

Patient UNK, 101320	Requesting Physician Not Provided	Accession Number 24050082
Date of Birth Age: NOT GIVEN	Report to F. HOFFMANN-LA ROCHE AG	Family Number/Kindred Number
Sex M	Address KREDITORENBUCHHALTUNG	Patient Number RG15N67FO
Specimen Type SERUM	Address GRENZACHERSTRASSE 124	Specimen Collection Date 07/03/2024
Test Category Diagnostic (Symptomatic)	Address 4070 BASEL	Date Received 07/08/2024
Test Requested Adeno-associated virus AAVrh74 Antibody	Additional Reports to:	Report Date 07/11/2024

Adeno-associated virus AAVrh74 Antibody

This analysis did not detect an elevated level of antibodies to adeno associated virus serotype Rh74 (AAV-Rh74).

INTERPRETIVE RESULTS TABLE

	Test	Technical Result	Reference Range
Not Elevated	Anti-AAV-Rh74	<1:400	<1:400

Recommendations: Health care providers, please contact the Athena Diagnostics Client Services Department at 1-800-394-4493 if you wish to speak with a clinical consultant regarding this test result.

Background information: Adeno-associated viruses (AAVs) are commonly used in gene therapy due to the ease of genome manipulation, ease of purification and safety (1). However, many AAV serotypes commonly infect humans resulting in pre-existing immunity which may reduce the efficiency of gene therapy that utilizes these serotypes. The AAV-Rh74 ELISA detects antibodies against AAV-Rh74 which may inhibit the efficacy of gene therapies.

Methods:

Detection of antibodies was performed by Enzyme Linked Immunosorbent Assay (ELISA) methodology.

Limitations of analysis: Although rare, false positive or false negative results may occur. All results should be interpreted in the context of clinical findings, relevant history, and other laboratory data.

Background References

- Naso, MF, et al. (2017) BioDrugs. 31(4):317-334. (PMID: 28669112)

This test was developed and its analytical performance characteristics have been determined by Athena Diagnostics. It has not been cleared or approved by the U.S. Food and Drug Administration. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes.

Laboratory oversight provided by Vivekananda Datta, M.D., Ph.D., CLIA license holder, Athena Diagnostics (CLIA# 22D0069726)