SEROLOGICAL TESTING LIST

SurForce® is thoroughly tested for safety in clinical procedures. Our donor serology test panel is the most extensive in the industry, testing for several potential pathogens that could be missed by less extensive testing observed in competitive industry products. SURGENEX® conducts 14-day product sterility tests performed by an independent, CLIA certified, third party lab. These safety barriers verify that SurForce® is the cleanest and safest amniotic membrane tissue allograft product on the market.

TEST REFERENCES

HIV-1/HIV-2 Plus O- BioRad GS HIV-1/HIV-2 Plus O EIA is FDA approved for living and cadaveric donor screening. This is a screening assay; it is neither a diagnostic assay nor a confirmatory test for the presence of HIV.

Ultrio HIV- The Procleix Ultrio Assay is FDA approved for living and cadaveric donor screening by TMA for the detection of HIV.

Hepatitis B Core Total Ab- Ortho HBc ELISA is a qualitative ELISA for the detection of total antibody.

Hepatitis B Surface Ag- BioRad Genetic Systems HBsAg EIA 3.0 is FDA approved for living and cadaveric donor screening.

Ultrio HBV- The Procleix Ultrio Assay is FDA approved for living and cadaveric donor screening by TMA for the detection of HBV RNA.

Hepatitis C Virus Ab- ORTHO HCV Version 3.0 ELISA is FDA approved for living and cadaveric donor screening.

Ultrio HCV- The Procleix Ultrio Assay is FDA approved for living and cadaveric donor screening by TMA for the detection of HCV RNA.

HTLV I/II Ab- The Avioq HTLV I/II Microelisa System is FDA approved for screening living donors, heart-beating organ, and cadaveric donors.

Syphilis Screening - Nontreponemal- ASI (ASIManager-AT) RPR flocculation card test for syphilis screening.

WNV NAT- The Gen-Probe Procleix WNV assay is FDA approved for living and cadaveric screening by TMA for the detection of WNV.

Endotoxin Testing- This test produces a quantitative result of the amount of endotoxin (a component of the cell wall of Gram Negative bacteria) present on the final product.

USP <71> Sterility Testing- This 14-day test ensures that there is no bacterial or fungal contamination present in the final product. The sampling plan is based on the United States Pharmacopoeia testing protocol for sterile injectable drugs.