

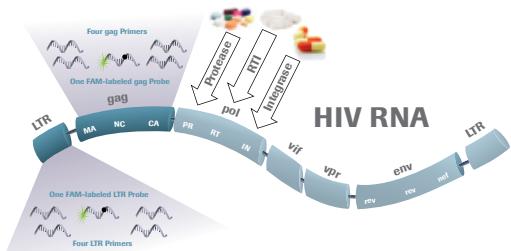
cobas® HIV-1

Stay one step ahead

It takes more than just a single target

As the challenges you face evolve, stay one step ahead with the next generation quantitative HIV-1 assay with a dual target approach

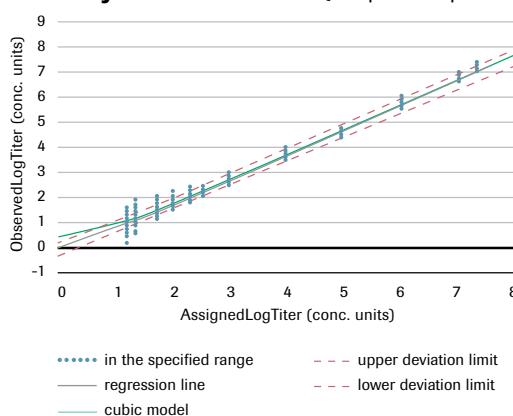
Rapidly mutating HIV-1 virus can evade quantification with a single target viral load assay. cobas® HIV-1 quantitative nucleic acid test for use on the cobas® 6800/8800 Systems targets two unique regions of the HIV-1 genome, gag and LTR, which are not subject to selective drug pressure. This approach improves test sensitivity, coverage and security in the event of mutation in one primer/probe region.



Drive better decisions for a positive impact on patients' lives

- Targeting two regions improves genotype inclusivity, detects HIV-1 variants and potentially avoids under quantification.
- Accurate quantification of HIV-1 RNA with a dual target assay contributes to optimal treatment decisions for patient management.

Linearity for cobas® HIV-1 (500 µL EDTA plasma)



Limit of detection of cobas® HIV-1

(500 µL EDTA plasma) using the WHO international standard and PROBIT analysis

Nominal input (HIV-1 RNA cp/mL)	Nominal input (HIV-1 RNA IU/mL)	Number of valid replicates	Number of positives	Hit rate in %
40.0	66.7	189	189	100.0%
20.0	33.3	189	186	98.4%
10.0	16.7	189	171	90.5%
5.0	8.3	189	125	66.1%
2.5	4.2	189	67	35.4%
0.0	0.0	189	0	0.0%

LoD by PROBIT at 95% hit rate

13.2 cp/mL;
(95% confidence range: 11.4–15.9 cp/mL)
22.0 IU/mL;
(95% confidence range: 19.0–26.5 IU/mL)

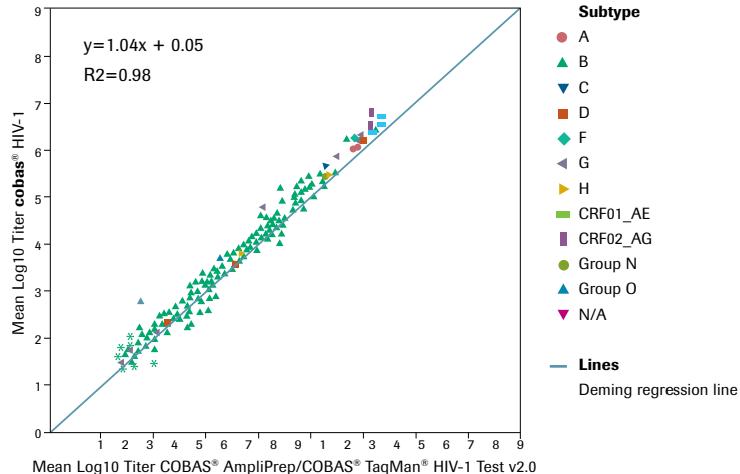


CE-IVD performance specifications. Not available in all markets.

cobas®

Life needs answers

Correlation (500 µL EDTA plasma)



Precision of cobas® HIV-1 (500 µL EDTA plasma)

Nominal concentration (cp/mL)	Assigned concentration (cp/mL)	Source material	EDTA plasma			
			Lot 1 SD	Lot 2 SD	Lot 3 SD	All Lots Pooled SD
1.00E+07	8.67E+06	Cell culture	0.04	0.06	0.03	0.05
1.00E+06	8.67E+05	Cell culture	0.06	0.05	0.04	0.05
1.00E+05	8.67E+04	Cell culture	0.05	0.07	0.04	0.05
1.00E+04	8.67E+03	Cell culture	0.06	0.06	0.04	0.05
1.00E+03	8.67E+02	Cell culture	0.07	0.06	0.07	0.07
4.00E+02	3.47E+02	Cell culture	0.09	0.10	0.09	0.09
2.00E+02	1.73E+02	Cell culture	0.11	0.08	0.14	0.11
1.00E+02	8.67E+01	Cell culture	0.15	0.11	0.10	0.12

* Titer data are considered to be log-normally distributed and are analyzed following log10 transformation. Standard deviations (SD) columns present the total of the log-transformed titer for each of the three reagent lots.

cobas® HIV-1 performance summary

Parameter	Performance
Sample type	EDTA plasma
Sample process volume	500 µL or 200 µL*
Analytical sensitivity	13.2 cp/mL (500 µL) 35.5 cp/mL (200 µL)
Linear range	500 µL: 20 cp/mL – 1.0E+07 cp/mL 200 µL: 50 cp/mL – 1.0E+07 cp/mL
Specificity	100% (one-sided 95% confidence interval: 99.5%)
Genotypes detected	HIV-1M (A-D, F-H, CRF01_AE, CRF02_AG), HIV-1O, HIV-1N

Performance for today; prepared for tomorrow

It takes more than just a single target to stay ahead of HIV-1. Use the dual target cobas® HIV-1 assay to gain complete confidence in test results.

cobas® HIV-1 ordering information

Material number	Product name	Tests per unit (cassette/bottle)
07000995190	cobas® HIV-1	96
06997767190	cobas® HBV/HCV/HIV control kit	8 runs
07002220190	cobas® NHP negative control kit	16 runs

Comprehensive menu for viral load testing

- cobas® HIV-1*
- cobas® HBV*
- cobas® HCV*
- cobas® CMV*

*For use with the cobas® 6800/8800 Systems

*200 µL processing volume not commercially available in the United States

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