FDA approves ARUP Labs AAV5 DetectCDx

August 2023—ARUP Laboratories announced that the FDA approved AAV5 DetectCDx as a companion diagnostic to aid in the selection of adult patients eligible for treatment with Roctavian (valoctocogene roxaparvovec-rvox). Roctavian, a gene therapy developed by BioMarin Pharmaceutical, received contemporaneous FDA approval for the treatment of adults with severe hemophilia A (congenital factor VIII deficiency with FVIII activity <1 IU/dL) without antibodies to adeno-associated virus serotype 5 (AAV5) detected by an FDA-approved test.

AAV5 DetectCDx is a single-site assay performed at ARUP Laboratories.

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