Human Procalcitonin CLIA Kit

Chemiluminescence Immunoassay for the quantitative determination of Procalcitonin in human serum

REF SKT-025 CE IVD 50,100 +2 +8 °C

INTENDED USE

Human Procalcitonin CLIA Kit is a Chemiluminescence Immunoassay (CLIA) intended for the quantitative measurement of human Procalcitonin concentration in serum using the ECL100 or ECL25 Fully Automated Chemiluminescence Analyzer. This test aids in evaluating whether there is a severe bacterial infection. It also aids in monitoring antibiotic therapy for patients diagnosed with severe bacterial infection.

For in-vitro diagnostics purposes only

SUMMARY OF PHYSIOLOGY

Calcitonin original rise in blood level is closely related to bacteria and virus infection. In the toxicity systemic bacterial infection and auxiliary diagnosis, prognostic and curative effect observation has high clinical value.

ASSAY PRINCIPLE

The Human Procalcitonin (PCT) CLIA Kit is designed, developed, and produced for the quantitative measurement of human PCT level in serum samples. The assay utilizes a two-site "sandwich" technique with two antibodies that bind to different epitopes of PCT.
Assay calibrators, controls, or patient serum samples are added directly to a reaction vessel together with magnetic particles antibody. The magnetic particles capture the PCT in the form of "magnetic particles–PCT antibody–PCT–acridinium ester PCT antibody". Materials bound to the solid beads are held in a magnetic field while unbound materials are washed away. Then trigger solutions are added to the reaction vessel, and light emission is measured with the ECL100 or ECL 25 analyzer. The relative light units (RLU) are proportional to the concentration of a PCT in the sample. The amount of analyte in the sample is determined from a stored, multi-point calibration curve and reported in serum PCT concentration.

REAGENTS: PREPARATION AND STORAGE

This test kit must be stored at 2 – 8°C upon receipt. For the expiration date of the kit refer to the label on the kit box. All components are stable until this expiration date. It can be stored for 1 month at 2 – 8°C after kit opening.

1. PCT Magnetic Particle Solution (02501)
Qty: 2.3mL (50/kit), 2.8mL (100/kit)
Storage: 2 – 8°C
Preparation: Ready to Use

2. Acridinium ester PCT antibody (02503)
Qty: 4.75mL (50/kit), 8.5mL (100/kit)
Storage: 2 – 8°C
Preparation: Ready to Use

3. PCT Calibrators (02507-02508)
Qty: 2 x vials
Storage: 2 – 8°C
Preparation: Ready to Use. Mix well. (Suggestion: use rotator to mix for a preferred time of 10 minutes. Make sure there are no air bubbles.)
After the first use, it is recommended to store at 2 - 8°C and can be used within one month. Do not freeze.

4. PCT Controls (02509-02510)
Qty: 2 x vials
Storage: 2 – 8°C
Preparation: Ready to Use. Mix well. (Suggestion: use rotator to mix for a preferred time of 10 minutes. Make sure there are no air bubbles.)
After the first use, it is recommended to store at 2 - 8°C and can be used within one month. Do not freeze.

SAFETY PRECAUTIONS

The reagents must be used in a professional laboratory environment and are for in vitro diagnostic use. Source material which contains reagents of bovine serum albumin was derived in the New Zealand. It was obtained only from healthy donor animals maintained under veterinary supervision and found free of contagious diseases. Wear gloves while performing this assay and handle these reagents as if they were potentially infectious. Avoid contact with reagents containing hydrogen peroxide. Do not get in eyes, on skin, or on clothing. Do not ingest or inhale fumes. On contact, flush with copious amounts of water for at least 15 minutes. Exercise Good Laboratory Practices.

MATERIALS REQUIRED BUT NOT PROVIDED

1. ECL100 Immunoassay Analyzer (ECL100) or ECL25 Immunoassay Analyzer (ECL25)
2. CL011 Cuvettes (for ECL100) or CL010 Cuvettes (for ECL25)
3. EDI™ Wash Reagent (P-594)
4. EDI™ Trigger Solutions A and B (P-595)

The instrument must operate using materials supplied by Epitope Biotechnology, Co., Ltd. or Epitope Diagnostics, Inc. When materials are sourced from third-party suppliers are being used, Epitope Biotechnology, Co., Ltd. and Epitope Diagnostics, Inc. takes no responsibility of the validity for obtained results. Materials are available to purchase from Epitope Biotechnology, Co., Ltd. and Epitope Diagnostics, Inc. Please contact your distributor for more information.

SPECIMEN COLLECTION AND PREPARATION

1. Blood sample should be collected under sterile conditions.
2. For human serum samples only; other body fluids and samples may not yield accurate results.
3. Clinical samples should be tested within 2 hours after collection. If the measurement cannot be completed within 2 hours, please store under the following conditions:
   - storage at low temperature and away from light (2 – 8°C) for 2 days,
   - storage at -20°C or below for 6 months
   - Freeze and thaw three times
4. Avoid heat-inactivated samples. Mixed, contaminated and hemolysis samples should be discarded.
5. Samples should be restored to room temperature before testing. Frozen samples should be completely melted and

mixed well before use. Due to possible volatilization, samples, calibrators and controls on the ECL platform should be tested within 2 hours.

6. Some substances in the samples will interfere with the test results. The common interfering substances and maximum allowable concentrations are as follows:
    - bilirubin: 100 mg/dL
    - triglyceride: 1500 mg/dL
    - hemoglobin: 900 mg/dL
    - biotin: 125 nmol/L
    - For patients receiving high-dose biotin therapy (5 mg/ day), samples must be collected 8 hours after taking the last dose of biotin.
7. A single assay of this item requires 30 µL sample. This quantity does not include the amount of dead volume in the sample container or the capacity required for retesting and other measurement items. For the definition of minimum required sample size, refer to the equipment manual.

CALIBRATION

An active calibration curve is required for all tests. For the assay, calibration must be performed when a reagent lot is used for the first time and remains valid for 28 days. After this period, recalibration is required. Additionally, we recommend performing calibration if control results fall outside the acceptable range.

QUALITY CONTROL

The use of controls is left to the discretion of the user, based on good laboratory practices, requirements, and applicable laws. It is strongly recommended to perform a control test before running patient samples. If no patient samples are tested, a control test is not necessary. Quality control results that fall outside the acceptable range may indicate invalid test results. Please refer to the Certificate of Analysis for the correct control range.

ASSAY PROCEDURE

1. Reagents from different kit lot numbers should not be combined or interchanged. Make sure that there are no air bubbles in any reagents, calibrator and control vials.
2. Reagent Preparation

2.1 Remove reagent cartridges from packaging and replace the solid caps with the provided soft caps for ECL100. For ECL25, carefully remove the aluminum foil seal on each container on the cartridges.

2.2 For the ECL100, hold the cartridge and place a finger against the textured uneven surface located on the bottom portion of the magnetic particle vial. While applying pressure roll the magnetic particle vial back and forth with the finger on the textured surface. Thoroughly mix until the magnetic particle solution is homogenous. The solution should be uniform with no clumps of magnetic particles visible; this step is vital for assay performance.

2.3 For ECL25, mix the magnetic beads by moving back and forth the bottom part of the cartridge at upright position. Make sure to look inside the cartridge until the solution is uniform with no clumps of magnetic particles visible and no air bubbles. Recap the bottle. Open the top soft cap of all reagent bottles, leaving only the hollow soft rubber.

2.4 The reagents are now ready to be loaded into the ECL100 or ECL 25 for calibration.

3. Assay Program

The following table illustrates the protocol used by the ECL100 or ECL25 for instrument operation.

Component	Quality Control Hole (µL)	Sample Hole (µL)
PCT Controls (02508-02509)	30	-
Samples	-	30
PCT Magnetic Particle Solution (02501)	25	25
Acridinium ester PCT antibody (02503)	75	75
Incubate at 37°C for 5 minutes		
Wash the reaction cuvette 3 times with wash reagent.		
Trigger Solution A (P-595)	100-200	100-200
Trigger Solution B (P-595)	100-200	100-200

NOTE FOR ASSAY PROCEDURE

All the reagents in this kit are ready-to-use. Make sure that there are **no air bubbles** in any reagents, calibrator, and control vials. Reagents from different kit lot numbers must not be combined or interchanged.

Please read the reagent instructions and equipment instructions carefully before using this kit and perform the test according to relevant requirements. When reagents are loaded, the equipment will automatically stir the magnetic particles to resuspend them. Allow the reagent to mix for minimum 15 min before starting the assay program.

INTERPRETATION OF RESULTS

1. The default unit for the PCT project is ng/mL.
2. Due to methodological differences or antibody specificity, there may be deviations between the test results of reagents from different manufacturers, so direct comparisons should not be made to avoid false interpretation.
3. When the concentration of PCT in the sample exceeds 130.0 ng/mL, the sample can be diluted before detection.
4. When the sample concentration of PCT was lower than the detection lower limit, the test result can be reported as < 0.04 ng/mL. When the sample concentration was higher than the detection upper limit, it can be reported as > 130.0 ng/mL.

EXPECTED VALUES

1. Concentration < 0.5 ng/mL does not indicate severe sepsis and/or a lower risk of septic shock.
2. Concentration > 2 ng/mL indicates severe sepsis and/or have a higher risk of septic shock.
3. The presence and low levels of procalcitonin may indicate a localized infection (without systemic symptoms) or an early-stage infection (< 6 hours), with concentrations below 0.5 ng/mL suggesting that an infection cannot be excluded. Procalcitonin levels ranging from 0.5 ng/mL to 2.0 ng/mL should be carefully evaluated in conjunction with the patient's medical history to determine the results. Reevaluation within 6 to 24 hours is advisable for any measured procalcitonin concentration below 2 ng/mL in the samples.

Note: each Laboratory is recommended to determine and establish its own reference range with local population.

LIMITATIONS OF THE PROCEDURE

1. This product is for use on the ECL100 Immunoassay Analyzer or ECL 25 Immunoassay Analyzer only. Refer to the appropriate system manuals and/or Help system for a specific description of installation, start-up, operation, system performance, instructions, calibration, precautions, hazards, maintenance, and troubleshooting.
2. Reagents from different kit lot numbers should not be combined or interchanged.
3. Test results obtained from the proposed kit should not be served as a sole basis for clinical diagnosis or patient management.
4. If the test sample result is higher than the upper limit of the calibration curve, it is recommended to re-measure after dilution according to a certain ratio. The measured value is recalculated according to the dilution ratio to ensure the accuracy of the result.

PERFORMANCE CHARACTERISTICS

1.Limit of Detection (LoD): 0.040 ng/mL.
2.Linearity: 0.040 ng/mL to 130.0 ng/mL, linearity correlation coefficient R ≥ 0.990.
3.Accuracy: relative deviation within ± 10%.
4.Precision: Intra-assay repeatability: CV ≤ 8%; Inter-assay reproducibility: CV ≤ 15%.

NOTES

1. Read the instructions carefully and gently mix the reagent well before use. Avoid any air bubble before loading the reagents onto the equipment.
2. Keep the reagent in storage condition as indicated in this IFU and on the reagent label. Do not freeze reagents.
3. Avoid contact with skin, eyes and mucous membrane, and flush the contact area with clean water immediately.
4. All patient samples must be treated as potential infectious material.
5. Components in different kits cannot be mixed.
6. All waste must be disposed complying with local regulations and laws

WARRANTY

This product is warranted to perform as described in its labeling and literature when used in accordance with all instructions. Epitope Biotechnology, Co., Ltd. and its distributors DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, and in no event shall Epitope Biotechnology, Co., Ltd. be liable for consequential damages. Replacement of the product or refund of the purchase price is the exclusive remedy for the purchaser. This warranty gives you specific legal rights and you may have other rights, which vary from state to state.

REFERENCE

1. Gendrel D, Bohuon C. Procalcitonin as a marker of bacterial infection. PediatrInfectDis J 2000:19:679-688.
2. Becker KL, Nylén ES, White JC, M ullerB,Snider RH. Procalcitonin and the CalcitoninGene Family of Peptides in Inflammation,Infection, and Sepsis: A Journey fromCalcitonin Back to Its Precursors. J ClinEndocrinolMetab 2004;89(4):1512-1525.

TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

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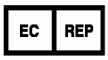

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GLOSSARY OF SYMBOLS (EN 980/ISO 15223)

In Vitro Diagnostic Device

European Conformity

Lot Number

Catalog Number

Read Instructions before Use

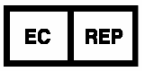
Number of Tests

Store at

Use by

Keep Away from Heat and Direct Sun light

Manufacturer



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