

Frequently Asked Questions

Pre-Processing Testing

Medical Suitability Assessment

Tissue is designated as suitable or unsuitable for transplantation in accordance with federal and state regulatory requirements, and as determined by one of LifeNet Health's Medical Directors. LifeNet Health's Donor Medical History & Behavioral Risk Assessment questionnaire is comprised of more than 30 types of questions, designed to identify behavioral and medical situations that increase risk of use for clinical implantation. Additionally, LifeNet Health acquires information from the healthcare professionals who treated the donor and relevant portions of the donor's medical record, including an autopsy report if applicable. A properly administered Risk Assessment, including serologic and microbiologic testing results, ensures that transmission of viral, bacterial, fungal, prion, and other pathogens is a remote risk to any recipient.

Microbiology Testing

All musculoskeletal, skin, cardiac, and vascular tissue donations are sampled to detect potential contamination prior to exposure to antibiotic-containing solutions or other disinfectants used in processing. Standard microbiologic methods are employed to detect and identify an array of aerobic, anaerobic, and fungal microorganisms. LifeNet Health's CLIA-certified QC laboratory performs many of the tests. Culture results are evaluated against stringent acceptability criteria, and the donation is accepted or rejected in accordance with regulatory and accreditation requirements.

Serologic Testing

All donor blood samples used for required infectious disease testing are evaluated and qualified for acceptability regarding the potential for hemodilution. **Qualified donor blood samples are tested for evidence of infectious agents including Human Immunodeficiency Virus (HIV), Hepatitis B/C, and syphilis.** LifeNet Health's CLIA-certified laboratory performs many of the tests. **FDA-licensed or approved donor screening tests are used when available. The donation is accepted or rejected in accordance with federal regulatory requirements.**

LifeNet Health's test regimen meets the requirements of AATB and FDA as illustrated in the following tables:

| Microbiologic Testing Performed by LifeNet Health | LifeNet Health | AATB | FDA |
|--|-----------------------|-------------|------------|
| Testing to identify bacteria | ✓ | ✓ | ✓ |
| Testing to identify fungi | ✓ | ✓ | ✓ |

| Serological Tests Performed | LifeNet Health | AATB | FDA |
|---|---|-------------|------------|
| HIV1/2Ab - detects antibody response to HIV 1 and 2 – the causative agents of AIDS | ✓ | ✓ | ✓ |
| HIV-1/HBV NAT/HCV NAT - test used for early detection of HIV & Hepatitis B and C viruses | ✓* | ✓* | ✓* |
| HBsAg - detects hepatitis B virus | ✓ | ✓ | ✓ |
| HBcAb - detects antibody response to hepatitis B virus | ✓ | ✓ | ✓ |
| HCVAb - detects antibody response to hepatitis C virus | ✓ | ✓ | ✓ |
| RPR/STS or equivalent – detects potential exposure to the causative agent of syphilis | ✓ | ✓ | ✓ |
| HTLV1/2Ab - detects antibody response to human T-cell lymphotropic viruses 1 and 2 | <i>Additional testing such as HTLV1/2Ab, WNV NAT, and/or Chagas may be performed at Medical Director discretion and as required by international regulations.</i> | | |

*For donors recovered on or after 12/16/16, HBV NAT is a required test.