	• How is adequacy of nucleic acid isolation and preparation evaluated? How often is this done? • How does your laboratory ensure RNase-free conditions are maintained?
	• Follow a sample from extraction through storage

BAP.04500 Specimen Identification **Phase II**

There is a system to positively identify all participant specimens, specimen types, and aliquots through all phases of the analysis, including specimen receipt, nucleic acid extraction, nucleic acid quantification, hybridization, detection, preparation of records, and storage.

BAP.04525 Extracted Nucleic Acid Specimens **Phase II**

If extracted nucleic acid is accepted as a specimen type, the biorepository 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

BAP.04700 Nucleic Acid Extraction/Isolation/Purification **Phase II**

Nucleic acids are extracted, isolated, and purified by methods reported in the literature, by an established commercially available kit or instrument, or by a validated method developed by the laboratory.

NOTE: The method should be assessed for its suitability for each source type that requires extraction. Any modification to established procedures must be recorded, as well as variations to procedures depending on anatomic site and biospecimen preservation format (eg, fresh frozen vs. OCT-embedded). Extraction procedures may combine purification or isolation of nucleic acids according to the level of purity needed for downstream applications.

Evidence of Compliance:

✓ Records to support nucleic acid extraction/isolation/purification is performed by a validated method

REFERENCES

1) Clinical and Laboratory Standards Institute. *Establishing Molecular Testing in Clinical Laboratory Environments*: CLSI Document MM19-A. Clinical and Laboratory Standards Institute, Wayne, PA; 2011.
2) Clinical and Laboratory Standards Institute. *Genomic Copy Number Microarrays for Constitutional Genetic and Oncology Applications. 1st ed*. CLSI guideline MM21-ED1. Clinical and Laboratory Standards Institute, Wayne, PA, 2015.