

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

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