

CELL AND TISSUE CULTURE

Inspector Instructions:

 READ	<ul style="list-style-type: none"> • Sampling of cell and tissue culture policies and procedures • Sampling of records of microbial contamination and other cell line testing
 ASK	<ul style="list-style-type: none"> • How does the biorepository ensure that the quality of cell lines is maintained? • How do you define and monitor maximum cell line passage?

BAP.05312 Culturing Environment
Phase II

Culturing is performed under aseptic conditions in a biological safety cabinet.

BAP.05315 Cell Line Loss
Phase I

There is a system in place to prevent loss of the cell line in case of culture failure, contamination or other problems.

NOTE: Potential systems include duplicate or independently established cultures, harvesting in duplicate or at different times, or other control processes.

BAP.05318 Monitoring of Passage Numbers
Phase I

The biorepository defines the maximum number of passages for each cell line by either reference or laboratory method.

NOTE: When passages have reached the maximum passage number, the cell line should be re-established using working stock with a lower passage number.

Evidence of Compliance:

- ✓ Records of tracking of cell line passages **OR**
- ✓ Records of growth curves

BAP.05321 Testing for Microbial Contamination
Phase I

The biorepository tests cell lines for microbial contamination at intervals defined by the biorepository director.

Evidence of Compliance:

- ✓ Records detailing the type(s) of tests and test outcomes

****REVISED** 12/26/2024**

BAP.05324 Testing for Functionality and/or Unique Characteristics
Phase I



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