



## CELL AND TISSUE CULTURE

### Inspector Instructions:

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

#### 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

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#### 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