

**Does LifeNet Health test for non-viral pathogens such as bacteria and fungi?**

LifeNet Health does test for non-viral pathogens, including bacteria and fungi. This testing is an integral part of the LifeNet Health safety strategy that begins with routine screening and a physical exam that includes culturing of each tissue recovered and blood drawn for serology testing. For screening LifeNet Health utilizes the Donor Risk Assessment Interview (DRAI), which is comprised of more than 30 categories of questions designed to uncover situations in any potential donor that would preclude the donation process, including infectious disease. Tissue cultures and blood are sent to a CLIA certified microbiology laboratory for testing. This safety strategy minimizes the likelihood of disease transmission by any viral, bacterial, fungal, parasitic or prion pathogens.

Post screening and recovery checkpoints include:

- Quality Assurance (QA) review of donor records for the presence, completeness and acceptability of all required elements.
- Quality Control (QC) CLIA certified microbiology laboratory performance of all required aerobic and anaerobic bacterial cultures and fungal cultures. Additional testing, including serology, may be requested by the Medical Director.
- Medical Director review of each donor record determining whether or not the tissues are medically safe to be used for transplantation.

**How does LifeNet Health's Allowash XG® process affect any potential bacterial and fungal bioburden?**

LifeNet Health's Allowash XG® technology encompasses a comprehensive patented and validated process during which greater than 99% of bone marrow and blood elements are removed from the internal bone matrix. This process, along with subsequent chemical treatment and sterilization steps, has been shown to render tissue sterile to a Sterility Assurance Level (SAL) of  $10^{-6}$ . This means that there is a probability that no more than one allograft per one million allografts processed will contain a live organism. It also inactivates enveloped and non-enveloped viruses, without compromising the biomechanical or biochemical properties of the tissue as needed for its intended surgical application.

Since 1995, millions of bio-implants processed using Allowash Technology have been distributed by LifeNet Health, with no disease transmission.