The presence of Procalcitonin (PCT) is recognized as a helpful tool for the diagnostic and sepsis. The PCT biomarker is now being optimized of antibiotic therapy and monitor treatment duration. PCT is the prohormone of calcitonin. Whereas calcitonin is only produced in the C cells of the thyroid gland as an inherent ability of binding to the specific structure of a molecule. In the mLabs immunometer, data can be removed for all subsequent related measurements.

TEST PROCEDURE

1. Analytical Sensitivity
   - PCT = 0.02 ng/ml

2. Measurable Range
   - PCT = 0.02 to 100 ng/ml

3. Ct
   - mLabs® PCT cartridge is only to be used together with mLabs® immunoassay technology in a microfluidic cartridge. The immunoassay technology relies on the inherent ability to binding to the specific structure of a molecule. In the mLabs® PCT microfluidic cartridge, one antibody pair is carefully chosen so as to have excellent specificity and sensitivity for PCT. The protein complex with a fluorescent reporter attached is pre-coated in the reaction zone of the cartridge, while the capture antibody is immobilized in the detection zone. As the sample flows through, the analyte PCT in the sample first encounters the capture antibody. As the sample continues its flow through the detection zone, the capture antibody binds to the PCT reporter complex by forming a sandwich structure and remains in the detection zone, while the reporter antibody without being washed away. The fluorescent signal in the detection zone is proportional to the PCT concentration in the sample.

MATERIALS PROVIDED

- 25 test cartridges
- 50 pipette tips
- mLabs® Data Drive (USB-disk or SIM card)

Instructions for use

SAMPLE COLLECTION & STORAGE

Always wear protective gloves and suitable lab coats when handling patient samples as they may potentially be infectious. All samples should be regarded as potentially hazardous and/or contaminated. Collect venous samples using Li-Heparin collection tube. Ensure that the collection tube is completely filled to maintain the correct performance CHARACTERISTICS

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INTERFERENCE TESTING

The following factors have been found to not significantly effect the assay results:

- Hemolysis (Hemoglobin 347 umol/l)
- Bilirubin (574 umol/l)
- Lipemia (Triglycerides as lipids to 30g/l equivalent)
- Hemolysis (Hemoglobin 347 umol/l)

It is noted that severely hemolyzed specimens should be avoided. Hematocrit in between 30% and 55% has no significant effect on the results. For outside mode, allow at least 9 (no more than 15) minutes for the sample to interact with the reagents in the cartridge before reading.
No hook effect was determined for PCT concentrations of 2600 ng/mL.

EXPECTED VALUES

In a study carried out using apparently healthy individuals' samples, the 95th percentile values were below 0.05 ng/mL. It is recommended that each laboratory should establish its own reference range.

LIMITATIONS

Carefully inspect the mLabs® PCT test pouch's integrity before use. If the pouch is found to be tampered with, i.e. torn or punctured, do NOT proceed to use the test cartridge. Contact your local technical support immediately.

The mLabs® PCT test kit is strictly for In Vitro Usage only. Instructions and procedures provided in this insert should be carefully adhered to.

The mLabs® PCT test kit is not intended to be used as absolute evidence for bacterial infection and sepsis. Obtained test results should be consulted with physician in addition with other test results.

All the provided items in the test kit are for single usage application and should be properly discarded after usage as inserted test samples may potentially be infectious.

REFERENCES


