LIMING BIO

Procalcitonin Rapid Test

REF 502050	**Specimen:** Plasma/ Serum
Language: English	**Version:** 01
Effective Date: 2012-03	

For professional *In vitro* diagnostic use only.

INTENDED USE

The StrongStep® Procalcitonin Test is a rapid immune-chromatographic assay for the semi-quantitative detection of Procalcitonin in human serum or plasma. It is used for diagnosing and controlling the treatment of severe, bacterial infection and sepsis.

INTRODUCTION

Procalcitonin(PCT) is a small protein that comprises 116 amino acid residues with a molecular weight of approximately 13 kDa which was first described by Moullec et al. in 1984.

PCT is produced normally in C-cells of the thyroid glands. In 1993, the elevated level of PCT in patients with a system infection of bacterial origin was reported and PCT is now considered to be the main marker of disorders accompanied by systemic inflammation and sepsis. The diagnostic value of PCT is important due to the close correlation between PCT concentration and the severity of inflammation. It was shown that "inflammatory" PCT is not produced in C-cells. Cells of neuroendocrine origin are presumably the source of PCT during inflammation.

PRINCIPLE

The *StrongStep*® Procalcitonin Rapid Test detects *Procalcitonin* through visual interpretation of color development on the internal strip. Procalcitonin monoclonal antibody is immobilized on the test region of the membrane. During testing, the specimen reacts with monoclonal anti-Procalcitonin antibodies conjugated to colored particles and precoated onto the conjugate pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there are sufficient Procalcitonin in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

A distinct color development in the test line region(T) indicates a positive result whereas the amount of Procalcitonin can be assessed semi-quantitatively by comparison of the test line intensity to the reference line intensities on the interpretation card. The absence of a colored line in the test line region(T) suggests a negative result.

KIT COMPONENTS

20 Individually packed test devices	Each device contains a strip with colored conjugates and reactive reagents pre-spreaded at the corresponding regions.
20 pipette	For specimens transfer
1 interpretation card	For interpretation of the results.
1 Package insert	For operation instruction.

MATERIALS REQUIRED BUT NOT PROVIDED

Timer	For timing use.
Specimen collection container	For specimen collection.

PRECAUTIONS

- This kit is for IN VITRO diagnostic use only.
- This kit is for PROFESSIONAL use only.
- Read the instructions carefully before performing the test.
- This product does not contain any human source materials.
- Do not use kit contents after the expiration date.
- Handle all specimens as potentially infectious.
- Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infective material. When the assay procedure is complete, dispose specimens after autoclaving them at 121℃ for at least 20 min. Alternatively, they can be treated with 0.5% Sodium Hypochlorite for hours before disposal.
- Do not pipette reagent by mouth and no smoking or eating while performing assays.
- Wear gloves during the whole procedure.

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 2-30℃ for the duration of the shelf life as indicated on the pouch.

SPECIMEN COLLECTION AND STORAGE

The test can be performed with plasma or serum. The collection and handling of the specimen is described below:

Plasma:

1. Collect blood into an appropriate collection tube containing EDTA, Heparin or citrate by vein puncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma for testing. Plasma can be stored at 2-8 ℃ for up to two weeks. If it will not be tested within two weeks plasma samples should be frozen.

Serum:

1. Collect blood into an appropriate collection tube containing no anticoagulants.
2. Allow the blood to clot.
3. Seprate the serum by centrifugation.
4. Carefully withdraw the serum for testing. Serum can be stored at 2-8℃ for up to two weeks. If it will not be tested within two weeks serum samples should be frozen.

The samples should preferably be examined immediately after collection. Samples can be stored for about 24 hours at 2-8℃ until examination. For long term storage samples should be frozen at -20℃. Avoid repeated thawing/freezing. Frozen samples should be warmed up to room temperature and carefully mixed before testing. Remove visible particles in samples by centrifugation. Do not use haemolytic samples since elevated haemoglobin concentrations(>5g/dl) might affect result interpretation.

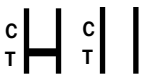
PROCEDURE

- Bring the kit components to room temperature before testing.
- Open the pouch and remove the Card. Once opened, the test card must be used immediately.
- Label the test card with patients identity.
- Apply 3 drops (120-150 μL) of serum, plasma or to the sample well marked as 'S'.
- At the end of 15 minutes read the results. A strong positive sample may show result earlier.

Note:

1. Some positive samples may show positive results before 15 minutes.
2. Results after 20 minutes may not be accurate.

INTERPRETATION OF RESULTS

NEGATIVE RESULT: 	One colored bands appears in the Control Zone (C) within 15 minutes. No colored band appears in the Test Zone (T). It is indicated that the amount of Procalcitonin in the sample is below 0.5ng/ml.
POSITIVE RESULT: 	Additional to a red colored line in the control region a red line in the test region appears. This result indicates that Procalcitonin could be detected. The color intensity of the lines may be different. The amount of Procalcitonin can be assessed of the test line intensity to the reference line intensities on the interpretation card.
INVALID RESULT: 	No colored band appears in the Control Zone (C) within 15 minutes. The test result is invalid. Repeat the test with a new test device.

REFERENCE VALUES

<0.05 ng/ml	Healthy
0.05 bls<0.5 ng/ml	Local infections
0.5 bls<2.0 ng/ml	Systemic infection(sepsis) possible
2.0 bls<10.0 ng/ml	Systemic infection(sepsis) likely
>10.0 ng/ml	Severe sepsis or Septic shock

LIMITATIONS OF THE TEST

- **As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.**

- **The cut-off value can differ according the clinical situation of the patient. Therefore the above mentioned reference values should be regarded as orientation guide.**
- **In same instances elevated Procalcitonin levels in due to non-infectious reasons can be observed:**
  - **During the first days after trauma or surgical intervention, burns, release of proinflammatoric cytokines, lung cancer (oat cell carcinoma), Medullary Thyroid Carcinoma (C-Cell Carcinoma)**
  - **New born children, < 48hours**
  - **Severe cardiogenic shock**

LITERATURE REFERENCES

1. Le Moullec JM, et al. (1984) The complete sequence of human procalcitonin. FEBS Letters 167(1), 93-97.
2. Assicot M, et al. (1993) High serum procalcitonin concentrations in patients with sepsis and infection. Lancet 341(8844), 515-518.
3. Meisner M and Reinhart K (2001) Is procalcitonin really a marker of sepsis? Int J Intensive Care 8(1), 15-25.
4. Sponholz C, et al. (2006) Diagnostic value and prognostic implications of serum procalcitonin after cardiac surgery: a systematic review of the literature. Critical Care 10, R145.
5. Meisner M, (2002) Pathobiochemistry and clinical use of procalcitonin. Clin Chim Acta 323, 17-29.

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer	Σ	Contains sufficient for <n> tests
	Do not reuse	EC REP	Authorized representative in the European Community

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