Sensit PCT Rapid Test Kit

Cat No.: S047-01

In vitro Diagnostics

INTENDED USE

Sensit PCT (Procalcitonin) Rapid Test is an immunochromatographic assay for the detection of Procalcitonin (PCT) in human whole blood/serum. It is used as an aid to see infection and inflammation and an early detection of clinically relevant bacterial infection. Sensit PCT (Procalcitonin) Rapid Test is only intended for initial screening and all reactive samples should be confirmed by supplemental assay.

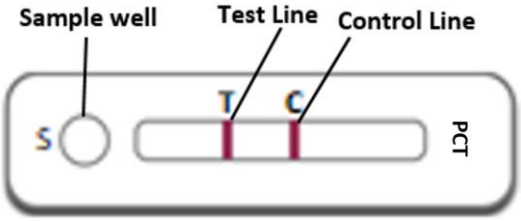
SUMMARY & TEST DESCRIPTION

Procalcitonin (PCT), normally present in the blood at a very low level, and is released in larger amounts in response to an infection, thereby acting as a risk indicator for sepsis. With a negative predictive value above 95%, procalcitonin is widely acknowledged as the most sensitive biomarker to aid in the diagnosis of bacterial sepsis. Sepsis or septicaemia (blood poisoning) is a potentially fatal condition that is usually associated with a bacterial infection. In order to detect sepsis before it becomes life-threatening, a sensitive and rapid diagnostic test that can test for an accurate biomarker is required.

Sensit PCT Rapid Test Kit qualitatively detects the presence of procalcitonin.

TEST DESCRIPTION & PRINCIPLE

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



Test sample that is added to the sample well, with an adequate amount of buffer migrates from the sample pad along the conjugate pad where PCT 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-PCT Ab (on the test line) producing a visible line on the membrane. If the PCT 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. Assay Diluent in dropper bottle
3. 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 AND PREPARATION

Whole Blood:

- Collect the whole blood using a syringe or vacutainer into a container containing anticoagulants such as heparin, EDTA or sodium citrate by venipuncture.

Serum:

- Collect the whole blood using a syringe or vacutainer (NOT containing anticoagulants such as heparin, EDTA or Sodium citrate) by venipuncture. Leave the syringe or vacutainer, preferably at an angle, to settle for 30 minutes. Once blood coagulants, centrifuge the blood to get the serum specimen as supernatant.

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^{0}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 10 µl of the specimen to the Sample well "S". (To take 10 µl, aspirate only up to the bubble point in the dropper provided Refer Diagram .1.)

Diagram 1. 10µl sample

Aspirate to the bubble to obtain a 10µl sample

3. When the sample is fully absorbed, add 2 drops of the diluent provided with the assay to the sample well.
4. Wait for 10 minutes and interpret the result. The result is considered invalid after 15 minutes.

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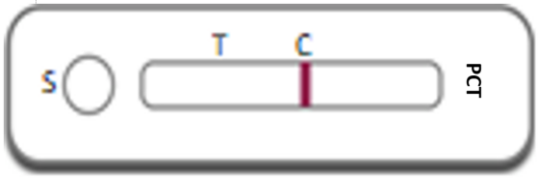
INTERPRETATION OF TEST RESULT

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

Negative: A pink colored band appears only at control region ("C") indicating the absence of PCT 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.

References

1. Cui, N., Zhang, H., Chen, Z., & Yu, Z. (2019). Prognostic significance of PCT and CRP evaluation for adult ICU patients with sepsis and septic shock: retrospective analysis of 59 cases. *The Journal of international medical research*, *47*(4), 1573–1579.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in the PCT Rapid Test for single-step detection of PCT 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]	LOT	Batch code
	Temperature limitation 2-30°C	IVD	In Vitro diagnostic medical device
Σ X	Contains sufficient for 'X ' kits		Do not use if package is damaged
REF	Catalogue No		Keep dry

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

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ubio Biotechnology Systems Pvt Ltd
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