

BAP.01721 IRB Release Phase II

For specimens that are released to a biorepository, an appropriate IRB release is in place.

BAP.01722 Specimen Handling Phase II



Specimens are handled in a manner that prevents specimen loss, alteration, or contamination.

NOTE: Because of the high sensitivity and potential for contamination in molecular testing involving amplification of DNA, the biorepository must be alert to the possibility of commingled specimens. An example of a potentially commingled specimen is one that is received after the specimen container was entered by a sampling device that enters multiple samples, albeit with rinses in between specimens. If such samples must be tested by molecular methods, the results should be interpreted with caution, considering the potential for contamination.

REFERENCES

- 1) Clinical and Laboratory Standards Institute (CLSI). *Establishing Molecular Testing in Clinical Laboratory Environments*: CLSI document MM19-A (ISBN 1-56238-773-1). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2011.
- 2) 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.01724 Specimen Collection/Handling Protocol Phase II



Collection, processing, and storage times are recorded, as required by the biorepository protocol in place at the time of biospecimen procurement.

NOTE: Time is kept to a minimum between when a specimen is removed from its site of origin and when it is preserved (eg, fixed, cooled, or frozen).

BAP.01727 Pre-Analytic Variables Phase II



There is a mechanism to capture pre-analytical variables that could impact potential uses of the specimens.

NOTE: While intended use of specimens is not always known, the specimens are typically stored for anticipated types of analysis (ie, serology, molecular, proteomic) and should be fit for purpose for the anticipated applications. Preservation procedures are optimized for the greatest number of molecular analytes/analysis platforms.

REFERENCES

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

BAP.01730 Processing/Preservation - Solid Specimens Phase II

The key elements related to the processing and preservation of solid specimens are recorded in the biospecimen QA report, when available.

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

1. Chilling/heating/drying of tissue during handling
2. Size and number of tissue pieces
3. Percentage of tumor/necrosis/stroma in the tissue
4. Liquid collection media
5. Use of gauze wrapping, additives, and embedding compounds
6. Variation in fixation (eg, temperature, buffer, pH of formalin, start/end time in fixative)
7. Freezing protocols
8. Time in fixative
9. Time to preserve

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