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

STANDARD F

PCT FIA (Serum)

REF F-PCT-01

STANDARD™ F PCT FIA (Serum)

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

STANDARD™

EXPLANATION AND SUMMARY

[Introduction]

Procalcitonin (PCT) is a precursor protein of the hormone calcitonin, a 116-peptide molecule with a molecular weight of 13kDa. It is produced by parafollicular cells (C cells) of the thyroid and by the neuroendocrine cells of the lung and the intestine. PCT is induced in the plasma of patients with severe bacterial infections or sepsis. The level of PCT of healthy individuals is below the limit of detection (0.1ng/mL) of clinical assays. The level of PCT rises in a response to a pro-inflammatory stimulus, especially of bacterial origin. PCT has a half-life of 25 to 30 hours. Therefore, 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 (Serum) is an *in vitro* diagnostic use to measures the PCT in human serum. The qualitative measurement of the PCT is useful in the diagnosis of bacterial infection and sepsis.

[Test principle]

STANDARD F PCT FIA (Serum) is based on the immunofluorescence technology with STANDARD F Analyzer manufactured by SD BIOSENSOR to measure the PCT concentration in serum. The specimen from human should be processed for the preparation using the components of the STANDARD F PCT FIA (Serum). 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 Extraction buffer ③ Fixed volume pipette (50µl) 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 (Serum) 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 (Serum) should be used with STANDARD F Analyzer.
4. STANDARD F PCT FIA (Serum) 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 (Serum) 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. Before testing, check the fluorescent tablet in the Spoit™ if it is not contaminated or broken.
9. Place the analyzer on a flat surface when in use.
10. Wash your hands in warm, and soapy water. Rinse well and dry completely before testing.
11. Discard the used test kit according to the proper method.
12. Mix the serum sample and extraction buffer thoroughly. And then, collect all of the mixed solution.
13. Check the expiration date printed on the pouch or package.
14. Check the volume (150µL) of extraction buffer.
15. Serum sample, PCT fluorescent tablet, and extraction buffer should be well mixed properly by using the Spoit™. Then, immediately apply the sample to the sample well within 30 seconds.
16. Use the STANDARD F PCT FIA (Serum) at 15-32°C / 59-90°F.
17. Mix Carefully to avoid bubble forming and do not put bubbles in the sample well of the test device.
18. All kit components are must be at room temperature 30 minutes before running the assay.
19. Do not write on the bar code or damage the bar code of the test device.

SPECIMEN COLLECTION AND PREPARATION

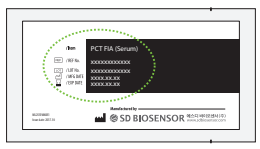
[Serum]

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 for up to 8 hours or at 2-8°C/36-46°F for up to 24 hours prior to testing.
3. For over 24 hours storage, specimens may be frozen under -20°C/-4°F for up to 3 months.
4. It should be brought to room temperature prior to use.

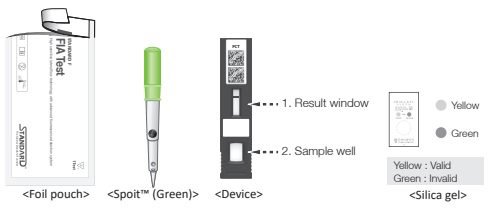
TEST PROCEDURE

[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 (Serum).
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 Spoit™ with PCT fluorescent tablet in the foil pouch.



CAUTION

- If the color of moisture indicators are changed from yellow to green, please do not use the test device.
- If there is no violet colored Check Band on membrane of test device, do not use it.
  * Check Band

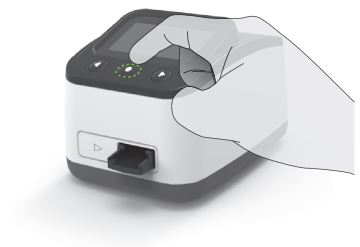
CAUTION

- Do not write on the bar code or damage the bar code of the test device.

[Test Procedure]

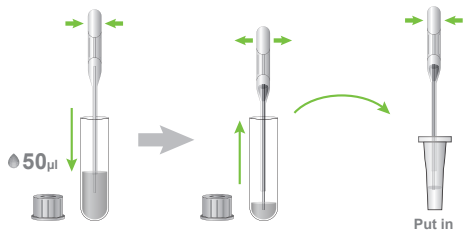
- **Using a STANDARD F100 Analyzer**

1. Prepare a STANDARD F100 Analyzer and set the 'Standard Test' mode according to the analyzer's manual.
2. Take the test device and the Spoit™ out of the foil pouch.

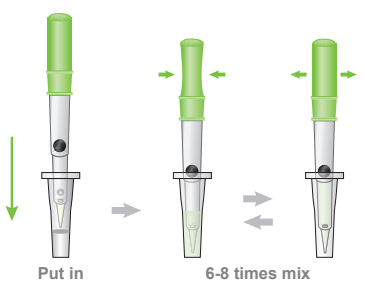


3. Insert the test device into the Test Slot of the analyzer. The analyzer automatically reads the information of bar code on the test device and releases the test device for adding sample.

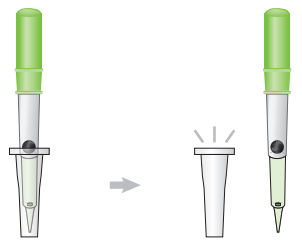
4. Collect the 50µl of serum sample with a fixed volume pipette (50µl). And then, put it in an extraction buffer tube and completely squeeze the sample into the tube. You may collect 50µl of serum with your own pipette.



5. Put the tip of the Spoit™ into an extraction buffer tube.
6. Mix the sample, fluorescent tablet, and buffer by carefully pressing and releasing the rubber at the top of the Spoit™ for 6-8 times. Mix carefully to avoid bubble forming.

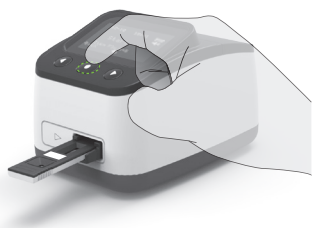


7. Collect all the reaction mixture with the Spoit™ from the tube.



8. Apply the sample at the sample well of the test device.

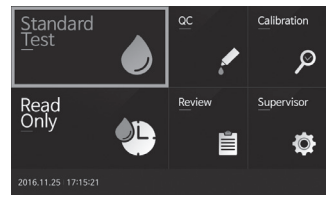
9. **After applying the sample, immediately press the center button to start the test.**



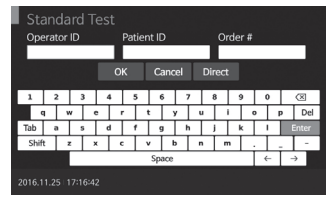
10. The analyzer will automatically display the test result after 15 minutes.

- **Using a STANDARD F200 Analyzer**

1. Prepare a STANDARD F200 Analyzer and select the `Standard Test' mode on the analyzer's screen



2. Enter operator ID, patient ID, and order # in sequence. If patient ID is not typed in, the analyzer will regard it as a "Guest".
3. Take the test device out of the foil pouch.

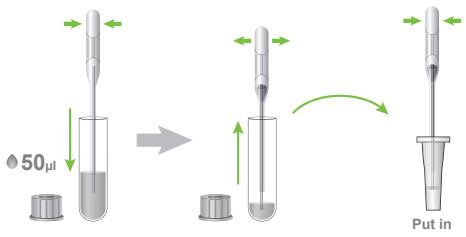


SD BIOSENSOR

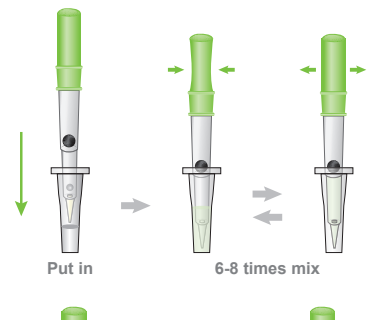
4. Once the 'Insert Device' is displayed in the screen, insert the test device into the Test Slot of the analyzer.

5. During "Device Checking" phase, the analyzer automatically reads information from the bar code on the test device to check whether the test is valid or not.

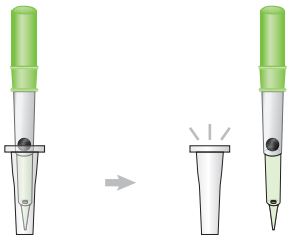
6. Collect the 50µl of serum sample with a fixed volume pipette (50µl). And then, put it in an extraction buffer tube and completely squeeze the sample into the tube. You may collect 50µl of serum with your own pipette.



7. Put the tip of the Spoit™ into an extraction buffer tube.
8. Mix the sample, fluorescent tablet, and extraction buffer by carefully pressing and releasing the rubber at the top of the Spoit™ for 6-8 times. Mix carefully to avoid bubble forming.

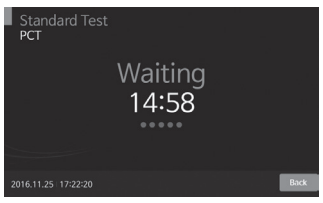


9. Collect all the reaction mixture with the Spoit™ from the tube.



10. Apply the sample at the sample well of the test device.
11. **After applying the sample, immediately press the start button.**

12. The analyzer will automatically display the test result after 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

The STANDARD F PCT FIA (Serum) reads PCT concentration between 0.1 - 50ng/mL. If the result is below 0.1ng/mL, it will be reported as "↓0.1ng/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**

PCT levels (ng/mL)	Interpretation
< 0.1	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**

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)

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.

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 (Serum) and STANDARD F Analyzers. STANDARD F PCT 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 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 Control and in accordance with local, state and federal regulations or accreditation requirements.

PERFORMANCE CHARACTERISTICS

[Accuracy (Method comparison)]

Results comparing the STANDARD F PCT FIA (Serum) with the reference method are presented at the below;

Regression Analysis	
Slope	0.9942
Y-intercept	0.0158
R	0.9933
R^2	0.9866
N	210

System Accuracy	
below -1.96SD	3/210 (1.4%)
within ±1.96SD	204/210 (97.1%)
over 1.96SD	3/210 (1.4%)

[Precision]

The precision evaluation was done at 3 sites. The within-run using the 3 levels of STANDARD F PCT Control and the Day-to-Day using the 3 levels of STANDARD F PCT Control for 20 days. The acceptance criterion is within 10% (CV) for both within-run CV and total-run CV.

Within Run	Level 1			Level 2			Level 3		
	Site 1	Site 2	Site 3	Site 1	Site 2	Site 3	Site 1	Site 2	Site 3
Ref.	1.4	1.4	1.4	14.9	14.7	14.8	38.1	37.5	38.9
AVG.	1.53	1.54	1.54	16.08	15.73	15.81	40.87	39.97	41.43
CV (%)	6.22	6.07	6.93	6.57	6.69	6.59	5.59	5.10	5.35
BIAS (%)	7.61	8.44	7.92	8.23	6.85	7.03	7.32	6.63	6.56

Day-to-Day	Level 1			Level 2			Level 3		
	Site 1	Site 2	Site 3	Site 1	Site 2	Site 3	Site 1	Site 2	Site 3
Ref.	4.2	4.2	4.2	11.8	11.7	11.7	30.6	30.6	30.5
AVG.	4.50	4.50	4.46	12.69	12.71	12.53	1.76	1.82	1.86
CV (%)	5.81	5.95	5.93	6.81	6.69	7.04	5.75	5.95	6.09
BIAS (%)	6.98	7.17	7.06	7.64	8.50	7.40	7.32	6.49	6.71

[Interfering Substances]

The following materials with up to the indicated concentration do not interfere with the test result.

Acetaminophen	100 mg/dL	**Dopamin**	2 mg/dL
Acetylsalicylic acid	30 mg/dL	**Ibuprofen**	10 mg/dL
Ampicillin	30 mg/dL	**Furosemide**	100 mg/dL
Ascorbic acid	35 mg/dL	**Rifampicin**	600 mg/dL
Bilirubin	30 mg/dL	**Rheumatoid factor**	760 IU/mL
Calcitonin	300 mg/dL	**Triglyceride**	900 mg/dL
Cholesterol	300 mg/dL		

BIBLIOGRAPHY

1. Morkline A. et al., procalcitonin: a diagnostic and prognostic biomarker of sepsis in burned patients. Annals of burns and fire disasters 2015; 28(2): 116-20.
2. Meisner M. et al., Comparison of procalcitonin (PCT) and C-reactive protein (CRP) plasma concentrations at different SOFA scores during the course of sepsis and MODS. Critical Care 1999; 3(1): 45-50.
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. Brunkhorst FM. et al., Procalcitonin, C-reactive protein and APACHE II score for risk evaluation in patients with severe pneumonia. Clinical microbiology and infection 2002; 8(2):93-100.
5. Grace, E. and Turner, RM., Use of procalcitonin in patients with various degrees of chronic kidney disease including renal replacement therapy. Clinical infectious diseases 2014; 59(12): 1761-1767.

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

Manufactured by SD BIOSENSOR
Head office : C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
Manufacturing site : 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA

EC REP **Authorized Representative**
MT Promedt Consulting GmbH
Altenhofstrasse 80 D-66386 St. Ingbert Germany
Phone : +49 6894 581020, Fax : +49 6894 581021

Any inquiries regarding instructions provided should be addressed to: sales@sdbiosensor.com
or you can also contact us through www.sdbiosensor.com

L28PCT1ENR2
Issue date : 2017.12

REF Reference number | 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