

components. Fractionation can simply be the separation of components of a biospecimen, such as blood into white blood cells, serum, and red blood cells.

Inspector Instructions:

	<ul style="list-style-type: none">Sampling of cell fractionation policies and procedures
	<ul style="list-style-type: none">System to maintain the identification of the derivatives to the parent biospecimenCell fractionation process follows the steps in the procedure
	<ul style="list-style-type: none">How is the quality of the cell fractionation process ensured?

BAP.05303 Specimen Identification

Phase II



Derivatives from fractionation of biospecimens maintain the identification associated with the parent biospecimen during the fractionation process.

NOTE: Records of specimen type, handling conditions, and, if applicable, storage information are elements of the identification that are maintained until the process is complete. If anonymity from the parent biospecimen is required, this can be accomplished after the fractionation is complete.

BAP.05306 Cell Fractionation

Phase II



The biorepository follows a defined process for all steps in the cell fractionation process.

NOTE: Deviations from the manufacturer instructions must be validated and recorded.

BAP.05309 Quality Control/Quality Assurance

Phase II

Biorepositories performing cell fractionation record all quality control and quality assurance measures.

NOTE: These measures would include the establishment of validation sets performed by the laboratory to establish consistent success in quality fractionation and where possible, enrollment in proficiency testing or performance of alternative assessment to demonstrate expertise and quality fractionation.