



Amplichek™ I

Molecular control for independent assessment of viral load assays

Guidelines call for independent controls because instrument manufacturer controls are less sensitive to slight changes in device performance and could fail to detect analytical error, resulting in the reporting of inaccurate data.

Amplichek™ I does not replace instrument manufacturer controls. It adds an independent assessment of your HIV-1, HBV and HCV nucleic acid testing results that can help mitigate the limitations of instrument manufacturer controls, giving you greater confidence in your test results. Unlike controls optimized for specific systems, this independent control from Bio-Rad can help reduce risk of reporting inaccurate results by:

- Monitoring the performance of the complete analytical process
- Detecting assay reagent lot-to-lot variation
- Providing access to the Unity™ QC Data Management Solutions, enabling labs to manage QC data and compare their results with peers in real time

Guideline

“ . . . Quality control materials should be different from the calibrator materials to ensure that the QC procedure provides an independent assessment of the measurement procedure’s performance in its entirety, including the procedure for calibration of the measurement.”

**CLSI Guidance Document
C24-A3, Statistical Quality Control for
Quantitative Measurement Procedures:
Principles and Definitions; Approved
Guideline**

Amplichek™ I

A multi-analyte control for HIV-1, HBV and HCV viral load assays with multiple levels: negative, high positive, and two low positive levels (targeted for either Roche or Abbott platforms). Amplichek™ I is the first assayed control that provides values (means and ranges) on these major platforms. This product is not intended for use with blood donor screening assays in the U.S. or Canada.



- Liquid, human plasma matrix—similar to patient samples
- 12 month shelf life at -20° to -70°C
- 7 day open vial stability at 2-8°C or three vial entries, whichever comes first
- Contains inactivated viral particles to control all analytical steps—provides increased safety and reproduces the steps involved in the analytical process, including nucleic acid extraction

Analytes

Hepatitis B Virus (HBV)
Hepatitis C Virus (HCV)
Human Immunodeficiency Virus Type 1 (HIV-1)

Refer to myinserts.com or the package insert of currently available lots for specific analyte and stability claims.

Ordering Information

Cat # Description

Amplichek™ I

12000527	Negative	10 x 1.2 mL
12000528	Level 1	10 x 1.2 mL
12000529	Level 2	10 x 1.2 mL
12000530	Level 3	10 x 1.2 mL
12000531	4 Level MiniPak (one of each level)	.4 x 1.2 mL

Product Level Selection Chart

Manufacturer / Assay(s)	Level	Negative	Level 1 (Low Positive)	Level 2 (Low Positive)	Level 3 (High Positive)
Roche					
COBAS® AmpliPrep / COBAS TaqMan® HBV Test v2.0		●	●		●
COBAS® AmpliPrep / COBAS TaqMan® HCV Test		●	●		●
COBAS® AmpliPrep / COBAS® TaqMan® HIV-1 Test v2.0		●	●		●
Abbott Diagnostics					
m2000 RealTime HBV		●		●	●
m2000 RealTime HCV		●		●	●
m2000 RealTime HIV-1		●		●	●

See package insert for assay values for each platform.

BIO-RAD

**Bio-Rad
Laboratories, Inc.**

**For further information, please contact the Bio-Rad office nearest you
or visit our website at www.bio-rad.com/molecularcontrols**

Clinical
Diagnostics Group

Web site www.bio-rad.com/qualitycontrol **USA** 1 800 224 6723 **Australia** 61 2 9914 2800 **Austria** 43 1 877 8901 **Belgium** 32 03 710 53 00
Brazil 55 31 3689 6600 **Canada** 1 514 334 4372 **China** 86 21 61698500 **Czech Republic** 420 241 430 532 **Denmark** 45 4452 1000 **Finland** 358 9 804 22 00
France 33 1 47 95 60 00 **Germany** 49 0 89 318 840 **Greece** 30 210 7774396 **Hong Kong** 852 2789 3300 **Hungary** 36 1 459 6100 **India** 1800 180 1224
Israel 972 3 9636050 **Italy** 39 02 216091 **Japan** 81 3 6361 7070 **Korea** 82 2 3473 4460 **Mexico** 52 55 5488 7670 **The Netherlands** 31 318 540666
New Zealand 64 9 415 2280 **Norway** 47 23 38 41 30 **Poland** 48 22 3319999 **Portugal** 351 21 472-7700 **Russia** 7 495 721 1404 **Singapore** 65 6415 3170
South Africa 27 11 442 85 08 **Spain** 34 91 590 5200 **Sweden** 46 8 555 127 00 **Switzerland** 41 0 26 674 55 05 06 **Taiwan** 886 2 2578 7189
Thailand 662 651 8311 **United Kingdom** 44 0 20 8328 2000