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**

A qualified pathologist reviews all solid tissue specimens to determine the histological characteristics of the specimens that are submitted to the biorepository.

NOTE: Histologic review of banked solid tissue biospecimens is important for the following reasons: 1) the review of banked solid tissue biospecimens ensures that well-annotated, high quality biospecimens will be utilized in downstream testing; and 2) the review of banked solid tissue biospecimens may be used to confirm diagnostic findings. The timing of the pathologists' histologic review is at the discretion of the biorepository director. There may be situations where the sponsor of the collection or the user arranges for pathology review outside of the biorepository. This should be recorded by the biorepository.

BAP.02600 Specimen Identity **Phase II**

The identity of every specimen is maintained through each step of processing and slide preparation.

NOTE: An unambiguous system of unique specimen identification coupled with a legible, sequential container labeling system that withstands exposure to anticipated reagents and temperature extremes are essential to fulfill this requirement. Containers can be various shapes and sizes and constructed from multiple materials (plastic, glass, cardboard). It is important to ensure that the container is suitable for the type of specimen and how it will be used/stored.

BAP.02700 Misidentification Risk **Phase II**

The biorepository monitors the risk of misidentification and subjects the related processes to continual process improvement.

NOTE: The biorepository must actively monitor the key elements of all sample types throughout the entire process. The program may include, but is not limited to: 1) maintaining identification of nucleic acids and protein derivatives from a biospecimen, 2) QC and application of a barcode or other identifier, and 3) record of the number of sample derivatives prepared.

Evidence of Compliance:

- ✓ Occurrence records/error logs demonstrating appropriate review and follow-up of significant errors and patterns of errors in identification and other processes

BAP.02800 Unique Identifier **Phase II**

Each specimen received into the biorepository receives a unique identifier.

BAP.02900 Specimen Tracking Mechanism **Phase II**

The biorepository maintains and tracks the identity of every specimen throughout the life of the specimen and its derivatives (eg, parent to children to grandchildren, etc.).

NOTE: An effective tracking system must be in place to ensure that biospecimens can be tracked accurately from the collection site through biospecimen arrival, processing, storage, and subsequent shipment from the biorepository.

BAP.03000 Specimen Rejection Criteria **Phase II**

The biorepository follows defined criteria for specimen condition exceptions to be recorded and communicated to researchers regarding conditions that may impact research results.