

HIV Drug Resistance Performance Panel

PRD250

INTENDED USE

PRD250, an HIV Drug Resistance Performance Panel, is a set of naturally occurring plasma specimens from HIV-infected individuals whose virus demonstrates multiple drug resistance mutations. This panel is intended for use by diagnostic test kit manufacturers and clinical laboratories to develop, verify or validate HIV drug resistance mutation assays, evaluate new kit lots, assess technician proficiency or compare test methods, using characterized specimens. For research use only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

SeraCare Life Sciences acquired the Teragenix T-20 Drug Resistance Panel (HIVDRP-002a) in 2008. The panel contains ten naturally occurring plasma samples, each demonstrating multiple reverse transcriptase and protease associated mutations. All specimens were collected in the United States. The order of the samples in the original Teragenix panel has been maintained. All samples have been maintained frozen, except for one freeze-thaw cycle when vials were relabeled. No preservatives were added. This panel is provided as 1.0 ml volume per vial.

REAGENTS

Cat No. PRD250-1.0 1 vial per member
10 members, 1.0 mL per vial

INTERPRETATION OF RESULTS

The attached data sheet provides the results of assays for HIV-1 RNA, HIV reverse transcriptase-associated mutations and HIV protease-associated mutations.

Tests dated 2009 were performed at SeraCare Life Sciences by individuals who routinely use these procedures. Drug resistance mutation results are as recorded by Teragenix in 2003.

PRECAUTIONS

BIOHAZARD CAUTION: Potentially infectious materials. Follow the Centers for Disease Control (CDC) recommended universal precautions for handling these product¹. Panel members were tested and most were found positive for HIV-1 RNA.

Never pipette by mouth. Do not smoke, eat or drink in areas where specimens are handled. These materials should be disposed of in a manner that will inactivate pathogenic agents.

STORAGE

Panel members should be stored frozen at -70°C. If turbidity or particulate matter is observed, the samples should be centrifuged in accordance with each test kit manufacturer's instructions for sample preparation.

LIMITATIONS

PRD250 is offered for research use only. Not for use in diagnostic procedures. Data are provided for informational purposes. Seracare Life Sciences does not claim that others can duplicate test results exactly.

REFERENCES

1. CDC recommendations for prevention of HIV transmission in health care settings. MMWR 36 (supp. 2) 1987.

For assistance, contact SeraCare Life Sciences Technical Support

Phone (508) 244-6400 or US Toll Free (800) 676-1881

Visit our website at www.seracare.com



25 Birch Street
Milford, MA 01757 USA

SeraCare Life Sciences
Teragenix HIV Drug Resistance Panel
PRD250 (formerly HIVDRP-002a)
Data Sheet (Lot 117177)

Member I.D. #	Roche Amplicor HIV-1 Monitor™ v 1.5 SeraCare (Copies/mL)	Visible Genetics TrueGene™ HIV-1 Assay Relevant RT Mutations <u>RL</u>	Visible Genetics TrueGene™ HIV-1 Assay Relevant Protease Mutation <u>RL</u>
PRD250-01	8.8 x 10 ^{1*}	K103N, M184V, T215Y	M36I, L63P, L90M
PRD250-02	4.27 x 10 ⁴	M41L, D67N, T69D, K70R, A98G, V118I, V179E, Y181C, M184V, G190A, T215F, K219Q	L10F, M46I, L63P, 184V, L90M
PRD250-03	1.55 x 10 ⁵	M41L, E44D, D67N, T69D, L74V, V106A, V118I, M184V, G190A, L210W, T215Y	L10F, M46I, I47V, 154M, L63P, A71T, 184V, L90M
PRD250-04	<50*	M41L, D67N, K70R, K103N, M184V, T216F, K219Q	M38I, L63P
PRD250-05	8.30 x 10 ⁵	M41L, D67N, V118I, M184V, L210W, T215Y, K219Q	L10I, K20R, M36I, M46I, 150V, L63P, V82T, L90M
PRD250-06	6.87 x 10 ⁵	M41L, E44D, D67N, K70R, L74V, K103N, V118I, Y181C, M184V, G190A, L210W, T215Y, K219E	L10F, K20R, M46I, 154V, L63P, V82F, 184V, L90M
PRD250-07	2.37 x 10 ⁵	M41L, D67N, T69D, K70R, V75M, V118I, M184V, Y188L, T215Y, K219Q	L10I/V, K20R, L24I, L33F, M36I, M46L, 154V, L63P, A71V, V82T, 184V
PRD250-08	<50*	K103N, Q181L, M184V, T215S	M36I, L63P, L90M
PRD250-09	6.40 x 10 ^{1*}	M41L, D67N, K70R, L74V, A98G, V118I, M184V, Y188L, T215F, K219Q	L10F, M36I, M46I, 154V, L63P, A71V, 184V, L90M
PRD250-10	3.14 x 10 ⁵	M41L, D67N, L74V, L100I, K103N, M184V, L210W, T215Y	L63P
Run Date:	09-Mar-09, 10-Mar-09, 12-Mar-09	1-Dec-03	1-Dec-03
Kit Lot #:	F04314	NA	NA
Exp. Date:	31-May-09	NA	NA
Product #:	21118560018	NA	NA

BIOHAZARD CAUTION: Potentially infectious materials. Follow Universal Precautions.

* HIV-1 RNA results generated using the Roche Amplicor Monitor v 1.5 Ultra method

For research use only. Not for use in diagnostic procedures. Data are offered for informational purposes. SeraCare Life Sciences does not claim that others can duplicate test results exactly. Test results were generated using assays commercially available in the U.S., performed at SeraCare Life Sciences and at internationally recognized referee laboratories (RL). Viral load results are means of duplicates expressed as copies per milliliter ratios (c/mL). Specimens are undiluted aliquots. No preservatives were added.