The biorepository has all known relevant annotations on a given biospecimen that may be made available to the researcher. Information regarding some of these elements may not be available to the biorepository for all biospecimen collections, especially those that were procured before recent best practices for biorepositories were published.

BAP.01733 Processing/Preservation - Fluid Biospecimens **Phase II**

The key elements related to the processing and preservation of fluid biospecimens are recorded.

NOTE: Key elements may include, but are not limited to:

1. *Collection preservative*
2. *Original volume received*
3. *Temperature and duration of specimen prior to processing*
4. *Temperature and speed of first centrifugation step*
5. *Temperature and speed of subsequent separation steps*
6. *Method used for separation*
7. *Derivative(s) preserved and their volume*
8. *Quality control results for derivatives (ie, cell viability, purity, hemolysis status, human versus non-human content)*
9. *Tumor content (%), if applicable*

The biorepository has all known relevant annotations on a given biospecimen that may be made available to the researcher. Under some circumstances some of this information may be "unknown" depending on the site and age of specimen. It is recommended that the biorepository encourage their source sites to gather/provide as much information as possible.

REFERENCES

1) Standard Preanalytical Coding for Biospecimens: Defining the Sample PREanalytical Code, Betsou, *et al*, *Cancer Epidemiol Biomarkers Prev* April 2010 19; 1004.

BAP.01734 Specimen Processing/Storage **Phase II**

Specimens are processed promptly or stored appropriately to minimize degradation of nucleic acids.

REFERENCES

1) Farkas DH, Kaul KL, Wiedbrauk DL, *et al*. Specimen Collection and Storage for Diagnostic Molecular Pathology Investigation. *Arch Pathol Lab Med*. 1996;120:591-596
2) Kiechle FL, Kaul KL, Farkas DH. Mitochondrial Disorders: Methods and Specimen Selection for Diagnostic Molecular Pathology. *Arch Pathol Lab Med*. 1996;120:597-603
3) Farkas DH, Drevon AM, Kiechle FL, *et al*. Specimen Stability for DNA-based Diagnostic Testing. *Diag Molec Pathol*. 1996;5(4):227-235
4) Rainen L, *et al.* Stabilization of mRNA expression in whole blood samples. *Clin Chem.* 2002;48:1883-1890
5) Pahl A, Brune K. Stabilization of gene expression profiles in blood after phlebotomy. *Clin Chem.* 2002;48:2251-2253
6) Clinical and Laboratory Standards Institute (CLSI). *Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods.* 2nd ed. CLSI guideline MM13. Clinical and Laboratory Standards Institute, Wayne, PA; 2020.
7) Compton CC, Robb JA, Anderson MW, et al. Preanalytics and Precision Pathology: Pathology Practices to Ensure Molecular Integrity of Cancer Patient Biospecimens for Precision Medicine. *Arch Pathol Lab Med.* 2019;143(11)1346-63.

BAP.01736 Specimen Storage Conditions **Phase II**

The biorepository has defined storage conditions for the different specimens handled and a protocol for the return of each specimen type to storage after issuance for use, as appropriate.

Evidence of Compliance:

- ✓ Records of storage conditions **AND**
- ✓ Records of return of specimens to storage

BAP.01739 Specimen Storage Temperature **Phase II**

Records show that specimens were stored at the protocol-required temperatures.

NOTE: Storage of specimens must be appropriate for the type of specimens and its means of preservation. Failure to adhere to requirements could result in a specimen not being suitable for the purpose for which it was intended.

INFORMED CONSENT AND INSTITUTIONAL REVIEW BOARD

This section applies to human subjects research only.

Inspector Instructions:

	• Privacy and confidentiality policies and procedures • Informed consent criteria • Waiver of Consent criteria
	• What action is taken if a sample is received without the records of proper informed consent? • How do you ensure that the proposed use of human tissue is consistent with the informed consent?
	• Select a specimen in storage and review that the proper informed consent records are complete

BAP.01742 Informed Consent Criteria **Phase II**

The biorepository ensures that the proposed uses of human tissue with or without data shared for research purposes are consistent with the informed consent and scope of services, when applicable.

NOTE: There are some instances when informed consent and/or waiver of consent are not applicable (eg, non-human specimens).

BAP.01745 Required Approval(s) Records **Phase II**

When human specimens are to be collected, all of the required approvals (eg, IRB or other ethics committees) have been recorded and appropriate patient consent processes are complete.

NOTE: The only exception to this is when there has been a waiver of consent.

BAP.01748 Informed Consent Records **Phase II**

Informed consent records are obtained for the collection, storage, distribution, and use of identifiable human specimens and data.