



## 5<sup>th</sup> GENERATION HIV TESTING

Mid-September 2017

Effective mid-September 2017, PCL Alverno will upgrade its platform for HIV testing to the Bio-Rad 5<sup>th</sup> Generation HIV detection and differentiation assay performed on the BioPlex 2200.

- The new assay simultaneously detects and differentiates HIV-1 p24 antigen, HIV-1 antibodies (groups M & O), and HIV-2 antibodies qualitatively.
- The assay will have highly sensitive HIV-1 p24 antigen detection, Limit of Detection = 0.33 IU/mL and 5.2 pf/mL, for improved identification of HIV-1 acute infections.
- The assay also has improved earlier seroconversion detection compared to the 4<sup>th</sup> generation assay.
- The new assay is the only U.S. HIV diagnostic assay with FDA approval for organ donor screening.

The upgrade will include additional interpretations, which are highlighted in the chart below.

Previous Reporting	New Reporting
Nonreactive	HIV-1 AB Nonreactive
	HIV-1 AG Nonreactive
	HIV-2 AB Nonreactive
Reactive	HIV-1 AB Reactive*
	HIV-1 AG Reactive*
	HIV-2 AB Reactive*

\*All Reactive tests will continue to reflex for confirmation testing.

### SPECIMEN REQUIREMENTS

**Specimen:** Serum (SST or red) preferred; EDTA, lithium heparin, and sodium citrate specimens are acceptable. **\*\*Primary tube required\*\***

**Stability:** Room temperature 4 days; refrigerated 7 days; freeze at -20°C for longer storage

### CAUSE FOR REJECTION

Aliquot samples  
Gross hemolysis  
Unspun >24 hours

### METHOD

Multiplex flow immunoassay

### REFERENCE RANGE

Nonreactive

### CPT CODE

**87389\***

### SOFT CODE\*\*

**HIVBP**

\*CPT codes provided are for informational purposes only. Questions regarding coding should be directed to the payer.

\*\*Code may differ in your EMR.