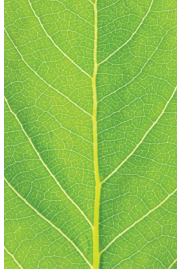
PCL ALVERNO


TEST BULLETIN

September 2017

Dear Healthcare Provider,

The information contained here may be very important to your practice. Please take a moment to review this document.

T-SPOT TB TESTING

Please see page 2 related to the new T-SPOT testing that will be available in September. T-SPOT is an indirect test for Mycobacterium tuberculosis infection and is intended for use in conjunction with risk assessment, radiography and other medical and diagnostic evaluation tools. T-SPOT can be used to screen at risk groups or as an aid in diagnosis of active TB disease. IGRAs cannot differentiate latent tuberculosis infection from active tuberculosis disease.

ANTI-XA ASSAY

Page 3 shows information on Anti-Xa Assay. The ACL TOP Family uses an automated chromogenic assay to quantitatively determine unfractionated heparin and low molecular weight heparin activity in citrated plasma. This assay can be utilized to provide clinicians with a heparin drug level to assist with monitoring patient dosages. It is suggested that Anti-Xa testing for Low Molecular Weight Heparin be performed 4 hours after the dose of heparin is given, and after the 3rd and 4th doses to be sure the heparin is at a steady state concentration.

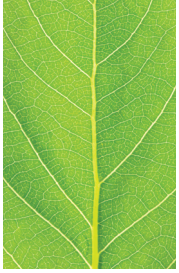
5th GENERATION HIV TESTING

Please review the information on page 5 if you order HIV testing in your office. Effective mid-September 2017, PCL Alverno will upgrade its platform for HIV testing to the Bio-Rad 5th 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 4th generation assay.
- The new assay is the only U.S. HIV diagnostic assay with FDA approval for organ donor screening.

Find Us on Facebook, LinkedIn and Google Plus!

2434 Interstate Plaza Drive, Hammond, IN 46324
toll free 800.937.5521 · **phone** 219.989.3700 · **fax** 219.989.3900
www.PCLAlverno.com


T-SPOT TB TESTING
An Interferon-Gamma Release Assay (IGRA)
September 2017

T-SPOT is an indirect test for Mycobacterium tuberculosis infection and is intended for use in conjunction with risk assessment, radiography and other medical and diagnostic evaluation tools. T-SPOT can be used to screen at risk groups or as an aid in diagnosis of active TB disease. IGRAs cannot differentiate latent tuberculosis infection from active tuberculosis disease.

The assay detects T cells that respond to stimulation by M. tuberculosis antigens ESAT-6 and CFP 10 by capturing interferon gamma in the vicinity of T cells in whole blood. These antigens are absent from BCG strains utilized in MTB vaccines and from most non-tuberculous mycobacteria.

Note: A false positive T-SPOT result may occur in individuals with a M. xenopi, M. kansasi, M. szulgai, M. gordonae or M. marium infection.

SPECIMEN REQUIREMENTS

Specimen: Whole blood, unspun
Minimum: **6 mLs** Lithium Heparin, Green Top Tube without separator.
Must be full draw Specimen collection Sunday – Thursday only

Stability: Room temperature; 32 hours

CAUSE FOR REJECTION

EDTA Plasma Tube
>32 hours from collection
Insufficient Sample (6mL min)
Samples collected Friday or Saturday due to Specimen Stability

METHOD

Enzyme-linked Immunospot

REFERENCE RANGE

Negative

PRODUCTION

Monday – Friday

CPT CODE*

86481

SOFT CODE**

TSPOT

***CPT codes provided are for informational purposes only. Questions regarding coding should be directed to the payer.**
****Codes in your EMR may differ.**



Anti-Xa Assay
Measuring Unfractionated and Low Molecular Weight Heparin
September 26, 2017

CLINICAL USE
The ACL TOP Family uses an automated chromogenic assay to quantitatively determine unfractionated heparin and low molecular weight heparin activity in citrated plasma. This assay can be utilized to provide clinicians with a heparin drug level to assist with monitoring patient dosages. It is suggested that Anti-Xa testing for Low Molecular Weight Heparin be performed 4 hours after the dose of heparin is given, and after the 3rd and 4th doses to be sure the heparin is at a steady state concentration.

CLINICAL BACKGROUND
Heparin is one of the most frequently used antithrombotic drugs. The biological activity of the heparin compound resides in its ability to accelerate the inhibitory effect of antithrombin on coagulation proteases. On the ACL TOP, heparin is measured as a complex with antithrombin present in the sample. The concentration of the heparin complex is dependent on the availability of the patient's endogenous antithrombin.

Unfractionated heparin has routinely been monitored using aPTT; however the aPTT is not sensitive enough to measure the effects of low molecular weight heparin and can be impacted by many patient-dependent physiological variables. These variables can lead to under-anticoagulation or over-anticoagulation due to the inability to establish an accurate baseline for the aPTT. Studies show that patients with heparin levels managed by Anti-Xa had fewer incidents of recurrent venous thromboembolism and fewer bleeding complications than patients monitored by aPTT. Below is a table outlining some of the benefits using the Anti-Xa Assay for heparin monitoring:

ADVANTAGES	DISADVANTAGES
Can be used to measure low molecular weight as well as unfractionated heparin levels	Effected by hemolysis, icterus, and lipemia
Fewer monitoring tests	Must by processed within one hour of collection (plasma separated from cells)
Assists with achieving the therapeutic range sooner and maintaining the range longer	
Not susceptible to interference by acute phase reactants, Factor VIII or fibrinogen	
Not influenced by factor deficiencies found in liver disease or DIC	

THERAPEUTIC RANGES:
Unfractionated heparin: 0.3 – 0.7 IU/mL1
Low Molecular Weight heparin: 0.6 – 1.0 IU/mL1

2434 Interstate Plaza Drive, Hammond, IN 46324
toll free 800.937.5521 · **phone** 219.989.3700 · **fax** 219.989.3900
www.PCLAlverno.com



SPECIMEN REQUIREMENTS:

SPECIMEN:
3.2% Sodium Citrate Plasma

STABILITY:
Specimens must be spun within 1 hour of collection and are stable at room temperature for 4 hours. When testing cannot be completed in 4 hours, specimens should be double spun to ensure platelet poor plasma and frozen. Frozen samples kept at -70°C are stable for 6 months.

CAUSE FOR REJECTION:
Whole blood samples beyond 1 hour stability
Plasma samples beyond 4-hour collection time that are not aliquoted double spun, and frozen
Tubes not filled properly
Plasma samples not meeting the minimum volume of 500uL
Samples with hemolysis and icterus

TURNAROUND TIME
Testing will be performed 7 days a week

SOFT CODES*
HXA – Low Molecular Weight Heparin
HXAUF – Unfractionated Heparin

CPT CODE**
85520

1. Therapeutic ranges were adopted from the ***Antithrombotic Therapy and Prevention of Thrombosis, 9th Ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines.*** Chest 2012; 141(2)(Suppl):e24S-e43S

***Code in your EMR system may differ.**
****CPT codes provided are for informational purposes only. Questions regarding coding should be directed to the payer.**



5th GENERATION HIV TESTING

Mid-September 2017

Effective mid-September 2017, PCL Alverno will upgrade its platform for HIV testing to the Bio-Rad 5th 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 4th 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.**