



## Amplichek™ II

An all-in-one quality control for Healthcare Associated Infection (HAI) molecular tests.

Amplichek™ II is a multi-analyte quality control designed to monitor the performance of *in vitro* nucleic acid test systems for HAI. This consolidated control can be used with test kits that detect nucleic acids in stool, swab or blood culture samples.

- Liquid, compatible with assay sampling tools, such as swabs and transfer pipets
- 2 year shelf life at 2-8°C
- Single use
- Contains inactivated bacteria to control both extraction and amplification steps

### Amplichek™ II provides a convenient means to meet accreditation requirements:

“ . . .Daily quality control must be run as follows: Qualitative tests, a positive and negative control at least daily. . . If an internal quality control process is used instead of an external control material to meet daily quality control requirements, the laboratory must have an individualized quality control plan (IQCP). . . ”

College of American Pathologists, Microbiology Checklist, CAP Accreditation Program, July 28, 2015, MIC.63262, Daily QC – Molecular Based Testing

- Reactive
- Non-reactive

Analytes

Level	Negative* (Non-reactive)	Level 1 (MSSA)	Level 2 (Low Positive)	Level 3 (High Positive)
<b><i>Clostridium difficile</i> (C diff.)</b> genes: Toxin B, Binary Toxin, TcdC	●	●	●	●
<b>Vancomycin Resistant <i>enterococci</i> (VRE or vanR)</b> genes: vanA, vanB**	●	●	●	●
<b>Methicillin Resistant <i>Staphylococcus aureus</i> (MRSA)</b> genes: SPA, SCCmec, mecA	●	●	●	●
<b>Methicillin Sensitive <i>Staphylococcus aureus</i> (MSSA)</b> gene: SPA	●	●		

\*Contains Methicillin Sensitive *Staphylococcus epidermidis* (MSSE).

\*\*Not available in the USA.

Refer to [myinserts.com](http://myinserts.com) or the package insert of currently available lots for specific analyte and stability claims.



## Amplichek™ II Product Level Selection Chart

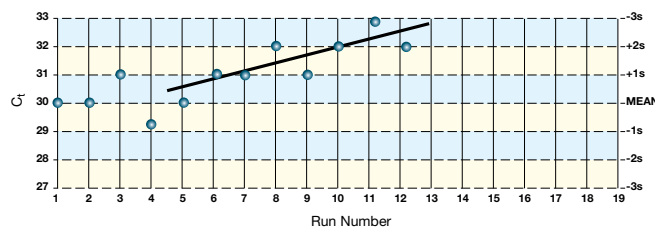
- Recommended positive levels    ● Recommended negative levels
- Compatible positive levels      ○ Compatible negative levels

Manufacturer/Assay(s)	Level	Negative	Level 1 (MSSA)	Level 2 (Low Positive)	Level 3 (High Positive)
<b>Cepheid®</b>					
Xpert® MRSA		●	○	●	○
Xpert® SA Nasal Complete		●	●	●	○
Xpert® MRSA/SA Blood Culture		●	●	●	○
Xpert® MRSA/SA SSTI		●	●	●	○
Xpert® C. difficile		●	○	●	○
Xpert® C. difficile/Epi		●	○	●	○
Xpert® van/A		●	○	●	○

*If your assay is not listed, please contact your nearest Bio-Rad office for current information.*

## Use C<sub>t</sub> value to monitor assay performance

Statistics-based quality control is the best way to monitor assay performance. In real-time PCR a positive reaction is identified by buildup of a fluorescent signal. The cycle threshold (C<sub>t</sub>) is defined as the number of cycles required for the reaction's fluorescence to exceed background levels



*The upward trending of the control's C<sub>t</sub> value may indicate a decreasing PCR efficiency (not actual data).*

and cross the threshold. C<sub>t</sub> levels are inversely proportional to the concentration of the specific nucleic acid in the sample that is being measured. A lower C<sub>t</sub> value indicates a greater concentration of the measured analyte in the sample. A shift in the C<sub>t</sub> value may signal a performance issue before it affects patient results.

Even though most HAI assays are qualitative, a C<sub>t</sub> value or other semi-qualitative measurement may be provided for each detected gene. These values can be reported in the Unity™ Interlaboratory Program for peer group comparison. The C<sub>t</sub> values can also be used with other Unity™ QC tools like Levey-Jennings charts and Westgard rules to monitor any trends or shifts over time.

## Ordering Information

Cat #	Description	Cat #	Description
<b>Amplichek™ II</b>			
12000201	Negative . . . . . 10 x 0.2 mL	12000575	Negative MiniPak . . . . . 1 x 0.2 mL
12000202	Level 1 . . . . . 10 x 0.2 mL	12000576	Level 1 MiniPak . . . . . 1 x 0.2 mL
12000203	Level 2 . . . . . 10 x 0.2 mL	12000577	Level 2 MiniPak . . . . . 1 x 0.2 mL
12000204	Level 3 . . . . . 10 x 0.2 mL	12000578	Level 3 MiniPak . . . . . 1 x 0.2 mL



**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](http://www.bio-rad.com/molecularcontrols)*

Clinical  
Diagnostics Group

**Web site** [www.bio-rad.com/qualitycontrol](http://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