



Cell lines, organoids, and patient-derived xenografts that are created by the biorepository are tested for functionality or unique characteristics and to ensure that they are fit for purpose.

NOTE: Such testing may be performed by analyzing aspects of the phenotype (eg, expression patterns), genotype or morphology. The biorepository should have a policy that addresses the need for identity testing.

Evidence of Compliance:

- ✓ Records of cell line evaluation **AND/OR**
- ✓ Records of (short tandem repeats) STR profiling or another method such as histologic staining or immunohistochemistry for cell lines to accomplish this goal

BAP.05327 Recording of Failures

Phase I

Culture failures are recorded.

NOTE: Records must indicate corrective actions.

Evidence of Compliance:

- ✓ Records of the results of testing and indication when a cell line has failed to pass the criteria established for successful passage of the quality tests