bio-techne® | R&D SYSTEMS

Specification Sheet
Avoid freeze-thaw

AAV9

Product Description

Simple Plex™ assay is for the detection of Adeno-Associated Virus type 9 (AAV9) intact capsids in Bioprocess samples in Sample Diluent SD19.

This assay uses PROGEN's AAV9 (ADK9) antibody.

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).

Sample Preparation

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

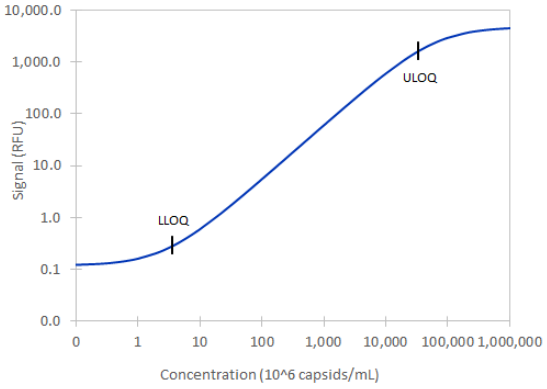
Bioprocess samples require a minimum 2-fold dilution with Sample Diluent SD19 (diluted 1:5). A suggested 2-fold dilution can be achieved by adding 35 µL of sample to 35 µL of Sample Diluent SD19 (diluted 1:5). Samples above the ULOQ require further dilution.

Precautions

Repeated freeze-thaw cycles will cause sample variation. When handling material avoid freeze thaw-cycles.

Calibration Curve

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



Limits of Quantification

Data shown represents typical performance results of the AAV9 Simple Plex Assay.

	Concentration (10^6 capsids/mL)
Limit of Detection (LOD)	0.72
Lower Limit of Quantitation (LLOQ)	3.44
Upper limit of Quantitation (ULOQ)	32,800

The LOD was calculated by adding three standard deviations to the mean background signal determined from multiple runs.

LLOQ and ULOQ are calculated across multiple cartridge lots and Ellas as the in-well concentration range in which curve points recover 80-120% with a coefficient of variation (CV) of less than 20%, and in which measured samples recover 80-120% upon serial dilution with a CV less than 15%.

Precision

Intra-Assay Precision: Multiple replicates of each control were tested in one assay.

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

Parameter	Intra-Assay		Inter-Assay	
Sample	**Low**	**High**	**Low**	**High**
n	16	16	34	34
Mean (10^6 capsids/mL)	295	13,656	286	13,670
Standard Deviation	10.2	357	16.4	654
CV (%)	3.5	2.6	5.7	4.8

Recovery

Recovery at three different spiked concentrations within the range of the assay was evaluated.

Sample Type	Average%	Range%
Bioprocess (n=6)	95	90-104

Linearity

Samples containing and/or spiked with high concentrations of AAV9 were serially diluted with Sample Diluent to produce samples within the dynamic range of the assay.

Dilution	Parameter	Bioprocess (n=18)
1:2	Avg % of Expected	100
	Range (%)	94-104
1:4	Avg % of Expected	102
	Range (%)	97-109
1:8	Avg % of Expected	102
	Range (%)	96-110
1:16	Avg % of Expected	103
	Range (%)	95-113

Specificity

This assay recognizes intact AAV9 capsids.

Assay Protocol

Refer to the Product Insert and CoA provided on our website for the specific assay protocol and precautions. A generic product protocol can be found online at: www.bio-techne.com/simple-plex-protocol

Download the CoA and product insert: www.bio-techne.com/resources/cofa-finder-tool

IN COOPERATION WITH PROGEN