

Memorandum

To: NMC and Community Providers

From: David Blin – Director, Laboratory Services Thomas Suppan, MD – Medical Director, Laboratory Services

Date: October 7, 2024

Re: New Coagulation Analyzers – Updated Reference Ranges

On October 16th the NMC Laboratory will transition coagulation testing to the ACL TOP 350 analyzers.

The new analyzers offer increased automation, improved reagent stability, better reagent management, the ability to load multiple assays simultaneously, closed-tube sampling, and pre-analysis detection of potential interfering factors (clotted tubes, hemolysis, ictericness, and lipemia).

Providers should be aware of important changes:

- Reference ranges for PT, aPTT, Fibrinogen, and DDimer assays have been updated
- <u>D-dImer will be reported in Fibrinogen Equivalent Units (FEU)</u> instead of D-Dimer Units (DDU). As a rough approximation, one FEU is roughly two DDU.

Assay	Current Reference Range	New Reference Range	Comment	
Prothrombin Time	9.5 to 11.2 seconds	<u>10.2 to 12.9</u> seconds		
INR	2.0 to 3.0	2.0 to 3.0	INR value valid only on patients on stabilized warfarin therapy. The recommended therapeutic range for warfarin (Coumadin) for most clinical indications is an INR of 2.0-3.0. An INR of 2.5- 3.5 is recommended for patients with mechanical heart valves.	
aPTT	21.6 to 36.0 seconds	<u>25.1 to 36.5</u> seconds	No longer including a comment related to the suggested therapeutic range for patient on Heparin	
Fibrinogen	195 to 394 mg/dL Critical Value < 100 mg/dL Critical Value > 600 mg/dL	200 to 395 mg/dL Critical Value < 100 mg/dL *Critical value no longer defined for elevated results	*No critical value defined for elevated results	
Anti Xa	0.3 to 0.7 IU/mL	0.3 to 0.7 IU/mL	DVT/PE: 0.3 - 0.7 IU/mL Acute Coronary Syndrom (ACS): 0.3 - 0.5 IU/mL	
D-Dimer	Less than 250 ng/mL DDU Critical value ≥ 600 ng/mL DDU		** Ddimer is now reported in Fibrinogen Equivalent Units (FEU)	
			***Critical value no longer defined for elevated D-Dimer	
		Less than 500 ng/mL FEU** Critical value no longer defined for elevated results ***	The ACL TOP 350 CTS D-Dimer test is a Latex Enhanced Immunoassay which is FDA approved for use in conjunction with a Clinical Pretest Probability (PTP) Assessment model to exclude venous thromboembolism (VTE) in outpatients suspected of deep vein thrombosis (DVT) and pulmonary embolism (PE).	
			The cutoff value for this exclusion is 500 ng/mL FEU	

• Refer to the chart below for additional information

- No Change for PT/INR, aPTT, Fibrinogen, and Anti-Xa
- Update for D-Dimer Testing

Live Date:	October 16, 2024				
Meditech Test Name	D-Dimer, PLSM	Previous Meditech Name: DDimer COAG			
Lab Order Code:	DDT				
CPT:	85379				
LOINC:	48065-7				
Sample: Blue Top Citrate Tube filled to the appropriate level					

	L-Code (Lab Code)	Test Name	СРТ	LOINC Code	Units of Measure
NEW ASSAY	DDT	D-DIMER, PLSM	85379	48065-7	ng/mL FEU
CURREN ASSAY	DIMERCOAG	D-DIMER COAG	85379	48058-2	ng/mL DDU

Please contact the Laboratory (802-524-1070) with any questions or concerns.