

Automated, Rapid, Reproducible Quantification of HIV-1 Gag p24:

Introduce Simple Plex into Your Cell & Gene Therapy Workflow

Introduction

With the growing use of Lentiviral vectors derived from HIV-1 in cell and gene therapies, the need for precise calculations of viral titres during throughout the manufacturing process is crucial.

Reliable methods for quantification of Lentiviral vectors support process development and enables quality control of both vector and cell manufacturing. Traditionally ELISA assays serve as a common methodology for calculating viral titres and are used to measure the amount of viral capsid p24 protein in the supernatant of packaging cell lines.

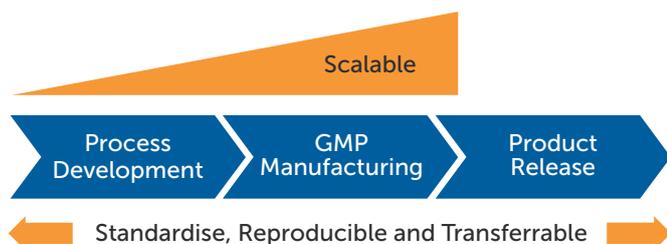
The 3.5 to 6 hours required to run a Standard ELISA is a challenge for operators who increasingly require results quickly to inform real time decision making.

The Simple Plex p24 assay, hosted on Ella - an automated immunoassay system, can rapidly quantify p24 levels expressed from lentiviral

vectors during different stages of cell and vector manufacturing. The automated, robust and reproducible nature of the Simple Plex p24 assay removes user error, and makes it amenable for GMP environments when quality, standardisation of process, assay transfer and scalability are highly desirable.

Simple Plex Assays are also designed to fit multiple assay requirements. Use our custom assay development service or choose from >180 available off the shelf biomarkers to create your single or multiplex assay formats.

Application of the Simple Plex HIV-1 Gag p24 assay in your process



AT A GLANCE

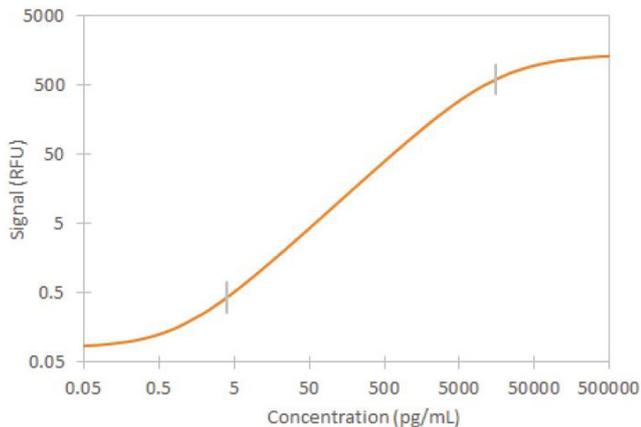
Faster process decisions: results in just 1 hour with only 10 minutes hands-on preparation

High reproducibility: eliminates the challenges and variability of manual ELISA

Transferable: fully automated assays deliver low digit CVs across multiple sites

Broad quantitative range: 3.93 – 15,000 pg/mL

HIV-1 Gag p24 Simple Plex Assay Specifications



Calibration Curve

Broad dynamic range and low picogram/mL detection. The factory generated calibration curve 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).

Excellent Precision in Quantification

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 (pg/mL)	105	4500
Intra-assay SD	7.37	237
Intra-assay CV (%)	7.1	5.3
Inter-Mean (pg/mL)	94.3	4074
Inter-assay SD	9.64	377
Inter-assay CV (%)	10.2	9.3

Outstanding Assay Linearity

Samples containing and/or spiked with high concentrations of HIV-1 Gag p24 were serially diluted with Sample Diluent to produce samples within the dynamic range of the assay.

Dilution	Parameter	CCS (N=4)	Serum (N=4)	EDTA PLASMA (N=4)	HEPARIN PLASMA (N=4)
1.2	105	96	96	97	95
	7.37	92-102	91-98	92-105	89-100
1.4	7.1	97	94	95	93
	94.3	90-109	90-99	92-101	90-94
1.8	9.64	94	95	97	92
	9.64	90-99	88-98	89-108	88-96
1.16	9.64	96	95	98	91
	10.2	90-110	87-104	88-111	83-100

Find out more about ELLA at www.proteinsimple.com/ella

Explore the HIV Gag p24 Simple Plex assay at www.proteinsimple.com/simple_plex_assays