Endotoxin Detection by *Limulus* Amebocyte Recombinant Factor C

**Indications for Ordering**

To monitor level of bacterial endotoxins (also called lipopolysaccharide or LPS) in hemodialysis reuse water

**Test Description**

- Quantitative enzymatic detection of endotoxins using recombinant factor C from *Limulus polyphemus* amebocytes
- Kinetic-based fluorescence detection

**Tests to Consider**

**Endotoxin Detection by Limulus Amebocyte Recombinant Factor C 2008110**

- Quantitative test used to detect gram-negative endotoxins in hemodialysis reuse water
- Analogous to *Limulus* Amebocyte Lysate (LAL) 0097328

**Disease Overview**

- Reuse of hemodialysis machines is common practice in U.S.
  - Associated with increased incidence of pyrogenic reactions in patients using hemodialysis machines
- Testing of endotoxins in hemodialysis reuse water is a means of monitoring water quality in hemodialysis machines

**Test Interpretation**

**Sensitivity/specificity**

- Analytical sensitivity – 0.05 EU/mL
- Analytical specificity
  - Specific for gram-negative bacterial LPS
  - Does not cross react with
    - Gram-positive bacteria
    - Yeast
    - Fungi

**Results**

- Calibrated to United States Pharmacopeia (USP)
- Bacterial Endotoxins Test (BET) standard curve
- Reported in endotoxin units/mL (EU/mL)
  - <0.05 – no endotoxins detected
  - 0.25 – USP acceptable limit for injectable or irrigation water
  - 0.50 – USP acceptable limit for inhalator water
  - 2.00 – USP acceptable upper limit for hemodialysis reuse water

**Limitations**

Not validated to detect bacterial endotoxins in biological specimens