

AAV6

Simple Plex assay for the detection of Adeno-Associated Virus type 6 (AAV6) intact capsids in bioprocess samples.

For research use only. Not for use in diagnostic procedures.

Sample Preparation

An appropriate dilution factor for each process matrix should be determined experimentally by assessment of sample linearity and spike recovery.

Bioprocess samples require a minimum 2-fold dilution with Sample Diluent SD19 (diluted 1:5). A suggested 2-fold dilution can be achieved by adding 35 μ L of sample to 35 μ L of Sample Diluent SD19 (diluted 1:5). Samples above the ULOQ require further dilution.

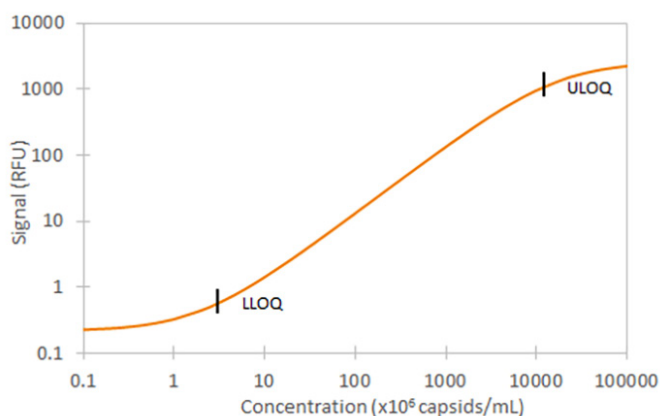
Reagent Preparation

Prior to use, allow reagents to reach room temperature.

SD19 Concentrate (Diluted 1:5) - Add 10 mL of SD19 Concentrate to 40 mL of deionized or distilled water to prepare 50 mL of Sample Diluent SD19 (diluted 1:5).

Calibration Curve

The factory generated calibration curve shown below was compiled by averaging 5 replicates of each calibrator from multiple runs. The 4PL curve fit shows calibrator concentration as a function of signal intensity (relative fluorescent units, RFU).



Limit of Quantitation

Data shown represents typical performance results for Lower Limit of Quantitation (LLOQ) and Upper Limit of Quantitation (ULOQ) of AAV6.

| | CONC. (capsids/mL) |
|------|----------------------|
| LLOQ | 3.00×10^6 |
| ULOQ | $11,600 \times 10^6$ |

Limit of Detection

The limit of detection (LOD) of AAV6 is 0.520×10^6 capsids/mL. The LOD was calculated by adding three standard deviations to the mean background signal determined from multiple runs.

Precision

Intra-Assay Precision: Each control was tested 16 times in one assay.

Inter-Assay Precision: Replicates of each control were tested in multiple assays performed by at least three technicians using two lots of reagents.

| PARAMETER | LOW QC | HIGH QC |
|--|--------|---------|
| Intra-Mean ($\times 10^6$ capsids/mL) | 57.3 | 2729 |
| Intra-assay SD | 1.2 | 77.7 |
| Intra-assay CV (%) | 2.0 | 2.8 |
| Inter-Mean ($\times 10^6$ capsids/mL) | 58.6 | 2657 |
| Inter-assay SD | 6.7 | 211 |
| Inter-assay CV (%) | 11.5 | 8.0 |

Correlation

This assay has been correlated to the PROGEN ELISA Kit with an R^2 value greater than 0.9.

Precaution

When handling AAV6 material avoid vortexing and freeze thaw cycles.

Linearity

Samples containing and/or spiked with high concentrations of AAV6 were serially diluted with Sample Diluent to produce samples within the dynamic range of the assay.

| DILUTION | PARAMETER | BIOPROCESS (n=5) |
|----------|-------------------|---------------------|
| 1:2 | Avg % of Expected | 99 |
| | Range (%) | 93-103 |
| 1:4 | Avg % of Expected | 104 |
| | Range (%) | 93.-109 |
| 1:8 | Avg % of Expected | 109 |
| | Range (%) | 96-119 |
| 1:16 | Avg % of Expected | 116 |
| | Range (%) | 94-134 |

Specificity

This assay recognizes intact AAV6 capsids. The AAV6 antibody (ADK1α) used in this assay cross-reacts with AAV1 and AAV12.



Toll-free: (888) 607-9692
 Tel: (408) 510-5500
 Fax: (408) 510-5599
 info@proteinsimple.com
 proteinsimple.com

IN COOPERATION WITH
PROGEN

Maaßstraße 30
 69123 Heidelberg
 Germany
 Tel: +49 6221 8278-0
 info@progen.com
 progen.com