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# ISO 17025 vs. GLP for *in vitro* testing

ViVitro Labs Inc. is frequently asked if we comply with GLP (Good Laboratory Practice) regulations. ViVitro Labs conducts bench tests that do not involve animals, plants or microorganisms, therefore GLP regulations are not applicable. ViVitro Labs' Laboratory Services (excluding PIV Flow Visualization) are ISO 17025 accredited and follow best laboratory industry practices. This paper clarifies the benefits that ViVitro Labs' ISO 17025 accreditation offers to our clients.

## ViVitro Labs Inc.

ViVitro Laboratory services are governed by a mature Quality Management System (QMS) that outlines management and technical requirements of an accredited laboratory, and as such is certified to ISO/IEC 17025 for the test methods that are based on the ISO 5840 standard. ViVitro Labs' A2LA Scope of Accreditation includes the mechanical testing of cardiovascular implants including heart valve substitutes.

ViVitro Labs' laboratory personnel are proficient in verification of hydrodynamic performance, durability testing, and assessment of flow fields for heart valve substitutes. Testing is conducted with equipment manufactured by ViVitro Labs, leveraging equipment validation over decades of testing and familiarity of regulatory protocols.

## GLP - Good Laboratory Practice

GLP – 21 CFR part 58 Good Laboratory Practices for Nonclinical Studies first introduced in 1978 in the US, refers to a quality system prescribed for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the Food and Drug Administration, including medical devices for human use.

From recently published FDA draft guidance "*The Applicability of GLP in Premarket Device Submissions: Questions and Answers*"

*"Q2: What is a nonclinical laboratory study?*

*A2: A nonclinical laboratory study is an in vivo or in vitro experiment in which a test article is studied prospectively in a test system under laboratory conditions to determine its safety (21 CFR 58.3(d)). A test article is a medical device for human use, or any other article subject to regulation under the Federal Food, Drug, and Cosmetic Act (the Act) or under sections 351 and 354-360F of the Public Health Service Act (21 CFR 58.3(b)). A test system is any animal, plant, microorganism, or subparts thereof to which the test or control article is administered or added for study. A test system also includes appropriate groups or components of the system not treated with the test or control articles (21 CFR 58.3(i)). Examples of nonclinical laboratory studies include in vitro and in vivo biocompatibility testing and animal studies used to evaluate the potential for adverse responses to a medical device.* ***Bench tests, such as chemical or physical testing, and any other studies that do not involve use of an animal, plant, or microorganism, are not included.*** *Studies utilizing human subjects, human specimens, clinical studies, or field trials in animals (e.g., wildlife studies) are not included, nor are basic exploratory studies carried out to determine whether a test article has any potential utility, or to determine physical or chemical characteristics of a test article."*

For the complete FDA guidance document please refer to the FDA website:

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm366338.htm

## ISO/IEC 17025

ISO/IEC 17025 is the standard used by testing and calibration laboratories to outline the general competency requirements. First published in 1999 the standard has many commonalities with the ISO 9000 standard in regards to management requirements, however ISO/IEC 17025 is more specific in technical requirements and applies directly to those organizations that produce testing and calibration results. Laboratories use ISO/IEC 17025 to implement a quality system aimed at improving their ability to consistently produce valid results. Laboratory customers, regulatory authorities and accreditation bodies across the world use the standard as the formal recognition of that competence of laboratories.

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Finally, we would like to point out that like GLP, ViVitro Labs embodies a set of principles that provide a framework within which our laboratory testing are planned, performed, monitored, recorded, reported and archived. For example, all test plans, data and reports are reviewed by Quality Assurance Manager before they are released to the client in order to ensure quality and integrity of the results.

**Summary**

ViVitro Labs has chosen ISO 17025 accreditation since it is the most appropriate and relevant approval for our laboratory services and product testing. We recognize the benefits of GLP compliance, however the regulation is not applicable to the type of testing our laboratory performs.

For further details or clarification please contact us at the above address.

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