Align OPTN Policy with U.S. Public Health Service Guideline, 2020: Donor Specimen Storage Resource

Donor blood specimen storage requirements

Donor Type	Collection Timeframe	Storage Timeframe	OPTN Policy
Deceased	Samples must be collected within 24 hours prior to organ procurement.	Samples must be stored for at least 10 years after the date of organ transplant.	2.2: OPO responsibilities 3/1/21 addition: Timeframe for specimen collection
Living*	Samples must be collected within 24 hours prior to organ recovery.	Samples must be stored for at least 10 years after the date of organ transplant.	14.8.B: Living Donor Specimen Collection and Storage 6/1/21 addition: Requirement for living donor sample storage and timeframe for specimen collection

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."[1]

What are the requirements for the living and deceased donor sample being stored?

- OPTN policy does not have specific requirements for type, number, preparation for the blood specimens to be stored, or for the temperature of sample storage.
- The 2020 PHS Guideline recommends two blood specimens be collected, one ethylenediaminetetraacetic acid (EDTA) plasma or serum specimen for serologic assays and a separate EDTA plasma specimen for NAT.
    - If it is only feasible to collect one specimen, a plasma specimen in EDTA is optimal (EDTA has the purple or lavender top).[2] The 2013 PHS Guideline notes that "Labeling each specimen with a minimum of two unique identifiers ensures a confidential and unbroken chain of traceability to the identity of the donor and recipient."[3]

[1] DL Seem, I Lee, C Umscheid, et al, " Public Health Service Guideline for Reducing Transmission of Human Immunodeficiency Virus (HIV) Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation", Public Health Reports, 128 (4), July 2013, 247-343, https://doi.org/10.1177/003335491312800403.

[2] Jones, JM, Kracalik, I, Levi, ME "Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection — U.S. Public Health Service Guideline, 2020" MMWR Recomm Rep 2020;69 (7-8) available at: https://www.cdc.gov/mmwr/volumes/69/rr/rr6904a1.htm.

[3] DL Seem, "PHS Guideline"

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.[4]
    - The specimens can be put into plastic vials with added glycerin[5] or DMSO[6] 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.[7]

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.[8,9]
    - 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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[4] Tuck, Melissa K., Daniel W. Chan, David Chia, Andrew K. Godwin, William E. Grizzle, Karl E. Krueger, William Rom, et al. "Standard Operating Procedures for Serum and Plasma Collection: Early Detection Research Network Consensus Statement Standard Operating Procedure Integration Working Group." *Journal of Proteome Research* 8, no. 1 (2008): 113–17. https://doi.org/10.1021/pr800545q.

[5] "Best Practices for PBMC Processing," Duke Human Vaccine Institute Immunology, Quality Assessment Cryopreservation Proficiency Testing Program, 2015 ACTG Network Annual Meeting. https://iqa.center.duke.edu/sites/iqa.center.duke.edu/files/ACTG_2015_FINAL_.pdf

[6] Hønge, Bo Langhoff, Mikkel Steen Petersen, Rikke Olesen, Bjarne Kuno Møller, and Christian Erikstrup. "Optimizing Recovery of Frozen Human Peripheral Blood Mononuclear Cells for Flow Cytometry." PLOS ONE 12, no. 11 (2017). https://doi.org/10.1371/journal.pone.0187440.

[7] James C. Todd, Sanford, Arthur H., Davidsohn, Israel, Henry, John B. *Clinical diagnosis and management by laboratory methods*, Philadelphia: Saunders, 1979. https://www.ncbi.nlm.nih.gov/nlmcatalog/7901210

[8] Halfon, Philippe, Hacène Khiri, Victoria Gerolami, Marc Bourliere, Jean M. Feryn, Pascal Reynier, André Gauthier, Guy Cartouzou, *Impact of various handling and storage conditions on quantitative detection of hepatitis C virus RNA*, Journal of Hepatology, Volume 25, Issue 3 (1996), Pages 307-311, https://doi.org/10.1016/S0168-8278(96)80116-4.

[9] Giocchio, Christine C, Xue-Ping Wang, Mark H Kaplan, Gaby Mulligan, Donald Witt, Joseph W Romano, Michael Cronin, and Richard Carroll. "Effects of Specimen Collection, Processing, and Storage Conditions on Stability of Human Immunodeficiency Virus Type I RNA Levels in Plasma." *Journal of Clinical Microbiology* 35, no. 11 (November 1997): 2886–93.

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

[10] Rothman, Nathaniel, Jimmie B Vaught, and Marianne K Henderson. Essay. In *Molecular Epidemiology: Principles and Practices*, 23–42. Lyon, France: International Agency for Research on Cancer, World Health Organization, 2011.