Quality Control and Assurance with Confidence

Since1995 there has been no incident of disease transmission directly linked to tissue screened and processed by LifeNet.

LifeNet leaves nothing to chance. From the control of incoming bioburden, through a strict recovery process, quality control is paramount. Our processing and cleaning methods are designed to eliminate the potential for disease transmission, while our donor and tissue testing exceeds the requirements of current industry regulations. The integrated quality assurance program ensures that all allografts delivered to our customers can be used with complete confidence.

A Stringent Donor Screening and Review

All LifeNet donors undergo a rigorous screening process that includes a medical history and behavioral risk assessment that mirrors the requirements set forth by the American Association of Tissue Banks (AATB) and the Food and Drug Administration (FDA).

A complete donor report is obtained from the next of kin and/or person most qualified to provide detailed information regarding the donor's medical, social, and sexual history. Specially trained professionals review the medical and behavioral findings to ensure medical suitability of the donor.

While autopsies are not required on every donor, when they are performed, the autopsy results are made part of the donor record. Autopsy results are evaluated when determining whether the donor tissue is suitable for transplantation.

All donors accepted for organ and/or tissue recovery are subject-ed to a meticulous screening

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routine using specific criteria designed to accept only suitable donors. LifeNet personnel with allied health care backgrounds, trained in the assessment of the potential donor, are utilized for the evaluation process. All events involved in this process are documented in the donor record. Provisions of the Uniform Anatomical Gift Act are followed in seeking authorization and carrying out the donation. A copy of the authorization document is included in the donor record maintained by LifeNet.

A Stringent Recovery Protocol

LifeNet follows the AATB and FDA guidelines concerning recovery of donated human tissue. LifeNet's primary concern during any tissue recovery is to ensure the highest degree of graft quality while respecting the donor's dignity.

Once the donor screening process has been completed and all criteria have been met for tissue recovery, a specialized team is dispatched to recover the donor's tissue for processing by LifeNet.

LifeNet's recovery process includes an extensive physical assessment supervised by the recovery team leader. This physical assessment supplements the medical history/behavioral risk assessment screening information and relevant medical records already obtained. All tissue is recovered using aseptic recovery techniques to assure the quality and safety of the tissue.

A Stringent Microbiologic Testing Regimen

All recovered tissue is sampled for microbiological contamination at the time of recovery or immediately prior to processing. Standard microbiological methods utilizing aerobic and anaerobic media are employed to culture and identify bacteria and fungi. In addition, cardiovascular tissue is tested for mycobacteria (acid fast bacilli) to detect the presence of the causative agent of tuberculosis and must be negative before release. Many of the tests are performed by LifeNet's Clinical Laboratory Improvement Amendments (CLIA) certified laboratory.

A Stringent Serologic Testing Regimen

All donor blood samples are also used for required infectious disease testing and evaluated for potential hemodilution that may impact acceptability. Samples are tested for evidence of infectious agents including human immunodeficiency virus (HIV), hepatitis, and syphilis. Tissue is designated as either suitable or unsuitable for transplantation following regulatory requirements. This extensive serological testing exceeds industry standards.

Figure 1. Pre-processing Testing Performed by LifeNet

Microbiologic Testing	Required by LifeNet	Required by AATB	Required by FDA
Testing to identify bacteria	✓	✓	
Testing to identify fungi	✓	✓	
Serological Tests	Required by LifeNet	Required by AATB	Required by FDA
HIV1/2Ab - detects antibody response to HIV 1 and 2 – the causative agents of AIDS	✓	✓	✓
HIV NAT - test used for early detection of HIV virus	✓		
HTLV1/2Ab - detects antibody response to human T-cell lymphotropic viruses 1 and 2	✓	✓	
HBsAg - detects hepatitis B virus	✓	✓	✓
HBcAb - detects antibody response to hepatitis B virus	✓		
HCVAb - detects antibody response to hepatitis C virus	✓	✓	✓
RPR or equivalent – detects potential exposure to the causative agent of syphilis	✓	✓	

Figure 2: Post-processing Testing Performed by LifeNet

Tissue Type/Family	Microbiologic Testing or Terminal Sterilization	Residual Calcium	Residual Moisture
CardioGraft™	✓		
FlexiGraft®	✓		
MatriGraft®	✓		✓ (if freeze-dried)
OraGraft®	✓	✓ (if demineralized)	✓ (if freeze-dried)
ReadiGraft®	✓	✓ (if demineralized)	✓ (if freeze-dried)
VertiGraft®	✓		✓ (if freeze-dried)
OsteoBiologics™	✓	✓	✓

LifeNet's Quality Assurance (QA) Record Review staff evaluates a collection of relevant medical records to ensure all required elements are complete (e.g., medical/behavioral history, donor authorization, recovery documentation, hemodilution assessment). Next, the LifeNet Medical Director reviews the chart and determines whether or not the donor is medically suitable.

Post-processing Review and Testing

Post-processing testing or terminal sterilization is required for all tissue types. Each lot is either designated for terminal sterilization or has representative samples taken for final microbiologic culture. Final culture results must be negative for the tissue to be released.

Analytic testing is performed on demineralized tissue to ensure that residual calcium levels are within AATB guidelines and LifeNet's internal requirements. In addition, freeze-dried tissue is tested to be certain that residual moisture levels meet internal and external requirements.

Final Review

QA Record Review staff performs a final review of all documentation. This is a final check for the presence and acceptability of all required elements. If approved, the tissue is then released to distributable inventory by the QA department.

LifeNet is the nation's largest nonprofit, full-service organ procurement organization and tissue bank.

LifeNet's donor and tissue testing exceeds the AATB's and FDA's current industry regulations.

It's clear – LifeNet leaves nothing to chance. Quality control is maintained throughout. LifeNet's process has been tried and tested – only to prove itself completely reliable. Since 1995, over one million allografts have been delivered to the industry and no incidence of disease transmission has been directly linked to tissue screened and processed by LifeNet. We take great pride in the fact that all final allografts delivered to our customers can be implanted with confidence.

KEY STEPS TAKEN BEFORE TISSUE IS RELEASED FOR TRANSPLANTATION

Stringent Donor Screening and Review	✓
Stringent Recovery Protocol	✓
Stringent Microbiologic Testing Regimen	✓
Stringent Serologic Testing Regimen	✓
Post-processing Review and Testing	✓
QA Final Review	✓
Tissue released	✓

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REV 10/05 LNPRO1425