

CERTIFICATE OF ANALYSIS

Product:

HIV-1 p24 Antigen Capture Assay

Cat#:

5421 and 5447

Lot#:

2170

Release Date:

11/08/2023

Expiry Date:

NOV2024

HIV-1 p24 Antigen Capture Assay kit of this lot consists of the following:

Disruption Buffer Lota	# DSB137
Microelisa Plate, Anti-HIV-1 p24	# 23102001
HIV-1 p24 Standard Lot	# P24STD109
Conjugate Solution Lot	# P24C160
Peroxidase Substrate Lot	# 230711
Stop Solution (2N H ₂ SO ₄) Lot#	# 4302F77
Wash Buffer (20X)	# 060623-02
Plate Sealers Lot	# 00923287

Storage condition for HIV-1 p24 Antigen Capture Assay is 2-8°C.

	Specifications	Results
Absorbance of 100 pg/ml Standard Antigen Determined p24 Control Antigen Concentration Absorbance of Negative Control Linear Regression R squared	1.4 to 2.0 45 to 55 pg/ml < 0.100 > 0.995	1.6 45 pg/ml 0.060 1.000

This product conforms to the specifications listed above.

Peter Silvera

Date

Program Director III, Innovation & Translation

Phone: 1-301-816-5459

Fax: 1-301-816-5438



MEMORANDUM

January 22, 2024

Product:

HIV-1 p24 Antigen Capture Assay

Catalog #:

5421 and 5447

This memorandum serves to document that the subject product was inappropriately released on 11/08/2023 prior to completion of review of the associated data (attached). However, review of the data on Document #: QC-H24.8 demonstrates that all acceptance criteria related to qualification/release of the kit were met.

Therefore, this occurrence does not impact the quality/integrity of the referenced product.

Peter Silvera, PhD

Program Director, Innovation and Translation

Date: January 27, 2024