PRODUCT NOTE

Genome Titer using Gator® AAV GeneSwift Kit

Genome titer is a CQA for safe and efficacious gene therapy products. The GeneSwift kit combines the advantages of DNA sequence specificity, immunoassay based signal amplification, and the speed and ease of BLI to accurately quantitate AAV genome titer. The wide dynamic range of this assay enables titer measurement without sample dilution that is needed in ddPCR assay. This results in very little hands-on time and better reproducibility. Gator's assay allows for up to 32 sample analysis in 35 minutes depending upon the instrument.

PRODUCT INFORMATION

Part Number

350006

Includes

Part 1 at 4°C

- Biotin PolyA, Part No: 130166
- Biotin Detection Reagent 200X, Part No: 120077
- GeneSwift Substrate, Part No: 120079
- GeneSwift Diluent, Part No: 120080
- Hybridization Buffer, Part No: 120076
- Q Buffer, Part No: 120010

Part 2 at RT

- Anti-Fluorescein Biosensors, Part No: 160045
- Lysis Tubes (x12), Part No: 130134
- Probe Picker, Part No. 130298

PERFORMANCE SUMMARY

Dynamic Range

4E+09 to 1E+12 vg/mL

Assay Time

Up to 8, 16 or 32 samples in 35 minutes (instrument dependent)

Precision

2-15% CV

PRECISION

- Applicable to all AAV serotypes
- Works in crude matrices
- Gene-of-Interest specific

DYNAMIC RANGE AND PRECISION

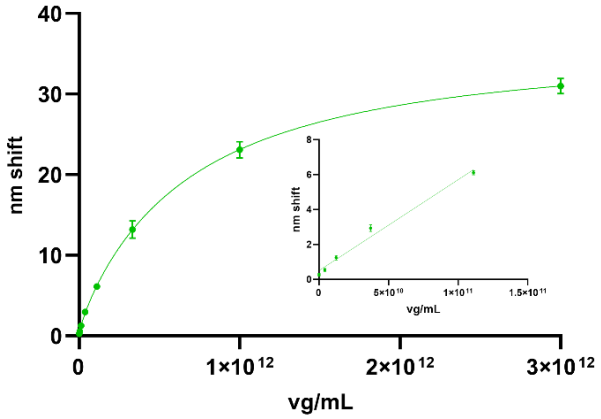

Figure 1. AAV genome titer dynamic range from 4E+09 – 1E+12 vg/mL. The % CV values for all data points are <10%. Data was obtained using GFP oligo pair.

COMPARABLE PERFORMANCE FOR AAV GENOME TITER IN DIFFERENT BUFFERS

	Determined AAV Titer (vg/ml)	
Bioprocess Sample	**ddPCR**	**GeneSwift**
Clarified Harvest	**8.10E+10**	**6.64E+10**
TFFI Retentate	**4.87E+11**	**6.04E+11**
AFF Neutralized Eluate	**8.45E+11**	**8.66E+11**
TFF2 Retentate	**3.00E+11**	**3.33E+11**
AEX Full	**2.93E+12**	**2.21E+12**
Purified AAV	**1.59E+13**	**1.99E+13**

Table 1. Titer comparison of the customer's AAV engineered bioprocess samples by GeneSwift and ddPCR showing very similar titer values.

GENOME TITER

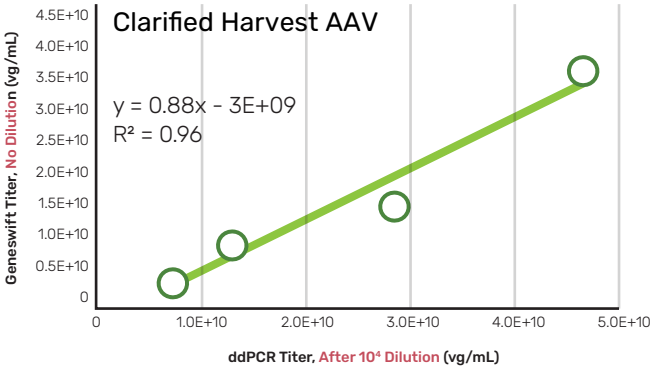

Figure 2. Correlation studies testing the clarified harvest AAV sample by GeneSwift and ddPCR. The data shows R^2 equal to 0.96.

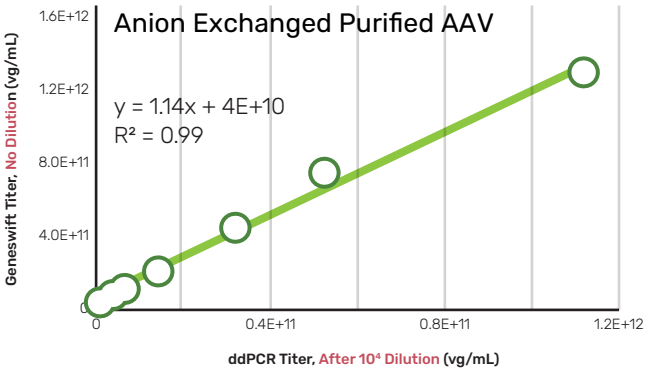

Figure 3. Correlation studies testing the anion exchanged purified AAV sample by GeneSwift and ddPCR. The data shows R^2 equal to 0.99.

Beta Trial's Sample	Correlation Coefficient	Slope of Correlation Curve
Clarified Harvest	**0.96**	**0.88**
TFFI Retentate	**0.97**	**0.77**
AFF Neutralized Eluate	**0.99**	**1.09**
TFF2 Retentate	**0.97**	**0.91**
AEX Full	**0.99**	**1.14**
Purified AAV	**0.98**	**0.89**

Table 2. Expected(ddPCR) vs calculated titer values using AAV2 samples

SUMMARY

The GeneSwift kit accurately determines AAV genome titer and integrity; and offers the following advantages:

- 35 minute assay
- Dynamic range 4E+9 to 1E+12 vg/mL
- 8, 16 or 32 samples in 35 minutes
- Crude sample compatible
- Serotype Agnostic

GATOR GENESWIFT GOI KIT - RELATED PRODUCTS

The GFP, CMV Promoter, CMV Enhancer and SV40 shown below also include Oligo Pre-mixes

Gator® GeneSwift GOI Kit (Optional)

- GFP Oligo Pre-Mix, Part No: 120089
- CMV Oligo Pre-Mix, Part No: 120090
- SV40 Oligo Pre-Mix, Part No: 120096

