

## In vitro Diagnostics

### INTENDED USE

Sensit Cortisol Rapid Test Kit is an immunochromatography-based one step *in vitro* test. It is designed for the qualitative determination of total Cortisol in human. This assay provides a preliminary diagnostic test result and can be used for screening of Cortisol abnormalities. The liquid chromatography with tandem mass spectrometry (LC-MS/MS) assays or other quantitative immunoassays are recommended to further confirm the diagnostic test results.

### SUMMARY & TEST DESCRIPTION

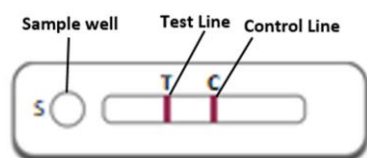
Cortisol is a glucocorticoid hormone released by the adrenal cortex, playing a vital role in stress response, regulating blood sugar, metabolism, blood pressure, and immune function. Its levels fluctuate throughout the day, being highest in the morning (50-250 ng/ml) and lowest in the evening (30-130 ng/ml). Prolonged elevated cortisol can lead to Cushing's syndrome, causing fatigue, depression, obesity, and cardiovascular issues. Conversely, insufficient cortisol causes Addison's disease and can lead to a life-threatening adrenal crisis.

Cortisol is found in biofluids like blood, urine, saliva, and sweat. Most cortisol in the blood is bound to corticosteroid-binding globulins (CBG), with only a small amount being biologically active. Blood testing measures both bound and free cortisol, while saliva and urine tests measure only free cortisol, correlating with blood levels.

Cortisol is essential for responding to stress, fighting infection, and regulating key bodily functions. Monitoring cortisol levels is crucial for diagnosing adrenal disorders and managing overall health.

### TEST DESCRIPTION & PRINCIPLE

Sensit Cortisol Rapid Test Kit works on chromatographic immunoassay. Basic components of test strip includes: a) Conjugate pad, which contains detection molecule, colloidal gold conjugated; b) a nitrocellulose membrane strip containing two lines T: anti-cortisol Ab and C: Goat Anti-Mouse antibody.



Test sample that is added to the sample well, with adequate amount of buffer migrates from the sample pad along the conjugate pad where Cortisol present in the sample will bind to the colloidal gold conjugate to form a complex. The sample then continues to migrate across the membrane until it reaches the capture zone where the complex will bind to the immobilized anti Cortisol Ab (on test line) producing a visible line on the membrane. The intensity of colored band in the test line region is Cortisol concentration-dependent, higher the concentration of Cortisol in the tested sample, the stronger the colored band is. If the Cortisol is not present in the sample, no reaction occurs in the capture zone and no test line is formed. The sample then migrates further along the strip until it reaches the control zone, where it produces another visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended.

### MATERIALS PROVIDED

1. Each test pouch contains:
  - a. One test card and dropper
  - b. Desiccant
2. Instruction Leaflet

### STORAGE & STABILITY

Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

### PRECAUTION & WARNING

- 1) Use within 10 minutes after opening pouch.
- 2) Do not touch result window.
- 3) Do not reuse test kit.
- 4) Do not use test kit beyond expiry date.
- 5) Use only for in-vitro diagnostic purpose.

### SAMPLE COLLECTION

#### Specimen: Blood (serum/plasma)

- Collect 2–5 mL blood in serum or plasma tubes, centrifuge at 1500-2000rpm for 10-15 min, and store at 2–8°C (48 hrs) or -20°C (long-term).

**Blood analysis is the gold standard in monitoring the physiological state of individuals.**

#### Specimen: Urine

- Collect the urine at any time in a clean, dry container either plastic or glass.
- First morning urine specimen is preferred since it generally contains the highest concentration.

#### Specimen: Saliva

- Avoid food, drink, and smoking for 30 minutes, rinse mouth 10 minutes before, collect 0.5 mL saliva, and store at 2–8°C (24 hrs) or -20°C (long-term).

#### Note:

- If the specimen is not used for testing immediately, they should be refrigerated at 2~8°C.
- For storage period longer than 5 days, freezing is recommended. Store at -20°C
- The specimen should be brought to room temperature prior to use.

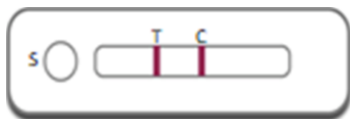
**Treat the specimen as infectious and handle with standard biosafety measures.**

### TEST PROCEDURE

1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 3 drops of the specimen to the Sample well "S"
3. Wait for 10 minutes and interpret the result. The result is considered invalid after 15 minutes.

## INTERPRETATION OF TEST RESULT

**Positive:** A clear pink control band (“C”) and a detectable test band (“T”) appear, indicating the presence of cortisol in the sample.

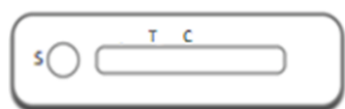
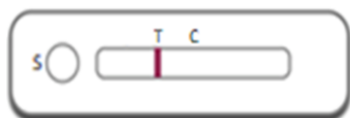


*\*Note: The intensity of the red color in the test region (T) will vary depending on the concentration of cortisol present in the sample.*

**Negative:** A pink colored band appears only at control region (“C”) indicating the absence of cortisol in the sample.



**Invalid:** If the control line fails to appear within the result window, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be retested.



## LIMITATIONS










1. The test may not detect very low cortisol levels, limiting its use for early detection or subclinical conditions.
2. Non-specific binding or interference with other substances may result in false positives or negatives.
3. Inaccurate results may occur if the sample is contaminated or insufficient in volume.
4. Temperature, humidity, and storage conditions can affect test performance and lead to inaccurate results.
5. The kit provides semi-quantitative results (color changes), which may lack precision compared to laboratory-based methods.
6. Certain medications or medical conditions may interfere with cortisol levels and affect test accuracy.
7. The test has a limited shelf life, requiring proper storage and handling to ensure reliability.

## References

- 1.R. Gatti, G. Antonelli, M. Prearo, P. Spinella, E. Cappellin, F. Elio, Cortisol assays and diagnostic laboratory procedures in human biological fluids, Clin. Biochem. 42 (2009) 1205–1217, <https://doi.org/10.1016/j.clinbiochem.2009.04.011>.
- 2.D. Corbalán-Tutau, J.A. Madrid, F. Nicolás, M. Garulet, Daily profile in two circadian markers “melatonin and cortisol” and associations with metabolic syndrome components, Physiol. Behav. 123 (2014) 231–235, <https://doi.org/10.1016/j.physbeh.2012.06.005>.

## DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in Cortisol Rapid Test Kit for single-step detection of cortisol are the most common signs appearing on medical devices and their packaging. They are explained in more detail in the European Standards EN 980: 2008 and INTERNATIONAL Standard ISO 15223-1:2016

Key to symbols used			
	Manufacturer		Expiration/use by date
	Do not reuse		Date of manufacture
	Consult IFU [Instructions For Use]	<b>LOT</b>	Batch code
	Temperature limitation 2-30°C	<b>IVD</b>	In Vitro diagnostic medical device
	Contains sufficient for 'X' kits		Do not use if package is damaged
<b>REF</b>	Catalogue No		Keep dry

Please read the user manual carefully before operating to ensure proper use

## Manufactured by,

ubio Biotechnology Systems Pvt Ltd  
 Plot # 15A, Biotechnology Zone  
 Kalamassery, Cochin, Kerala, India 683503  
 Ph.: +91-484-2970043  
<http://www.ubio.in>  
 e-mail: [contact@ubio.co.in](mailto:contact@ubio.co.in)

UBD/QA/IFU/S099-01  
 Rev. No: A1.1/13-02-2025