

Laboratory News

VOL. 41, NO. 3 - JUNE 12, 2018

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AGE-ADJUSTED D-DIMER CUTOFFS TO ASSIST IN RULING OUT PULMONARY EMBOLISM AND DEEP VENOUS THROMBOSIS

Gene Shaw, MD, PhD, Clinical Pathology; Steve Mattila, Technical Manager, Hematology Laboratory

Effective June 18, 2018, Marshfield Labs will change the reporting units for D-dimer testing to "**ng/mL**" with the recommendation that age-adjusted cutoffs be used for patients over age 50. The new units will have a cutoff of \leq 500 ng/mL fibrinogen equivalent units (FEU) compared with our current cutoff of \leq 0.50 ug/mL. This allows a simple calculation of "*AGE x 10*" for patients over 50 years old. For example, a 65 year-old patient would now have a cutoff of \leq 650 ng/mL (i.e., values of 650 ng/mL or less considered negative).

An elevation of D-dimer indicates activation of coagulation with formation and degradation of cross-linked fibrin. It is a very sensitive, albeit very nonspecific, marker of pulmonary embolism (PE) or deep venous thrombosis (DVT). The main value of D-dimer testing in the setting of possible PE or DVT is its negative rule-out capability. A negative D-dimer result, when the pretest probability of PE or DVT is low to intermediate, essentially excludes PE and DVT. Other disorders should be considered and these patients can avoid the costs and risks of imaging studies that may include contrast.

In healthy adults, D-dimer levels increase in a linear fashion after age 50. By optimizing the cutoffs with age, the very high sensitivity of the test can be maintained while providing greater specificity. This allows a greater percentage of older adults to be ruled-out. In two relatively recent studies, the number of

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patients over 70-75 years-old who could safely forego imaging increased from 6% to 21-30%. Of course, clinical judgement is needed and the conventional recommendation is that patients with a high clinical probability of PE or DVT will need to proceed directly to imaging regardless of D-dimer results.

The method of D-dimer testing by Marshfield Labs will not change. We use an Innovance D-dimer assay supplied by Siemens which has been validated for age adjusted cutoff in clinical studies. Within the year, we anticipate having our flagging of results as "High" to be adjusted for age. The following interpretive comment will accompany all D-dimer results:

To assist in ruling out PE or DVT, an age adjusted cutoff is recommended: 500 ng/mL FEU for age \leq 50 year and AGE x 10 (ng/mL FEU) for >50 years.

CONTACTS

For clinical and technical information, contact:

- Gene Shaw, MD, PhD or Kajal Sitwala, MD, PhD, Hematopathologists.
- Steve Mattila, Technical Manager, Hematology Laboratory.
- Phone number: 800-222-5835.

REFERENCES

- Righini M, Van Es J, Exter D, et al. *Age-Adjusted D-Dimer Cutoff Levels to Rule Out Pulmonary Embolism The ADJUST-PE Study.* JAMA. 2014;311:1117.
- Raja AS, Greenberg JO, Qaseem A. Evaluation of Patients With Suspected Acute Pulmonary Embolism: Best Practice Advice From the Clinical Guidelines Committee of the American College of Physicians. Ann Intern Med. 2015;163:701. Implication Physicians.

HER2 FISH NOW A SENDOUT TEST

Alyssa Barnes, Assistant Manager, Cytogenetics Laboratory

Effective April 9, 2018, Marshfield Labs ceased to perform HER2 FISH testing in-house, test code: FHER2. All HER2 FISH testing is now being sent to Mayo Laboratories, test codes: HER2F (breast cancer), H2GEF (gastroesophageal tumor), H2MTF (misc. tumor), H2URF (urothelial tumor). This test will confirm the presence of HER2 amplification and is used for guiding cancer therapies that target the human epidermal growth factor receptor 2 (HER2) protein (e.g., trastuzumab [Herceptin], pertuzumab, lapatinib).

TEST QUESTIONS

For test information, see <u>Mayo Test Catalog</u>.

CONTACTS

For clinical information, contact:

- Gene Shaw, MD, PhD, Hematopathologist.
- Phone number: 800-222-5835. 🧌