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4) Clinical and Laboratory Standards Institute. *Establishing Molecular Testing in Clinical Laboratory Environments*: CLSI Document MM19-A. Clinical and Laboratory Standards Institute, Wayne, PA; 2011.
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CYG.49535 Nucleic Acid Quantity and Quality Determination — Phase II

The quantity and quality of nucleic acids are determined, when appropriate.

NOTE: The quantity and quality of nucleic acids (DNA or RNA) must be measured prior to use in a procedure whose success depends on accurately determining the quantity, concentration, integrity, and/or purity of the nucleic acids. Techniques commonly used to assess nucleic acid quantity and/or quality include electrophoresis, UV/VIS spectrophotometry, and fluorescence spectroscopy.

Evidence of Compliance:

- ✓ Records of nucleic acid quantity and/or quality determination

REFERENCES

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CYG.49540 Extracted Nucleic Acid Specimens — Phase II

If extracted nucleic acid is accepted as a specimen type, the laboratory ensures that isolation of nucleic acids for clinical testing occurs in a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by the CAP and/or the CMS. This policy is clearly displayed to ordering clients.

NOTE: All clinical testing must be performed in CLIA-certified laboratories or laboratories meeting equivalent requirements (refer to GEN.41350). This includes all components of testing that may impact the quality of the test result, including isolation or extraction of nucleic acids. Laboratories may choose to have referring clients formally attest that extracted nucleic acid submitted for testing has been isolated or extracted in an appropriately qualified laboratory.

Evidence of Compliance:

- ✓ Written statement on the test requisition, test catalog, or policy available to referring clients stating that the laboratory only accepts isolated or extracted nucleic acids for which extraction or isolation is performed in an appropriately qualified laboratory

CYG.49545 Validation Studies for DNA-Based Copy Number Array - Specimen Types — Phase II

Validation studies for DNA-based copy number arrays are performed for each specimen type that can be affected by different preanalytic variables, that requires different processes for DNA extraction, and for those specimens with potentially interfering substances (eg, FFPE tissue, decalcified tissue, tissue containing melanin or mucin).

NOTE: A number of preanalytic and analytic processing variables can significantly influence the quality and integrity of nucleic acids extracted from a specimen. Commonly tested tissue sources must be included in the validation, but it is not expected for the laboratory to include every tissue source that could be examined by the assay.

It is the responsibility of the laboratory director or designee meeting CAP director qualifications to determine when a separate validation is needed versus a limited study to demonstrate that the DNA obtained from the specimen performs the same. For example, an array platform that has