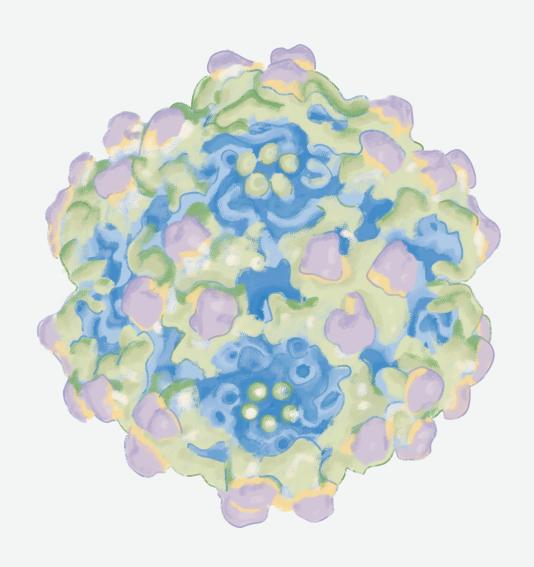


# AAV Titration ELISA Kits



Distributed by:
CliniSciences Group

### Accurate, Reliable, and Specific Quantification of AAV Capsids

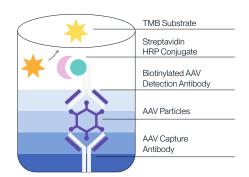
# Detect full and empty AAV capsids specific to AAV2, AAV5, AAV6, AAV8, or AAV9 serotypes via ELISA.

With the rapid development of the gene therapy market using AAV as a vector, regulatory agencies are increasingly demanding stringent quality control (QC) testing for AAV drugs. Empty AAV capsids lacking the transgene of interest cause unwanted immune response without providing the therapeutic benefit of the transgene. Alongside DNA and infectious titers, determination of the capsid titer is crucial for validating the efficacy and safety of your AAV gene therapy.

Reliable and stable methods for quantifying AAV particle titer are essential to ensure the safety and effectiveness of AAV drugs. Among various methods for quantifying AAV particle titer, ELISA is widely used due to its high reproducibility and specificity, and is one of the titer determination methods recommended by regulatory agencies.

#### Sandwich ELISA Protocol with Optimized Antibodies

Our AAV Titration ELISA kits use a standard sandwich ELISA method utilizing exclusive AAV antibodies developed using our proprietary immunization scheme.



## **Product Advantages**

# Optimized Recombinant Monoclonal Antibodies.

Our AAV Titration ELISA kits using recombinant monoclonal antibodies developed using our proprietary immunization scheme that overcomes the weak AAV immunogenicity. This method maintains a remarkable level of consistency as the serum titers within the same group of mice consistently align. Across all AAV serotypes, our technique consistently elevates AAV anti-serum titers, resulting in the production of high-performance monoclonal antibodies.

#### High Specificity.

KACTUS proprietary AAV capsid antibodies recognize native, non-denatured AAV capsids (full and empty) for the quantification of intact AAV particles. They are also highly specific to each AAV serotype.

#### Broad Linear Range.

To ensure accurate quantification, minimizing the need for extensive sample dilution is essential to have a broad linear range in AAV Titration ELISA kits. Since the characteristics of the antibodies directly impact the kit's detection span, greater MAb sensitivity results in a more limited linear range. Consequently, we selected MAbs with extended detection ranges during the antibody screening process for the development of the KACTUS AAV titration ELISA kits.

#### High Accuracy.

Our KACTUS AAV Titration ELISA Kit exhibit recovery rates (%) in the range of 80-120%, in dilution buffer and cell lysate, indicating high accuracy with minimal interference from the diluent or matrix.

#### High Precision.

Our kits offer high intra-assay precision, with %CV less than 10% for high, medium, and low capsid sample concentrations.

#### Easy-to-Operate.

Our kits follow a standard sandwich antibody ELISA protocol with a pre-coated microtiter plate including single-break strips.

#### **Product List**

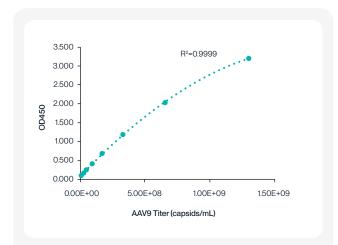
Catalog #	Product Description	Size
AV2-MM00B	AAV2 Titration ELISA Kit	96T
AV5-MM00B	AAV5 Titration ELISA Kit	96T
AV6-MM00B	AAV6 Titration ELISA Kit	96T
AV8-MM00B	AAV8 Titration ELISA Kit	96T
AV9-MM00B	AAV9 Titration ELISA Kit	96T

Distributed by:



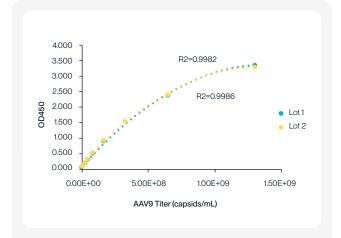
# Wide Linear Range

# **Batch Consistency**



Example standard curve for AAV9 Titration ELISA Kit.

The quantitative range of this kit is 2.03x10<sup>7</sup> - 1.3010<sup>9</sup> capsids/mL.

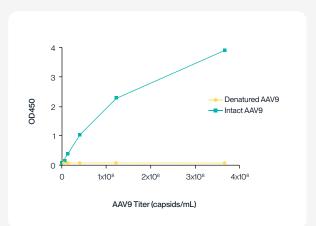


KACTUS AAV9 Titration ELISA kit standard curve tested across two batches.

The standard curve is highly reproducible and exhibits an R<sup>2</sup>>0.99.

# **High Specificity**

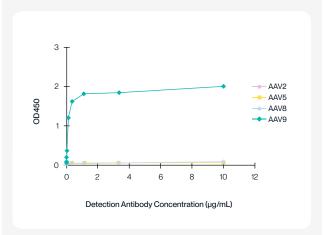
#### Specificity to intact capsids



The ELISA sandwich assay was used to detect the binding of AAV9 antibodies to intact and denatured AAV9 capsid proteins.

The AAV9 detection antibody does not exhibit binding to denatured AAV9 capsid protein.

#### Specificity to individual serotype



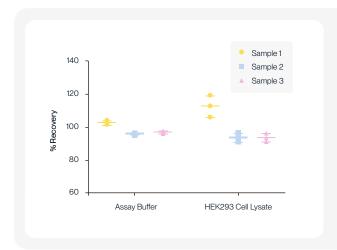
The cross-binding of different concentrations of AAV9 antibodies to capsid proteins of other serotypes (AAV2/5/8/9) was detected by indirect ELISA.

The AAV9 titration ELISA kit is highly specific to the AAV9 serotype and does not exhibit cross-reactivity with other AAV serotypes.

Distributed by:



# **High Accuracy**



KACTUS AAV9 Titration ELISA kit was used to test the recovery rate of three AAV9 titers (high, medium, and low) in spiked dilution buffer (left) and HEK293 cell lysate (right).

The sample recovery rates of AAV9 samples with different titers detected in the dilution buffer and cell lysate were all between 80% and 120%, indicating that this kit has high accuracy in detecting AAV9 titers.

# **High Precision**

Sample	# Runs	Average (capsids/mL)	Coefficient of Variation (%CV)
6.5E+08 capsids/mL	n=10	6.18E+08	2.80%
1.63E+08 capsids/mL	n=10	1.92E+08	1.90%
2.03E+07 capsids/mL	n=10	2.17E+07	5.90%

The same batch of AAV9 test kits were used to test three different titer AAV9 samples (high, medium and low). Each sample was tested 10 times. The average and coefficient of variation (%CV) of these 10 titer tests was calculated.

The %CV for all three sample concentrations (high, medium and low) was less than 10%, indicating that the AAV9 Titration ELISA kit has good intra-batch repeatability.

#### **Product List**

Catalog #	Product Description	Size
AV2-MM00B	AAV2 Titration ELISA Kit	96T
AV5-MM00B	AAV5 Titration ELISA Kit	96T
AV6-MM00B	AAV6 Titration ELISA Kit	96T
AV8-MM00B	AAV8 Titration ELISA Kit	96T
AV9-MM00B	AAV9 Titration ELISA Kit	96T

Distributed by:



# CliniSciences Group

#### Austria

Company: CliniSciences GmbH Address: Sternwartestrasse 76, A-1180

Wien - Austria

Telephone: +43 720 115 580 Fax: +43 720 115 577

Email: <u>oesterreich@clinisciences.com</u>
Web: <u>https://www.clinisciences.com</u>

#### Finland

Company: CliniSciences ApS Address: Oesterbrogade 226, st. 1, Copenhagen, 2100 - Denmark Telephone: +45 89 888 349 Fax: +45 89 884 064

Email: suomi@clinisciences.com Web: https://www.clinisciences.com

#### Iceland

Company: CliniSciences ApS Address: Oesterbrogade 226, st. 1, Copenhagen, 2100 - Denmark Telephone: +45 89 888 349 Fax: +45 89 884 064

Email: island@clinisciences.com Web: https://www.clinisciences.com

#### Netherlands

Company: CliniSciences B.V. Address: Kraijenhoffstraat 137A, 1018RG Amsterdam, Netherlands Telephone: +31 85 2082 351 Fax: +31 85 2082 353

Email: nederland@clinisciences.com Web: https://www.clinisciences.com

#### Portugal

Company: Quimigen Unipessoal LDA Address: Rua Almada Negreiros, Lote 5, Loja 14, 2615-275 Alverca Do Ribatejo - Portugal Telephone: +351 30 8808 050

Fax: +351 30 8808 052 Email: info@quimigen.com Web: https://www.quimigen.pt

#### Switzerland

Company: CliniSciences AG Address: Fracht Ost Flughafen Kloten CH-8058 Zürich - Switzerland Telephone: +41 (044) 805 76 81 Fax: +41 (044) 805 76 75

Email: <a href="mailto:switzerland@clinisciences.com">switzerland@clinisciences.com</a>
Web: <a href="mailto:https://www.clinisciences.com">https://www.clinisciences.com</a>

#### Belgium

Company: CliniSciences S.R.L Address: Avenue Stalingrad 52, 1000

Brussels - Belgium Telephone: +32 2 31 50 800 Fax: +32 2 31 50 801

Email: belgium@clinisciences.com Web: https://www.clinisciences.com

#### France

Company: CliniSciences S.A.S Address: 74 Rue des Suisses, 92000

Nanterre- France Telephone: +33 9 77 40 09 09

Fax: +33 9 77 40 10 11
Email: info@clinisciences.com
Web: https://www.clinisciences.com

#### Iroland

Company: CliniSciences Limited
Address: Ground Floor, 71 lower Baggot street

Dublin D02 P593 - Ireland Telephone: +353 1 6971 146 Fax: +353 1 6971 147

Email: <u>ireland@clinisciences.com</u>
Web: <u>https://www.clinisciences.com</u>

#### Norway

Company: CliniSciences AS Address: c/o MerVerdi Munkerudtunet 10

1164 Oslo - Norway
Telephone: +47 21 988 882
Email: norge@clinisciences.com
Web: https://www.clinisciences.com

#### Snain

Company: CliniSciences Lab Solutions Address: C/ Hermanos del Moral 13 (Bajo E), 28019, Madrid - Spain Telephone: +34 91 269 40 65 Fax: +34 91 269 40 74

Email: <u>espana@clinisciences.com</u>
Web: <u>https://www.clinisciences.com</u>

Company: CliniSciences Limited
Address: 11 Progress Business center, Whittle
Parkway, SL1 6DQ Slough- United Kingdom

or +44 (0) 330 684 0982 Fax: +44 (0)1753 208 899 Email: uk@clinisciences.com

Telephone: +44 (0)1753 866 511

IWeb: https://www.clinisciences.com

#### Denmark

Company: CliniSciences ApS Address: Oesterbrogade 226, st. 1, Copenhagen, 2100 - Denmark Telephone: +45 89 888 349 Fax: +45 89 884 064

Email: danmark@clinisciences.com Web: https://www.clinisciences.com

#### Germany

Company: Biotrend Chemikalien GmbH Address: Wilhelm-Mauser-Str. 41-43,

50827 Köln - Germany Telephone: +49 221 9498 320 Fax: +49 221 9498 325 Email: info@biotrend.com Web: https://www.biotrend.com

#### Italy

Company: CliniSciences S.r.I Address: Via Maremmana inferiore 378 Roma 00012 Guidonia Montecelio - Italy Telephone: +39 06 94 80 56 71

Fax: +39 06 94 80 00 21
Email: italia@clinisciences.com
Web: https://www.clinisciences.com

#### oland

Company: CliniSciences sp.Z.o.o.
Address: ul. Rotmistrza Witolda Pileckiego 67

lok. 200 - 02-781 Warszawa -Poland Telephone: +48 22 307 0535 Fax: +48 22 307 0532

Email: polska@clinisciences.com Web: https://www.clinisciences.com

#### Sweden

Company: CliniSciences ApS Address: Oesterbrogade 226, st. 1, Copenhagen, 2100 - Denmark Telephone: +45 89 888 349 Fax: +45 89 884 064

Email: sverige@clinisciences.com Web: https://www.clinisciences.com

#### USA

Company: Biotrend Chemicals LLC Address: c/o Carr Riggs Ingram, 500 Grand Boulevard, Suite 210 Miramar

Beach, FL 32550- USA Telephone: +1 850 650 7790 Fax: +1 850 650 4383 Email: info@biotrend-usa.com Web: https://www.biotrend-usa.com





