Verify®

PRODOTTI ISCRITTI AL
Ministero della Salute

- Accurato
- Facile da usare
- Risultato rapido

Test Cortisolo
(COR) (Fluido Orale)

contiene 1 test

RISULTATO IN 3-10 MINUTI

Solo per uso diagnostico professionale *in vitro*.

CERTIFICATE ◆ CERTIFICATE ◆ CERTIFICATE

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

European Representative:
Name: VidaQuick Biotech S.L.
Address: No.132, Rosello Street, Barcelona, Barcelona Province, 08036, Spain

Product Name: Cortisol Rapid Test (Oral Fluid)
Cat. No.: FCOR-802/FCOR-803
Model: Cassette/Midstream
Classification: Other Device, non-listed in Annex II of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III, excluding article 6

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 products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

Standard Applied: EN ISO13485:2016, EN ISO14971:2019, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, ISO 17511:2020, EN ISO23640:2015, EN 13641:2002, EN ISO 15223-1:2021

Place, Date of Issue: in Hangzhou on 15/05/2022

Signature: _____
Name: GAO FEI (Position: General Manager)
Name: Gao Fei
Position: General Manager

HANGZHOU ALLTEST BIOTECH CO.,LTD. 330118008416S

CE

Registration File of Cortisol (COR) Rapid Test (Oral fluid)

FCOR-802/803

Version: 01

HANGZHOU ALLTEST BIOTECH CO., LTD.

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

310018 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

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1. PRODUCT DESCRIPTION

1.1 Product Name

COR(Cortisol) Rapid Test（Oral fluid）

1.2 Intended Use

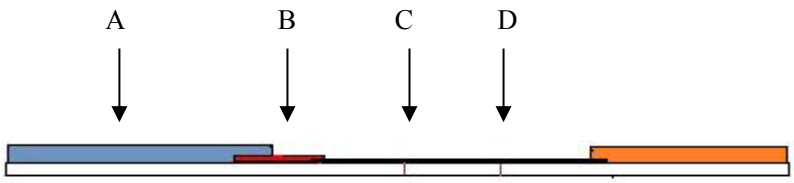
The Cortisol (COR) Rapid Test (Oral Fluid) is a rapid chromatographic immunoassay for the detection of Cortisol in human oral fluid.

1.3 Background

Cortisol is a steroid hormone that is also commonly referred to as a "stress hormone." is a biomarker for many diseases such as circadian rhythm, Cushing's syndrome, Addison's disease, and stress-related disorders. Cortisol secretion is follow a circadian rhythm, with cortisol levels peaking at dawn (30 minutes after waking up) during a 24-hour cycle and gradually decreasing during nighttime sleep.
Abnormally elevated cortisol levels suppress inflammation, suppress the immune system, and increase levels of fats and amino acids in the blood. And excess cortisol levels have been shown to be associated with the development of Cushing's disease. Accompanied by symptoms of obesity, fatigue, and brittle bones. Decreased cortisol levels can lead to Addison's disease, which manifests as weight loss, fatigue, skin folds, and darkening of scars.Salivary cortisol measurement has been widely reported in the literature and can be used to characterize circadian rhythms, Cushing's syndrome,Addison's disease,and stress-related disorders.

1.4 Principles

COR Rapid Test (Oral fluid) is a rapid chromatographic immunoassay based on the principle of competitive binding. Cortisol that may be present in the oral fluid specimen compete against its conjugate for binding sites on their specific antibody. During testing, a portion of the oral fluid specimen migrates upward by capillary action. COR, if present in the oral fluid specimen below 50ng/ml, will not saturate the binding sites of the antibody coated particles in the device. The antibody coated particles will then be captured by immobilized. COR conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the COR level is above 50ng/ml because it will saturate all the binding sites of anti- COR antibody.
A positive oral fluid specimen will not generate a colored line in the test line region because of competition, while a negative oral fluid specimen or a specimen containing a concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred



As shown in illustration above, the specimen (A) migrates via capillary action along the membrane to react with the colored conjugate (B) COR present in the specimen binds to the conjugate, forming a colored antibody-antigen complex. COR antigen immobilized in the test zone of the membrane captures the test region (C). The formation of a visible color line in the test region indicates a negative result (C). The absence of a color line in the test zones suggests a positive result. In the control zone of the membrane, immobilized reagents capture colored conjugate regardless of test specimen composition. The resulting visible colored band (D) confirms control line.

1.5 Performance and Specification

The COR (Cortisol) Rapid Test is a rapid chromatographic immunoassay for the detection of COR (Cortisol) in human oral fluid at a cut-off concentration as validated in the studies done in further sections (50ng/ml). The test utilizes a combination of COR antigen to selectively detect levels of COR in oral fluid. At the level of claimed sensitivity, The COR (Cortisol) Rapid Test (Oral fluid) shows no cross-reactivity with Bilirubin and so on.

1.5.1 Precautions

- For professional in vitro diagnostic use only.
- For Oral fluid specimen use only.
- Single-use device.Do not reuse.
- Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used device should be discarded according to local regulations.
- Wait a least 30 minutes after eating, drinking of any kind before the test. Storage and Stability

1.5.2 Storage and Stability

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch .The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

1.5.3 Standard Testing Procedure

Allow the test, specimen and/or controls to reach room temperature (15-30℃) prior to testing. Instruct the donor to not place anything in the mouth including food, drink, gum or tobacco products for at least 30 minutes prior to collection.

Cassette

① Bring the pouch to room temperature before opening it. Remove the test from the sealed pouch and use it within one hour.

② Remove the collector from the sealed pouch and collect oral fluid specimen as follows:

Important: Place the tongue against the upper and lower jaws and roots to enrich the oral fluid before oral fluid collection.

Insert the sponge end into the mouth, actively swab around the gums on both sides of the mouth and under the tongue and chew the sponge tenderly, place the sponge end under the tongue for a total of 2-3 minutes until the sponge becomes fully saturated.

Gently pressing the sponge between the tongue and teeth will assist saturation. No hard spots should be felt on the sponge when saturated.

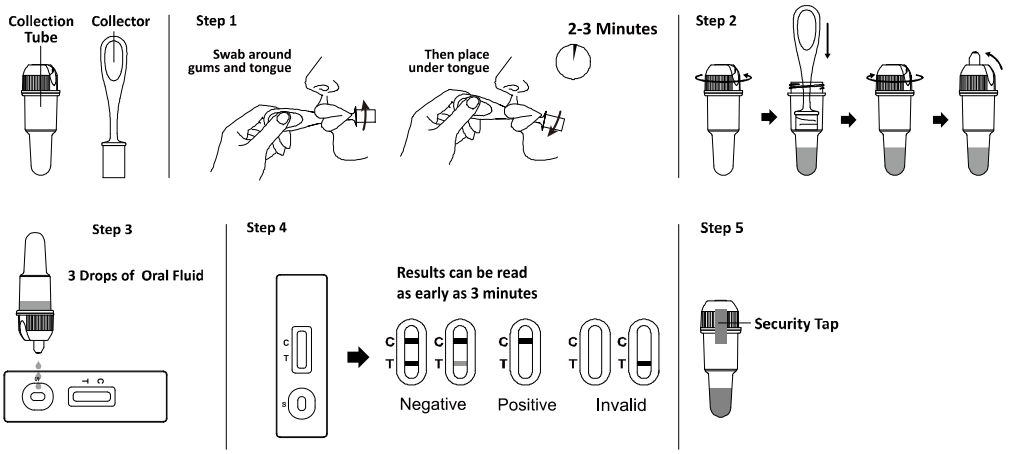
③ Remove the collector from the mouth. Place saturated oral fluid collector into collection tube and press sponge fully against the strainer to collect oral fluid. Discard the collector. Snap the cap shut on the Collection tube.

④ Place the test cassette on a clean and level surface. Unscrew cap cover from the Collection tube. Invert the Collection tube and transfer **3 drops of oral fluid** (approximately 120 µL) into specimen well of the test cassette. Avoid trapping air bubbles in the specimen well. Place screw cap on the collection tube. Wait for the flow to appear in the test windows and start the timer.

⑤ Read the test results at **3-10 minutes**.

If all lines are clearly visible at 3 minutes or sooner， then the test can be interpreted as negative and discarded. If any lines not visible at 3 minutes, then the test should be re-read at 10 minutes.

⑥ Apply the security seal over screw cap and send to the laboratory for confirmation if necessary.



Midstream

① Bring the pouch to room temperature before opening it. Remove the test from the sealed pouch and use it within one hour.

② Take off the Device cap and collect oral fluid specimen as follows.

Allow oral fluid to pool in your mouth for at least 30 seconds. Put the absorbent wick under the tongue to collect oral fluid for 60 seconds, then actively swab around the gums on both sides of the mouth (10-15 times) to assist absorbtion.

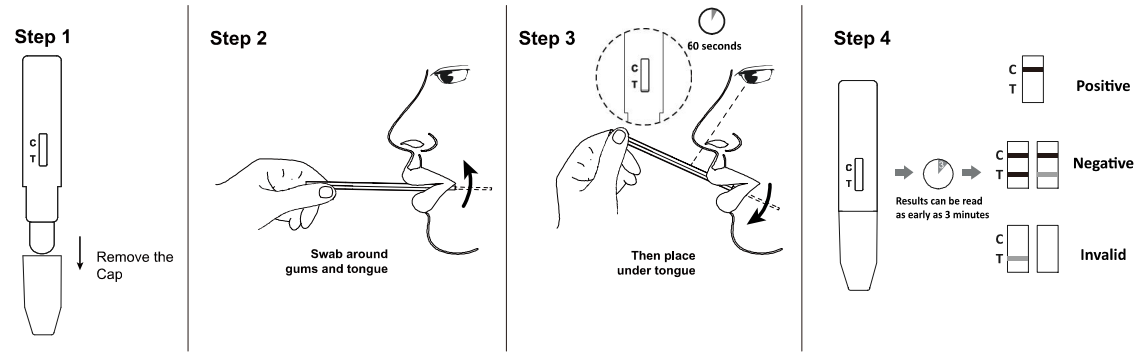
③ Wating the flow appear in the test window (approximately 60 seconds) and then take out the device and start a timer.

Note: If no flow appeared, repeat the procedure in steps above until the flow appear. If no flow appeared after triplicate of steps above, discard the device, review procedures with the donor and repeat the test using a new device.

④ Place the test device on a clean and level surface.

⑤ Read the test result at **3-10 minutes.**

If all lines are clearly visible at 3 minutes or sooner, then the test can be interpreted as negative and discarded. If any lines are not visible at 3 minutes, then the test should be re -read at 10 minutes.



1.5.4 Interpretation of Results

(Please refer to the illustration above)

NEGATIVE:* Two colored lines appear. One colored line should be in the control line region (C), and another colored line should be in the test line region (T). A negative result indicates that the Cortisol concentration is below the detectable level.

*NOTE: The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). A positive result indicates that the Cortisol concentration exceeds the detectable level.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test. If the problem persists, discontinue using the lot immediately and contact your local distributor.

1.5.5 Quality Control

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative procedural control.

1.5.6 Limitations

1. The Cortisol (COR) Rapid Test (Oral Fluid) is a preliminary qualitative test, therefore, neither the quantitative value nor the rate of increase in COR can be determined by this test.
2. It is possible that technical or procedural errors, as well as other interfering substances in the Oral Fluid specimen may cause erroneous results.
3. A negative result may not necessarily indicate free Oral Fluid. Negative results can be obtained when drug is present but below the cut-off level of the test.

1.6 Product Detail

1.6.1 All materials

- **MATERIALS**
  - **Absorbent Pad**: Filter paper AN3

Thickness: 0.587mm
Water absorption: 991.2g/m^2
Composition: 100% Cotton fiber

- **Label Pad**: 6613 Polyester film

Weight: 99.86g/m^2
Thickness: 16.7mils
Composition: Polyester film

- **Sample Pad**: Fiberglass

Weight: 50.12g/ m^2
Thickness: 12.53mils
Composition: Fiberglass

- **Nitrocellulose Membrane**: Sartorius CN140

Thickness of membrane layer (μm): 120-160
Capillary wicking rate along the roll (mm/5min): ＞52

- **Backing Card**: Polystyrene (PS)

Thickness of card: 0.455mm
Composition: Polystyrene

- **MAJOR ANTIBODY**
  - **Control Zone**: Goat anti-rabbit IgG
  - **Test Zone**: COR antigen
  - **Conjugate pad**:COR antibody
- **MAJOR Buffer**

  Phosphate Buffer, Tris-buffer

1.6.2 Production Process

- Nitrocellulose membrane which has applied to an adhesive-backed is coated with a Goat Anti – rabbit IgG Antibody solution in the Control Reaction Zone, and coated with COR antigen solution in the Test Reaction Zone. The coated membrane is dried overnight.
- A phosphate buffered solution of COR antibody – Colloidal Gold Conjugate is sprayed on polyester and then dried overnight.
- Treatment the fiberglass with a Tris-buffer solution dried them in an oven house for one night. Humidity is an important factor to influence the performance of the product, please keep dried when storage.
- Assemble the semi-product with absorbent pad, dried NC membrane, conjugate pad and sample pad, cut them with the cutting machine.
- Put the test dipstick into moisture-proof foil and sealed in moisture-proof foil pouches along with a desiccant packet.
- Put the test strip into a suitable cassette and sealed in moisture-proof foil pouches along with a desiccant packet and a disposable plastic pipette.
- Put the test strip into a suitable midstream with absorbent wick and sealed in moisture-proof foil pouches along with a desiccant packet.

1.7 Bibliography

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2 TECHNICAL REPORT

2.1 Technical Report for COR Rapid Test (Oral fluid) Cut-off:50ng/ml

2.1.1 Analytical Sensitivity

The analytical sensitivity was determined by spiking negative oral fluid specimens with intact COR standard at 0, 25,37.5,50,62.5,75,150ng/ml. The COR standards were randomized and coded. Each sample was run in replicate of five on three different transfer lots with visual at 10 minutes after sample application. Results are presented in Table below.

Table: Analytical Sensitivity Study

Cassette:

COR Standard	COR23050001-T										COR23050002-T										COR23050003-T									
0ng/ml	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25ng/ml	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37.5ng/ml	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	+	+
50ng/ml	-	-	-	-	-	+	+	+	+	+	-	-	-	-	-	+	+	+	+	+	-	-	-	-	-	+	+	+	+	+
62.5ng/ml	-	-	-	+	+	+	+	+	+	+	-	-	-	+	+	+	+	+	+	+	-	-	-	+	+	+	+	+	+	+
75ng/ml	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
150ng/ml	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

Midstream:

COR Standard	COR23050004-T										COR23050005-T										COR23050006-T									
0ng/ml	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25ng/ml	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37.5ng/ml	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	+	+
50ng/ml	-	-	-	-	-	+	+	+	+	+	-	-	-	-	-	+	+	+	+	+	-	-	-	-	-	+	+	+	+	+
62.5ng/ml	-	-	-	+	+	+	+	+	+	+	-	-	-	+	+	+	+	+	+	+	-	-	-	+	+	+	+	+	+	+

75ng/ml	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
150ng/ml	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

Conclusion: The results indicated the cut-off concentration of KET Rapid Test is determined to be 50ng/ml.

2.1.2 INTERFERING SUBSTANCES

Analytes were spiked individually, at the concentrations indicated, into negative Oral fluid sample and positive Oral fluid containing 25ng/ml and 75ng/ml COR. The samples were tested in triplicate with 3 lots of different format. The results were rated as either positive or negative at 3 and 10 minutes. Results are presented in Table below

Table: Interfering Substances study

Cassette:

ANALYTE	CONCENTRATION	COR23050001-T						COR23050002-T						COR23050003-T					
		(3 minutes)																	
		25ng/ml			75ng/ml			25ng/ml			75ng/ml			25ng/ml			75ng/ml		
Estradiol	600 ng/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Estriol	500 ng/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Progesterone	600 ng/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Danazol	500 ng/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Testosterone	50 ng/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Bilirubin	1 g/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+

ANALYTE	CONCENTRATION	COR23050001-T						COR23050002-T						COR23050003-T					
		(10 minutes)																	
		25ng/ml			75ng/ml			25ng/ml			75ng/ml			25ng/ml			75ng/ml		
Estradiol	600 ng/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Estriol	500 ng/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Progesterone	600 ng/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Danazol	500 ng/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Testosterone	50 ng/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Bilirubin	1 g/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+

Midstream:

ANALYTE	CONCENTRATION	COR23050004-T						COR23050005-T						COR23050006-T					
		(3 minutes)																	
		25ng/ml			75ng/ml			25ng/ml			75ng/ml			25ng/ml			75ng/ml		
Estradiol	600 ng/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Estriol	500 ng/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Progesterone	600 ng/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+

ANALYTE	CONCENTRATION	COR23050004-T						COR23050005-T						COR23050006-T					
		(3 minutes)																	
Danazol	500 ng/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Testosterone	50 ng/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Bilirubin	1 g/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+

ANALYTE	CONCENTRATION	COR23050004-T						COR23050005-T						COR23050006-T					
		(10 minutes)																	
		25ng/ml			75ng/ml			25ng/ml			75ng/ml			25ng/ml			75ng/ml		
Estradiol	600 ng/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Estriol	500 ng/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Progesterone	600 ng/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Danazol	500 ng/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Testosterone	50 ng/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Bilirubin	1 g/mL	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+

Conclusion: No substances showed any interference with the test. There were no differences observed between the results at 3 and 10 minutes

2.1.3 Variability Study (Intra lot and Inter lot)

0, 25, 50 and 75 ng/ml Oral fluid specimens were run in replicates of ten in three lots of different format products. Results were read as positive or negative at 3 and 10 minutes after specimen application. Results were presented in Table below.

Table: Variability Study

Cassette:

Lot:COR23050001-T								
Specimens	0ng/ml		25ng/ml		50ng/ml		75ng/ml	
	3 minutes	10 minutes	3 minutes	10 minutes	3 minutes	10 minutes	3 minutes	10 minutes
1	-	-	-	-	+	+	+	+
2	-	-	-	-	+	+	+	+
3	-	-	-	-	+	+	+	+
4	-	-	-	-	+	+	+	+
5	-	-	-	-	+	+	+	+
6	-	-	-	-	+	+	+	+
7	-	-	-	-	+	+	+	+
8	-	-	-	-	-	-	+	+
9	-	-	-	-	-	-	+	+
10	-	-	-	-	-	-	+	+
Lot: COR23050002-T								
Specimens	0ng/ml		25ng/ml		50ng/ml		75ng/ml	
	3 minutes	10 minutes	3 minutes	10 minutes	3 minutes	10 minutes	3 minutes	10 minutes
1	-	-	-	-	+	+	+	+
2	-	-	-	-	+	+	+	+
3	-	-	-	-	+	+	+	+
4	-	-	-	-	+	+	+	+
5	-	-	-	-	+	+	+	+
6	-	-	-	-	+	+	+	+
7	-	-	-	-	+	+	+	+
8	-	-	-	-	-	-	+	+
9	-	-	-	-	-	-	+	+
10	-	-	-	-	-	-	+	+
Lot:COR23050003-T								
Specimens	0ng/ml		25ng/ml		50ng/ml		75ng/ml	
	3 minutes	10 minutes	3 minutes	10 minutes	3 minutes	10 minutes	3 minutes	10 minutes
1	-	-	-	-	+	+	+	+
2	-	-	-	-	+	+	+	+
3	-	-	-	-	+	+	+	+
4	-	-	-	-	+	+	+	+
5	-	-	-	-	+	+	+	+
6	-	-	-	-	+	+	+	+
7	-	-	-	-	+	+	+	+
8	-	-	-	-	-	-	+	+

9	-	-	-	-	-	-	+	+
10	-	-	-	-	-	-	+	+

Midstream:

Lot:COR23050004-T								
Specimens	0ng/ml		25ng/ml		50ng/ml		75ng/ml	
	3 minutes	10 minutes	3 minutes	10 minutes	3 minutes	10 minutes	3 minutes	10 minutes
1	-	-	-	-	+	+	+	+
2	-	-	-	-	+	+	+	+
3	-	-	-	-	+	+	+	+
4	-	-	-	-	+	+	+	+
5	-	-	-	-	+	+	+	+
6	-	-	-	-	+	+	+	+
7	-	-	-	-	+	+	+	+
8	-	-	-	-	-	-	+	+
9	-	-	-	-	-	-	+	+
10	-	-	-	-	-	-	+	+
Lot: COR23050005-T								
Specimens	0ng/ml		25ng/ml		50ng/ml		75ng/ml	
	3 minutes	10 minutes	3 minutes	10 minutes	3 minutes	10 minutes	3 minutes	10 minutes
1	-	-	-	-	+	+	+	+
2	-	-	-	-	+	+	+	+
3	-	-	-	-	+	+	+	+
4	-	-	-	-	+	+	+	+
5	-	-	-	-	+	+	+	+
6	-	-	-	-	+	+	+	+
7	-	-	-	-	+	+	+	+
8	-	-	-	-	-	-	+	+
9	-	-	-	-	-	-	+	+
10	-	-	-	-	-	-	+	+
Lot:COR23050006-T								
Specimens	0ng/ml		25ng/ml		50ng/ml		75ng/ml	
	3 minutes	10 minutes	3 minutes	10 minutes	3 minutes	10 minutes	3 minutes	10 minutes
1	-	-	-	-	+	+	+	+
2	-	-	-	-	+	+	+	+
3	-	-	-	-	+	+	+	+
4	-	-	-	-	+	+	+	+
5	-	-	-	-	+	+	+	+
6	-	-	-	-	+	+	+	+
7	-	-	-	-	+	+	+	+
8	-	-	-	-	-	-	+	+
9	-	-	-	-	-	-	+	+
10	-	-	-	-	-	-	+	+

Conclusion: Test results showed that the performances were consistent between the three lots of different format product.

2.1.4 ACCELERATED STABILITY

Accelerated Stability of the COR Rapid test was evaluated using samples from three lots of different format. These were placed in an incubator with the temperature calibrated at 45℃ and 55℃. Relative humidity (RH) calibrated at about 60%. A series of stability tests were performed at 0, 7, 14, 21, 28, 35, 42, 56, 77, 91,105,112,119,126,133 days at 45℃, and some performance study would be tested at 0, 7, 14, 21, 28, 35, 42,49,56,60 days at 55℃. Test products were assayed using 0, 25, and 75ng/ml specimens. Testing at each specific time interval consisted of 3 replicates for each specimen. The tests were performed according to the package insert. Results are presented in Table below.

Table: Time line for Accelerate Stability Study

Day / Temp.	0 day	7 Days	14 days	21 days	28 days	35 days	42 days	49 days	56 days	60 days	77 days	91 days	105 days	112 days	119 days	126 days	133 days
45^0C.	√	√	√	√	√	√	√		√		√	√	√	√	√	√	√
55^0C.	√	√	√	√	√	√	√	√	√	√							

Cassette：

Accelerated Stability study of 45^0C										
Day	Specimen	Lot								
		COR23050001-T			COR23050002-T			COR23050003-T		
0	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
7	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
14	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
21	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
28	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
35	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
42	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
56	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
77	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-

	75ng/ml	+	+	+	+	+	+	+	+	+
91	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
105	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
112	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
119	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
126	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
133	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
Accelerated Stability study of 55^0 C										
Day	**Specimen**	**Lot**								
		COR23050001-T			COR23050002-T			COR23050003-T		
0	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
7	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
14	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
21	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
28	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
35	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
42	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
49	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
56	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
60	0ng/ml	-	-	-	-	-	-	-	-	-

	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+

Midstream：

Accelerated Stability study of 45^{0}C										
Day	**Specimen**	**Lot**								
		COR23050004-T			COR23050005-T			COR23050006-T		
0	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
7	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
14	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
21	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
28	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
35	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
42	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
56	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
77	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
91	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
105	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
112	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
119	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
126	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
133	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-

	75ng/ml	+	+	+	+	+	+	+	+	+
Accelerated Stability study of 55^{0}C										
Day	**Specimen**	**Lot**								
		COR23050004-T			COR25020005-T			COR25020006-T		
0	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
7	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
14	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
21	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
28	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
35	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
42	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
49	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
56	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+
60	0ng/ml	-	-	-	-	-	-	-	-	-
	25ng/ml	-	-	-	-	-	-	-	-	-
	75ng/ml	+	+	+	+	+	+	+	+	+

Conclusion: COR Rapid Test was stable at 45℃ for 133 days and at 55℃ for 60 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 date of manufacture.

2.1.5 IN-HOUSE CLINICAL STUDY

The In-house clinical study used a specimen number (n) equal to 406(100 positive specimens and 306 negative specimens (confirmed by Elisa). Specimens were rated as either positive or negative at 10 minutes. Results are shown in Table below.

Table: In-house clinical Study

Cassette:

Method	Elisa	total

		Positive	Negative	
Cortisol Rapid Test	Positive	93	4	97
	Negative	7	302	309
Total		100	306	406
Relative Sensitivity		93.0% (95%CI*: 86.11%-97.14%)		
Relative Specificity		98.7% (95%CI*: 96.69%-99.64%)		
Totally accuracy		97.3% (95%CI*:95.20%-98.64%) *Confidence Intervals		

Midstream:

Method		Elisa		total
		Positive	Negative	
Cortisol Rapid Test	Positive	93	4	97
	Negative	7	302	309
Total		100	306	406
Relative Sensitivity		93.0% (95%CI*: 86.11%-97.14%)		
Relative Specificity		98.7% (95%CI*: 96.69%-99.64%)		
Totally accuracy		97.3% (95%CI*:95.20%-98.64%) *Confidence Intervals		

Conclusion: : From the data above, the relative sensitivity for COR Rapid Test was 93.0%, and the relative specificity was 98.7%, and total agreement is 97.3%.

2.1.6 PRECISION

A study was conducted at three hospitals by untrained operators using three different format and a format of each batch of COR products to demonstrate the within run, between run and between operator precision. An identical device of coded specimens, containing no COR, 25ng/ml COR,50ng/ml COR and 75ng/ml COR was provided to each site.

Results:

Cassette:

Specimen	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0ng/ml COR	10	10	0	10	0	10	0
25ng/ml COR	10	10	0	10	0	10	0
50ng/ml COR	10	4	6	4	6	5	5
75ng/ml COR	10	0	10	0	10	0	10

Midstream:

Specimen	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0ng/ml COR	10	10	0	10	0	10	0
25ng/ml COR	10	10	0	10	0	10	0
50ng/ml COR	10	4	6	4	6	5	5
75ng/ml COR	10	0	10	0	10	0	10

Conclusion: Specimens determined to be negative,25ng/ml COR,50ng/ml COR and 75ng/ml COR values demonstrate high precision for COR rapid test.

Document History Summary

Version No.	Date	Description	Remark
01	2025.09.15	Initial Release	N/A

Test rapido del cortisolo (COR) (Fluido orale) Foglietto illustrativo

REF FCOR-803	Italiano

Un test rapido per la rilevazione qualitativa del cortisolo nel fluido orale umano.
Solo per uso diagnostico professionale in vitro.

【USO PREVISTO】

Il test rapido del cortisolo (COR) (fluido orale) è un immunodosaggio cromatografico rapido per la rilevazione del cortisolo nel fluido orale umano.

【RIEPILOGO】

Il cortisolo è un ormone steroideo comunemente chiamato "ormone dello stress" ed è un biomarcatore per molte patologie come il ritmo circadiano, la sindrome di Cushing, il morbo di Addison e disturbi correlati allo stress. La secrezione di cortisolo segue un ritmo circadiano, con livelli di cortisolo che raggiungono il picco all'alba (30 minuti dopo il risveglio) nell'arco di 24 ore e diminuiscono gradualmente durante il sonno notturno.

Livelli di cortisolo anormalmente elevati sopprimono l'infiammazione, sopprimono il sistema immunitario e aumentano i livelli di grassi e aminoacidi nel sangue. È stato dimostrato che livelli eccessivi di cortisolo sono associati allo sviluppo della malattia di Cushing, accompagnata da sintomi di obesità, affaticamento e fragilità ossea. Livelli ridotti di cortisolo possono portare alla malattia di Addison, che si manifesta con perdita di peso, affaticamento, pieghe cutanee e scurimento delle cicatrici.[1] La misurazione del cortisolo salivare è stata ampiamente riportata in letteratura e può essere utilizzata per caratterizzare i ritmi circadiani, la sindrome di Cushing,[2] Malattia di Addison,[3] e disturbi correlati allo stress.[4]

Il test rapido del cortisolo (COR) (fluido orale) è un test rapido che rileva qualitativamente la presenza di COR in campioni di fluido orale. Il test utilizza un anticorpo monoclonale per rilevare selettivamente livelli elevati di cortisolo nel fluido orale.

【PRINCIPIO】

Il test rapido del cortisolo (COR) (fluido orale) è un immunodosaggio basato sul principio del legame competitivo. Il cortisolo, eventualmente presente nel campione di fluido orale, compete con il coniugato del cortisolo per i siti di legame sull'anticorpo.

Durante il test, un campione di fluido orale migra verso l'alto per capillarità. Il cortisolo, se presente nel campione di fluido orale al di sotto del livello di cut-off, non saturerà i siti di legame delle particelle ricoperte di anticorpi nel dispositivo di test. Le particelle ricoperte di anticorpi verranno quindi catturate dal coniugato di cortisolo immobilizzato e una linea colorata visibile apparirà nella zona della linea di test. La linea colorata non si formerà nella zona della linea di test se il livello di cortisolo supera il livello di cut-off, poiché saturerà tutti i siti di legame degli anticorpi anti-cortisolo.

Un campione di fluido orale positivo non genererà una linea colorata nella zona di test, mentre un campione di fluido orale negativo o un campione contenente una concentrazione di farmaco inferiore al cut-off genererà una linea nella zona di test. Come controllo procedurale, una linea colorata apparirà sempre nella zona di controllo, a indicare che è stato aggiunto il volume corretto di campione e che la membrana si è asciugata.

【REAGENTI】

Il test contiene particelle legate ad anticorpi anti-cortisolo e coniugato cortisolo-proteina. Nel sistema di controllo viene utilizzato un anticorpo di capra.

【PRECAUZIONI】

- Solo per uso diagnostico professionale *in vitro.*
- Solo per uso su campioni di fluido orale.
- Dispositivo monouso. Non riutilizzare.
- Non utilizzare dopo la data di scadenza.
- Il test deve essere conservato nella busta sigillata fino al momento dell'uso.
- Tutti i campioni devono essere considerati potenzialmente pericolosi e maneggiati allo stesso modo di un agente infettivo.
- dispositivo usato deve essere smaltito secondo le normative locali.
- Attendere almeno 30 minuti dopo aver mangiato o bevuto qualcosa prima del test.

【CONSERVAZIONE E STABILITÀ】

Conservare nella confezione originale a temperatura ambiente o in frigorifero (2-30 °C). Il test è stabile fino alla data di scadenza stampata sulla busta sigillata. Il dispositivo di test deve rimanere nella busta sigillata fino al momento dell'uso. **NON CONGELARE**. Non utilizzare oltre la data di scadenza.

【RACCOLTA E PREPARAZIONE DEI CAMPIONI】

Il campione di fluido orale deve essere raccolto seguendo le istruzioni dettagliate per l'uso riportate di seguito. Nessun altro dispositivo di raccolta deve essere utilizzato con questo test. È possibile utilizzare il fluido orale raccolto in qualsiasi momento della giornata.

【MATERIALI】

Materiali forniti

- Dispositivo di test
- Foglietto illustrativo

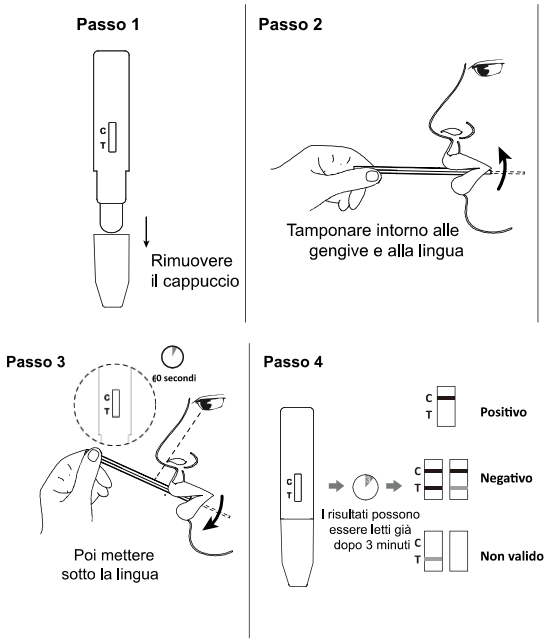
Materiali richiesti ma non forniti

- Timer

【ISTRUZIONI PER L'USO】

Lasciare che il dispositivo di test e il campione raggiungano la temperatura ambiente (15-30 °C) prima del test. Informare il donatore di non mettere nulla in bocca, inclusi cibo, bevande, gomme da masticare o prodotti del tabacco, per almeno 30 minuti prima del prelievo.

1. Portare la busta a temperatura ambiente prima di aprirla. Estrarre il test dalla busta sigillata e utilizzarlo entro un'ora.
2. Rimuovere il tappo del dispositivo e raccogliere il campione di fluido orale come segue. Lasciare che il fluido orale si raccolga in bocca per almeno 30 secondi. Posizionare lo stoppino assorbente sotto la lingua per raccogliere il fluido orale per 60 secondi, quindi tamponare attivamente intorno alle gengive su entrambi i lati della bocca (10-15 volte) per favorire l'assorbimento.
3. Attendere che il flusso compaia nella finestra di prova (circa 60 secondi), quindi estrarre il dispositivo e avviare un timer.
   Nota: Se non si verifica alcun flusso, ripetere la procedura descritta nei passaggi precedenti fino alla comparsa del flusso. Se non si verifica alcun flusso dopo aver ripetuto tre volte i passaggi precedenti, eliminare il dispositivo e rivedere le procedure con il donatore e ripetere il test utilizzando un nuovo dispositivo.
4. Posizionare il dispositivo di prova su una superficie pulita e piana.
5. Leggere il risultato del test dopo **3-10 minuti.**
   Se tutte le linee sono chiaramente visibili dopo 3 minuti o prima, il test può essere interpretato come negativo e scartato. Se dopo 3 minuti non sono visibili linee, il test deve essere riletto dopo 10 minuti.



【INTERPRETAZIONE DEI RISULTATI】

(Fare riferimento all'illustrazione sopra)

NEGATIVO:* Compaiono due linee colorate. Una linea colorata dovrebbe trovarsi nella zona di controllo (C) e un'altra linea colorata dovrebbe trovarsi nella zona di test (T). Un risultato negativo indica che la concentrazione di cortisolo è inferiore al livello rilevabile.

*NOTA: la tonalità di colore nella zona della linea di test (T) può variare, ma deve essere considerata negativa ogni volta che è presente anche una debole linea colorata.

POSITIVO: Una linea colorata appare nella zona di controllo (C). Nessuna linea appare nella zona di test (T). Un risultato positivo indica che la concentrazione di cortisolo supera il livello rilevabile.

NON VALIDO: La linea di controllo non appare. Le cause più probabili della mancata comparsa della linea di controllo sono un volume di campione insufficiente o tecniche procedurali errate. Rivedere la procedura e ripetere il test utilizzando un nuovo test. Se il problema persiste, interrompere immediatamente l'uso del lotto e contattare il distributore locale.

【CONTROLLO QUALITÀ】

Il test include un controllo procedurale. Una linea colorata che compare nella zona di controllo (C) è considerata un controllo procedurale interno. Conferma un volume di campione sufficiente e la corretta tecnica procedurale. Uno sfondo trasparente è un controllo procedurale interno.

【LIMITAZIONI】

1. Il test rapido del cortisolo (COR) (fluido orale) è un test qualitativo preliminare; pertanto, né il valore quantitativo né la velocità di aumento del COR possono essere determinati da questo test.
2. È possibile che errori tecnici o procedurali, nonché altre sostanze interferenti nel campione di fluido orale, possano causare risultati errati.
3. Un risultato negativo non indica necessariamente la presenza di fluido orale libero. Risultati negativi possono essere ottenuti quando il farmaco è presente ma al di sotto del livello soglia del test.

【CARATTERISTICHE DI PRESTAZIONE】

Accuratezza

È stato condotto un confronto tra i due metodi utilizzando il test rapido del cortisolo (COR) (fluido orale) e la GC/MS. Sono stati tabulati i seguenti risultati:

Metodo		GC/MS		Risultati totali
Test rapido del cortisolo (COR)	Risultati	Positivo	Negativo	
	Positivo	93	4	97
	Negativo	7	302	309
Risultati totali		100	306	406
% di accordo		93,0%	98,7%	97,3%

Sensibilità: 93,0% (95%CI*: 86,11%~97,14%)*
Specificità: 98,7% (95%CI*: 96,69%~99,64%)*
Accuratezza: 97,3% (95%CI*: 95,20%~98,64%)* * Intervalli di confidenza del 95%

Sensibilità analitica

Il test rapido del cortisolo (COR) (fluido orale) è in grado di rilevare livelli di cortisolo pari a 50 ng/mL nel fluido orale.

Precisione

Intra-test

La precisione intra-test è stata determinata utilizzando 10 replicati di quattro campioni contenenti 75 ng/mL, 50 ng/mL, 25 ng/mL e 0 ng/mL di COR. I valori negativi e positivi sono stati identificati correttamente nel 100% dei casi.

Inter-Assay

La precisione inter-serie è stata determinata utilizzando gli stessi quattro campioni di 75 ng/mL, 50 ng/mL, 25 ng/mL e 0 ng/mL di COR in 10 test indipendenti. Sono stati testati tre diversi lotti del test rapido del cortisolo (COR). I campioni sono stati identificati correttamente nel 100% dei casi.

Sostanze interferenti

Le seguenti sostanze interferenti sono state testate utilizzando il test rapido del cortisolo (COR) (fluido orale) e non è stata osservata alcuna interferenza.

Sostanza	Concentrazione
Estradiolo	600 ng/mL
Estriolo	500 ng/mL
Progesterone	600 ng/mL
Danazolo	500 ng/mL
Testosterone	50 ng/mL
Bilirubina	1 g/mL

【BIBLIOGRAFIA】

1. Kaushik A, Vasudev A, Arya SK, Pasha SK, Bhansali S. Recent advances in cortisol sensing technologies for point-of-care application. Biosens Bioelectron. 2014 Mar 15;53:499-512.
2. Price DA, Close GC, Fielding BA. Age of appearance of circadian rhythm in salivary cortisol values in infancy. Arch Dis Child. 1983 Jun;58(6):454-6.
3. McEwen BS. Cortisol, Cushing's Syndrome, and a shrinking brain-new evidence for reversibility. J Clin Endocrinol Metab. 2002 May;87(5):1947-8.
4. Løvås K, Thorsen TE, Husebye ES. Saliva cortisol measurement: simple and reliable assessment of the glucocorticoid replacement therapy in Addison's disease. J Endocrinol Invest. 2006 Sep;29(8):727-31.

Indice dei simboli

	Consultare le istruzioni per l'uso o consultare le istruzioni per l'uso elettroniche	Σ	Contiene sufficiente per <n> test	30°C 2°C	Limite di temperatura
IVD	Dispositivo medico diagnostico *in vitro*	LOT	Codice batch	REF	Catalogare numero
	Attenzione		Data di scadenza		Non riutilizzare
	Non utilizzare se la confezione è danneggiata e consultare le istruzioni per l'uso		Produttore	EU REP	European Authorized representative

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VidaQuick Biotech S.L.
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Barcelona Province, 08036, Spain
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Importato da:
Verify SRL
Torino - Italy
info@verifytest.it
www.verifytest.it

Numero: 14603512800
Data di revisione: 2026-01-09

Cortisol (COR) Rapid Test (Oral Fluid) Package Insert

REF FCOR-803	English

A rapid test for the qualitative detection of Cortisol in human oral fluid.
For professional in vitro diagnostic use only.

【INTENDED USE】

The Cortisol (COR) Rapid Test (Oral fluid) is a rapid chromatographic immunoassay for the detection of Cortisol in human oral fluid.

【SUMMARY】

Cortisol is a steroid hormone that is also commonly referred to as a "stress hormone" is a biomarker for many diseases such as circadian rhythm, Cushing's syndrome, Addison's disease, and stress-related disorders. Cortisol secretion is follow a circadian rhythm, with cortisol levels peaking at dawn (30 minutes after waking up) during a 24-hour cycle and gradually decreasing during nighttime sleep.

Abnormally elevated cortisol levels suppress inflammation, suppress the immune system, and increase levels of fats and amino acids in the blood. And excess cortisol levels have been shown to be associated with the development of Cushing's disease. Accompanied by symptoms of obesity, fatigue, and brittle bones. Decreased cortisol levels can lead to Addison's disease, which manifests as weight loss, fatigue, skin folds, and darkening of scars.[1] Salivary cortisol measurement has been widely reported in the literature and can be used to characterize circadian rhythms, Cushing's syndrome,[2] Addison's disease,[3] and stress-related disorders.[4]

The Cortisol (COR) Rapid Test (Oral fluid) is a rapid test that qualitatively detects the presence of COR in oral fluid specimen. The test utilizes a monoclonal antibody to selectively detect elevated levels of Cortisol in Oral fluid.

【PRINCIPLE】

The Cortisol (COR) Rapid Test (Oral fluid) is an immunoassay based on the principle of competitive binding. Cortisol which may be present in the oral fluid specimen compete against the Cortisol conjugate for binding sites on the antibody.

During testing, oral fluid specimen migrates upward by capillary action. Cortisol, if present in the oral fluid specimen below the cut-off level, will not saturate the binding sites of antibody-coated particles in the test device. The antibody-coated particles will then be captured by immobilized Cortisol conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Cortisol level exceeds the cut-off level because it will saturate all the binding sites of anti-Cortisol antibodies.

A positive oral fluid specimen will not generate a colored line in the test line region, while a negative oral fluid specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test device contains anti-Cortisol antibody-coupled particles and Cortisol-protein conjugate. A goat antibody is employed in the control line system.

【PRECAUTIONS】

- For professional *in vitro* diagnostic use only.
- For oral fluid specimen use only.
- Single-use device. Do not reuse.
- Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used device should be discarded according to local regulations.
- Wait at least 30 minutes after eating, drinking of any kind before the test.

【STORAGE AND STABILITY】

Store as packaged at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

The oral fluid specimen should be collected following the detailed of Directions for Use below. No other collection device should be used with this assay. Oral fluid collected at any time of the day may be used.

【MATERIALS】

Materials Provided

- Test Devices
- Package Insert

Materials Required But Not Provided

- Timer

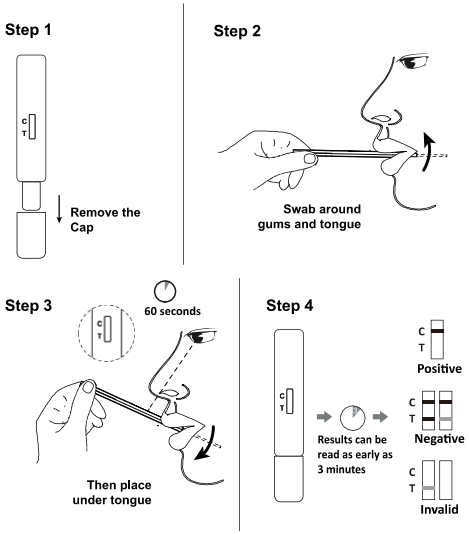
【DIRECTIONS FOR USE】

Allow the test device, specimen to reach room temperature (15-30 ºC) prior to testing. Instruct the donor to not place anything in the mouth including food, drink, gum or tobacco products for at least 30 minutes prior to collection.

1. Bring the pouch to room temperature before opening it. Remove the test from the sealed pouch and use it within one hour.
2. Take off the device cap and collect oral fluid specimen as follows.
   Allow oral fluid to pool in your mouth for at least 30 seconds. Put the absorbent wick under the tongue to collect oral fluid for 60 seconds, then actively swab around the gums on both sides of the mouth (10-15 times) to assist absorbtion.
3. Waiting the flow appear in the test window (approximately 60 seconds) and then take out the device and start a timer.

Note: If no flow appeared, repeat the procedure in steps above until the flow appear. If no flow appeared after triplicate of steps above, discard the device, review procedures with the donor and repeat the test using a new device.

4. Place the test device on a clean and level surface.
5. Read the test result at **3-10 minutes**.
   If all lines are clearly visible at 3 minutes or sooner, then the test can be interpreted as negative and discarded. If any lines are not visible at 3 minutes, then the test should be re - read at 10 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

NEGATIVE:* Two colored lines appear. One colored line should be in the control line region (C), and another colored line should be in the test line region (T). A negative result indicates that the Cortisol concentration is below the detectable level.

*NOTE: The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). A positive result indicates that the Cortisol concentration exceeds the detectable level.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test. If the problem persists, discontinue using the lot immediately and contact your local distributor.

【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal procedural control.

【LIMITATIONS】

1. The Cortisol (COR) Rapid Test (Oral fluid) is a preliminary qualitative test; therefore, neither the quantitative value nor the rate of increase in COR can be determined by this test.
2. It is possible that technical or procedural errors, as well as other interfering substances in the Oral fluid specimen may cause erroneous results.
3. A negative result may not necessarily indicate free Oral fluid. Negative results can be obtained when drug is present but below the cut-off level of the test.

【PERFORMANCE CHARACTERISTICS】

Accuracy

A side-by-side comparison was conducted using the Cortisol (COR) Rapid Test (Oral fluid) and GC/MS. The following results were tabulated:

Method		GC/MS		Total Results
Cortisol (COR) Rapid Test	Results	Positive	Negative	
	Positive	93	4	97
	Negative	7	302	309
Total Results		100	306	406
% Agreement		93.0%	98.7%	97.3%

Sensitivity: 93.0% (95%CI*: 86.11%~97.14%)*
Specificity: 98.7% (95%CI*: 96.69%~99.64%)*
Accuracy: 97.3% (95%CI*: 95.20%~98.64%) * * 95% Confidence Intervals

Analytical sensitivity

The Cortisol (COR) Rapid Test (Oral fluid) can detect levels of cortisol 50ng/mL in oral fluid.

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of four specimens containing 75ng/mL, 50ng/mL, 25ng/mL and 0ng/mL of COR. The negative and positive values were correctly identified 100% of the time.

Inter-Assay

Between-run precision has been determined by using the same four specimens of 75ng/mL, 50ng/mL, 25ng/mL and 0ng/mL of COR in 10 independent assays. Three different lots of the Cortisol (COR) Rapid Test have been tested. The specimens were correctly identified 100% of the time.

Interfering Substances

The following interfering substances have been tested using the Cortisol (COR) Rapid Test (Oral fluid) and no interference was observed.

Substance	Concentration
Estradiol	600 ng/mL
Estriol	500 ng/mL
Progesterone	600 ng/mL
Danazol	500 ng/mL
Testosterone	50 ng/mL
Bilirubin	1 g/mL

【BIBLIOGRAPHY】

1. Kaushik A, Vasudev A, Arya SK, Pasha SK, Bhansali S. Recent advances in cortisol sensing technologies for point-of-care application. Biosens Bioelectron. 2014 Mar 15;53:499-512.
2. Price DA, Close GC, Fielding BA. Age of appearance of circadian rhythm in salivary cortisol values in infancy. Arch Dis Child. 1983 Jun;58(6):454-6.
3. McEwen BS. Cortisol, Cushing's Syndrome, and a shrinking brain-new evidence for reversibility. J Clin Endocrinol Metab. 2002 May;87(5):1947-8.
4. Løvås K, Thorsen TE, Husebye ES. Saliva cortisol measurement: simple and reliable assessment of the glucocorticoid replacement therapy in Addison's disease. J Endocrinol Invest. 2006 Sep;29(8):727-31.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use	Σ	Contains sufficient for <n> tests	30°C 2°C	Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
	Caution		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer	EU REP	European Authorized representative

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www.verifytest.it

Number: 14603512800
Revision date: 2026-01-09

Cortisol (COR) Schnelltest (Speichelprobe) Packungsbeilage

REF FCOR-803	Deutsch

Ein Schnelltest zum qualitativen Nachweis von Cortisol in menschlicher Mundflüssigkeit.
Nur für den professionellen Einsatz in der In-vitro-Diagnostik.

【BESTIMMTER VERWENDUNGSZWECK】

Das Cortisol (COR) Schnelltest (Speichelprobe) ist ein schneller chromatographischer Immunoassay zum Nachweis von Cortisol in menschlichem Speichel.

【ZUSAMMENFASSUNG】

Cortisol ist ein Steroidhormon, das auch als „Stresshormon "bezeichnet wird und als Biomarker für zahlreiche Erkrankungen wie zirkadiane Rhythmusstörungen, Cushing-Syndrom, Morbus Addison und stressbedingte Störungen dient. Die Cortisolsekretion folgt einem zirkadianen Rhythmus: Der Cortisolspiegel erreicht seinen Höhepunkt im Morgengrauen (30 Minuten nach dem Aufwachen) und sinkt während des Nachtschlafs allmählich ab.

Abnorm erhöhte Cortisolwerte hemmen Entzündungen, schwächen das Immunsystem und erhöhen den Fett-und Aminosäuregehalt im Blut. Zudem wurde ein Cortisolüberschuss mit der Entwicklung des Cushing-Syndroms in Verbindung gebracht, das mit Symptomen wie Adipositas, Müdigkeit und Osteoporose einhergeht. Erniedrigte Cortisolwerte können zu Morbus Addison führen, der sich durch Gewichtsverlust, Müdigkeit, Hautfaltenbildung und Narbenverdunkelung äußert.[1] Die Messung des Speichelcortisols ist in der Literatur vielfach beschrieben und kann zur Charakterisierung des zirkadianen Rhythmus und des Cushing-Syndroms herangezogen werden.[2] Morbus Addison,[3] und stressbedingte Störungen.[4]

Das Cortisol (COR) Schnelltest (Speichelprobe) ist ein Schnelltest, der das Vorhandensein von Cortisol in Speichelproben qualitativ nachweist. Der Test verwendet einen monoklonalen Antikörper, um erhöhte Cortisolspiegel im Speichel selektiv zu detektieren.

【PRINZIP】

Das Cortisol (COR) Schnelltest (Speichelprobe) ist ein Immunoassay, der auf dem Prinzip der kompetitiven Bindung basiert. Cortisol, das in der Speichelprobe vorhanden sein kann, konkurriert mit dem Cortisol-Konjugat um die Bindungsstellen am Antikörper.

Während des Tests wandert die Speichelprobe durch Kapillarwirkung nach oben. Ist Cortisol in der Speichelprobe unterhalb des Grenzwerts vorhanden, werden die Bindungsstellen der antikörperbeschichteten Partikel im Testgerät nicht gesättigt. Die antikörperbeschichteten Partikel werden dann vom immobilisierten Cortisol-Konjugat gebunden, und es erscheint eine sichtbare farbige Linie im Testlinienbereich. Diese farbige Linie bildet sich nicht im Testlinienbereich, wenn der Cortisolspiegel den Grenzwert überschreitet, da alle Bindungsstellen der Anti-Cortisol-Antikörper gesättigt sind.

Eine positive Speichelprobe erzeugt keine farbige Linie im Testlinienbereich, während eine negative Speichelprobe oder eine Probe mit einer Wirkstoffkonzentration unterhalb des Grenzwerts eine Linie im Testlinienbereich erzeugt. Als Verfahrenskontrolle erscheint immer eine farbige Linie im Kontrolllinienbereich. Dies zeigt an, dass die korrekte Probenmenge hinzugefügt wurde und die Membranbenetzung stattgefunden hat.

【REAGENZIEN】

Das System test device enthält anti-Cortisol-Antikörper-gekoppelte Partikel und ein Cortisol-Protein-Konjugat. Im Kontrolllinien system wird ein Ziegenantikörper verwendet.

【VORSICHTSMASSNAHMEN】

- Nur für die professionelle *In-vitro*-Diagnostik bestimmt.
- Nur für Speichelproben geeignet.
- Einwegprodukt. Nicht wiederverwenden.
- Nicht nach dem Verfallsdatum verwenden.
- Der Test sollte bis zur Verwendung im versiegelten Beutel bleiben.
- Alle Proben sind als potenziell gefährlich zu betrachten und wie infektiöses Material zu behandeln.
- Das gebrauchte Gerät ist gemäß den örtlichen Vorschriften zu entsorgen.
- Warten Sie vor dem Test mindestens 30 Minuten nach dem Essen oder Trinken.

【LAGERUNG UND STABILITÄT】

Lagern Sie das Produkt in der Originalverpackung bei Raumtemperatur oder gekühlt (2-30 °C). Der Test ist bis zum auf dem versiegelten Beutel aufgedruckten Verfallsdatum haltbar. Das Testgerät muss bis zur Verwendung im versiegelten Beutel verbleiben. **Nicht einfrieren.** Nach Ablauf des Verfallsdatums nicht mehr verwenden.

【PROBENENTNAHME UND-PRÄPARATION】

Die Speichelprobe sollte gemäß den untenstehenden detaillierten Anweisungen entnommen werden. Für diesen Test darf kein anderes Entnahmegerät verwendet werden. Die Speichelprobe kann zu jeder Tageszeit entnommen werden.

【MATERIALIEN】

Bereitgestellte Materialien

- Testgeräte
- Packungsbeilage

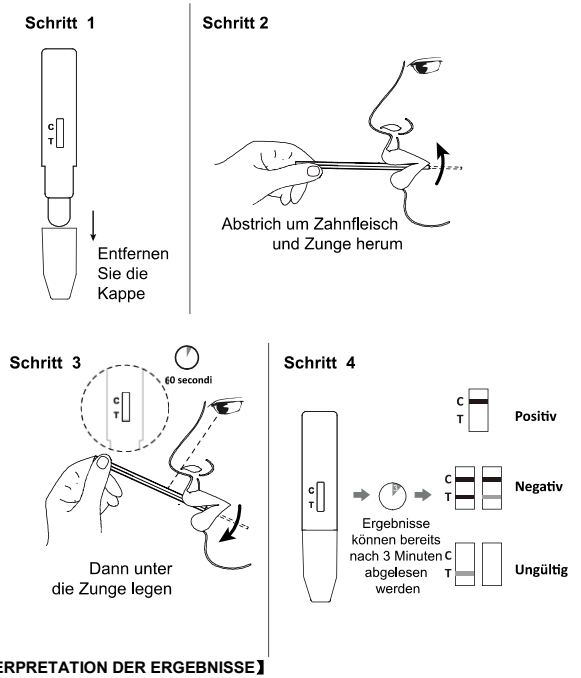
Benötigte, aber nicht bereitgestellte Materialien

- Timer

【GEBRAUCHSANWEISUNG】

Die Testprobe sollte vor der Untersuchung Raumtemperatur (15-30 °C) annehmen device. Weisen Sie den Spender darauf hin, mindestens 30 Minuten vor der Probenentnahme nichts in den Mund zu nehmen, weder Essen, Trinken, Kaugummi noch Tabakwaren.

1. Den Beutel vor dem Öffnen auf Raumtemperatur bringen. Den Test aus dem versiegelten Beutel entnehmen und innerhalb einer Stunde verwenden.
2. Nehmen Sie die device Kappe ab und entnehmen Sie oral fluiddie Probe wie folgt.
   Lassen Sie oral fluiddie Flüssigkeit mindestens 30 Sekunden im Mund einwirken. Legen Sie den saugfähigen Docht unter die Zunge und lassen Sie ihn 60 Sekunden einwirken. Tupfen Sie anschließend aktiv (oral fluid10-15 Mal) um das Zahnfleisch auf beiden Seiten des Mundes, um die Absorption zu fördern.
3. WaitingDer Ablauf erscheint im Testfenster (ca. 60 Sekunden). Nehmen Sie dann das Gerät heraus und starten Sie einen Timer.
   Notiz: Wenn kein Fluss auftritt, wiederholen Sie die oben beschriebenen Schritte, bis ein Fluss auftritt. Wenn nach dreimaliger Wiederholung der oben genannten Schritte immer noch kein Fluss auftritt, entsorgen Sie das Gerät und überprüfen Sie die Vorgehensweise mit den Spender und wiederholen Sie den Test mit einem neuen Gerät..
4. Platzieren Sie das Testgerät auf einer sauberen und ebenen Fläche.
5. Lesen Sie das Testergebnis nach **3-10 Minuten ab.**
   Sind alle Linien nach 3 Minuten oder früher deutlich sichtbar, kann der Test wie folgt interpretiert werden: negativ und verworfen. Wenn nach 3 Minuten keine Linien sichtbar sind, sollte der Test nach 10 Minuten erneut abgelesen werden.



【INTERPRETATION DER ERGEBNISSE】

(Siehe Abbildung oben)

NEGATIV:* Es erscheinen zwei farbige Linien. Eine farbige Linie sollte sich im Kontrollbereich (C) und die andere im Testbereich (T) befinden. Ein negatives Ergebnis bedeutet, dass die Cortisolkonzentration unterhalb der Nachweisgrenze liegt.

*HINWEIS: Die Farbnuance im Testlinienbereich (T) kann variieren, aber ein Test gilt immer dann als negativ, wenn auch nur eine schwache Farblinie sichtbar ist.

POSITIV: Im Kontrollbereich (C) erscheint eine farbige Linie. Im Testbereich (T) erscheint keine Linie. Ein positives Ergebnis bedeutet, dass die Cortisolkonzentration den Nachweisgrenzwert überschreitet.

UNGÜLTIG: Die Steuerlinie wird nicht angezeigt. Unzureichendes Probenvolumen oder Fehlerhafte Verfahrenstechniken sind die wahrscheinlichste Ursache für einen Ausfall der Steuerleitung. Überprüfen Sie das Verfahren und wiederholen Sie den Test mit einem neuen Test. Sollte das Problem weiterhin bestehen, verwenden Sie die Charge nicht mehr und kontaktieren Sie Ihren Händler vor Ort.

【QUALITÄTSKONTROLLE】

Der Test beinhaltet eine Verfahrenskontrolle. Eine farbige Linie im Kontrolllinienbereich (C) dient als interne Verfahrenskontrolle. Sie bestätigt ein ausreichendes Probenvolumen und die korrekte Durchführung der Probenentnahme. Ein transparenter Hintergrund ist ebenfalls eine interne Verfahrenskontrolle.

【EINSCHRÄNKUNGEN】

1. Der Cortisol (COR) Schnelltest (Speichelprobe) ist ein vorläufiger qualitativer Test test; daher können weder der quantitative Wert noch die Anstiegsrate des Cortisols mit diesem Test bestimmt werden.
2. Es ist möglich, dass technische oder verfahrenstechnische Fehler sowie andere Störsubstanzen in der Oral fluidProbe zu fehlerhaften Ergebnissen führen.
3. Ein negatives Ergebnis bedeutet nicht zwangsläufig, dass keine Droge vorhanden ist Oral fluid. Negative Ergebnisse können auch dann auftreten, wenn die Droge zwar vorhanden ist, die Konzentration aber unter dem Grenzwert des Tests liegt.

【LEISTUNGSMERKMALE】

Genauigkeit

Es wurde ein direkter Vergleich zwischen dem Cortisol (COR)-Schnelltest (Speichelprobe) und der GC/MS-Methode durchgeführt. Die folgenden Ergebnisse wurden tabellarisch erfasst:

Verfahren		GC/MS		Gesamtergebnisse
Cortisol (COR) Schnelltest	Ergebnisse	Positiv	Negativ	
	Positiv	93	4	97
	Negativ	7	302	309
Gesamtergebnisse		100	306	406
% Vereinbarung		93,0%	98,7%	97,3%

Sensitivität: 93,0 % (95 %-KI*: 86,11 %–97,14 %)*
Spezifität: 98,7 % (95 %-KI*: 96,69 %–99,64 %)*
Genauigkeit: 97,3 % (95 %-KI*: 95,20 %–98,64 %)* * 95 %-Konfidenzintervalle

Analytische Sensitivität

Der Cortisol (COR)-Schnelltest (Speichelprobe) kann Cortisolkonzentrationen von 50 ng/mL im Speichel nachweisen.

Präzision

Intra-Assay

Die Präzision innerhalb einer Testreihe wurde anhand von 10 Wiederholungen von vier Proben mit 75 ng/mL, 50 ng/mL, 25 ng/mL und 0 ng/mL COR bestimmt. Die negativen und positiven Werte wurden in 100 % der Fälle korrekt identifiziert.

Inter-Assay

Die Präzision zwischen verschiedenen Testreihen wurde anhand derselben vier Proben mit 75 ng/mL, 50 ng/mL, 25 ng/mL und 0 ng/mL COR in 10 unabhängigen Tests bestimmt. Drei verschiedene Chargen des Cortisol (COR)-Schnelltests wurden getestet. Die Proben wurden in 100 % der Fälle korrekt identifiziert.

Störsubstanzen

Die folgenden Störsubstanzen wurden mit dem Cortisol (COR)-Schnelltest (Speichelprobe) getestet, und es wurden keine Interferenzen beobachtet.

Substanz	Konzentration
Estradiol	600 ng/mL
Estriol	500 ng/mL
Progesteron	600 ng/mL
Danazol	500 ng/mL
Testosteron	50 ng/mL
Bilirubin	1 g/mL

【BIBLIOGRAPHIE】

1. Kaushik A, Vasudev A, Arya SK, Pasha SK, Bhansali S. Recent advances in cortisol sensing technologies for point-of-care application. Biosens Bioelectron. 2014 Mar 15;53:499-512.
2. Price DA, Close GC, Fielding BA. Age of appearance of circadian rhythm in salivary cortisol values in infancy. Arch Dis Child. 1983 Jun;58(6):454-6.
3. McEwen BS. Cortisol, Cushing's Syndrome, and a shrinking brain-new evidence for reversibility. J Clin Endocrinol Metab. 2002 May;87(5):1947-8.
4. Løvås K, Thorsen TE, Husebye ES. Saliva cortisol measurement: simple and reliable assessment of the glucocorticoid replacement therapy in Addison's disease. J Endocrinol Invest. 2006 Sep;29(8):727-31.

Symbolverzeichnis

	Beachten Sie die Gebrauchsanweisung oder die elektronische Gebrauchsanweisung.	Σ	Enthält ausreichend für <n> Tests	30°C 2°C	Temperaturgrenze
IVD	*In-vitro*-Diagnostikum	LOT	Batch-Code	REF	Katalog Nummer
	Vorsicht		Mindesthaltbarkeitsdatum		Nicht wiederverwenden
	Nicht verwenden, wenn die Verpackung beschädigt ist. Gebrauchsanweisung beachten.		Hersteller	EU REP	European Authorized representative

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