

Molecular Diagnostics

DNA/RNA Positive Controls



Control templates for molecular DNA/RNA diagnostics

As the number and scope of disease-producing pathogens and their genetic variants that cause human disease have continued to increase, there has been a commensurate and rapid increase in the use of nucleic acid based tests for routine clinical diagnosis. Due to the complex nature of nucleic acids, these molecular tests must be fully controlled to accurately ascertain their specificity and sensitivity. However, the success of molecular diagnostics is often impeded by the availability of DNA- or RNA-based positive controls with the same or similar number of mutations as the organism being screened for in the scenario of a pandemic or newly emerging disease, where it can be difficult to acquire necessary positive controls.

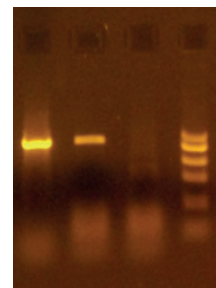
As Good Laboratory Practices, government agencies, and standards organizations require diagnostic laboratories to use stringent quality controls (QCs) guidelines that include **calibrating equipment against control samples and performing tests of patient samples in tandem with consistent references**, it is critical that reference samples be used in a manner that provides comprehensive evaluation of every component in these highly complex procedures and reagent mixtures. The need for these controls and/or standards became particularly acute with the widespread use of high complexity and high volume DNA- or RNA-based real time testing platforms.

Bio-Synthesis provides molecular assay services, focused on the **design and development of nucleic acid-based, positive control templates (PCT)** to monitor the molecular diagnostic testing process, including the extraction, amplification, and detection components of test systems used to measure disease producing organisms. We provide thousands of **PCTs** to genotype high value polymorphisms for various drug metabolism and transporter genes. These PCTs can be manufactured in our cutting edge molecular diagnostic facilities and significantly shorten your path from RESEARCH to RESULT by providing you with the full development process for control templates that may be used as standard references in the simultaneous detection of mutations in any genome. These laboratory-safe, synthetic or semi-synthetic **DNA/RNA Positive Controls** can be a relatively cost effective, simple and efficient alternative to difficult-to-acquire controls from infectious samples.

Our contract services are confidential, fast, efficient and well-documented, with objective to support the improvement of analysis and control of human infectious diseases by providing high quality evaluation materials to aid in the advancement of nucleic acid technologies.

Advantages:

- **Select Platform:** DNA/RNA control templates, length >1000 bp
- **Technology Friendly:** Suitable for Real-Time PCR, qPCR, microarray...
- **Laboratory-Safe:** Non-infectious, laboratory-safe synthetic controls
- **Accurate and Reliable:** Reproducible results - known input copy number
- **Well-Documented:** Well-characterized sequence to assure maximum fidelity
- **Customized Solutions:** Optimized preparation for specific applications



Lane 1: Unknown Sample gDNA
Lane 2: Positive Control (HPV-16 vDNA)
Lane 3: Negative Control (Normal Human gDNA)
Lane 4: Bio-Marker B (Bio-Synthesis, inc.)

BSI's **On-demand HPV and HLA controls** can be used as positive controls in nucleic acid amplification reactions. These quantitative controls can also be used to generate standard curves for qPCR assays.

HPV Controls

14 High Risk HPV Controls
16, 18, 31, 33, 35, 39, 45, 51, 52,
56, 58, 59, 68, 69

HLA Controls

Genomic / Synthetic DNA controls:

- Class I (A,B,C)
- Class II (DRB, DQ, DP) alleles

Your Source of Quality DNA/RNA Controls



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