

Patient UNK, 102280	Requesting Physician DR ARIFKHAN	Accession Number 25007818
Date of Birth Age: NOT GIVEN	Sex M	Report to F. HOFFMANN-LA ROCHE AG
Specimen Type SERUM	Address KREDITORENBUCHHALTUNG	Family Number/Kindred Number
Test Category Diagnostic (Symptomatic)	GRENZACHERSTRASSE 124	Patient Number 10199970
Test Requested Adeno-associated virus AAVrh74 Antibody	4070 BASEL	Specimen Collection Date 01/28/2025
	Additional Reports to:	Date Received 01/31/2025
		Report Date 02/03/2025

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: Creatine Kinase (CK-MM) at concentrations above 45,000 U/L may interfere with test results. 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)