Quality approved by SD BIOSENSOR / For *In vitro* diagnostic use only

STANDARD F

PCT FIA

REF F-PCT-02

STANDARD™ F PCT FIA

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

EXPLANATION AND SUMMARY

[Introduction]

Procalcitonin (PCT) is a precursor protein of the hormone calcitonin, a 116-peptide molecule with a molecular weight of 13kDa.[1] It is produced by parafollicular cells (C cells) of the thyroid, by the neuroendocrine cells of the lung, and by the intestine. PCT has the highest accuracy for the diagnosis of sepsis in various settings. The lag time for PCT induction is approximately 2 to 4 hours after the onset of sepsis. Peak levels of PCT occur at 24 to 48 hours after sepsis.[2] In healthy individuals, plasma PCT concentrations are found to be below 0.05 ng/ml, but can increase up to 1,000 ng/ml in patients with severe sepsis or septic shock.[3] PCT has been studied as a sepsis biomarker to help with diagnosing and ruling out sepsis and to guide the initiation and cessation of antibiotics. The high PCT levels produced during infections are not followed by a parallel increase in calcitonin or a decrease in serum calcium levels.

[Intended use]

STANDARD F PCT FIA is an *in vitro* diagnostic use to measure the PCT in serum, plasma, and whole blood. The quantitative measurement of the PCT is useful in the diagnosis of bacterial infection and sepsis.

[Test principle]

STANDARD F PCT FIA is based on the immunofluorescence technology with STANDARD F Analyzer manufactured by SD BIOSENSOR to measure the PCT concentration in human serum, plasma, and whole blood. The specimen from human should be processed for the preparation using the components of the STANDARD F PCT FIA. After applying the sample mixture to the test device, the complex will be formed on the membrane as the result of the antigen-antibody reaction. The intensity of the fluorescence light is scanned and converted into an electric signal which is proportional to the intensity of fluorescence light produced on the membrane. STANDARD F Analyzers can analyze the PCT concentration of the clinical specimen based on a pre-programmed algorithms and display the test result on the screen.

[Kit contents]

① Test device ② Disposable dropper (100 µl) ③ Extraction buffer ④ Instructions for use

[Materials required but not provided]

- STANDARD™ F Analyzer

KIT STORAGE AND STABILITY

Store the kit at 2-30°C / 36-86°F, out of direct sunlight. Kit materials are stable until expiration date printed on the outer box. Do not freeze the kit.

WARNINGS AND PRECAUTIONS

1. STANDARD F PCT FIA is for *in vitro* diagnostics use only.
2. Carefully follow the instructions and procedures described in this instructions before testing.
3. STANDARD F PCT FIA should be used with STANDARD F Analyzer.
4. STANDARD F PCT FIA should remain in its original sealed pouch until ready to use. Do not use the if the pouch is damaged or the seal is broken.
5. STANDARD F PCT FIA is single use only. Do not re-use it.
6. Do not use hemolyzed samples or frozen samples.
7. Do not use any artificial materials.
8. Place the analyzer on a flat surface when in use.
9. Wash your hands in warm, soapy water. Rinse well and dry completely before testing.
10. Discard the used test kit according to the proper method.
11. Silica gel in foil pouch is to absorb moisture and keep humidity from affecting products. If the moisture indicating silica gel beads change from yellow to green, the test device in the pouch should be discarded.
12. Check the expiration date printed at the pouch or package.
13. Check the volume (100µL) of extraction buffer.
14. Use the STANDARD F PCT FIA at 15-32°C / 59-90°F.
15. All kit components are must be at room temperature 30 minutes before running the assay.
16. Do not write on the bar code or damage the bar code of the test device.

SPECIMEN COLLECTION AND PREPARATION

[Whole blood]

Venous whole blood

1. Collect the venous whole blood into the commercially available EDTA tube by venipuncture.
2. It is recommended that collected venous whole blood samples are used immediately. If venous whole blood in an anticoagulant tube is stored at room temperature or at 2-8°C/36-46°F or in a refrigerator at 2-8°C, the specimen can be used for testing within 8 hours after collection.
3. Do not use hemolyzed blood samples.

[Serum]

1. Collect the whole blood into the commercially available plain tube, NOT containing anti-coagulants such as heparin, EDTA or sodium citrate by venipuncture and leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
2. Serum specimen may be stored at room temperature or at 2-8°C/36-46°F for up to 24 hours prior to testing.
3. It should be brought to room temperature prior to use.

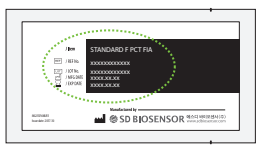
[Plasma]

1. Collect the venous whole blood into the commercially available EDTA tube by venipuncture, and centrifuge blood to getplasma specimen.
2. Plasma in an anti coagulant tube may be stored at room temperature or at 2-8°C/36-46°F for up to 3 days prior to testing.
3. It should be brought to room temperature prior to use.

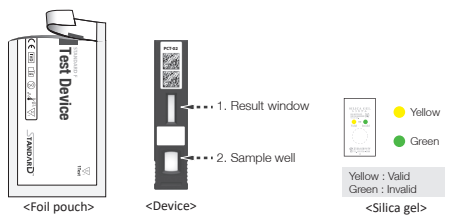
TEST PROCEDURE

[Preparation]

1. Allow kit components and collected sample to room temperature (15-30°C/59-86°F) at least 30 minutes before staring the test.
2. Carefully read instructions for the STANDARD F PCT FIA.
3. Check the expiry date at the back of the foil pouch. Use another lot if expiry date has passed.



4. Open the foil pouch, and check the test device and the silica gel pack inside the foil pouch.



<Foil pouch> <Device> <Silica gel>

CAUTION

The control line appears on the membrane of the test device after use.

CAUTION

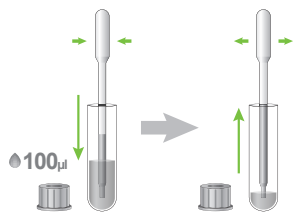
- Do not write on the bar code or damage the bar code of the test device.
- If the color of moisture indicators are changed from yellow to green, please do not use the test device.

[Analysis of sample]

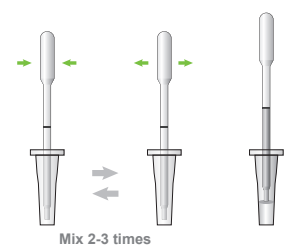
- **Using a 'STANDARD TEST' mode**
  - **STANDARD F100, F200 and F2400 analyzer**

1. Prepare a STANDARD F Analyzer and select the 'Standard Test' mode according to the analyzer's manual. In case of STANDARD F2400 analyzer, go to the 'Workplace' in the main screen. And select the 'Run Test'
2. In case of STANDARD F200 and F2400 analyzer, input patient ID and/or operator ID on the analyzer.
3. Take the test device out of the foil pouch.
4. Insert the test device to the test slot of the analyzer. When inserting the test device to the analyzer, the analyzer will read the barcode data, and check the test device is valid.

5. Collect 100 µl of sample to the black line of a Disposable dropper (100 µl).



6. Mix sample and buffer 2-3 times with the disposable dropper (100 µl). Then, collect 100 µl of sample mixture.



7. After applying the sample, immediately press the **'TEST START'** button.

<F100> <F200> <F2400>

8. The analyzer will automatically display the test result within 15 minutes.

CAUTION

- Do not put bubbles in the sample well of the test device.
- Discard the used test kit in proper container, according to your healthcare professional's recommendation.
- If you feel the test result is inaccurate or do not agree your test result, do not change the treatment and contact your healthcare professional.

INTERPRET THE TEST RESULT

STANDARD F PCT FIA reads PCT concentration between 0.05 - 50 ng/mL. If the result is below 0.05ng/mL, it will be reported as "↓0.05ng/mL". If the result is above 50ng/mL, it will be reported as "↑50ng/mL".

CAUTION

- Results should be considered in conjunction with the clinical history and other data available to the physician.
- If an error message appears on the analyzer's screen, refer to the analyzer's manual.

- **Diagnosis of Sepsis[4]**

PCT levels (ng/mL)	Interpretation
< 0.05	Healthy individual
< 0.5	Low risk or local bacterial infection
> 0.5 – 2.0	Moderate risk for progression to severe systemic infection (Sepsis)
> 2.0 – 10.0	High risk for progression to severe systemic infection (Severe Sepsis)
> 10.0	High likelihood of severe sepsis or septic shock

- **Diagnosis of Lower Respiratory Tract Infections[5]**

PCT levels (ng/mL)	Interpretation
< 0.1	Absence of bacterial infection (ABX Strongly discouraged)
> 0.1 - 0.25	Bacterial infection unlikely (ABX discouraged)
> 0.25 - 0.5	Bacterial infection is possible (ABX encouraged)
> 0.5	Presence of bacterial infection (ABX strongly encouraged)

- **Normal age-adapted PCT ranges in newborns[6]**

Age (hours)	0~6	6~12	12~18	18~36	36~48	48~60	60~72	72~90
PCT (ng/ml)	0.5	2	5	10	5	2	1	0.5

NOTE

The Procalcitonin reference ranges are provided for orientational purpose only. Clinicians should use the test results in conjunction with the patient's other diagnostic findings and clinical signs, and interpret the concrete values in the context of the patient's clinical situation.

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QUALITY CONTROL

[STANDARD F Analyzers Calibration Check]

The calibration set test of STANDARD F Analyzers should be conducted according to the analyzers' manual.

- **When to use calibration set**
  1. Before using the analyzer for the first time
  2. When you drop the analyzer
  3. Whenever you do not agree with your result
  4. When you want to check the performance of an analyzer and test device
- **How to use calibration set**
  Calibration set test is a required function that ensures optimal performance by checking the internal analyzer optics and functions.
  1. Select the 'Calibration' menu.
  2. The specific calibration set is included with the analyzer.
  3. Insert the CAL-1 first, and then insert the CAL-2 for UV-LED testing and the CAL-3 for RGB-LED testing in order.

[External quality control]

Quality control testing should be run to check the performance of STANDARD F PCT FIA and STANDARD F Analyzers. STANDARD F PCT-02 Control manufactured by SD BIOSENSOR should be used for quality control testing. Control test should be conducted in accordance with the instructions of STANDARD F PCT-02 Control.
Control test should be run:

- once for each new lot.
- once for each untrained operator.
- as required by test procedures in instructions for use of STANDARD F PCT-02 Control and in accordance with local, state and federal regulations or accreditation requirements.

BIBLIOGRAPHY

1. Ming, Jin,; I., Khan, Adil (2010-03-01). "Procalcitonin: Uses in the Clinical Laboratory for the Diagnosis of Sepsis". Laboratory Medicine. 41 (3).
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3. Baki C. et al., Usefulness of procalcitonin for diagnosis of sepsis in the intensive care unit. Critical Care 2003; 7(1): 85-90.
4. Christ-Crain M, Müller B. Procalcitonin in bacterial infections – hype, hope or more or less? Swiss Med Wkly 2005; 135: 451-60.
5. Schuetz P et al., Clinical Infectious Disease, 2012;55: 651-662.
6. Stocker et al.: Neonatal Procalcitonin Intervention Study (NeoPInS): Effect of Procalcitonin-guided decision making on Duration of antibiotic Therapy in suspected neonatal early-onset Sepsis: A multi-centre randomized superiority and non-inferiority Intervention Study. BMC Pediatrics 2010 10:89.

Product Disclaimer
Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the SD BIOSENSOR and distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

Warning
The SD BIOSENSOR and distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect of consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

CE IVD

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IVD *In vitro* Diagnostics
Consult Instructions for Use
Contains Sufficient for <n> Tests
Caution
To indicate the temperature limitations in which the transport package has to be kept and handled.
Note
Do not re-use.
Use by
LOT Batch code
Manufacturer
Date of manufacture
CE Fulfill the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices