ACCU-TELL®
PCT Semi-Quantitative Cassette (Whole Blood/Serum/Plasma)
For in vitro diagnostic Use only

For Whole Blood/Serum/Plasma Samples

This package insert is applied to the below products:

Catalog No.	Product Name
ABT-IDT-B266	PCT Semi-Quantitative Cassette (Whole Blood/Serum/Plasma)

A rapid test for the semi-quantitative detection of Procalcitonin in whole blood, serum or plasma.
For professional in vitro diagnostic use only.

INTENDED USE
ACCU-TELL® PCT Semi-Quantitative Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the semi-quantitative detection of Procalcitonin in whole blood, serum or plasma.

SUMMARY
The Procalcitonin (PCT) is a peptide hormone mainly produced by C cells of the thyroid and certain endocrine cells of the lung [1] [2]. Under normal expression conditions, procalcitonin is immediately cleaved into three specific fragments, an N terminal residue, calcitonin and katacalcin, levels of unprocessed procalcitonin rise significantly after bacterial infection, trauma of shock[3][4].

PRINCIPLE
ACCU-TELL® PCT Semi-Quantitative Cassette (Whole Blood/Serum/Plasma) detects Procalcitonin through visual interpretation of color development on the internal strip. Anti-PCT antibodies are immobilized on the test region of the membrane. During testing, the specimen reacts with anti-PCT antibodies conjugated to colored particles and precoated on the sample pad of the test. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If Test line 1 (T1) appears, it indicates that the PCT level in the specimen is between 0.5-2.0ng/ml. If the test line 1 and 2 (T1 and T2) appear, it indicates that the PCT level in the specimen is between 2.0-10.0ng/ml. If all the test lines (T1, T2, T3), it indicates that the PCT level is above 10.0ng/ml. The appearance of control line serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS
The test cassette contains PCT antibody conjugated colloid gold and PCT antibody coated on the membrane.

PRECAUTIONS
- For professional in vitro diagnostic use only. Don't use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY
The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Don't use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION
- ACCU-TELL® PCT Semi-Quantitative Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- **To collect Fingerstick Whole Blood specimens:**
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick Whole Blood specimen to the test by using a capillary tube:
  - Touch the end of the capillary tube to the blood until filled to approximately 120 µL. Avoid air bubbles.
  - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below 20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

MATERIALS
Materials provided
Test cassettes
Droppers
Buffer
Package insert
Materials required but not provided
Specimen collection containers
Centrifuge (for plasma only)
Timer
Lancets (for fingerstick whole blood only)
Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

TEST PROCEDURE
Allow test cassette, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the cassette on a clean and level surface.
   For Serum or Plasma specimen:
   Hold the dropper vertically and transfer 2 drops of serum or plasma (approximately **80µl)** to the specimen well of the test cassette, and then add 1 drops of buffer (approximately 40µl) and start the timer. Avoid trapping air bubbles in the specimen well.

See the illustration below.

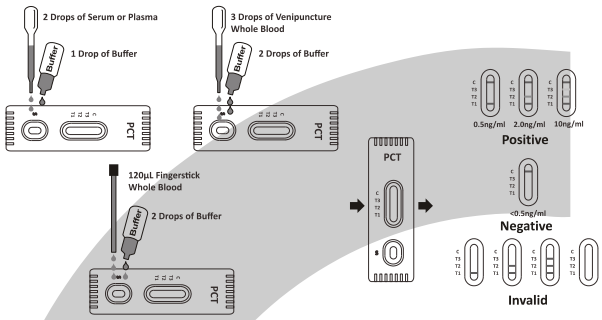
For venipuncture Whole Blood specimen:

Hold the dropper vertically and transfer 3 drops of whole blood (approximately 1**20μl**) to the specimen well of the test cassette, then add 2 drops of buffer (approximately 80μl) and start the timer. See the illustration below.

For Fingerstick Whole Blood specimen:

Fill the capillary tube and transfer **120μl** of Fingerstick whole blood to the specimen well of the test cassette, then add 2 drops of buffer (approximately 80μl) and start the timer. See the illustration below.

3. Wait for the colored line(s) to appear. The test result should be read at **5 minutes**. Do not interpret the result after 8 minutes.



INTERPRETATION OF RESULTS
(Please refer to the illustration above)

Positive(+)： One color line appears in the control region (C). One color line appears in the test region (T) least.

Test line(T)	Semi quantitative result	Recommended interpretation
Only T1 appears	PCT level is between 0.5-2.0ng/ml	High possibility of Systemic inflammatory response
Only T1 and T2 appear	PCT level is between 2.0-10.0ng/ml	Systemic inflammatory response associated with bacterial infection
T1,T2and T3 appear	PCT level is above 10.0ng/ml	Progressing on sever sepsis or septic shock

Negative(-)：One color line appears in the control region (C).

No apparent purple line appears in the test region (T).Negative result showed: There was not PCT in the sample, or the content of PCT below the detectable range.

Test line (T)	Semi quantitative result	Recommended interpretation
No line	PCT level is lower than 0.5ng/ml	Local inflammation or infection is possible with a low risk for progression to systemic inflammation response

INVALID: C line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL
Internal procedural controls are included in the test. A color line appearing in the control region (C) is internal positive procedural control. It confirms sufficient specimen volume.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS
1. ACCU-TELL® PCT Semi-Quantitative Cassette (Whole Blood/Serum/Plasma) is for professional in vitro diagnostic use, and should only be used for the semi‐quantitative detection of Patent Cooperation Treaty.
2. ACCU-TELL® PCT Semi-Quantitative Cassette (Whole Blood/Serum/Plasma) will only indicate the semi-quantitative level of PCT in the specimen and should not be used as the sole criteria for evaluating inflammatory conditions.
3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. PCT values near the cut‐off level Test line 1 (T1: 0.5ng/ml), Test line 2 (T2: 2.0ng/ml), and Test line 3 (T3: 10.0ng/ml) should be reported with caution as with all quantitative assays there exists some level of variation. Therefore, a T line with slightly higher intensity than T3 can also represent a value slightly below 10.0ng/ml. Similar observations may occur with values near 2.0ng/ml and 0.5ng/ml. A repeat test or further quantitative test is recommended.

EXPECTED VALUES
ACCU-TELL® PCT Semi-Quantitative Cassette (Whole Blood/Serum/Plasma) has been compared with PCT FEIA test, demonstrating an overall accuracy of 98%.

PERFORMANCE CHARACTERISTICS
Sensitivity and specificity

ACCU-TELL® PCT Semi-Quantitative Cassette (Whole Blood/Serum/Plasma) has been tested in comparison with a leading commercial PCT FEIA test using clinical specimens.

Method		FEIA				Total
		Negative	Positive			
ACCU-TELL® PCT Semi-Quantitative Cassette (Whole Blood/Serum/ Plasma)	Result	0-0.5 ng/ml	0.5-2.0 ng/ml	2.0-10 ng/ml	⩾10 ng/ml	
	0-0.5ng/ml	99	1	0	0	100
	0.5-2.0ng/ml	1	26	1	0	28
	2.0-10ng/ml	0	0	23	0	23
	⩾10ng/ml	0	0	0	8	8
Total		100	27	24	8	159
% Relative Accuracy		99.0%	96.3%	95.8%	100%	98.1%
			96.6%			

Relative Sensitivity:(26+23+8)/(27+24+8)=96.6% (CI*: 88.3%~99.6%)
Relative Specificity: 99/ (99+1) =99.0 % (CI*: 94.6%~99.9%)
Relative Accuracy: 26+23+8+99)/(27+24+8+100)=98.1%(CI*:94.6% ~99.6%)
*95% Confidence Interval

Precision

Intra-Assay

Assays were carried out to determine assay reproducibility using replicates of 10 tests in three different runs for each of three lots using PCT specimen levels at 0ng/ml, 0.5ng/ml, 2.0ng/ml, 10.0ng/ml and 100ng/ml. The specimens were correctly identified >99.9% of the time.

Inter-Assay

Between-run precision has been determined by using the five PCT specimen levels at 0ng/ml, 0.5ng/ml, 2.0ng/ml, 10.0ng/ml and 100ng/ml of PCT in 3 independent assays. Three different lots of ACCU-TELL® PCT Semi-Quantitative Cassette (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified >99.9%of the time.

Interfering Substances

The following substances do not interfere with the test results at the indicated concentrations: Human Albumin at 20mg/ml, Bilirubin at 6mg/ml, Hemachrome at 10mg/ml, Cholesterol at 5mg/ml and Triglyceride at 15mg/ml.

BIBLIOGRAPHY
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GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer		Do not reuse

AccuBioTech Co., Ltd.
Building 10, No. 28 Yuhua Road, Beijing 101300, China.
EC REP
Medical Device Safety Service GmbH
Schiffgraben 41, 30175 Hannover, Germany