

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 cobas[®] HIV-1 quantitative test with a dual target approach

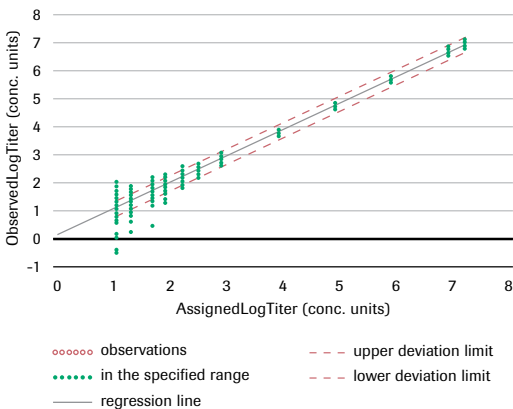
Rapidly mutating HIV-1 virus can evade quantification with a single target viral load assay. cobas[®] HIV-1 quantitative nucleic acid test for use on the cobas[®] 4800 Systems targets two unique regions of the HIV-1 genome, gag and LTR, which are not subject to selective drug pressure. This approach 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 (400 µL EDTA plasma)



Limit of detection of cobas[®] HIV-1 (400 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 %
60.0	100.0	252	252	100%
30.0	50.0	251	251	100%
20.0	33.3	252	247	98.0%
10.0	16.7	252	227	90.1%
5.0	8.3	252	160	63.5%
2.0	3.3	252	86	34.1%
0.0	0.0	71	0	0%

LoD by PROBIT at 95% hit rate

14.2 cp/mL;

(95% confidence range: 12.5–16.6 cp/mL)

23.7 IU/mL;

(95% confidence range: 20.8–27.7 IU/mL)

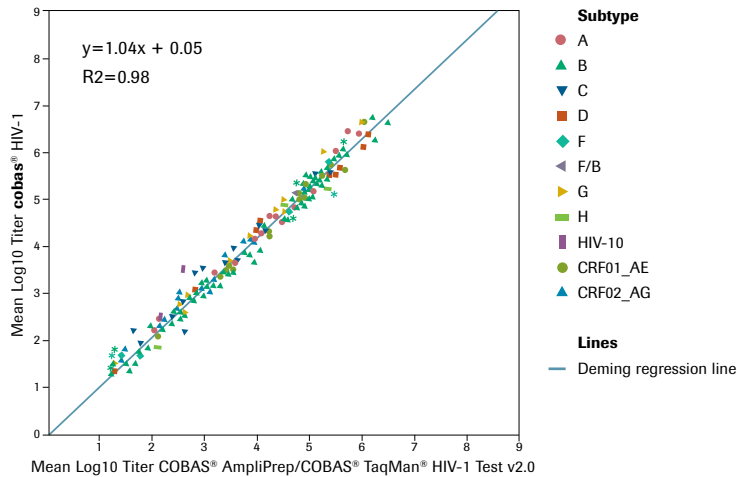


Not available in all markets, including the U.S.

cobas[®]

Life needs answers

Correlation (400 µL EDTA plasma)



Precision of **cobas**® HIV-1 (400 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
2.0E+07	1.54E+07	Cell culture	0.05	0.05	0.04	0.05
1.0E+06	7.70E+05	Cell culture	0.05	0.05	0.05	0.05
1.0E+05	7.70E+04	Cell culture	0.05	0.05	0.05	0.05
1.0E+04	7.70E+03	Cell culture	0.04	0.06	0.07	0.06
1.0E+03	7.70E+02	Cell culture	0.09	0.10	0.07	0.09
4.0E+02	3.08E+02	Cell culture	0.08	0.10	0.09	0.09
6.0E+01	7.70E+01	Cell culture	0.18	0.24	0.15	0.19

* 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	400 µL or 200 µL
Analytical sensitivity	14.2 cp/mL (400 µL) 43.9 cp/mL (200 µL)
Linear range	400 µL: 20 cp/mL – 1.0E+07 cp/mL 200 µL: 60 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-10, 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	Package size
06979599190 test	cobas ® HIV-1	120 (10x12)

Roche Diagnostics Scandinavia AB

Box 1228

171 23 Solna

PM2019-00458

© 2015 Roche Molecular Systems, Inc.

Product names and trademarks are the property of their respective owners.

07816065-001 0915

COBAS, AMPLIPREP, TAQMAN and LIFE NEEDS ANSWERS are trademarks of Roche.