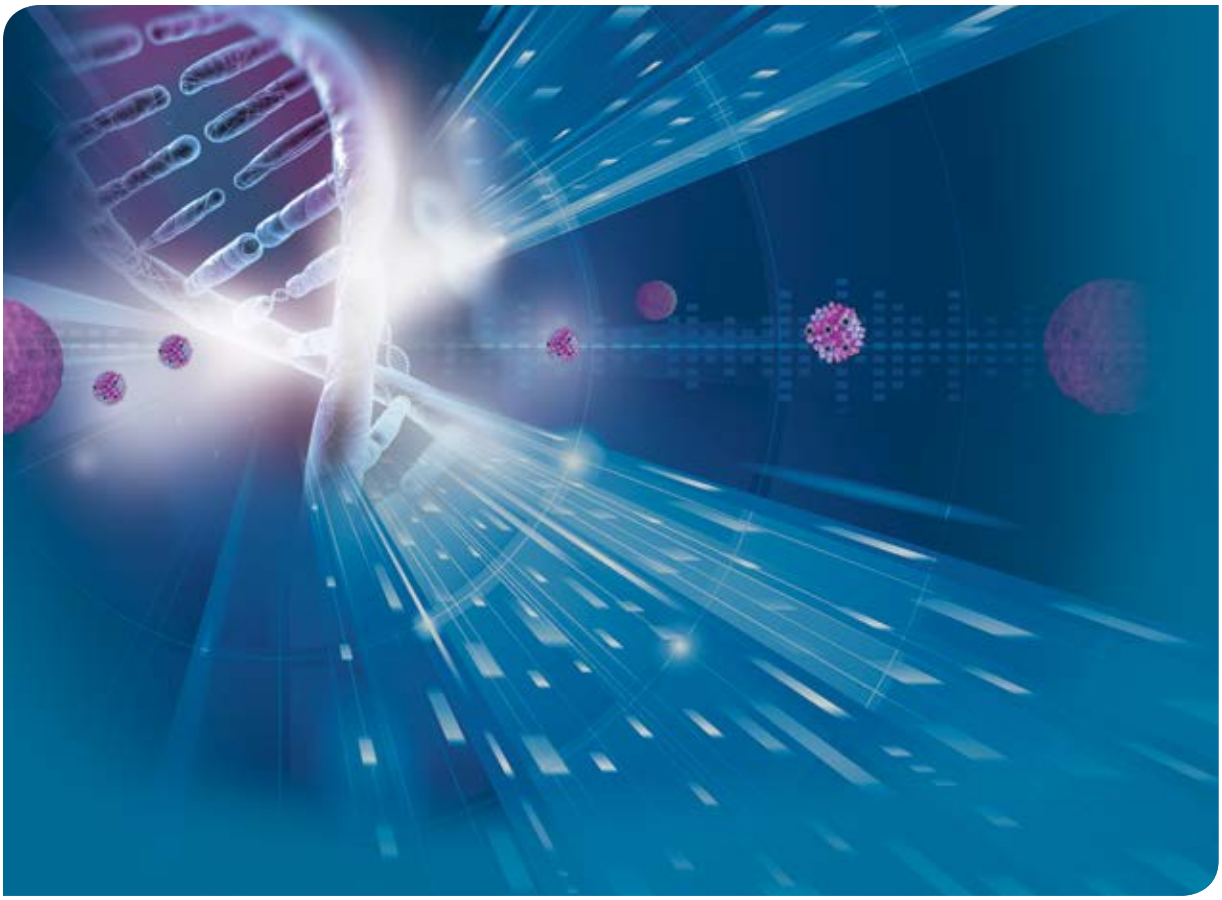


Amplichek Molecular Quality Controls

For Infectious Disease Nucleic Acid Testing

BIO-RAD

Providing molecular laboratories with a reliable quality control source

Advances in Molecular Diagnostic Testing, including testing for infectious disease, have been at the forefront of ***in vitro*** diagnostics in recent years. The use of Nucleic Acid Tests in clinical medicine has become more established, and molecular test systems are being integrated into laboratories worldwide.

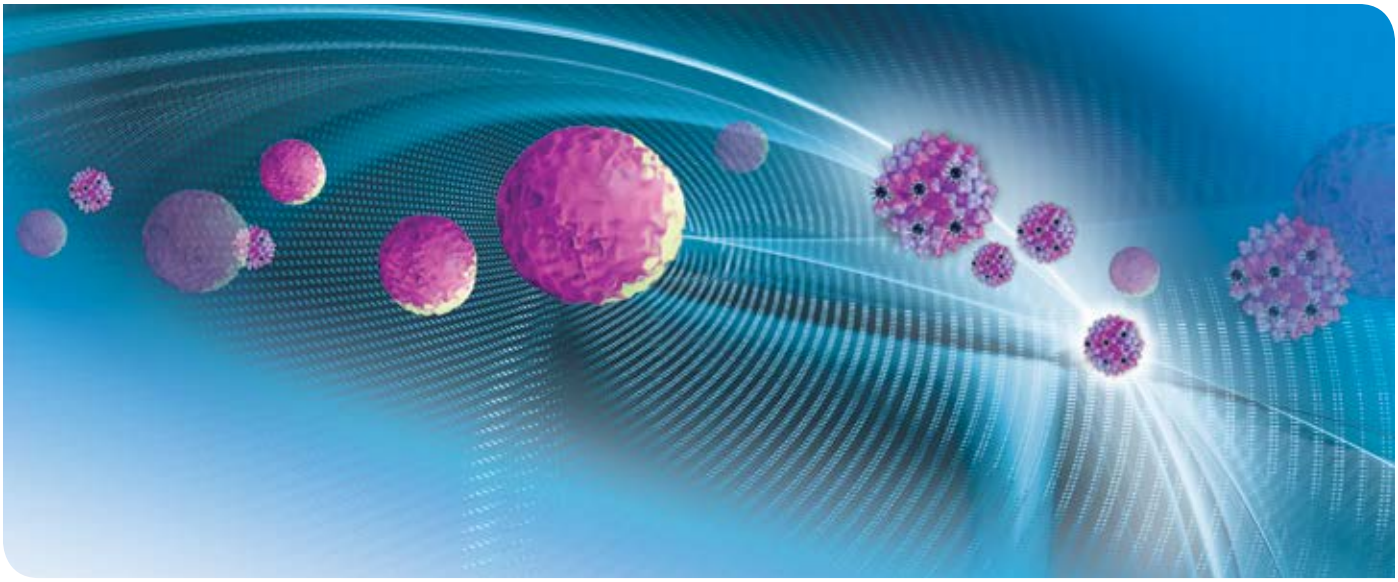
As a result, quality standards in the molecular laboratory are becoming more stringent, and there's constant pressure on laboratories to maintain compliance. The highly sensitive nature of Nucleic Acid tests makes robust quality control processes critical.

Contamination errors at any stage, particularly pre-amplification, can adversely affect patient results.

Drive analytical laboratory performance forward for your molecular QC processes by using Amplichek controls to help reduce errors and ensure reliability of test results.

Did You Know. . .

ISO 15189 suggests that the use of independent third party control materials should be considered, either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer.



Introduce your lab to an unbiased independent assessment

While many molecular test manufacturers provide their own assay specific quality control material, molecular labs are often left without an independent assessment of their test processes. A lack of standardized quality control processes has resulted in additional time constraints and labor intensive requirements for labs. The use of patient samples and laboratory developed controls can result in inconsistent testing protocols. Independent quality controls can enhance your laboratory's performance by providing an unbiased, independent assessment of your molecular testing processes.

Independent quality controls

- Manage risk more effectively with controls that are manufactured independently from calibrators and reagent materials
- Ensure quality patient results by monitoring the analytical process step-by-step to improve performance of extraction, amplification and detection
- Increase confidence in patient results by effectively monitoring lot-to-lot consistency when compared to assay manufacturer or laboratory developed controls
- Provide Unity peer group comparisons for greater confidence in patient test results

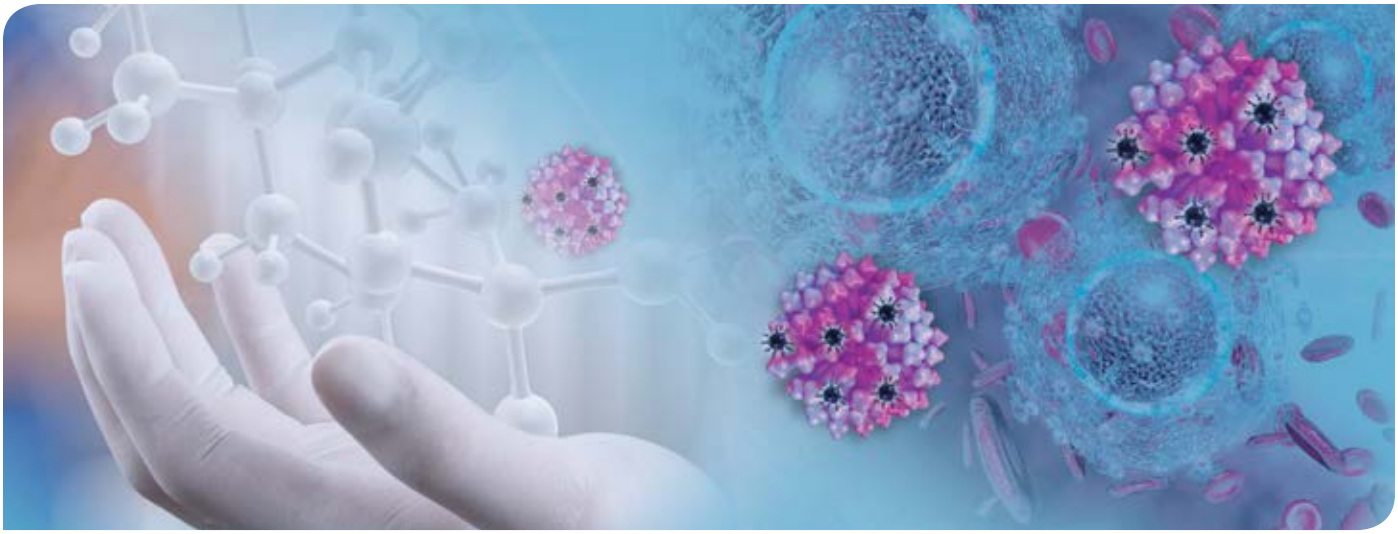
The limitations of other quality controls

- May use synthetic materials such as plasmid or Armored RNA that are different from intact pathogens in patient samples
- Do not provide an unbiased independent assessment
- Lot-to-lot variation may not be detected

Other Quality Control Options

Internal Controls	Laboratory Developed Controls	RUO – Research Use Only Controls
▪ May not monitor extraction or pathogen specific amplification steps ▪ Do not monitor analyte specific reagent functionality (primers, probe etc.)	▪ May vary in quality, reproducibility and reliability ▪ Labor intensive process to source, test, and assay	▪ Require additional validation before use

Bio-Rad's growing portfolio of molecular quality control products makes it easy to meet risk reduction goals by enabling labs to use the best QC practices and advanced data management tools.



Viral Load Assasys

Amplichek I

Multi-analyte control for independent assessment of viral load assays

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 occurs 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

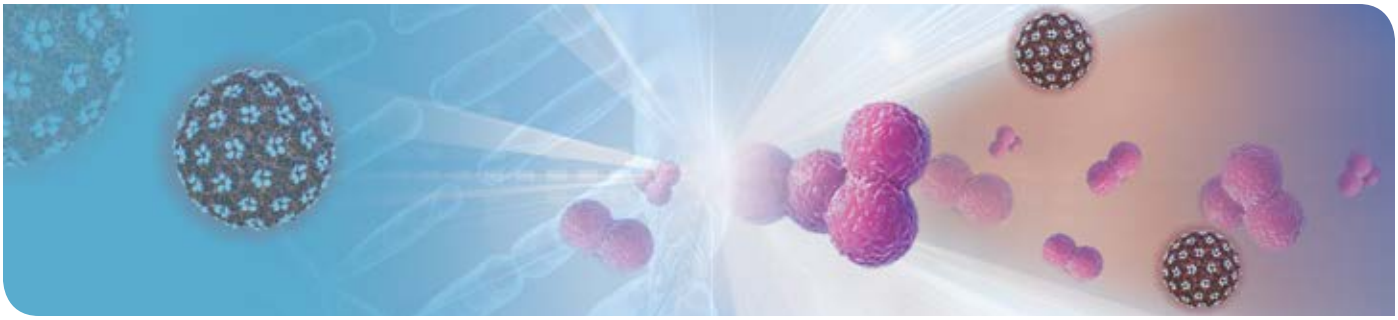
Hepatitis B Virus (HBV)
Hepatitis C Virus (HCV)
Human Immunodeficiency Virus Type 1 (HIV-1)

Product Level Selection Chart

Level / Manufacturer/Assay(s)	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				
*m*2000 RealTime HBV	●		●	●
*m*2000 RealTime HCV	●		●	●
*m*2000 RealTime HIV-1	●		●	●

See package insert for assay values for each platform.

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



Healthcare Associated Infections

Amplichek II

A multi-analyte quality control for Healthcare Associated Infections (HAI) molecular tests

Amplichek II is designed to monitor the performance of *in vitro* molecular test systems for Methicillin Resistant *Staphylococcus aureus* (MRSA), Methicillin Sensitive *Staphylococcus aureus* (MSSA), *Clostridium difficile (C diff.)*, and Vancomycin-resistant *enterococci* (VRE, or vanR). This multi-analyte quality control with four levels and multiple target genes can be used as a control for detection in stool, swab or blood culture samples.

- Liquid, aqueous samples
- 2 year shelf life at 2-8ºC
- Single use, reduces contamination
- Contains inactivated bacteria to control both extraction and amplification steps

Analytes

● Reactive
● Non-reactive

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

*Contains Methicillin Sensitive *Staphylococcus epidermidis* (MSSE).
**Not available in the USA.

Amplichek II Product Level Selection Chart

● Recommended positive levels
❍ Compatible positive levels
● Recommended negative levels
❍ Compatible negative levels

Level / Manufacturer/Assay(s)	Negative	Level 1 (MSSA)	Level 2 (Low Positive)	Level 3 (High Positive)
Cepheid®				
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.

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

Sexually Transmitted Infections

Amplichek STI

Multi-analyte molecular control for sexually transmitted infections (STI)

Amplichek STI is a multi-analyte, unassayed quality control for use with nucleic acid testing procedures used for detection of the most commonly tested pathogens responsible for sexually transmitted infections. This control provides an independent assessment by monitoring the analytical process including nucleic acid extraction, amplification and detection.

- Liquid format provides ease of use
- 2 year shelf life at -20° to -70°C
- Single use packaging reduces risk of contamination
- Provides an independent assessment
- Positive level prepared from inactivated, intact bacteria and human cell lines containing high risk HPV genotypes 16, 18 and 68
- Negative level contains HPV negative human cell lines required for compatibility with some STI assays

Analytes

Chlamydia trachomatis (CT)
Neisseria gonorrhoeae (NG or GC)
Human Papillomavirus (HPV)

Popular STI Assays

BD ProbeTec™ ET System and Viper™ System

- CT/GC Amplified DNA Assays

Hologic (Gen-Probe) Analyzers (Tigris, Panther, DTS)

- Aptima® Combo 2
- Aptima® NG Assay
- Aptima® CT Assay
- Aptima® HR HPV Assay
- Aptima® HPV 16 18/45 Genotype Assay

Roche TaqMan® 4800 System

- COBAS® 4800 CT/NG Test
- COBAS® 4800 HPV Test

Abbott *m*2000

- RealTi*m*e CT/NG Assay
- RealTi*m*e High Risk HPV Assay

Cepheid

- Xpert® CT/NG Assay
- Xpert® HPV Assay

Not all assays or systems are available in all countries. Each laboratory should verify Amplichek STI performance prior to use.

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

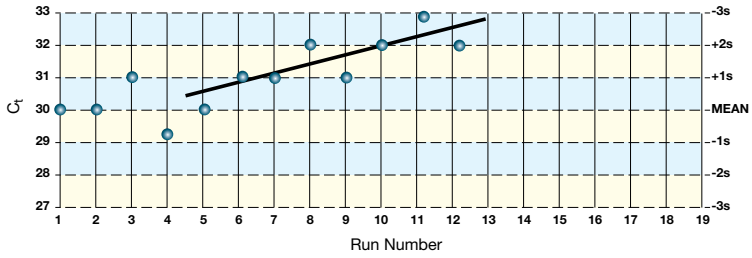
Unity Data Management

Molecular controls, like all Bio-Rad quality controls, are supported by the Unity Interlaboratory Program. Consolidate your entire laboratory into one QC system with industry-leading features for benchmarking laboratory performance.

- Simplify quality data interpretation and analysis
- Anticipate quality performance trends before patients are affected by monitoring underlying quantitative data
- Compare results with peer groups in real time
- Demonstrate compliance easily with graphical reporting

Analyze Quantitative Data

Unity can be utilized for monitoring quantitative values and is an excellent fit for viral load assays. Qualitative assays used for health care associated or sexually transmitted infections can also be tracked. Additionally, many of these assays report underlying quantitative C_t or other numeric values which can also be effectively monitored.



The upward trending of the control's C_t value may indicate a decreasing PCR efficiency (not actual data).

Bio-Rad Quality Controls are part of the Unity Program with its industry-leading features for benchmarking laboratory performance.

- Facilitate compliance with simple tools to review rule violations and document corrective actions
- Define your own quality requirements and track key quality performance indicators
- Facilitate run-time decisions with optimized Westgard rules
- Utilize real-time access to peer group comparisons to help with troubleshooting

You can consolidate your entire laboratory into one QC system through our Unity Program. This sophisticated software includes best-in-class tools to support releasing results, benchmarking laboratory performance, and designing your QC system.

Ordering Information

Catalog #	Description
Amplichek STI	
12000991	Negative . . . . . 10 x 0.2 mL
12000992	Positive . . . . . 10 x 0.2 mL
12000993	Negative MiniPak . . . . . 1 x 0.2 mL
12000994	Positive MiniPak . . . . . 1 x 0.2 mL
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

Catalog #	Description
Amplichek II	
12000201	Negative . . . . . 10 x 0.2 mL
12000202	Level 1 . . . . . 10 x 0.2 mL
12000203	Level 2 . . . . . 10 x 0.2 mL
12000204	Level 3 . . . . . 10 x 0.2 mL
12000575	Negative MiniPak . . . . . 1 x 0.2 mL
12000576	Level 1 MiniPak . . . . . 1 x 0.2 mL
12000577	Level 2 MiniPak . . . . . 1 x 0.2 mL
12000578	Level 3 MiniPak . . . . . 1 x 0.2 mL

Learn more about Bio-Rad Molecular Quality Control Products by visiting wwww.qcnet.com/molecular

EQAS
An independent, external assessment of performance in comparison to your peers.

Independent QC
Ongoing, proactive, unbiased daily QC that helps identify errors as they occur or begin to trend.

Unity
QC Data Management tools that help you create a strategy to reduce risk and streamline QC workflow.

BIO-RAD

Bio-Rad Laboratories, Inc.

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*

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