

AAV2

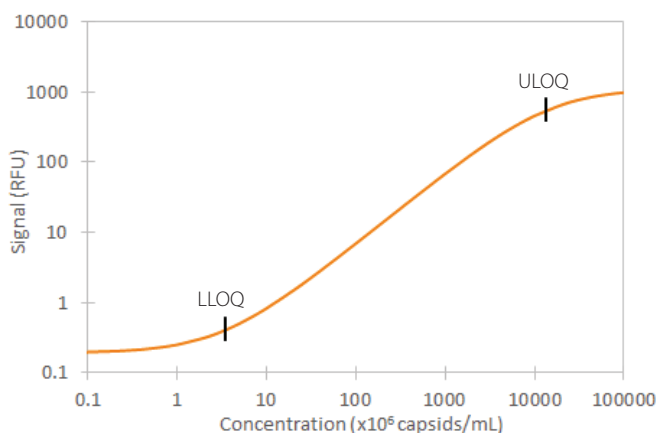
Simple Plex assay for the detection of Adeno-Associated Virus type 2 (AAV2) intact capsids in bioprocess samples.

This assay uses Progen's AAV2 (A20R) antibody.

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

Calibration Curve

The factory generated calibration curve shown below was compiled by averaging 5 replicates of each calibrator from multiple runs. The 5PL 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 AAV2.

	CONC. (capsids/mL)
LLOQ	3.41×10^6
ULOQ	1.3×10^{10}

Limit of Detection

The limit of detection (LOD) of AAV2 is 0.9×10^6 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)	40	2103
Intra-assay SD	3.5	55.3
Intra-assay CV (%)	8.8	2.6
Inter-Mean ($\times 10^6$ capsids/mL)	42.2	2045
Inter-assay SD	4.7	158
Inter-assay CV (%)	11.2	7.7

Correlation

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

Precautions

When handling AAV2 material avoid vortexing and freeze thaw cycles.

Linearity

Samples containing and/or spiked with high concentrations of AAV2 were serially diluted with Sample Diluent to produce samples within the dynamic range of the assay.

DILUTION	PARAMETER	BIOPROCESS (n=6)
1:2	Avg % of Expected	88
	Range (%)	87-90
1:4	Avg % of Expected	96
	Range (%)	82-105
1:8	Avg % of Expected	96
	Range (%)	83-108
1:16	Avg % of Expected	95
	Range (%)	82-105

Notes

Specificity

This assay recognizes natural and recombinant AAV2. The AAV2 (A20R) antibody used in this assay cross-reacts with AAV3.

Sample Preparation

Bioprocess samples require a minimum 2-fold dilution with sample diluent. A suggested 2-fold dilution can be achieved by adding 35 μ L of sample to 35 μ L of Sample Diluent. Samples above the ULOQ require further dilution.



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