PCT

Procalctionin Test Kit
(Rate Scattering Turbidimetric Method)

Instructions for Use

Version: A/6

REF HP-PCT-25

Manufacturer

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Product Name

General Name：Procalctionin Test Kit
(Rate Scattering Turbidimetric Method)

Specification

Package Specification

25 Tests/ Kit.

Intended Use

This product is used to determine the content of Procalctionin (PCT) in human serum or plasma.

PCT is a prohormone which composed of 116 amino acids, its molecular weight of about 12.7kD. PCT is expressed by neuro-endocrine cells (including C cells of the thyroid, lung and pancreas), and only a small amount of PCT is present in healthy human blood. The PCT concentration is significantly increased after bacterial infection and sepsis. Quantitative determination of PCT can be used for early diagnosis and prognosis evaluation of systemic bacterial infection and sepsis, but also as an indicator for antibiotic selection and treatment.

Test Principle

The antibody of mouse anti human procalctionin is coated on the latex surface. The Procalctionin in the sample and the antibody become to immune complexes by Latex agglutination reaction. The immune complexes will produce the phenomenon of light scattering which is proportional to the intensity of scattered light and samples of PCT levels. Using specific protein analyzer to measure the intensity of scattered light, the concentration of PCT is determined by comparing the turbidity of samples to the standard concentration.

Component

The PCT test kit consists of two reagents R1 and R2, as shown on Figure 1.

Figure 1
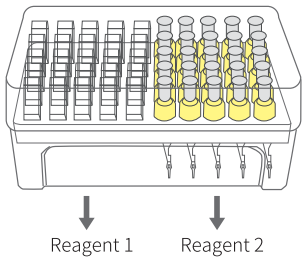
Reagent 1   Reagent 2

Name	Content	Quantity
Reagent 1 (R1)	Phosphate buffer	0.1mol/L
	Polyethylene glycol 6000	Appropriate
	Sodium azide	0.1%
Reagent 2 (R2)	Mouse anti human procalctionin antibody with latex	2g/L
IC card (optional)	/	1

Do not mix different batches of reagents.

Storage&stability

Store the test kit at 2°C-8°C until the expiration date indicated on the label. The test kit is stable for one year when unopened. Use up the test kit within one month after opening the package.
Do not freeze the test kit.
Do not mix different lots of the test kit.

Special Instrument Requirements

HP-083/4-I POCT Immunoassay System,
HP-083/4-II POCT Immunoassay System,
HP-AFS/1 Automatic Immunoassay System,
HP-AFS/3 Automatic Immunoassay System.

Specimen type

Plasma or serum, anticoagulation including EDTA, heparin, and citrate，avoid hemolysis. Fasting blood collection and separation of serum as soon as possible. The sample store at 2-8°C for 34 hours, -20°C for 1 month. Avoid repeated freezing. Before test, ensure fully mixed.

Procedures

### HP-083/4-I&HP-083/4-II POCT Immunoassay System

Note:
- Please read user manual of HP-083/4-I and HP-083/4-II before use;
- The analyzer will finish self check after start-up;
- Insert the IC card of PCT test kit to let analyzer read the parameter;
- The analyzer calibration can be done with app. It is recommended that analyzer calibration should be done for each new lot of test kit.

Step 1 Sample Preparation
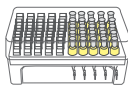
3a Allow the test kit back to room temperature for 30 minutes before use

Step 1 Sample Preparation
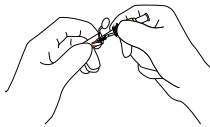
1b Use the R2 with quantitative capillary to collect sample.

**1c** Insert the R2 into R1.

Note:
- The parameter is built in the IC card.
- Please insert the corresponding IC card into analyzer to let the analyzer read the parameter before each assay test.
- The capillary of the R2 should be fully filled.

Step 2 Testing

2a Hold the narrow side of R1 and shake from left to right for 12 times to let the sample completely mix with R1.
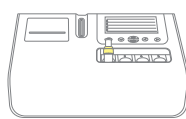
Note: Do not hold the wide sides of R1.
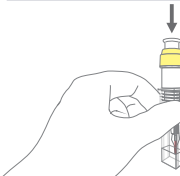
2b Press the piston on R2.

**2c** Hold the narrow sides of R1 and shake for 3-5 seconds to let R1 and R2 mix well.

2d Insert the R1 into test channel of HP-083/4-II and the analyzer will finish the test and print out results automatically.
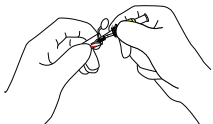
HP-AFS/1&HP-AFS/3 Automatic Immunoassay System

Note:
- Please read user manual of HP-AFS/1 and HP-AFS/3 before use;
- The analyzer will finish the self check after start-up;
- It is recommend to do analyzer calibration monthly and for each new lot of test kit.
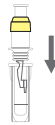
Step 1 Sample Preparation
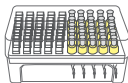
3a Allow the test kit back to room temperature for 30 minutes before use

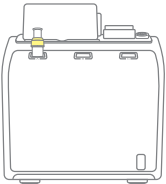**3b** Use the R2 with quantitative capillary to collect sample.

Step 1 Sample Preparation

3c Insert the R2 into R1.

Note:

- Please update the standard curve with the barcode on the R1 cuvette if a new lot test kit is to be used.
- The capillary of the R2 should be fully filled.

Step 2 Testing

4a Insert the R1 into test channel of analyzer.

4b The analyzer will mix the sample from R2 capillary with R1 automatically.

4c The analyzer will mix the R2 and R1 automatically.

4d The analyzer will test and print the results automatically.

Calibration

The calibration values for the different lots of the kits are stored on the calibration IC card or the two-dimensional code on the cuvette. Before test the new lot of kits, read the calibration card parameters first. Or the instrument automatically scan the two-dimensional code on the cup to obtain the corresponding calibration curve during testing.

Quality control

3- level calibration system guarantee the results' reliability for each lot of test kits, including the instrument calibration, remote reagent calibration and the third party calibration.
The third party calibration applicable for:

1. The daily indoor quality control test.
2. New lots of reagent.
3. New operator training.
4. The results can not match the clinical symptoms.
5. The first use of the reagent.

If still can not be calibrated, contact the manufacture for further technical support.

Reference Value

<0.5ng/mL	Normal Indicate low possibility of systemic bacterial infection and low risk of severe sepsis and septic shock
0.5-2.0 ng/mL	Indicate medium possibility of systemic bacterial infection and medium risk of severe sepsis and septic shock
2-10 ng/mL	Indicate more possibility of systemic bacterial infection and high risk of severe sepsis and s eptic shock
>10 ng/mL	Indicate high possibility of systemic bacterial infection and very high risk of severe sepsis and septic shock

Interpretation

The test results≥0.5ng/mL indicate local inflammation or local infection, it is recommended to look for infections or other

causes of increased PCT. The test results between 0.5-2.0ng/mL indicate moderate systemic inflammatory response, may be infected or other situations such as severe trauma, major operation or cardiogenic shock, it is recommended to look for possible factors for infections, re-test the PCT in 6-24 hours. The test results between 2.0-10.0ng/mL indicate Sepsis or septic shock, it is recommended test PCT everyday, reconsider the Sepsis treatment plan if PCT remains high levels (> 4 days). The test results are above 10ng/mL indicate seriously bacterial sepsis or septic shock, often with organ failure, it is recommended test PCT every day to evaluate treatment effect.

The result only for clinical reference, comprehensive consideration should be combined with the clinical management of patients with symptoms / signs, medical history, other laboratory tests and treatment response.

All laboratory tests depend on random errors. If the test results are in doubt, or if they do not match the clinical symptoms, re-test the sample or confirm the results with other methods.

Limitations

Hemoglobin>5g/L, triglyceride>18mmol/L, bilirubin＞500μmol/L will affect the test result.

Performance Characteristics

1. Linearity range: 0.2ng/mL ～ 60ng/mL.
2. Detection limit: ≤0.12ng/mL.
   The limit of detection means the lowest detectable analyte level that can distinguish the concentration. Calculate based on the minimum standard above the two standard deviation of the data (Blank table, 1+2SD, within-run precision, n=21).
3. Precision
   Test the control material by Procalctionin Test Kit (Rate Scattering Turbidimetric Method) 2 times per day for 20 days (n=80) according to EP5-A2 of CLSI.

The data as below:

a.

HP-083/4-II POCT Immunoassay System					
Sample	Mean ng/mL	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	0.66	0.04	6.1	0.04	6.1
Control 2	2.98	0.15	5.0	0.15	5.0
Control 3	19.38	0.93	4.8	0.95	4.9

b.

HP-AFS/3 Automatic Immunoassay System					
Sample	Mean ng/mL	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	0.68	0.03	4.4	0.02	2.9
Control 2	3.02	0.16	5.3	0.14	4.6
Control 3	20.31	1.02	5.0	1.11	5.5

c.

HP-AFS/1 Automatic Immunoassay System					
Sample	Mean ng/mL	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	0.72	0.03	4.2	0.04	5.6
Control 2	3.04	0.17	5.6	0.15	4.9
Control 3	19.68	1.05	5.3	1.06	5.4

4.Methodology comparison
Compared to BRAHMS PCT LIA(x) by test the same sample, the relative data as below:

HP-AFS/3 Automatic Immunoassay System				
Site No.	Sample Type	No.of Assays	Regression Line	Coefficient correlation
1	Serum	50	Y= 0.93X+0.18	0.95

The concentration of sample is about 0.2 ng/mL -60ng/ mL.

Precautions

⚠ **Attention：**

Only for in vitro diagnostic.
Only for professional use.
All samples and reactive wastes are treated as sources of infection.
Do not use the kits beyond shelf life.
Do not mix different batches of reagents.

⚠ **Warning：**

To avoid error, do not forced to take out the cuvette from the device. Follow the device operation manual strictly, If the problem cannot be solved, contact the manufacturer for further technical support.

SYMBOLS USED ON LABELS

Symbol	Usage	Symbol	Usage
⧗	Use-By date	❄	Do not freeze
LOT	Batch code	☣	Biological risks
🏭	Manufacturer	⊘	Do Not Reuse
↕8℃2℃	Temperature Limit		
∇	Contains sufficient for <n> tests		
⊗	Do not use if package is damaged		
📖	Consult Instructions for use		
☀	Keep Away from Sunlight		
IVD	In Vitro Diagnostic Medical device		
EC REP	Authorized Representative in the European Community		

References

1、Harbarth S.et al.:Diagnasitic value of procalcitonin, interleukin-6 and interleukin 8 in critically ill patients admitted with suspected sepsis.Am.J.Resp.Crit.Care Med.2001,164:396-402.
2、Meisner,M.,Procalcitonin-Biochemistry and Clinical Diagnosis,ISBN 978-3-8374-1241-3,UNIMED. Bremen 2010.
3、Brunkhorst F.M.etal.Procalcitonin for early diagnosis And differentiation of SIRS，sepsis,severe sepsis and septic shock. Intensive Care Med.2000,26(suppl.2):148-152.

Approval Date&Revision Date

Approval Date：Sept 9,2015
Revision Date：May 6,2016
Revision Date：May 1, 2017
Revision Date：Jan 1, 2021
Revision Date：Apr 1, 2021
Revision Date：Jan 1, 2023
Revision Date：Dec 22,2023

CE IVD

尺寸:24*25cm展开尺寸,横向三折页再垂直方向两次对折