BIOSPECIMEN PROCESSING AND QUALITY

BIOSPECIMEN QUALITY

The biorepository must have a written quality assessment process applicable to the scope of activities performed. This quality process should be capable of detecting, reducing and correcting any deviation from acceptable standards set by the biorepository. Examples may include enrollment in a proficiency testing program or using sets of testing control materials to check the biorepository samples over time.

The processing, embedding, and quality check for all biospecimens is critical to the overall quality and diversity of the sample inventory.

Inspector Instructions:

	• Sampling of policies and procedures for specimen processing including aliquoting, relabeling, and specimen retrieval • Sampling of records for the assessment of the quality of stored specimens • Specimen rejection criteria policy and records of rejection
	• Specimen processing area for clean environment • Aliquot sizes of specimens • Specimen identifiers • Specimen storage conditions during sample processing • Tracking of samples as they move from one station to another • Sampling of reagents (expiration date)
	• How does your biorepository maintain and track temperature excursion information? • Explain your quality assessment process for stored specimens • How is the risk of specimen misidentification monitored and the process improved? • What do you do if the sample size is too small relative to the requirements or it does not meet researchers' needs?
	• Follow a tissue sample released for research from the pathologist to storage, verifying specimen identification throughout the process • Select several specimens and follow their tracking throughout the life of the specimen, including from parent to child, etc.

BAP.01800 Quality Assessment of Stored Specimens **Phase II**

The biorepository periodically assesses the quality of stored specimens for each class of biospecimens in the biorepository.

NOTE: The frequency of the checks may be determined by the following:

1. *Type of specimens being stored*
2. *Preservation method*
3. *Turnover of the material*

The form and frequency for the periodic assessment is to be defined by the biorepository. The assessment may take a variety of forms including direct observation of materials, sampling, integrity of records, enrollment in proficiency testing, or other alternate performance assessment.

The quality of stored specimens may be assessed at the time of disbursement.

Evidence of Compliance:
- ✓ Records of inventory sampling **OR**
- ✓ Records of unsuitable specimens by collection, as applicable **OR**
- ✓ Records of inventory QA/QC processes **OR**
- ✓ Assessment from researchers using the specimens

BAP.01900 Aliquot Size **Phase II**

Aliquot sizes are appropriate for the intended use of the specimen.

NOTE: Freeze/thaw cycles may be deleterious to the macromolecules intended for analysis; therefore, it is important to provide some aliquots that have a suitable volume for single-use. Storage and cost logistics may require that some larger volume aliquots are maintained.

Evidence of Compliance:
- ✓ Records of sample size stated in protocols

BAP.02000 Temperature Excursions **Phase II**

Temperature excursions beyond recommended storage requirements are tracked during routine processing and distribution.

NOTE: The biorepository has all known relevant annotations on a given biospecimen that may be made available to the researcher.

BAP.02100 Clean Environment **Phase II**

Specimens are processed in a clean environment, when required.

*NOTE**:** RNA is particularly sensitive to RNases that may be present on tools and surfaces that have not been sterilized.*

BAP.02200 Biological Safety Cabinet **Phase II**

Aliquots are made using sterile pipettes within a biological safety cabinet, when required.

BAP.02300 Safe Handling of Specimens for Infectious Diseases **Phase II**

The biorepository follows a defined process for receipt and management of potentially infectious material that includes application of standard precautions.

NOTE: Elements of the procedure must include proper handling of specimens for biohazard protection. The procedure may include information about prior testing for infectious hazards.

REFERENCES
1) OSHA regulation 29CFR1910.1020.
2) Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline.* 4th ed. CLSI document M29-A4. Clinical and Laboratory Standards Institute, Wayne, PA; 2014.

BAP.02500 Histological Characteristic Review **Phase II**