

CHANGES TO AATB STANDARDS FOR TISSUE BANKING
14th Edition

SECTION D
**AUTHORIZATION, INFORMED CONSENT, DONOR SCREENING, AND TISSUE RECOVERY,
COLLECTION, AND ACQUISITION**

Current (14th Edition)

D4.200 Donor Testing

D4.240 Archived Samples

A serum or plasma sample from each *donor shall* be archived if any sample remains after testing. A policy *shall* be established to collect and archive serum, plasma, or hematopoietic *tissue* samples from *donors*. Samples *shall* be retained for ten years after the *recovery, collection, or acquisition* date. If a *donor* is determined to be unsuitable, archived serum, plasma, or hematopoietic *tissue* samples *should* still be retained for use for possible unforeseen future investigational purposes (e.g., emerging infectious diseases, medical/legal, blood borne pathogen exposure, etc.).

- (DM) Appropriate brain *tissue* specimens (i.e., formalin-fixed brain *tissue*, histological sections from examination of brain, *donor* serum) from each *donor of dura mater shall* be archived under appropriate storage conditions, and for the appropriate duration.
- (R) Archived serum or plasma from *reproductive donors* whose *tissue* has been *stored* but subsequently destroyed and never *distributed* does not require retention.

With Amendments

D4.200 Donor Testing

D4.240 Archived Samples

~~A serum or plasma sample from each donor shall be archived if any sample remains after testing.~~ A policy *shall* be established to collect and ~~archive~~ **preserve**, according to individual establishment's *quality, safety, and legal risk assessments*, serum, plasma, or hematopoietic *tissue* samples from *donors*. Samples *shall* be retained for ~~ten years~~ **appropriate duration** after the *recovery, collection, or acquisition* date, **to mitigate the establishment's specific risk exposure according to its quality, safety, and legal assessments.** ~~If a~~For samples from *donors* ~~is~~ determined to be unsuitable, **or samples from eligible donors approaching expiration of their preservation term as defined by organizational policy, tissue establishments may have written agreements with third parties for long-term archiving of archived** serum, plasma, or hematopoietic *tissue* samples ~~should still be retained~~ for use for possible unforeseen future investigational purposes (e.g., emerging infectious diseases, medical/legal, blood borne pathogen exposure, etc.).

- (DM) Appropriate brain *tissue* specimens (i.e., formalin-fixed brain *tissue*, histological sections from examination of brain, *donor* serum) from each *donor of dura mater shall* be archived under appropriate storage conditions, and for the appropriate duration.

- (R) Archived serum or plasma from *reproductive donors* whose *tissue* has been *stored* but subsequently destroyed and never *distributed* does not require retention.

As Amended

D4.200 Donor Testing

D4.240 Archived Samples

A policy *shall* be established to collect and preserve, according to the individual establishment's *quality, safety,* and legal risk assessments, serum, plasma, or hematopoietic *tissue* samples from *donors*. Samples *shall* be retained for appropriate duration after the *recovery, collection,* or *acquisition* date, to mitigate the establishment's specific risk exposure according to its *quality, safety,* and legal assessments. For samples from *donors* determined to be unsuitable, or samples from eligible donors approaching expiration of their preservation term as defined by organizational policy, tissue establishments may have written agreements with third parties for long-term archiving of serum, plasma, or hematopoietic *tissue* samples for use for possible unforeseen future investigational purposes (e.g., emerging infectious diseases, medical/legal, blood borne pathogen exposure, etc.).

- (DM) Appropriate brain *tissue* specimens (i.e., formalin-fixed brain *tissue,* histological sections from examination of brain, *donor* serum) from each *donor* of *dura mater* *shall* be archived under appropriate storage conditions, and for the appropriate duration.
- (R) Archived serum or plasma from *reproductive donors* whose *tissue* has been *stored* but subsequently destroyed and never *distributed* does not require retention.

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