

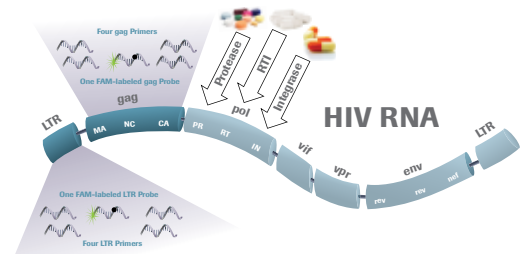
# cobas<sup>®</sup> HIV-1

## 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

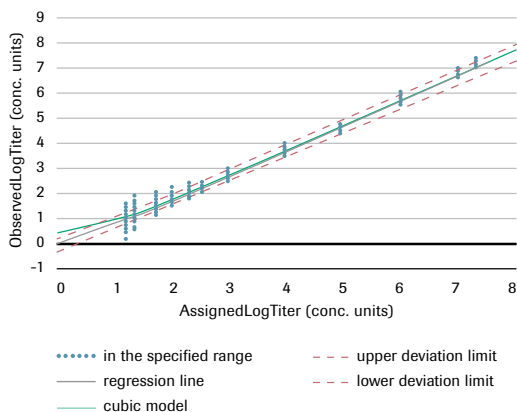
Rapidly mutating HIV-1 virus can evade quantification with a single target viral load assay. **cobas<sup>®</sup> HIV-1** quantitative nucleic acid test for use on the **cobas<sup>®</sup> 6800/8800 Systems** targets two unique regions of the HIV-1 genome, gag and LTR, which are not subject to selective 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<sup>®</sup> HIV-1 (500 µL EDTA plasma)



### Limit of detection of cobas<sup>®</sup> HIV-1 (500 µL EDTA plasma) using the WHO international standard and PROBIT analysis

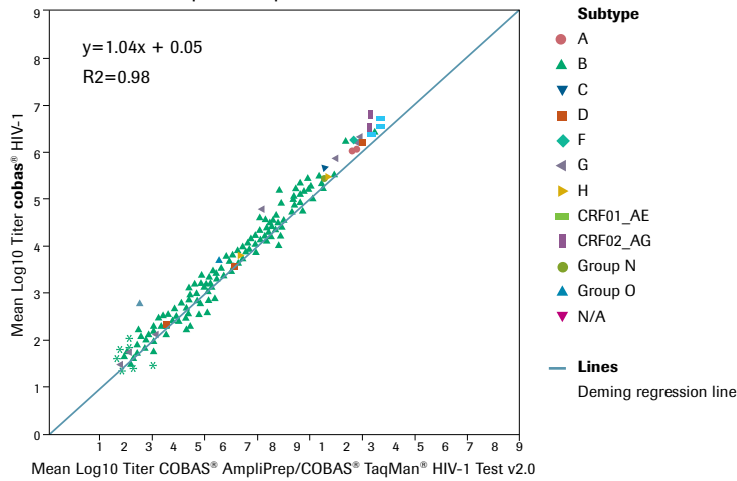
Nominal input (HIV-1 RNA cp/mL)	Nominal input (HIV-1 RNA IU/mL)	Number of valid replicates	Number of positives	Hit rate in %
40.0	66.7	189	189	100.0%
20.0	33.3	189	186	98.4%
10.0	16.7	189	171	90.5%
5.0	8.3	189	125	66.1%
2.5	4.2	189	67	35.4%
0.0	0.0	189	0	0.0%

### 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)



### 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	<b>cobas® HIV-1</b>	96
06997767190	<b>cobas® HBV/HCV/HIV control kit</b>	8 runs
07002220190	<b>cobas® NHP negative control kit</b>	16 runs

### Comprehensive menu for viral load testing

<b>cobas® HIV-1*</b>
<b>cobas® HBV*</b>
<b>cobas® HCV*</b>
<b>cobas® CMV*</b>

\*For use with the **cobas® 6800/8800 Systems**

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