

Accreditations, Certifications, and Registrations

LifeNet Health is the nation’s largest non-profit, full service Organ Procurement Organization (OPO) and tissue banking system. We are registered with the Food and Drug Administration (FDA) and are an Accredited Tissue Bank of the American Association of Tissue Banks (AATB).

LifeNet Health holds tissue bank licenses, certifications and registrations from the, Delaware Health and Social Services, Illinois Department of Public Health, Maryland Department of Health and Mental Hygiene, Oregon Department of Human Services, New York State Department of Health, State of California Department of Health Services, and the State of Florida’s Agency for Health Care Administration. In addition, LifeNet Health’s laboratory is Clinical Laboratory Improvement Amendments (CLIA) certified.

In addition to its tissue banking services, LifeNet Health maintains an Organ Procurement Division providing organ recovery services to eastern, central, and southwestern Virginia and six organ transplant centers in Virginia. LifeNet Health is a member of the United Network for Organ Sharing (UNOS) and the Association of Organ Procurement Organizations (AOPO).

LifeNet Health holds concurrent certification to ISO 13485:2003, the quality management system standard specific to medical devices.

Summary of Accreditations/Certifications	
AATB accreditation	✓
FDA Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)	✓
FDA Device Establishment registration	✓
UNOS member	✓
AOPO accreditation	✓
Licensed in required states	✓
ISO 13485:2003 certified	✓
CLIA Lab certified	✓
CMS OPO certified	✓
Health Canada CTO Registration	✓
CMDCAS – Canadian Medical Devices Conformity Assessment System (this can be found on LNH’s ISO certificate)	✓
Certificate of Exports (applicable to various countries)	✓

Current copies of these forms can be obtained under the Certificates and Accreditations link on LifeNet Health’s Web site: <https://www.lifenethealth.org/about/accreditations-certifications>