 20220202 (37 °C)

Performance \ Weeks		1	2	3	4	5	6	7	8	9	10
Physical Detection	Exterior	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
	Width	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Limit of detection	0.02% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	0.3% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	0.5% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	Negative Saliva	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-
Repeatability	Positive control	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+

Note: “-” means negative; “+” means positive

Table Accelerated stability test study results table of Lot 20220203 (37 °C)

Performance \ Weeks		1	2	3	4	5	6	7	8	9	10
Physical Detection	Exterior	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
	Width	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Limit of detection	0.02% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	0.3% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	0.5% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	Negative Saliva	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-
Repeatability	Positive control	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+

Note: “-” means negative; “+” means positive

Accelerated stability of reagents stored at 45°

Table Accelerated stability test study results table of Lot 20220201 (45 °C)

Performance \ Weeks		1	2	3	4	5	6	7	8	9	10
Physical Detection	Exterior	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
	Width	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass



ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.

Website: <http://www.dbluemedical.com/>

Limit of detection	0.02% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	0.3% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	0.5% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	Negative Saliva	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-
Repeatability	Positive control	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+

Note: “-” means negative; “+” means positive

Table Accelerated stability test study results table of Lot 20220202 (45 °C)

Weeks		1	2	3	4	5	6	7	8	9	10
Physical Detection	Exterior	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
	Width	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Limit of detection	0.02% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	0.3% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	0.5% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	Negative Saliva	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-
Repeatability	Positive control	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+

Note: “-” means negative; “+” means positive

Table Accelerated stability test study results table of Lot 20220203 (45 °C)

Weeks		1	2	3	4	5	6	7	8	9	10
Physical Detection	Exterior	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
	Width	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Limit of detection	0.02% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	0.3% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	0.5% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	Negative Saliva	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-
Repeatability	Positive control	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+



Note: “-” means negative; “+” means positive

Accelerated stability of reagents stored at 60°C

Table Accelerated stability test study results table of Lot 20220201 (60 °C)

Weeks		1	2	3	4	5	6	7	8	9	10
Performance											
Physical Detection	Exterior	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
	Width	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Limit of detection	0.02% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	0.3% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	0.5% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	Negative Saliva	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-
Repeatability	Positive control	10/10 +	10/10 +	10/10 +	10/10 +	10/10 +	10/10 +	10/10 +	10/10 +	10/10 +	10/10 +

Note: “-” means negative; “+” means positive

Table Accelerated stability test study results table of Lot 20220202 (60 °C)

Weeks		1	2	3	4	5	6	7	8	9	10
Performance											
Physical Detection	Exterior	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
	Width	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Limit of detection	0.02% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	0.3% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	0.5% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	Negative Saliva	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-
Repeatability	Positive control	10/10 +	10/10 +	10/10 +	10/10 +	10/10 +	10/10 +	10/10 +	10/10 +	10/10 +	10/10 +

Note: “-” means negative; “+” means positive

Table Accelerated stability test study results table of Lot 20220203 (60 °C)

Weeks		1	2	3	4	5	6	7	8	9	10
Performance											
Physical	Exterior	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass



Detection	Width	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Limit of detection	0.02% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	0.3% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	0.5% Alcohol	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+	5/5+
	Negative Saliva	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-	5/5-
Repeatability	Positive control	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+	10/10+

Note: “-” means negative; “+” means positive

Conclusion:

Finished product inspection

The results can meet the requirements of the technical index.

Accelerated stability study

Accelerate the statistics of experimental results

Performance		37°C	45°C	60°C
Physical detection	Exterior	70 days	70 days	70 days
	Width	70 days	70 days	70 days
Limit of detection	0.02% Alcohol	70 days	70 days	70 days
	0.3% Alcohol	70 days	70 days	63 days
	0.5% Alcohol	70 days	70 days	70 days
	Negative Saliva	70 days	70 days	70 days
Repeatability	Positive control	70 days	70 days	70 days

As can be seen from the above table, all performances are normal when stored at 37 degrees and 45 degrees for 70 days (10 weeks). The shortest time at 60 degrees is 91 days, so we calculate the accelerated aging factor (AAF) based on the data at 60 degrees (T_{AA}). At this time, the accelerated aging time (AAT) is 63 days. The storage temperature (T_{RT}) of this product at room temperature is 23 degrees. Q_{10} is set to 2.0, and the estimated product validity period (t_e) is as follows:

$$AAF = Q_{10}^{((T_{RT}-T_{AA})/10)} = 2^{((60-23)/10)} = 2^{3.7} = 13.0$$

$$t_e = AAT * AAF = 63 * 13.0 = 819 \text{ days} > 730 \text{ days (24 months)}$$

According to the results of accelerated experiments, it is estimated that the actual



ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.

Website: <http://www.dbluemedical.com/>

validity period of the product is greater than 24 months, and it is reasonable to set the validity period of the product to 24 months.

The performance indexes did not change and fully met the requirements of the technical index. Therefore, the reagent will not affect the stability of the product within 27 months in the temperature range of 2 °C ~ 30 °C, in order to exclude other possible influencing factors, so it is reasonable for the product to be valid for 24 months.