LifeNet Health®
Saving Lives. Restoring Health. Giving Hope.

VIVIGEN® DONOR SUITABILITY & RELEASE CRITERIA

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Not only does LifeNet Health hold the longest continuous accreditation from the American Association of Tissue Banks, but we have a comprehensive range of measures in place to ensure the safety of ViviGen™, including stringent donor screening methods and release criteria. To obtain suitable donors, LifeNet Health maintains an extensive network of recovery partners. Additionally, LifeNet Health is a leading, Federally designated Organ Procurement Organization (OPO) that coordinates recovery and transplants of organs in Virginia and part of West Virginia.

LifeNet Health only accepts donors from federally designated Organ Procurement Organizations and qualified tissue recovery partners. These partners are regularly audited to determine that their recovery process meets current U.S. Food and Drug Administration (FDA) regulations, American Association of Tissue Banks (AATB) standards and LifeNet Health's own stringent guidelines.

INITIAL SCREENING

Our goal is to identify all potential medically-suitable donors. As a federally designated Organ Procurement Organization, LifeNet Health is made aware of every potential donor within the geography we represent. Our Call Center and Recovery Staff are available 24 hours/7 days a week. A Medical Director is always accessible to offer technical and/or medical assistance.

All tissue is evaluated to meet appropriate age limits. ViviGen donors must adhere to specific age limits.*

LifeNet Health reviews the potential ViviGen donor's past medical history for specific rule outs including cancer, diabetes, renal disease, CJD, auto-immune diseases as well as numerous other diseases and illnesses. LifeNet Health utilizes a medical conditions database of over 1,500 diseases and medical conditions that affect donor suitability.

LifeNet Health will review the medical history reports along with an Incidence-Window Period Model to identify donors who are at risk of having a recent infection that may not be detected by routine serology or NAT testing. The model evaluates possible high risk behaviors based on drug use, tattoos, body art, body modifications, and sexual behaviors. This is to minimize the risk of a donor having a false negative screening test result for hepatitis B, hepatitis C, and/or HIV.**

Once the initial screening is complete, the potential ViviGen donor is recovered and a stringent medical screening is performed.

RECOVERY Recovery technicians do positive identification and review all medical documents. A physical inspection of the deceased donor is administered to make sure physical evidence matches medical information provided prior to recovery. LifeNet Health has trained its recovery personnel as well as LifeNet Health Partners' recovery personnel to take pictures and obtain biopsies of any suspicious lesions.

In 2004, the first known national recovery biopsy program was initiated by LifeNet Health and included all of our tissue recovery partners. Its purpose is to identify any possible occult infection or cancer in the donor. Biopsies taken at recovery are processed by an independent pathology lab. Evidence of any unexpected cancer or infection will prevent the tissue from being released.***

MEDICAL SCREENING / PROCESSING

After the initial screening process, the potential medically-suitable ViviGen donor goes through a more in-depth medical screening. Due to the sensitive nature of ViviGen, the donor is processed in tandem with the in-depth medical screening.

Blood cultures and independent tissue cultures are collected. Tests for HIV and Hepatitis are administered. Biopsy results and the initial chart are reviewed.

LifeNet Health performs the following quality control testing on each lot of ViviGen. The finished product must pass USP‹71› Sterility Tests. Each lot is tested to contain ›16,000 viable bone cells per cubic centimeter (cc) post thaw. Finally, calcium content in the demineralized bone is measured to ensure average residual calcium levels in the optimal range of 1% to 4%. Quality assurance compiles and places all relevant technical and medical chart information for final review by the Medical Director.

The final disposition of tissue is the responsibility of the Medical Director who makes their determination based on all relevant information including autopsy results, medical chart, recovery and quality records. The Medical Directors Advisory Group, a cross-departmental team unique to LifeNet Health, meets quarterly to discuss and provide decisions regarding any technical, medical, or social issue relevant to donor suitability. It is responsible for reviewing and modifying donor suitability criteria and establishing new donor suitability criteria as needed.

The ViviGen donor is acceptable for release.

*Data on file at LifeNet Health.

** The Incidence-Window Period Model and its Use to Assess the Risk of of Transfusion-Transmitted Human Immunodeficiency Virus and Hepatitus C Infection. Kleinman, S., et. al. Transfusion Medicine Reviews, Vol. 11, No 3 (July), 1997: pp155-172.

***The Utility of Recovery Biopsies in Determining Donor Suitability, Singh, S., et.al. Cell and Tissue Banking, Vol. 13, Issue 4 (December), 2012: pp565-567.

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LifeNet Health helps to save lives, restore health and give hope to thousands of patients each year. We are the world's most trusted provider of transplant solutions, from organ procurement to new innovations in bio-implant technologies and cellular therapies — a leader in the field of regenerative medicine, while always honoring the donors and healthcare professionals that allow the healing process.

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