AAV5 DetectCDx™

Visit **aruplab.com/AAV5** or contact your local account executive to learn more about AAV5 DetectCDx and ARUP Laboratories.

ARUP LABORATORIES

aruplab.com/AAV5

500 Chipeta Way
Salt Lake City, UT 84108-1221
Phone: 800-522-2787

Reference: DetectCDx

PD-0008-LABEL-004, Rev. 00

Hemophilia A

AAV5 DetectCDx™

For In Vitro Diagnostic Use | Rx Only

ARUP LABORATORIES

AAV5 DetectCDx™ Explained

AAV5 DetectCDx is a prescription-only companion diagnostic (CDx) test that helps identify if patients with hemophilia A are eligible for the gene therapy treatment ROCTAVIAN (valoctocogene roxaparvovec-rvox).

ARUP is the only lab that offers the FDA-approved CDx assay for the gene therapy treatment ROCTAVIAN. We are a CAP-, ISO 15189-, and CLIA-certified reference lab with more than 35 years of experience supporting laboratories, physicians, and patients with unparalleled quality and service.

AAV5 DetectCDx is sponsored by BioMarin and offered at no cost to evaluate eligibility for an FDA-approved use. No patient, private health plan, government health program, or any other individual or entity shall be billed for this serotype test.[6]

This information is intended for laboratory use.

1. The AAV5 Total Antibody Assay for ROCTAVIAN (valoctocogene roxaparvovec-rvox) Eligibility in Hemophilia A ("AAV5 TAb Assay") or AAV5 DetectCDx is a qualitative in vitro diagnostic test by electrochemiluminescence intended for detection of antibodies in human plasma collected in 3.2% sodium citrate that bind to the adeno-associated virus serotype 5 (AAV5). The AAV5 TAb Assay is indicated as an aid in the selection of adult hemophilia A patients for whom ROCTAVIAN treatment is being considered. Patients that are anti-AAV5 antibody positive (result of Detected) are not eligible for treatment with ROCTAVIAN; patients that are anti-AAV5 antibody negative (result of Not Detected) are eligible for treatment with ROCTAVIAN. This assay is for professional use and is a single-site assay performed at ARUP Laboratories. **2.** For more detailed information about ROCTAVIAN and its safety and efficacy, please go to biomarin-rareconnections.com.

How to Order

If you are a hospital, health system, or reference laboratory that is partnered with ARUP, testing will be available through ARUP Connect™ or can be ordered with a manual client requisition. Test orders and results may also be built to electronically interface with your medical record and laboratory information systems.

Otherwise, contact ARUP's Client Services at 1-800-522-2787 and reference DetectCDx to request the specimen shipping kit (**ARUP Supply Number 55016**).

Test Information

AAV5 Total Antibody (TAb) Assay or AAV5 DetectCDx for ROCTAVIAN (Valoctocogene Roxaparvovec-Rvox) Eligibility in Hemophilia A (3000959)

Shipping

Ship the sealed kit via FedEx overnight or with an ARUP contracted courier. Visit **aruplab.com/AAV5** for more detailed collection and shipping instructions and to learn more about AAV5 DetectCDx.

3. When drawing blood for the AAV5 DetectCDx™ Assay, universal precautions for bloodborne pathogens should be observed
4. The stability of the patient sample during whole blood collection has been established for 72 h at room temperature or refrigerated (2 to 8 oC) in the AAV5 TAb Assay or AAV5 DetectCDx. Stability of the patient sample during processing has been established for 72 h at room temperature and 72 h refrigerated 2 to 8 oC) in the AAV5 DetectCDx. Patient samples with rheumatoid factor levels greater than 476 IU/mL will interfere with the ability of the AAV5 DetectCDx to accurately detect anti-AAV5 antibodies. Patient samples with triglyceride levels greater than 500 mg/dl w the ability of the AAV5 DetectCDx to accurately detect anti-AAV5 antibodies. Patient samples with hemoglobin levels greater than 800 mg/dL may interfere with the ability of AAV5 DetectCDx to accurately detect anti-AAV5 antibodies. Collected patient samples must not exceed 7.3% sodium citrate. Patients with a Not Detected result may receive ROCTAVIAN infusion. **5.** This test can only be conducted on plasma from adult male patients collected in 3.2% sodium citrate anticoagulant. Other specimen types and conditions have not been validated. **6.** Enrollment and eligibility requirements may apply and BioMarin reserves the right to terminate or amend this program without notice at any time.