



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

VIVITRO LABS, INC.
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MECHANICAL

Valid To: January 31, 2025

Certificate Number: 3224.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following types of tests on medical products:

<u>Test:</u>	<u>Test Method(s):</u>
<i>Endovascular Devices:</i>	
Number and size of fine particles (2-70 micrometers) under steady or constant Flow	ISO 25539-2; ASTM F2743
<i>Cardiac Valve Prostheses and Cardiac Valve Repair Devices:</i>	
Systemic pressure, Upstream pressure / Downstream pressure, Loss of transvalvular charge, Transvalvular flow, Ejection volume, Regurgitant volume (closing volume + leak volume), Pressures, flow rate and pulsation in physiological ranges	ISO 5840-1, -2, -3, ISO 5910
<i>Steady Flow Testing:</i>	
(0 to 30) L/min flow rate (1 to 300) mmHg pressure (20 to 45) °C temperature (1 to 10) cP fluid viscosity	ISO 5840-1, -2, -3, ISO 5910
<i>Durability (AWT/RWT) Testing:</i>	
(-200 to 315) mm Hg pressure (20 to 45) °C temperature (1 to 10) cP fluid viscosity (1 to 30) Hz Frequency	ISO 5840-1, -2, -3, ISO 5910

<u>Test:</u>	<u>Range:</u>	<u>Test Method(s):</u>
<i>Testing Parametric Envelope for measuring particles in fluids:</i>		
Average Flow Rate	(63 to 77) ml/min	OLE 1032
Particle Size	(2 to 70) µm	
Particle Concentration	Up to 10 000 particles/ml	
Temperature	(20 to 39) °C	
<i>Testing Parametric Envelope for fluid testing:</i>		
Pressure	(-200/+315) mmHg	OLE 1714 OLE 2107 OLE 2105 OLE 2106
Average Flow Rate	(0 to 30) l/min	
Temperature	(20 to 45) °C	
Frequency	(0 to 30) Hz	
Fluid viscosity	(1 to 10) cP	



Accredited Laboratory

A2LA has accredited

VIVITRO LABS, INC.

Victoria, British Columbia, Canada

for technical competence in the field of

Mechanical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).



Presented this 9th day of May 2023.

A blue ink signature of Mr. Trace McInturff, written in a cursive style.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3224.01
Valid to January 31, 2025

For the types of tests to which this accreditation applies, please refer to the laboratory's Mechanical Scope of Accreditation.