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.

NOTE: This requirement is not intended to imply that all "unacceptable" specimens be discarded or not analyzed. For example, if an unacceptable specimen is received, there must be a mechanism to notify the requesting researcher, and to note the condition of the specimen on the report. For example, many semen specimens are sub-optimal; all specimens should be evaluated and unusual properties noted. The biorepository may wish to record that a dialogue was held with the requesting researcher.

BAP.03100 Relabeling **Phase II**

The biorepository has a defined process for relabeling of a biospecimen and/or aliquots.

NOTE: Circumstances under which relabeling may occur may include, but are not limited to: a) inadvertent duplication of ID from internal or external sources; b) full de-identification; c) replacement of a label (eg, original label has fallen off).

Evidence of Compliance:
- ✓ Records, including reason for relabeling

BAP.03700 Retrieval Procedures **Phase II**

All specimen retrieval procedures ensure specimen integrity.

NOTE: The integrity of the biospecimen must be maintained throughout the retrieval process.

BAP.03800 Paraffin Embedding and/or Fixation QC **Phase II**

The biorepository has a process for paraffin embedding and/or fixation that includes quality checks at a defined frequency (eg, 24 hours/48 hours).

NOTE: This requirement applies only to biorepositories that perform their own fixation and embedding and are not a part of a CAP-accredited laboratory.

Evidence of Compliance:
- ✓ Records of quality checks

DNA/RNA EXTRACTION/AMPLIFICATION

Inspector Instructions:

	• Sampling of nucleic acid extraction and amplification policies and procedures • Sampling of nucleic acid measurement records • Records of nucleic acid integrity and purity assessment • Records of internal controls • Sampling of specimen processing, handling, aliquoting, and storage policies and procedures
	• Nucleic acid amplification procedures for proper physical containment and procedural controls to prevent carryover • Observe quantitation and quality control assessments