

PRODUCT:

WJ-PURE+

LOT: 737 1mL

TISSUE ID: **EXP DATE:**

07/13/2024

566

TESTING FACILITY

VRL Eurofins

6933 S Revere PKWY

Centennial, CO 80112

VOLUME OF LOT TESTED: 20%

Test	Result	Ref Range
Lyme disease	Negative	Negative
CMV Total Ab	Negative	Negative
Hepatitis B Core Total Ab	Non Reactive	Non Reactive
Hepatitis B Surface Ag	Non Reactive	Non Reactive
Hepatitis C Virus Ab	Non Reactive	Non Reactive
HIV-1/HIV-2 Plus O	Non Reactive	Non Reactive
HTLV I/II Ab	Non Reactive	Non Reactive
Syphilis Screening - Nontreponemal	Non Reactive	Non Reactive
Ultrio Elite HBV	Non Reactive	Non Reactive
Ultrio Elite HCV	Non Reactive	Non Reactive
Ultrio Elite HIV-1/2	Non Reactive	Non Reactive
WNV NAT	Non Reactive	Non Reactive
Zika NAT	Non Reactive	Non Reactive
Anti-SARS-COV-2-IGG	Negative	Negative
Sterility Testing		
(encompasses aerobic and anaerobic organisms as well as spore formers, yeast and fungus.)	No Growth	No Growth
USP <71>, 21CFR610.12		
Endotoxin Testing		
USP <85>, ANSI/AAMI ST72:2011	Result: <0.025	<0.025
Environmental Testing		
End Process RODAC and Trypticase	No Growth	No Growth
USP <1116>		
Additional Testing		
E.Coli	Negative	Negative
Clostridium Species	Negative	Negative
Pseudomonas Aeruginosa	Negative	Negative
Bacillus Subtilis	Negative	Negative
Candida Albicans	Negative	Negative
Asperigillus Brasiliensis	Negative	Negative

Results meet LOT acceptance criteria requirements and quality assurance specifications.

Approved:

Philipp R. Vitti, CSO

11/22/2022

The communicable disease testing was performed by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the the FDA, Clinical Laboratory Improvement Amendments Act of 1988 (CLIA) and 42 CFR part 493.

Although Vittl Labs birth tissue derived products (HCT/P's) are subjected to rigorous donor screening, all required serology testing, aseptic processing, and USP <71> final Sterility Testing Guidelines, and USP <85> Endotoxin Guidelines, as with all aseptically processed HCT/Ps the possibility remains that this tissue may transmit infectious agents.

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