



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

LABS INC.
 6933 South Revere Parkway
 Centennial, CO 80112
 Ann Niedzinski Phone: 720 528 4774

BIOLOGICAL

Valid To: October 31, 2017

Certificate Number: 3906.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following biological tests on biologics, medical devices, cellular therapies, water, media washes, tissues, raw materials, and agar plates:

| <u>Test</u> | <u>Test Method</u> |
|-------------------------------|---|
| Bacterial Endotoxin | USP <85>, ANSI/AMII ST 72:2011 |
| Bioburden Testing | USP <61> |
| Biological Indicators / Spore | USP <55>, ISO 11138-1 |
| Organism Identification | USP <1113> |
| Final Sterility Testing | USP <71> |
| Bacteriostasis/Fungistasis | USP <71>, USP<1227> |
| Water Testing | USP <1231> |
| Environmental Monitoring | USP <1116>, ISO 14644 |
| VDmax25 | AAMI TIR37:2007, AAMI TIR33:2005, USP <71>, USP <61> |



Accredited Laboratory

A2LA has accredited

LABS INC.

Centennial, CO

for technical competence in the field of

Biological Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005 *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 8 January 2009).



Presented this 16th day of September 2015.

A handwritten signature in blue ink, which appears to read "Jim C. Bunt".

Senior Director of Quality and Communications
For the Accreditation Council
Certificate Number 3906.01
Valid to October 31, 2017
Revised: August 24, 2016

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