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
**ASSAY SPECIFICATIONS**

<table>
<thead>
<tr>
<th>Method</th>
<th>Latex Enhanced Immunoturbidimetric</th>
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| 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  
   R² = 0.9837  
   Sample Range = 0.21 - 51.26 ng/mL |
| Linearity | Up to 52 ng/mL |
| LOB | 0.06 ng/mL |
| LOD | 0.16 ng/mL |
| LOQ | 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**

R1: 180 μL  
Sample: 20 μL  
R2: 60 μL  
H₂O: 20 μL  
600 nm  
37°C  
0  
4.5 min  
6.5 min  
10 min  
A1  
A2

**Analyzer Dependent

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