AAV ELISAs

Reliable AAV Capsid Titer determination for safe gene therapy





Quick: Xpress ELISA kits give results in less

than 2 hours

Reliable: specific recognition of intact AAV particles

Reproducible: low inter- and intra-assay variance

Accurate: validated by international studies and

internal gold standards









Reliable AAV Capsid Titer determination for safe gene therapy

Recombinant Adeno-Associated Virus (rAAV) vectors are frequently used for in vivo gene transfer to target inherited genetic diseases. Yet it is essential to carry out a reliable quantification of rAAV capsid titers to ensure a safe gene transfer.

As the industry gold standard you can always rely on PROGEN'S AAV ELISAS to consistently deliver reliable capsid titer determination.

You can select from a portfolio of AAV quantification ELI-SAs and Xpress ELISAs for the most commonly used AAV serotypes (see page 2). These are based on PROGEN's exclusive portfolio of capsid-specific AAV antibodies.

The AAV2 and AAV8 assays have been validated in international studies^{1,2} and classified as a superior method for reliable, standardized rAAV capsid titer quantification.

1 Ayuso E *et al.*, 2014, Human Gene Therapy 25:977 – 987 2 Lock M *et al.*, 2010, Human Gene Therapy 21:1273 – 1285

Figure 1

Table showing variance within laboratories using the AAV2 and AAV8 ELISA versus qPCR and infectious titer.

| Physical titer by qPCR | | | | | |
|------------------------|---------------|-----------------|---------------|--|--|
| | RSM (ATCC) | qPCR (vg/ml) | CV* (qPCR) | | |
| Α | rAAV2** | 3.82E+10 | 78% | | |
| В | rAAV8*** | 9.62E+11 | 113% | | |

^{**16} labs, 36 replicates | ***16 labs, 44 replicates

| In | Infectious titer | | | | | |
|----|------------------|--------------------------|------------------------|--|--|--|
| | RSM (ATCC) | Infectious titer (IU/ml) | CV* (infectious titer) | | | |
| Α | rAAV2** | 7.00E+9 | 96% | | | |
| В | rAAV8*** | 2.67E+9 | 124% | | | |

^{**10} labs, 23 replicates | ***13 labs, 29 replicates

| Capsid titer by PROGEN ELISA | | | | | |
|------------------------------|---------------|------------------|----------------|--|--|
| | RSM (ATCC) | ELISA (pt/ml) | CV* (ELISA) | | |
| Α | rAAV2** | 9.43E+11 | 34% | | |
| В | rAAV8*** | 5.50E+11 | 40% | | |

^{**15} labs, 31 replicates | ***14 labs, 28 replicates

Your AAV ELISA Benefits

Easy-to-use:

all assays use a similar workflow for all AAV serotypes and do not require expensive equipment or special training. Includes single-break strips that can be used separately for different test runs.

Quick:

the ELISA Kits are ready to order and easy to implement into all workflows. The Xpress ELISA Kits generate results in less than 2 hours without compromising performance.

Reliable:

PROGEN's exclusive capsid antibodies recognize native, non-denatured AAV capsids (full and empty) for the quantification of intact AAV particles.

Reproducible:

an established and robust method that generates reproducible data. Exhibiting a low inter- & intra-assay variance with a coefficient of variation (CV) below 10%. (See Figure 1)

Accurate:

AAV2 and AAV8 ELISAs are based on the ATCC international reference standard material and all remaining ELISAs (AAV1, 3, 5, 6, 9 and rh10) adhere to internal gold standards.

GMP-ready:

can be validated for use in a GMP setting and adhere to FDA guidelines for the development of AAV gene therapies. An industry gold standard with established success in clinical trials.

Lock, M. *et al.* Characterization of a recombinant adeno-associated virus type 2 Reference Standard Material. Hum. Gene Ther. 21, 1273–1285 (2010)

Ayuso, E. et al. Manufacturing and characterization of a recombinant adeno-associated virus type 8 reference standard material. Hum. Gene Ther. 25, 977–87 (2014)







Available Serotypes

of your assays.

| Serotypes | ELISA | XPress ELISA |
|-----------|--------------|--------------|
| AAV1 | \checkmark | |
| AAV2 | \checkmark | \checkmark |
| AAV3 | \checkmark | |
| AAV5 | \checkmark | \checkmark |
| AAV6 | \checkmark | \checkmark |
| AAV8 | \checkmark | \checkmark |
| AAV9 | \checkmark | \checkmark |
| AAVrh10 | \checkmark | |





Making gene therapy better. Together.

Our commitment to scientists is to support them in making new scientific discoveries and groundbreaking research within the life sciences and gene therapy. It is our underlying mission, to help progress new therapies safely, quickly and affordably, so together we can provide solutions to people suffering from poor health and affected by disease every day.

PROGEN is made up of a team of experts within AAV and the life sciences and is partnered with gene therapy experts worldwide. We are more than just a manufacturer of antibodies, proteins and ELISAs kits. We strive to understand what scientists need, so we can create solutions and ultimately deliver high quality antibodies

and exclusive AAV products, which solve your research challenges within academia, biotech and pharma, and ensure PROGEN can continue to be a trusted and reliable partner.

