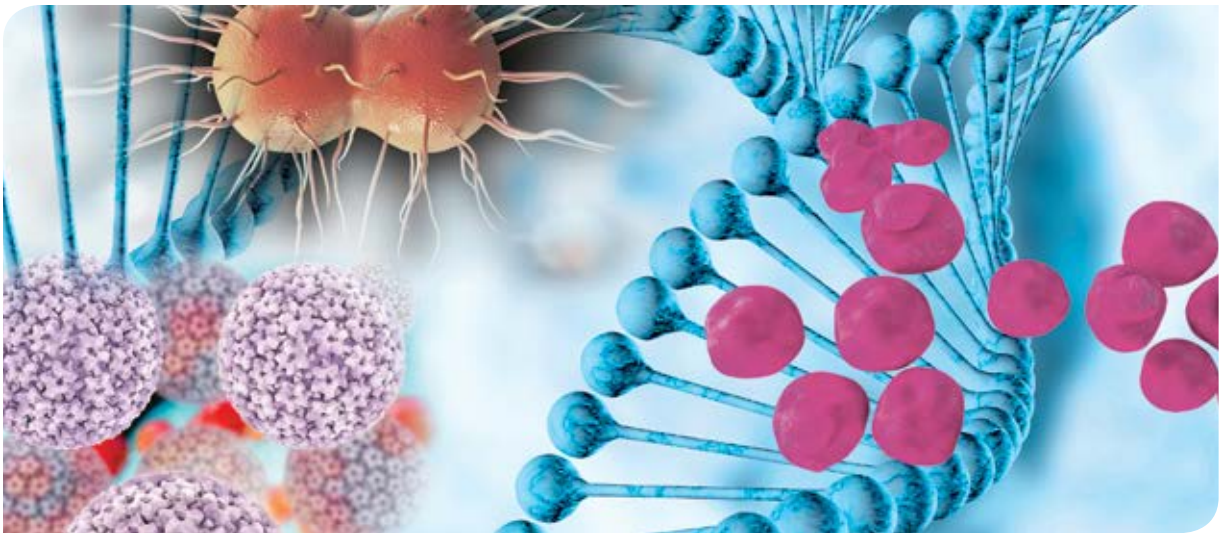


Amplichek STI

Quality Control for an independent assessment of sexually transmitted infections (STI)

Amplichek STI is a multi-analyte, unassayed quality control for use with nucleic acid testing procedures used to detect the most commonly tested pathogens responsible for sexually transmitted infections, including *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG or GC) and high risk strains of Human Papillomavirus (HPV). This control provides an independent assessment by monitoring the analytical process including nucleic acid extraction, amplification and detection.

Amplichek STI can be used to monitor many popular assays and specimen types including urine, urogenital swabs and liquid Pap samples.

- Liquid format provides ease of use
- 2 year shelf life at -20ºC to -70ºC
- 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

Not intended to replace any controls or calibrators required by assay kit manufacturers

Popular STI Assays

BD ProbeTec™ ET System and Viper™ System

- CT/GC Amplified DNA Assays

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

- 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*me* CT/NG Assay
- RealTi*me* 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 before use.

BIO-RAD

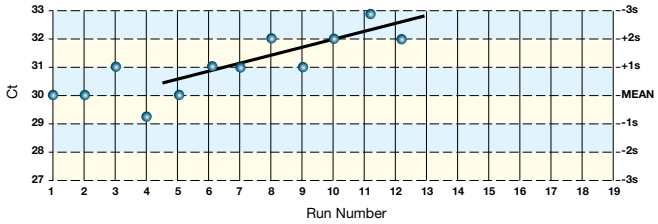
Analytes

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

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

Use C_t values to monitor assay performance

Statistics-based quality control is an excellent way to monitor assay performance. Although most STI tests yield qualitative results, some of the assay methods also report an underlying quantitative value. This is especially true for qPCR methods where a Ct (cycle threshold) value may be provided for each nucleic acid target monitored.



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

The cycle threshold (C_t) is defined as the number of cycles required for the reaction's fluorescence to exceed background levels and cross the threshold. C_t levels are inversely proportional to the concentration of the specific nucleic acid target in the sample that is being measured. A lower C_t value indicates a greater concentration of the measured analyte in the sample. A shift in the C_t value may signal a performance issue before it affects patient results.

These underlying quantitative values can be reported in the Unity Interlaboratory Program for peer group comparison. The C_t 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	
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

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

Clinical Diagnostics Group

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