HSC.35292 Loading Analytical Gels **Phase II**

Standard amounts of nucleic acid are loaded on analytical gels, when possible.

HSC.35479 Gel Images **Phase II**

Gel images are of sufficient resolution and quality (low background, clear signal, absence of bubbles, etc.) to permit the reported interpretation.

HSC.35666 Specimen Handling **Phase II**

The laboratory uses appropriate processes to prevent specimen loss, alteration, or contamination.

HSC.36040 Carryover - Enzymatic Amplification **Phase II**

Enzymatic amplification procedures (eg, PCR) use appropriate physical containment and procedural controls to minimize carryover (false positive results).

NOTE: This item is primarily directed at ensuring adequate physical separation of pre- and post-amplification samples to avoid amplicon contamination. The extreme sensitivity of amplification systems requires that the laboratory take special precautions. For example, pre- and post-amplification samples should be manipulated in physically separate areas; gloves must be worn and frequently changed during processing; dedicated pipettes (positive displacement type or with aerosol barrier tips) must be used; manipulations must minimize aerosolization; following complete reagent addition to the reaction tubes, the patient samples should be added one at a time. The best way to avoid cross-contamination is to use the following order of preparation within an amplification run: actual samples, followed by positive controls, followed by negative controls.

REFERENCES
1) Kwok S, Higuchi R. Avoiding false positives with PCR. *Nature* 1989;339:237-238
2) Clinical and Laboratory Standards Institute. *Establishing Molecular Testing in Clinical Laboratory Environments; Approved Guideline.* CLSI document MM19-A. Clinical and Laboratory Standards Institute, Wayne, PA; 2011.

HSC.36414 Electrophoretic Gel Interpretation **Phase II**

Electrophoretic gels are interpreted independently by at least two qualified readers using an objective method.

Evidence of Compliance:
- ✓ Patient testing records or worksheets

HSC.36601 End-Point Amplification QC **Phase II**

For end-point amplification assays such as sequence-specific priming, adequate internal controls are used, and criteria defined for a positive reaction.

HSC.36788 Daily Controls **Phase II**

For qualitative and quantitative tests, positive and negative controls are included for each assay, where appropriate, in every run, and as specified in the manufacturer's instructions (as applicable) and laboratory procedure.

Evidence of Compliance:
- ✓ Records of QC results, including external and internal control processes **AND**
- ✓ Manufacturer's product insert or manual, as applicable