

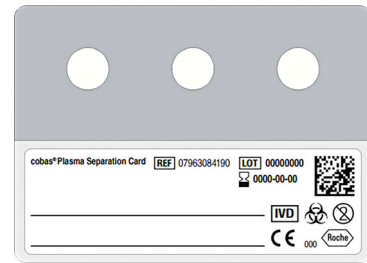


Global Access Program
take aim
at HIV

cobas[®] Plasma Separation Card

Spot it. Move it. Prove it.

Diverse infrastructure demands innovative solutions. The **cobas[®]** Plasma Separation Card helps tackle the HIV/AIDS epidemic by making sample collection simple and achievable in remote and challenging areas.



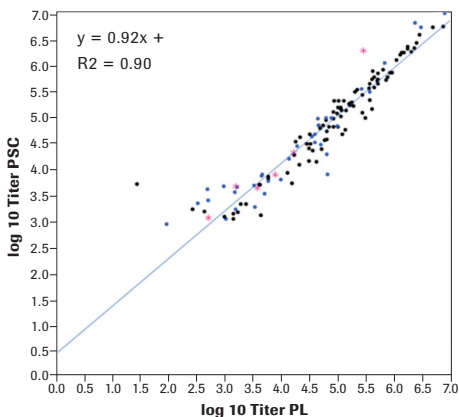
Advanced performance

cobas[®] Plasma Separation Card on the **cobas[®]** 6800/8800 Systems

Within laboratory precision of cobas[®] HIV-1 in combination with the Plasma Separation Card

Measured concentration (cp/mL in centrifuged EDTA plasma)	Source material	Pooled SD
1.02E+07	Cell Culture	0.08
9.12E+05	Cell Culture	0.08
8.32E+04	Cell Culture	0.09
7.94E+03	Cell Culture	0.13
2.00E+03	Cell Culture	0.23

Correlation of cobas[®] Plasma Separation Card versus plasma viral load



- FP (finger prick) = 6
- VL (patients getting their routine viral load testing) = 35
- CD (patients getting a CD4 count) = 91



SPOT IT. MOVE IT. PROVE IT.



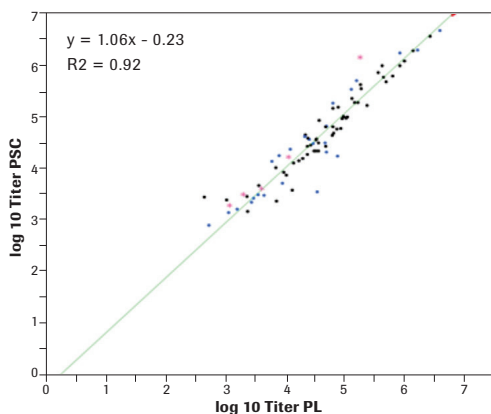
Advanced performance

cobas® Plasma Separation Card on the COBAS® AmpliPrep/COBAS® TaqMan® System

Within laboratory precision of COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, v2.0 in Combination with the Plasma Separation Card

Measured concentration (cp/mL)	Source material	Pooled SD
6.31E+06	Cell Culture	0.08
1.05E+06	Cell Culture	0.09
1.02E+05	Cell Culture	0.12
1.05E+04	Cell Culture	0.19
2.29E+03	Cell Culture	0.25

Correlation of cobas® Plasma Separation Card versus plasma viral load



The **cobas®** Plasma Separation Card solution will allow for increased access to testing in resource limited settings, easy-to-use for transportation and storage while also providing a state-of-the-art stabilizer membrane for transporting samples under extreme heat and humidity.

- Provides an updated technology for easy plasma sample collection and transportation in resource limited settings
- Meets the World Health Organization sensitivity requirement for determining HIV treatment
- Stable under harsh condition that eliminates the need for refrigeration in transporting plasma samples to the laboratory

- FP (finger prick) = 5
- VL (patients getting their routine viral load testing) = 25
- CD (patients getting a CD4 count) = 53
- SP (spiked samples) = 2

Performance Summary

	cobas® 6800/8800 Systems	COBAS® AmpliPrep/COBAS® TaqMan® System
Sample type	Dried plasma spot coming from Plasma Separation Card	Dried plasma spot coming from Plasma Separation Card
Minimum amount of sample required	140 µL whole blood	140 µL whole blood
Sample processing volume	850 µL	850 µL
Analytical sensitivity	790.2 cp/mL	737.9 cp/mL
Linear range	790 cp/mL – 1.0E+07 cp/mL	738 cp/mL – 1.0E+07 cp/mL
Specificity	100% (one-sided 95% confidence interval: 98.3%)	99.4% (95% confidence limit: ≥ 97.07%)
Transportation: Up to 21 days at 18-45°C and up to 85% humidity		
Post transportation storage at room temperature (18-30°C), at 2-8°C or at -10°C for up to 56 days (with and without layer separation)		

Please contact your local Roche representative for more information.
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