



## Calibration

The Spectrum PCT Assay should be calibrated using Spectrum PCT Calibrator

PCT concentration in sample is determined from a calibration curve obtained from the PCT Calibrators. The PCT Calibrators are lyophilized powder and require reconstitution with DI water before use.

calibration frequency

Biweekly calibration is recommended

## Quality Control

Good laboratory practice recommends the use of control materials. Users should follow the appropriate federal, state and local guideline concerning the running of external quality control. To ensure adequate quality control, normal and abnormal controls with known values should be run as unknown samples. PCT Control are lyophilized powder and require reconstitution with cold DI water before use.

## Linearity

The linearity of the assay is from 0.17-60 ng/mL. Results that exceed 60 ng/mL. should be diluted with saline and retested.

## Interfering Substances

The substances normally present in the plasma were tested. Less than 10% deviation was produced when tested up to the concentrations shown below

|                       |            |
|-----------------------|------------|
| Ascorbic Acid         | 10 mM      |
| Bilirubin, free       | 40 mg/dL   |
| Bilirubin, conjugated | 40 mg/dL   |
| Hemoglobin            | 400 mg/dL  |
| Triglyceride          | 1000 mg/dL |
| Rheumatoid Factor     | 200 IU/mL  |

## Analytical characteristics

### Precision

Within-run precision of the Diazyme PCT Assay was evaluated. In the study, three levels of PCT controls containing 0.5 ng/mL, 2.14 ng/mL and 13.13 ng/mL PCT respectively were tested with 20 replicates in one run.

|                       | Level 1 | Level 2 | Level 3 |
|-----------------------|---------|---------|---------|
| Number of Data Points | 20      | 20      | 20      |
| Mean (ng/mL)          | 0.50    | 2.14    | 13.13   |
| SD (ng/mL)            | 0.036   | 0.069   | 0.353   |
| CV (%)                | 7.2%    | 3.2%    | 2.7%    |

## Accuracy

The performance of this assay was compared with the performance of a legally marketed PCT Assay using lithium heparin plasma samples. For the 41 plasma samples with PCT ranging from 0.18 ng/mL to 58.44 ng/mL, the correlation coefficient between the two methods was 0.9141, slope was 0.9815, and y intercept was 0.3137

## Limit of Quantitation

The Limit of Quantitation (LOQ) of the PCT Assay was determined to be 0.17 ng/mL.

## Expected Values

1. Spectrum Procalcitonin < 0.5 ng/mL: systemic infection (sepsis) is not likely,

Local bacterial infection is possible; PCT > 0.5 ng/mL and < 2 ng/mL: systemic infection (sepsis) is possible but other conditions are known to increase PCT as well;

PCT > 2 ng/mL and < 10 ng/mL: systemic infection (sepsis) is likely, unless other cause are known;

PCT > 10 ng/mL, important systemic inflammatory response, almost exclusively due to severe bacterial or septic shock.

## Limitation

Samples with PCT level exceeding the linearity limit of 60 ng/mL should be

diluted with negative sample. Rerun the tests and multiply the results by the dilution factors. As with any latex turbidimetric immunoassays, Diazyme PCT Assay runs should be followed with appropriate and thorough wash steps. Please consult specific instrument manuals for further information.

## References

- Müller B, *et al.*, Ubiquitous expression of the calcitonin-*i* gene in multipletissues in response to sepsis. *J Clin Endocrinol Metab* 2001; 86(1):396-404.
- Christ-Crain M, *et al.*, Procalcitonin in bacterial infections hype, hope or more or less? *Swiss Med Wkly* 2005; 135:45160.
- Schuetz P, *et al.*, Long-term stability of procalcitonin in frozen samples and comparison of Kryptor and VIDAS automated immunoassays. *Clin Biochem*.2010;43(3):3414
- Stolz D, Christ-Crain M, Bingisser R, Leuppi J, Miedinger D, Muller C, Huber P, Muller B, Tamm M. Antibiotic treatment of exacerbations of COPD: a randomized, controlled trial comparing procalcitonin-guidance with standard therapy. *Chest*. 2007;131:9-19.

## ORDERING INFORMATION

| CATALOG NO. | QUANTITY |
|-------------|----------|
| 567 001     | 50 test  |



### Egyptian Company for Biotechnology (S.A.E)

Obour city industrial area. block 20008 piece 19 A. Cairo. Egypt.

Tel: +202 4665 1848 - Fax: +202 4665 1847

www.spectrum-diagnostics.com

E-mail: info@spectrum-diagnostics.com



MDSS GmbH  
Schiffgraben 41  
30175 Hannover, Germany



IFUFTI 42

Rev.(1), 30/3/2014