

Anti-AAV Antibody ELISA Kits



Researchers have used AAV-based vectors in pre-clinical research and in clinical trials, where AAV-based vectors have demonstrated a good safety profile. AAVs have also demonstrated sustained therapeutic gene expression after a single treatment in preclinical and clinical studies.

AAV is used in a growing number of FDA applications and clinical trials worldwide. Due to the viral origin of AAV, the capsids can induce cellular and humoral immune responses that trigger neutralization of the vector with anti-AAV antibodies, preventing transduction in patients. Over 90 percent of humans have preexisting binding antibodies to some AAV serotypes. Some of these antibodies are neutralizing and may cause loss of efficacy even on the first dose. Therefore, there is a critical need to better understand the risks of AAV immunogenicity and to develop technologies for evaluating and mitigating this response.

Methods to detect pre-existing AAV immunity include in vitro cell-based TI assays, in vivo (e.g., mouse) TI assays, and enzyme-linked immunosorbent assay (ELISA)-based detection of total anti-capsid antibody (TAb) assays. The TAb assay may be able to detect low potency NAb below the threshold of TI assays, but may not detect non-antibody neutralizing factors.

Creative Diagnostics has developed a portfolio of anti-AAV antibody ELISA kits for the most commonly used AAV serotypes. The standardized assay developed to screen for AAV seropositivity has proven to be an essential tool in screening patients for pre-existing antibodies to minimize safety concerns and improve therapeutic efficacy with AAV-based gene therapies.

Key Features

- Efficient & sensitive monitoring of immune responses against AAV capsids
- High reproducibility of measured values
- Qualitative or semi-quantitative
- Lot-to-lot consistency
- Faster & simpler than cell-based assays

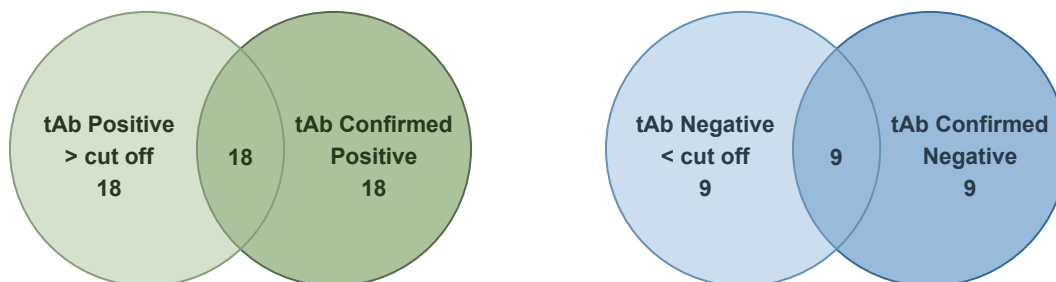
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Verification instance

- Precision**

Non-scaled Venn diagram depicting the relationship between total (tAb) and specifically confirmed total antibodies in samples. Results are highly consistent, indicating that the ELISA is highly accurate in detecting AAV antibodies.

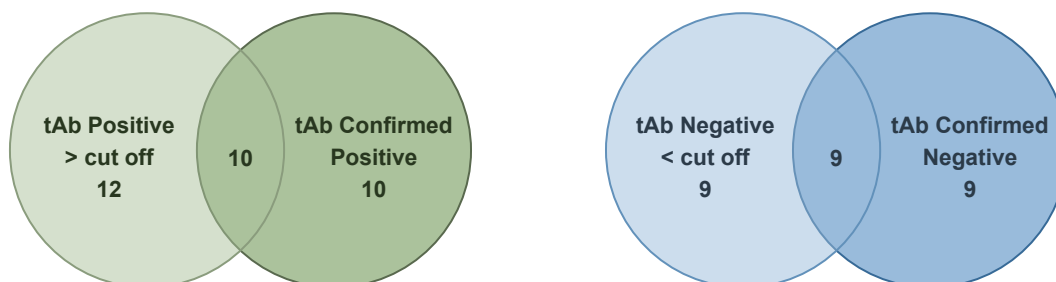
Anti-AAV2 antibody ELISA Kit (DEIASL347):



Anti-AAV6 antibody ELISA Kit (DEIASL344):

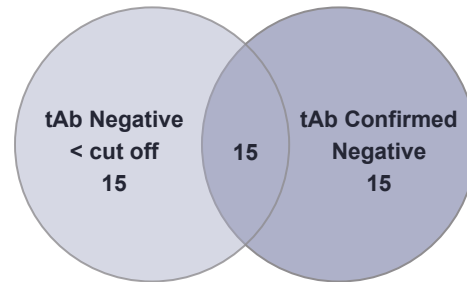
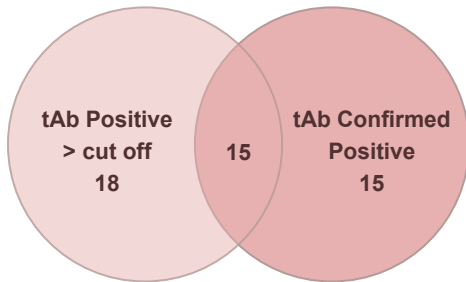


Anti-AAV8 antibody ELISA Kit (DEIASL345):

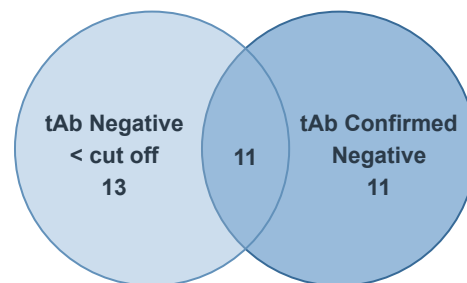
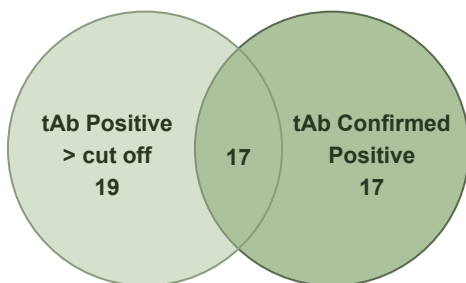


Anti-AAV Antibody ELISA Kits

Anti-AAV9 antibody ELISA Kit (DEIASL348):



Anti-AAV5 antibody ELISA Kit (DEIASL343):



- Lot-to-lot consistency**

Anti-AAV2 antibody ELISA Kit (DEIASL347):

Intra-Assay		
Sample	Mean	CV(%)
1	0.325	5%
2	0.762	3%
3	1.524	3%

Inter-Assay		
Sample	Mean	CV(%)
1	0.368	5%
2	0.815	5%
3	1.422	6%

Anti-AAV6 antibody ELISA Kit (DEIASL344):

Intra-Assay		
Sample	Mean	CV(%)
1	0.225	3%
2	0.503	4%
3	1.028	6%

Inter-Assay		
Sample	Mean	CV(%)
1	0.207	4%
2	0.533	6%
3	0.993	8%

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Anti-AAV8 antibody ELISA Kit (DEIASL345):

Intra-Assay		
Sample	Mean	CV(%)
1	0.238	6%
2	0.488	3%
3	0.962	5%

Inter-Assay		
Sample	Mean	CV(%)
1	0.268	7%
2	0.505	6%
3	0.925	4%

Anti-AAV9 antibody ELISA Kit (DEIASL348):

Intra-Assay		
Sample	Mean	CV(%)
1	0.504	4%
2	1.058	2%
3	0.540	2%

Inter-Assay		
Sample	Mean	CV(%)
1	0.520	5%
2	1.059	5%
3	0.990	6%

Anti-AAV5 antibody ELISA Kit (DEIASL343):

Intra-Assay		
Sample	Mean	CV(%)
1	0.165	5%
2	0.358	4%
3	1.859	5%

Inter-Assay		
Sample	Mean	CV(%)
1	0.148	7%
2	0.409	6%
3	1.396	9%

● Function verification

Anti-AAV2 antibody ELISA Kit (DEIASL347): The levels of the Anti-AAV2 antibodies (IgG) were analysed with this ELISA in a panel of 76 healthy blood donors. With a cut-off of 1 U, 76% of the blood donors were Anti-AAV2 positive (IgG) which reflects the known percentage of infections in the general population.

	No.of samples	Percentage
Positive	58	76.3%
Equivocal	3	3.9%
Negative	15	19.7%

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Anti-AAV6 antibody ELISA Kit (DEIASL344): The levels of the Anti-AAV6 antibodies (IgG) were analysed with this ELISA in a panel of 72 healthy blood donors. With a cut-off of 1 U, 52% of the blood donors were Anti-AAV6 positive (IgG) which reflects the known percentage of infections in the general population.

	No.of samples	Percentage
Positive	38	52.8%
Equivocal	9	12.5%
Negative	25	34.7%

Anti-AAV8 antibody ELISA Kit (DEIASL345): The levels of the Anti-AAV8 antibodies (IgG) were analysed with this ELISA in a panel of 83 healthy blood donors. With a cut-off of 1 U, 30% of the blood donors were Anti-AAV8 positive (IgG) which reflects the known percentage of infections in the general population.

	No.of samples	Percentage
Positive	25	30.1%
Equivocal	3	3.6%
Negative	55	66.3%

Anti-AAV9 antibody ELISA Kit (DEIASL348): The levels of the Anti-AAV9 antibodies (IgG) were analysed with this ELISA in a panel of 118 healthy blood donors. With a cut-off of 1 U, 35.6% of the blood donors were Anti-AAV9 positive (IgG) which reflects the known percentage of infections in the general population.

	No.of samples	Percentage
Positive	42	35.6%
Equivocal	5	4.2%
Negative	71	60.2%

Anti-AAV5 antibody ELISA Kit (DEIASL343): The levels of the Anti-AAV5 antibodies (IgG) were analysed with this ELISA in a panel of 101 healthy blood donors. With a cut-off of 1 U, 37% of the blood donors were Anti-AAV5 positive (IgG) which reflects the known percentage of infections in the general population.

	No.of samples	Percentage
Positive	37	36.6%
Equivocal	8	7.9%
Negative	56	55.4%

Anti-AAV Antibody ELISA Kits

Products

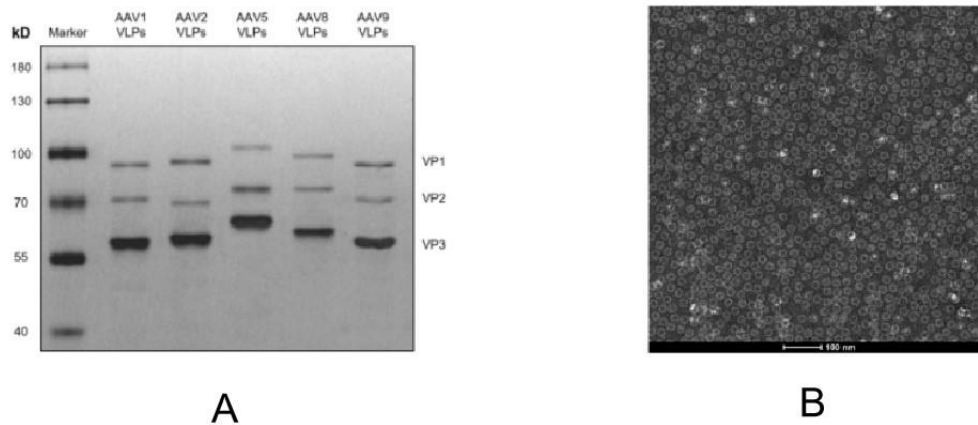
Anti-AAV Antibody ELISA Kit

Cat.	Product Name	Application	Sample
DEIASL347	Human Anti-AAV2 Antibody ELISA Kit	Qualitative	Serum
DEIASL343	Human Anti-AAV5 Antibody ELISA Kit	Qualitative	Serum
DEIASL344	Human Anti-AAV6 Antibody ELISA Kit	Qualitative	Serum
DEIASL345	Human Anti-AAV8 Antibody ELISA Kit	Qualitative	Serum
DEIASL348	Human Anti-AAV9 Antibody ELISA Kit	Qualitative	Serum
DEIASL345M	Mouse Anti-AAV8 Antibody ELISA Kit	Qualitative	Serum
DEIASL345MQ	Mouse Anti-AAV8 Antibody ELISA Kit (Quantitative)	Quantitative	Serum
DEIASL348M	Mouse Anti-AAV9 Antibody ELISA Kit	Qualitative	Serum
DEIASL347Y	Monkey Anti-AAV2 Antibody ELISA Kit	Qualitative	Serum
DEIASL343Y	Monkey Anti-AAV5 Antibody ELISA Kit	Qualitative	Serum
DEIASL344Y	Monkey Anti-AAV6 Antibody ELISA Kit	Qualitative	Serum
DEIASL345Y	Monkey Anti-AAV8 Antibody ELISA Kit	Qualitative	Serum
DEIASL348Y	Monkey Anti-AAV9 Antibody ELISA Kit	Qualitative	Serum

Related Products

Creative Diagnostics provides several AAV ELISA controls and VLPs of serotypes 1, 2, 5, 8, and 9. The AAV ELISA controls can be used as positive controls with the corresponding AAV ELISAs. They consist of fully assembled, empty AAV particles and have been characterized by qPCR & ddPCR (DNA quantification) as well as electron microscopy including negative stain EM and cryo EM (ratio of full to empty capsids). Our AAV virus-like particles are extensively characterized and therefore, serve as reliable standards for evaluating the quality of AAV virus-like particles generated in-house.

Anti-AAV Antibody ELISA Kits



- A. Silver stained SDS-PAGE of AAV virus-like particles of serotypes 1, 2, 5, 8, and 9.
- B. Transmission electron microscopy of AAV9 VLPs showing empty (black-filled spheres) and filled (white-filled spheres) capsids.

AAV Antigen List

Cat. No.	Product Name	Application
DAGC255	AAV1 capsids (ELISA Control)	ELISA
DAGC256	AAV2 capsids (ELISA Control)	ELISA
DAGC256L	AAV2 Empty Capsids	ELISA
DAGC582	AAV2 Null Capsids	ELISA
DAGC257	AAV5 capsids (ELISA Control)	ELISA
DAGC258	AAV6 capsids (ELISA Control)	ELISA
DAGC259	AAV8 capsids (ELISA Control)	ELISA
DAGC521	AAV9 capsids (ELISA Control)	ELISA
DAGC521L	AAV9 Empty Capsids	ELISA
DAG-WT823	Recombinant AAV1 VLP	ELISA
DAG-WT824	Recombinant AAV2 VLP	ELISA
DAG-WT825	Recombinant AAV5 VLP	ELISA
DAG-WT826	Recombinant AAV8 VLP	ELISA
DAG-WT827	Recombinant AAV9 VLP	ELISA

CREATIVE DIAGNOSTICS

Anti-AAV Antibody ELISA Kits



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