

REFERENCES

- 1) Clinical and Laboratory Standards Institute (CLSI). *Establishing Molecular Testing in Clinical Laboratory Environments; Approved Guideline*. CLSI document MM19-A. Clinical and Laboratory Standards Institute, Wayne, PA; 2011.
- 2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR1256(d)(3)(i) and (ii)].

HSC.36795 Internal Controls - Nucleic Acid Amplification**Phase II**

In nucleic acid amplification procedures, internal controls are run to detect a false negative reaction secondary to extraction failure or the presence of an inhibitor, when appropriate.

NOTE: The laboratory should be able to distinguish a true negative result from a false negative due to failure of extraction or amplification. Demonstration that another sequence can be successfully amplified in the same specimen should be sufficient to resolve this issue. For quantitative amplification assays, the effect of partial inhibition must also be addressed.

The internal control should not be smaller than the target amplicon.

Evidence of Compliance:

- ✓ Records of assay validation and monitoring statistics for test result trends

REFERENCES

- 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1256(d)(3)(iv)(v)].

HSC.36975 DNA Contamination**Phase II**

There is a process to detect and control for DNA contamination.

NOTE: Contamination must be monitored in different areas by wipe tests using the regular detection for testing. There are records of the results of monitoring and corrective action taken when contamination is detected.

HSC.37162 Molecular Weight Markers**Phase II**

Known molecular weight markers that span the range of expected bands are used for each electrophoretic run.

Evidence of Compliance:

- ✓ Records of appropriate markers with each run

HSC.37349 Amplification Quality**Phase II**

For hybridization techniques, there are records that the different components and steps are monitored and acceptable, including the amount and integrity of amplified product and the signal intensity produced by each probe.

REFERENCES

- 1) Clark JR, Scott SD, Jack AL, et al. Monitoring of chimerism following allogeneic haematopoietic stem cell transplantation (HSCT): Technical recommendations for the use of short tandem repeat (STR) based techniques, on behalf of the United Kingdom National External Quality Assessment Service for Leucocyte Immunophenotyping Chimerism Working Group. *Br J Haematol*. 2015;168(1):26-37.

HSC.37536 Pre-Analytic Testing Requirements**Phase II**

The conditions (temperature, salt concentration, probe concentration, etc.) for pre-hybridization, hybridization, and solid-phase support systems are optimized to consistently produce accurate results.

HSC.37723 Probe Labeling Validation**Phase II**