

*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*. 4<sup>th</sup> ed. CLSI document M29-A4. Clinical and Laboratory Standards Institute, Wayne, PA; 2014.

**BAP.02500 Histological Characteristic Review**

**Phase II**