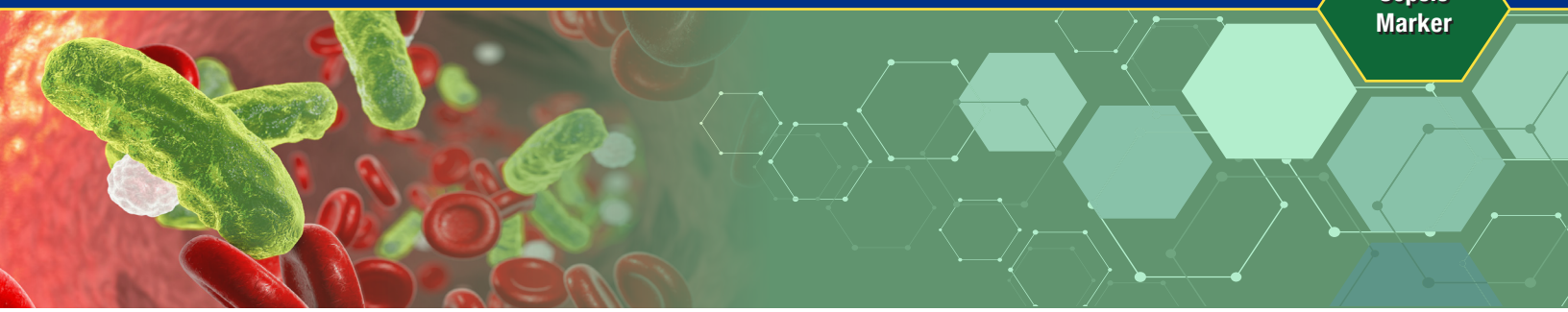
PROCALCITONIN (PCT) ASSAY



Diazyme Laboratories, Inc. introduces the first homogeneous FDA 510k cleared PCT assay for use on validated clinical chemistry analyzers thereby eliminating the need for high priced dedicated instrumentation. Diazyme's PCT assay is a cost effective latex enhanced immunoturbidimetric methodology which utilizes multiple monoclonal antibodies for enhanced assay sensitivity and specificity. In a recent multicenter study, the performance of the Diazyme PCT method was found to be aligned with the VIDAS® B•R•A•H•M•S PCT™ Assay.[1]

DIAZYME PCT ASSAY ADVANTAGES

- Fast test results (10 minutes) for a rapid turnaround time
- Low sample volume required
- Wide range of instrument parameters available for simplifying implementation
- Liquid stable reagent kit, calibrator and control sets offered separately
- Liquid stable format requires no reagent preparation saving time and reducing sample handling

REGULATORY STATUS

510(k) Cleared; EU: CE IVD;

Health Canada Registered

DIAZYME

Innovations in Clinical Diagnostics

PROCALCITONIN (PCT) ASSAY

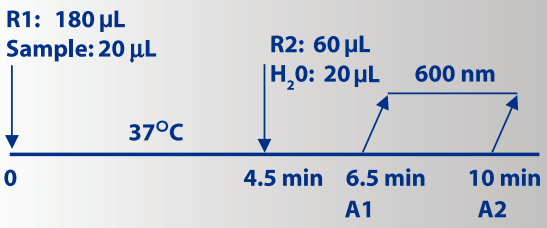
Dual Vial
Liquid Stable

ASSAY SPECIFICATIONS

Method	Latex Enhanced Immunoturbidimetric
Sample Type & Volume	• Serum • Plasma - EDTA - Li-heparin Sample Volume 20 µL
Method Comparison	Regular Regression: N = 219 y-intercept = -0.225 Slope = 1.041 R^2 = 0.9837 Sample Range = 0.21 - 51.26 ng/mL
Linearity	Up to 52 ng/mL
LOB **LOD** **LOQ**	0.06 ng/mL 0.16 ng/mL 0.20 ng/mL*
Calibration Levels	6-Point Calibration
Reagent On-Board Stability	Opened: Four weeks on board analyzer

**Results below 0.20 ng/mL are reported as < 0.20 ng/mL*

PCT Assay Procedure**



****Analyzer Dependent**

For a list of validated parameters please contact Diazyme technical support at 858-455-4768 or email support@diazyme.com

1. Dipalo, Mariella, Lorena Guido, Gianmatteo Micca, Salvatore Pittalis, Massimo Locatelli, Andrea Motta, Vincenza Bianchi, Tiziana Callegari, Rosalia Aloe, Giorgio Da Rin, and Giuseppe Lippi. "Multicenter Comparison of Automated Procalcitonin Immunoassays." Practical Laboratory Medicine 2 (2015): 22-28. Web.

ASSAY PRECISION

The precision of the Diazyme PCT Assay was evaluated according to CLSI EP5-A2 guideline. In the study, six serum samples and 2 levels of serum based controls were tested in duplicate per run, 2 runs per day for 20 days using three lots of the reagents. The results of the within-run, between-run, between-day, between-lot, and total CV% for three lots of the reagent combined are listed in the following table (N=240):

INTERNAL PRECISION

Sample	Mean ng/mL	Within-Run SD/CV%	Between-Run SD/CV%	Between-Day SD/CV%	Between-lot SD/CV%	Total SD/CV%
S1	0.27	0.034 / 12.3%	0.027 / 10.0%	0.019 / 6.9%	0.047 / 17.3%	0.047 / 17.3%
S2	0.48	0.035 / 7.3%	0.033 / 6.8%	0.031 / 6.4%	0.057 / 11.8%	0.057 / 11.9%
S3	1.80	0.062 / 3.4%	0.032 / 1.8%	0.059 / 3.2%	0.09 / 5.0%	0.091 / 5.0%
S4	5.30	0.085 / 1.6%	0.140 / 2.6%	0.130 / 2.5%	0.21 / 3.9%	0.209 / 4.0%
S5	23.56	0.058 / 2.5%	0.482 / 2.0%	0.891 / 3.8%	1.20 / 5.1%	1.168 / 5.0%
S6	47.65	0.069 / 1.5%	0.712 / 1.5%	0.657 / 1.4%	1.18 / 2.5%	1.196 / 2.5%
Con 1	1.16	0.046 / 4.0%	0.038 / 3.3%	0.031 / 2.7%	0.07 / 5.8%	0.068 / 5.8%
Con 2	18.30	0.477 / 2.6%	0.126 / 0.7%	0.751 / 4.1%	0.88 / 4.8%	0.899 / 4.9%

ASSAY INTERFERENCE

The following substances normally present in the samples produced less than 10 deviation when tested at levels equal to the concentrations listed below.

Interference Substances	Concentration
Ascorbic acid	129 mg/dL
Free Bilirubin	30 mg/dL
Bilirubin Conjugated	30 mg/dL
Hemoglobin	750 mg/dL
Triglyceride	750 mg/dL
Rheumatoid Factor	75 IU/mL

Interference Substances	Concentration
Albumin	4 g/dL
Human Calcitonin	60 ng/mL
Human Katacalcin	10 ng/mL
Human alpha-CGRP	10 µg/mL
Human beta-CGRP	10 µg/mL
Human Anti-mouse IgG (HAMA)	350 ng/mL

The following therapeutic drugs showed no significant interference (< ± 10%) up to the concentrations summarized below.

Tested Drugs	Concentration
Imipenem	0.5 mg/mL
Cefotaxime	180 mg/dL
Noradrenalin	4 µg/mL
Dobutamine	22.4 µg/mL

Tested Drugs	Concentration
unfractionated Heparin	16,000 U/L
Furosemide	4 mg/dL
Vancomycin	3 mg/mL
Dopamine	26 mg/dL

PRODUCT INFORMATION

Diazyme PCT Assay is a latex particle enhanced immunoturbidimetric method intended for the quantitative determination of PCT in human serum, EDTA or lithium heparin plasma. Measurement of PCT in conjunction with other laboratory findings and clinical assessments aids in the risk assessment of critically ill patients on their first day of ICU admission for progression to severe sepsis and septic shock.

Please refer to product package insert (IFU) for product use details.

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