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To: VCU Health Physicians, House staff, and Nurses

From: Andrea Ferreira-Gonzalez, Ph.D.
Chair, Division of Molecular Diagnostics
Director, Molecular Diagnostics Laboratory

Date: 12/11/2023

RE: **New VCU Main Lab test for the detection (qualitative) and quantification of adenovirus DNA in plasma**

Effective Tuesday, January 16th, 2024, the Molecular Diagnostics Laboratory will offer a new test for detecting (qualitative) and quantifying adenovirus (Adv) DNA in the patient's plasma.

New test order name: **Adenovirus DNA, Quant (Blood) [LAB1232921].**

Intended use: The *Adenovirus DNA Quant (Blood)* is a sensitive and accurate test for detecting (qualitative) and quantifying Adv DNA in plasma.

Indications for use: Early detection of AdV DNA in plasma has been shown helpful in identifying patients at risk of invasive AdV disease. Quantifying AdV DNA in plasma has been beneficial for monitoring patients' risk for invasive AdV disease, disease progression, and monitoring response to treatment. No international standard is currently available for the calibration of this assay. Caution should be taken when interpreting results generated by different assay methodologies.

The new test will **replace** the "Adenovirus PCR, Qualitative, Blood" [LAB1232906] send-out test.

Additional send-out testing options are available for AdV in body fluids other than plasma (i.e., CSF, urine):

1) Adenovirus DNA, Quant (Body Fluid)
2) Adenovirus DNA, Qual (Body Fluid)

The new test order was added to the "Preferred Lists" and "Order Sets and Panels" lists in EPIC.

Analytical Interpretation:

Limit of detection and quantification: 2.3 $\log_{10}$ copies/mL (200 copies/mL). Results below that value will be reported as *Undetectable*.

Assay reportable range: from 2.3 to 8.0 $\log_{10}$ copies/mL (200 – 100,000,000 copies/mL). Results above 8.0 $\log_{10}$ copies/mL will be reported as positive, above that value.

Specimen Requirements:

Blood: one 5 mL lavender (EDTA); deliver to the lab (ambient; unspun) immediately for separation into plasma.

Plasma: 1,2 mL. Spin blood within 4 hours of collection and aliquot in Sarstedt 7 ml (catalog no. 60.550.049). Refrigerate the plasma for up to 24 hours or freeze at -20C.

Remote locations: separate plasma within 4 hours of collection, refrigerate and send to main lab with cold packs within 24 hours of collection. Plasma should be freeze upon received in main lab.

Pediatric Minimums: plasma: 400 µL.

Clinical Interpretation: Adenovirus is a significant cause of infectious complications in stem cell and solid organ transplant patients, and its detection should be correlated with clinical symptoms. Serial quantitative real-time PCR may assist in initiating therapy and monitoring response to treatment in a symptomatic patient, as there is no established threshold value at which to start therapy.

Limitations: Potential mutations within the target regions of the HAdV genome covered by this assay may result in under-quantification and/or failure to detect the virus in the patient specimen.

Turn-around time: 6 days.

We in the Molecular Diagnostics Laboratory are pleased to be able to offer this added service to our clinicians, patients, and outreach clients. Questions and comments are welcome at 804-828-9564.