

## NEW TEST – Available Now

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### AAV8 Total Antibody Assay

3003895, AAV8 Scrn

#### Specimen Requirements:

##### Patient Preparation:

Collect: Serum separator tube

Specimen Preparation: Transfer 1 mL serum to an ARUP standard transport tube. (Min: 0.5 mL)

Transport Temperature: Critical frozen

Unacceptable Conditions: Hemolyzed specimens. Anything other than published.

##### Remarks:

Collect the patient's whole blood in a serum separator tube. NOTE: When drawing blood for the AAV8 Total Antibody Assay, universal precautions for bloodborne pathogens should be observed. Centrifuge the specimen and separate the serum 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 serum into a polypropylene pour-off (transport) tube. Sample stability for the AAV8 Total Antibody Assay 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 patient's first and last name, date of birth, and sex. Freeze serum specimen at -10 C or below. Ship frozen serum specimens to ARUP as soon as possible and use overnight delivery to ensure next day arrival at ARUP. NOTE: Serum specimens must be frozen before they are shipped to ARUP Laboratories. NOTE: HCPs in New York who would like to order this test should contact ARUP Client Services for more information.

Stability: Frozen (-10 C or colder): Acceptable; Ambient: Unacceptable; Refrigerated: Unacceptable

Methodology: Qualitative Electrochemiluminescent Immunoassay (ECLIA)

##### Note:

Sponsored testing program eligibility criteria: Patients must be 8 years of age or older and have a confirmed diagnosis of glycogen storage disease type Ia (GSD Ia).

1. AAV8 Total Antibody Assay is offered at no cost to support an FDA-approved therapeutic. While the assay is provided at no cost, shipping supplies and any other expenses, charges, services, costs, materials, or lab tests 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 test, and no reimbursement will be sought for any tests or materials provided at no cost in connection with such test. No-cost access to the test is not contingent upon the recommendation, order, prescription, or purchase of any other product or service.

2. The test should be ordered using the ARUP AAV8 Total Antibody Assay test requisition form or via ARUP's web-based ordering interface (available only to existing ARUP clients). The full name of the ordering physician, NPI number, and physician attestation must be included on the ARUP test requisition form to ensure timely testing of the specimen. Incomplete information may delay testing.

3. To send a specimen to ARUP, contact your local hospital/reference lab to determine if they have an existing process for shipping specimens to ARUP laboratories. If not, contact ARUP Client Services at 800-522-2787 to be directed to an alternative ordering mechanism.

4. This testing is being offered by ARUP as part of a collaboration between ARUP and a collaborator. The ordering provider acknowledges that ARUP may report information related to the number of tests ordered and the ordering facility to ARUP's collaborator. The terms applicable to ARUP's performance of this test are established through this program and ARUP's performance is not subject to the services agreement, if any, between ARUP and the ordering facility.

#### CPT Codes:

New York DOH Approval Status: Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.

#### Interpretive Data:

This test has only been validated on human serum samples. Other specimen types or conditions have not been validated.

#### Reference Interval:

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