Regional Medical Laboratory
4142 South Mingo Road
Tulsa, OK. 74146-3632

MEMORANDUM

To: All RML Clients

From: Sonya Bruening, BS, MLT(AMT), Manager of Coagulation
Adam Hoffhines, MD, PhD, Chief of Coagulation

Date: May 31, 2017

Subject: Updated FDA Clearance for D-Dimer Exclusion of DVT

Regional Medical Laboratory (RML) is pleased to announce our D-dimer reagent vendor, Stago Diagnostica Inc., has received FDA 510(k) clearance for exclusion of deep vein thrombosis (DVT), without additional testing, when used in conjunction with a clinical pre-test probability assessment. This approval is suggested to result in fewer unnecessary referrals for additional testing and improved patient care. Stago previously received FDA clearance for exclusion of pulmonary embolism (PE) following the same model in 2014. Due to this enhanced clearance, the cutoff to aid in the diagnosis of DVT is <0.50 ug/mL FEU. The cutoff for exclusion of PE has been updated and is also <0.50 ug/mL FEU (previous cutoff was <0.47 ug/mL FEU). When the quantified D-Dimer value is <0.50 ug/mL FEU and patients have a low or moderate pre-test probability of having venous thromboembolism (PE or DVT), the negative predictive value of this test is 100% (95% CI of 99.3%-100.0%) for DVT and is 99.7% (95% CI of 99.2%-100.0%) for PE.

Please contact Sonya Bruening, Manager of Coagulation, or Adam Hoffhines, MD, PhD, at 918-744-2553 with any questions regarding this update.