

PROCALCITONIN (PCT) ASSAY

Dual Vial Liquid Stable

Diazyme Laboratories, Inc. introduces the first homogeneous FDA 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

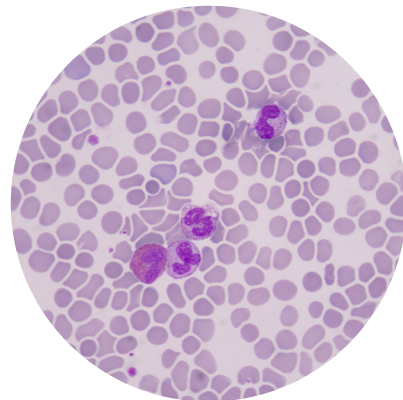
- Fast test results (10 minutes) for a rapid turnaround time
- Low sample volume required
- Wide range of instrument parameters available for facilitating and simplifying implementation
- Liquid stable reagent kit, calibrator and control sets offered separately
- Liquid stable format requires no reagent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

REGULATORY STATUS

510(k) Cleared



Health Canada Registered



PROCALCITONIN (PCT) ASSAY

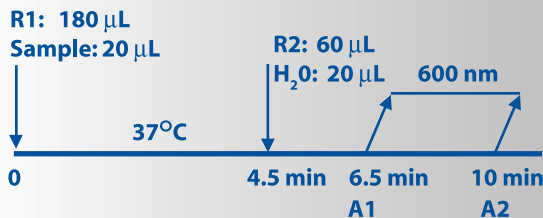
Dual Vial Liquid Stable



ASSAY SPECIFICATIONS

Method	Latex Enhanced Immunoturbidimetric
Sample Type & Volume	<ul style="list-style-type: none"> • Serum • Plasma - EDTA - Li-heparin <p>Sample Volume 20 µL</p>
Method Comparison	<p>Regular Regression: N = 219 y-intercept = -0.225 Slope = 1.041 R² = 0.9837</p> <p>Sample Range = 0.21 - 51.26 ng/mL</p>
Linear Range	Up to 52 ng/mL
LOB LOD LOQ	<p>0.06 ng/mL</p> <p>0.16 ng/mL</p> <p>0.20 ng/mL</p>
Calibration Levels	6-Point Calibration
Reagent On-Board Stability	<p>Opened:</p> <p>Four weeks on board analyzer</p>

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

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

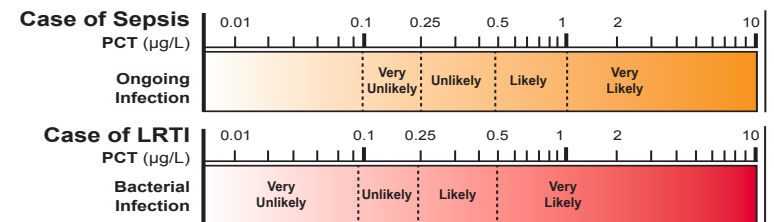
The following substances normally present in the samples produced less than 10 deviation when tested at levels equal to the concentrations listed below.

Interference Substances	Concentration	Interference Substances	Concentration
Ascorbic acid	129 mg/dL	Albumin	4 g/dL
Free Bilirubin	30 mg/dL	Human Calcitonin	60 ng/mL
Bilirubin Conjugated	30 mg/dL	Human Katakalcin	10 ng/mL
Hemoglobin	750 mg/dL	Human alpha-CGRP	10 µg/mL
Triglyceride	750 mg/dL	Human beta-CGRP	10 µg/mL
Rheumatoid Factor	75 IU/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	Tested Drugs	Concentration
Imipenem	0.5 mg/mL	unfractionated Heparin	16,000 U/L
Cefotaxime	180 mg/dL	Furosemide	4 mg/dL
Noradrenalin	4 µg/mL	Vancomycin	3 mg/mL
Dobutamine	22.4 µg/mL	Dopamine	26 mg/dL

PCT LEVELS AND BACTERIAL INFECTION²



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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.
2. Li H, et al., Meta-analysis and systematic review of procalcitonin-guided therapy in respiratory tract infections. *Antimicrob Agents Chemother.*, 2011; 55:5900-6. *LRTI - (Lower Respiratory Tract Infection)