**Why is it necessary to store donor blood specimens?**

<table>
<thead>
<tr>
<th>Donor Type</th>
<th>Storage Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Living</td>
<td>Date of organ transplant, at least 10 years after the date of organ transplant. Samples must be stored for a period of 2 hours prior to organ recovery.</td>
</tr>
<tr>
<td>Deceased</td>
<td>Date of organ transplant, at least 10 years after the date of organ transplant. Samples must be collected within 2 hours prior to organ procurement.</td>
</tr>
</tbody>
</table>

**OPTN Policy**

- Collection timeframe for specimen collection:
  - Living: 3/1/21 addition: 2.2 OPO responsibilities
  - Deceased: 3/1/21 addition: 14.8.B: Living Donor Specimen Collection and Storage

**What are the requirements for the Living and Deceased donor sample being stored?**

- Separate EDTA plasma specimen for NAT.
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- The 2020 PHS Guideline recommends two blood specimens be collected, one ethylenediaminetetraacetic acid (EDTA) plasma for serologic assays and a separate EDTA plasma specimen for serologic assays.
- Specimens to be stored at the recommended temperature for sample storage.
- OPTN policy does not have specific requirements for type, number, preparation for the blood specimens to be stored.
- Brady B, Partiala P, et al, "Appropriate specimen collection, labeling, transportation, handling, and storage facilitate the accuracy of reported laboratory test results.", MMWR Recomm Rep 2020;69 (7-8) available at: https://www.cdc.gov/mmwr/volumes/69/rr/rr6904a1.htm.

**Why is it necessary to store donor blood specimens?**

- To identify if transplant recipient HIV, HBV, HCV infection is donor-derived, as the CDC has previously stated, "Appropriate specimen collection, labeling, transportation, handling, and storage facilitate the accuracy of reported laboratory test results.", MMWR Recomm Rep 2020;69 (7-8) available at: https://www.cdc.gov/mmwr/volumes/69/rr/rr6904a1.htm.

**What is the maximum timeframe for the donor blood specimen storage?**

- Living: 24 hours prior to organ recovery.
- Deceased: 24 hours prior to organ procurement.

**DONOR SPECIMEN STORAGE REQUIREMENTS**

Do the donor samples have to be stored at the living donor hospital or OPO?

- No, OPTN policy does not require that these specimens be stored on-premises. OPOs and living donor recovery hospitals are able to contract with an outside facility for specimen storage, including histocompatibility (HLA) labs.
  - Many HLA labs store samples long term. The labs are used to storing specimens for long periods of time and have systems in place to manage it.

How should samples be prepared for storage?

- Note: OPTN and CDC do not provide information on sample preparation; policy does not require the specimens be stored on premises, only that the OPO or hospital arrange for storage.
- Consult with your laboratory personnel on those who have experience with the proper preparation for long-term storage. Below are some factors to consider:
  - Samples should be spun down to separate out red blood cells.
  - The specimens can be put into plastic vials with added glycerin or DMSO before storing.
  - Laboratories do not need to separate out white blood cells and plasma from serum in order to store samples, but can choose to do so.
  - Laboratories are not required to separate out granulocytes and erythrocytes from peripheral blood mononuclear cells (PBMCs), but may do so.
  - It is essential that the plasma be maintained to test for viral nucleic acids if laboratories choose to separate out white blood cells.

At what temperature should the donor sample be stored?

- The OPTN and 2020 PHS Guideline do not provide information on optimal storage of serum specimens, but lower-temperature storage (-70 or -80 Celsius) has been shown to improve long-term viral detection for both HIV and HCV.
  - The CDC provided additional information on temperature storage in the 2013 PHS Guideline: “For archived blood specimens, viral nucleic acid may deteriorate over time

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depending on storage conditions. For example, repeated freeze-thaw cycles can cause a moderate reduction in viral nucleic acid levels. Procedures to maximize sample quality include separating specimens that might be used for NAT into multiple aliquots prior to long-term storage, with storage temperature maintained at –70°C or colder.

Furthermore, avoiding temperature extremes when archived specimens are shipped for testing inhibits specimen hemolysis, which can result in both false-positive serologic results and false-negative NAT results. Therefore, transporting archived specimens to a testing laboratory on dry ice is a common practice, as well as documenting the specimen quality and condition, with respect to both temperature and hemolysis, upon receipt in the testing laboratory.”

- The maximum temperature recommended for long-term DNA stability is -27 C, but -80 to -130 C would be more ideal for plasma or serum specimens and is still feasible with a mechanical freezer.10

Additional Resources:

- College of American Pathologists (CAP) provides a database to help find accredited biorepositories.
- CDC Biorepository provides offer sample management expertise to programs, contactable at biorepository@cdc.gov