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*