





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:

	<ul style="list-style-type: none"> • 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
	<ul style="list-style-type: none"> • 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)
	<ul style="list-style-type: none"> • 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?
	<ul style="list-style-type: none"> • 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