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AAV5 Detect CDxTM -AAV5 Total Antibody Assay for ROCTAVIAN (valoctocogene roxaparvovec-rvox) Eligibility in Hemophilia A

3000959, AAV5 TAB

Specimen Requirements:	
Patient Preparation:	
Collect:	3.2% sodium citrate
Specimen Preparation:	Separate from cells ASAP or within 72 hours of collection. Transfer 1 mL plasma to an ARUP standard transport tube. (Min: 0.5 mL)
Transport Temperature:	Critical frozen
Unacceptable Conditions:	Hemolyzed specimens and lipemic specimens
Remarks:	Ship frozen specimens to ARUP as soon as possible. Collection Instructions: Collect the patient's whole blood in a 3.2% sodium citrate tube. Samples that exceed 7.3% sodium citrate cannot be evaluated and may require patient redraw. NOTE: When drawing blood for the AAV5 DetectCDx test, universal precautions for bloodborne pathogens should be observed. Centrifuge the specimen and separate the plasma within 72 hours of collection. Refer to your manufacturer's manual for recommended centrifuge speed and duration. Transfer 1 mL (minimum: 0.5 mL) of plasma into a polypropylene pour-off (transport) tube. Sample stability for the AAV5 DetectCDx has not been evaluated in tube types other than the ARUP transport tube (polypropylene). Failure to provide sufficient volume may result in the need for patient redraw. Label the transport tube with the patients first and last name, date of birth, and sex. Freeze plasma specimen at -10C or below. Ship frozen plasma specimens to ARUP as soon as possible. NOTE: Plasma specimens must be frozen before they are shipped to ARUP Laboratories.
Stability:	Frozen (-10 or colder): Acceptable, Refrigerated: Unacceptable, Ambient: Unacceptable
Methodology:	Qualitative Electrochemiluminescent Immunoassay (ECLIA)
Performed:	Mon-Fri
Reported:	8-10 days

Note:	Test validated for male patients only. 1. AAV5 DetectCDx is offered at no cost to evaluate eligibility for an FDA-approved indication. While the assay is provided at no cost, any other expenses, charges, services, costs, materials, or lab work that are not provided by ARUP are not covered under this program. No patient, private health plan, government health program, or any other individual or entity shall be billed for this serotype test and no reimbursement will be sought for any tests or materials provided at no cost in connection with such test. Access to the test at no cost is not contingent upon the recommendation, ordering, prescription, or purchase of any other product or service. 2. The test should be ordered using the ARUP test requisition form or via ARUP's web-based ordering interface (available only to existing ARUP clients). The full name of the ordering physician must be included on the ARUP form to ensure timely testing of the specimen. Specimens submitted with incomplete information may delay specimen testing. 3. To send a specimen to ARUP, contact your local hospital/reference lab to determine if they are an ARUP client and can send the specimen. If they cannot send the specimens to ARUP, contact ARUP Client Services at 800-522-2787 to be directed to an alternative ordering mechanism.
CPT Codes:	
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

The AAV5 Total Antibody Assay is indicated as an aid in the selection of adult hemophilia A patients for whom valoctocogene roxaparvovec treatment is being considered. Patients who have a result of Detected are not eligible for treatment with valoctocogene roxaparvovec; patients who have a result of Not Detected are eligible for treatment with valoctocogene roxaparvovec.

Reference Interval:

HOTLINE NOTE: Refer to the Hotline Test Mix for interface build information.