LAB TESTING

Certification
Save time and build regulatory confidence with independent lab results from ViVitro Labs. Our laboratory testing services are accredited by the American Association for Laboratory Accreditation (A2LA) and are based on ISO 5840. ViVitro Labs Inc. holds ISO/IEC 17025:2005 accreditation for:
Cardiovascular Implants – Cardiac Valve Prostheses.
• Durability Testing
• Pulsatile-Flow Testing
• Steady Flow Testing

We also offer non-accredited testing service for clients seeking quicker, less costly Preliminary Evaluation and Feasibility Testing.

ViVitro Labs is a member of the ISO standards working committee and is actively engaged in developing testing standards to assist in regulatory submission. ViVitro Labs ensures that test protocols will meet evolving regulatory requirements.

Cardiovascular Device Testing
For new classes of cardiovascular devices without existing testing standards, we break down complex device and pathophysiology into a justifiably simplified bench top test. Each will have well defined:
• Operating conditions [inlet pressure, outlet pressure, internal chamber pressure (if applicable), inflow, outflow, relevant mock heart chamber pressures, cardiac output, and systolic duration]
• Test fluid properties (Chemical composition, temperature, viscosity, density, pH)
• A priori defined acceptance criteria such as acceptable pressure drops, retrograde flow, etc.

Our test plans and reports are designed around approval bodies, thoroughly researched, and justified to ensure they are regulatory appropriate. Contact us today to discuss your cardiovascular testing needs.
Lab Services
Customer Feedback

Lab Services Customer Overall Satisfaction 8.8/10
Rating for 2014 - 2015

Occluder Testing 9.1/10
“We look for professionals with quality products used for testing. Someone we can trust, that can give us ideas. It’s important to work with peers for information.”

Ventricular Assist Device Testing 10/10
“We value their experience. They really know what they are doing. We appreciate all the support they are giving us; everyone is very cooperative.”

Transcatheter Mitral Valve Testing 9.3/10
“ViVitro’s Lab Services greatest strength is its experience.”

Transcatheter Mitral Valve Testing 9.5/10
“Flexibility of test dates, technical expertise.”

Shunt Testing
Quote from Market Research Feedback
“We’re such a new device and we’re not a valve. We did testing early on with an early generation device. Quite frankly I’ve been very pleased with all my interactions with you guys. You’ve been really good about getting everything together, communicating and following up.”
Customized Testing

*In-house experts develop testing solutions unique to your device ensuring the right tests are conducted to determine device safety and efficacy.*

Like our test equipment, ViVitro laboratory testing includes heart valves, artificial hearts, Left Ventricle Assist Devices (LVAD), Occluders for Left Atrial Appendage closure (LAA) and Atrial Septal Defects (ASD), and other cardiovascular devices.

- On-call subject matter experts
- Integral part of a client’s team
- Experience and knowledge base for reliable results
- Dependable and immediate service
- Advice or partnerships

**Time to Market**

We understand how critical your timelines are. We work to your schedule and deliver on our commitments.

**Free Set-up Consultations**

All of our “*in vitro*” studies are developed via no-cost, no obligation, collaborative consultation. We design unique tests to meet specific developmental or regulatory needs.

**Guaranteed Confidentiality**

We happily provide Non-Disclosure Agreements for all services, including initial consultation.
Hydrodynamic Testing

**Pulsatile Flow**
We use ViVitro Pulse Duplicator and SuperPump equipment to document pressure and flow performance characteristics for Valves (Transcatheter, Biological, Mechanical, Venous, Conduits) and other cardiovascular devices including:
- Total artificial hearts (TAH) (ISO 14708-5:2010 Annex DD)
- Valvular repair or reconstruction devices
- Shunts
- Intra-aortic balloon pumps

Obtain key indicators of performance:
- Leakage rate
- Forward flow pressure drop
- Other design-specific parameters

Receive qualitative high speed video and high resolution photography of devices in operation. Simulate pathophysiolgies including hypertension, hypotension, and arrhythmias.

**Steady Flow**
We test for steady forward flow or reverse flow leakage using the ViVitro steady flow bench. Burst testing measures the hydrostatic load at which failure occurs and is useful for determining failure modes of devices.

For new classes of cardiovascular devices without existing testing standards, we break down complex device and pathophysiology into a justifiably simplified bench top test.
Durability Testing

We offer unlimited capacity for ISO 17025 accredited durability assessment and expedite time to market. Our bank of HiCycle durability testers allows millions of test cycles to be accumulated in a short period of time. ViVitro Real-Time Wear Testers provide quasi-real-time rates for additional physiological failure mechanism data.

Dynamic Failure Mode:
Potential failure modes of devices associated with structure deterioration should be identified and well understood. We test a device sample until failure after it has successfully survived the target lifetime. Alternately we obtain faster results by increasing the cycling rate and/or device load.

Testing Outputs:
• Well documented operating conditions and resulting device performance
• Assessment of Pass/Fail criteria if applicable
• High-speed videography and daily visual inspections for feedback and peace of mind throughout the process
• High resolution photography and microscopy (including SEM) for wear characterization
• Optional calcification of devices
Ex-Vivo Testing

We use the ViVitro SuperPump with an excised heart incorporated into a circulatory loop to generate physiological flows for ex-Vivo simulated use testing. This provides the anatomical and functional clinical similarity needed for testing of some transcatheter devices. The ex-Vivo beating heart combines the anatomical and functional clinical similarity with physiological flow and pressure signatures.

Pressure transducers acquire the aortic, ventricular and mitral pressures. A flow meter measures the cardiac output of the simulator. Access sites at the aorta, atrium and apex allows for the insertion of devices. Valve movement is investigated with an endoscope and a transthoracic ultrasound probe. Pathological states such as low ejection fractions and high beat rates are simulated as loading conditions on the heart by control of the pulsatile pump.

Degenerative and functional mitral regurgitation are simulated by severing the mitral chords and pressurizing the left ventricle, respectively. Assess therapeutic mitral valve repair performance with a leaflet clipping device.

Endovascular Testing

We use the ViVitro Endovascular (EV) Simulator to test and document endovascular device physiological pulsatile flow and pressures. Powered by the ViVitro SuperPump, the EV Simulator’s programmable waveform system provides physiological pulsatile flow. We test cardiovascular medical devices and delivery systems by adding anatomical models, including abnormalities or custom patient-specific modeling.

ViVitro Laboratory tests demonstrate that devices can be delivered and deployed in a safe, consistent and accurate manner within the intended implant site and with intended use conditions.

**EV Simulator testing evaluates:**
- Stents
- Stent Grafts
- Balloons
- Wires
- Coils
- Filters
- Transcatheter Heart Valves
- Occluders
- Shunts
- Valves
- VADs

**Assess:**
- Pulsatile Flow Interactions
- Positioning
- Deployment Accuracy
- Sizing
- Conformability
- Trackability and Pushability
- Torquability
- Securement Measuring
- Deployment Force