



# PERRY JOHNSON LABORATORY ACCREDITATION, INC.

## *Certificate of Accreditation*

*Perry Johnson Laboratory Accreditation, Inc., has assessed the Laboratory of:*

***Biotest Laboratories, Inc  
8990 Springbrook Drive NW Suite 100  
Minneapolis, MN 55433***

*(Hereinafter called the Organization) and hereby declares that Organization is accredited in accordance with the recognized International Standard:*

***ISO/IEC 17025: 2005***

*This accreditation demonstrated technical competence for the following scope and the operation of a laboratory quality management system (as outlined by the joint ISO-ILAC-IAF Communiqué dated June 18, 2005):*

***Microbiological and Chemical Testing and Verification of Customer-Supplied Products;  
Validation of Customer-Defined Manufacturing Processes as Applied to Medical Products, and  
Commissioning Certification and Testing of Clean Room and Associated Controlled Environments  
(As detailed in the supplement)***

*Such testing and/or calibration services shall only be offered at or from the address given above. This Accreditation is granted subject to the system rules governing the Accreditation referred to above, and the Organization hereby covenants with the Accreditation body's duty to observe and comply with the said rules.*

For PJLA:

President/Operations Manager

*The validity of this certificate is mandated through ongoing surveillance.*

Perry Johnson Laboratory  
Accreditation, Inc. (PJLA)  
26555 Evergreen, Suite 1325  
Southfield, Michigan 48076

*Initial Accreditation Date:*  
January 16, 2003

*Accreditation No.:*  
59230

*Issue Date:*  
July 10, 2008

*Certificate No.:*  
L08-52

*Expiration Date:*  
July 09, 2010

*Page No.:*  
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## Certificate of Accreditation: Supplement

**Biotest Laboratories, Inc**  
 8990 Springbrook Drive NW Suite 100  
 Minneapolis, MN 55433

*Accreditation is granted to this facility to perform the following testing:*

FIELD OF TEST	ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	DETECTION LIMIT
Biological Testing	Medical Devices, Aqueous Solutions	Bacterial Testing CFU (Colony Forming Units) Enumeration and Identification	AAMI/ANSI/ISO USP Customer Protocol EN	Lower: 0 CFU
	Medical Devices, Aqueous Solutions	Mycology Testing CFU (Colony Forming Units) Enumeration and Identification	AAMI/ANSI/ISO USP Customer Protocol EN	Lower: 0 CFU
	Medical Devices, Aqueous Solutions	Sterility Testing Absence or Presence of Bacteria	AAMI/ANSI/ISO USP Customer Protocol EN	Positive/Negative
	Medical Devices, Aqueous Solutions	Bioburden Testing CFU (Colony Forming Units) Enumeration and Identification	AAMI/ANSI/ISO USP Customer Protocol EN	Lower: 0 CFU
	Medical Devices, Aqueous Solutions	Bacterial Endotoxin Testing Endotoxin Units per Device or per mL	AAMI/ANSI/ISO USP Customer Protocol EN	Lower: 0.01 EU
Chemical Testing	Medical Devices, Aqueous Solutions	Determination of Calcium Chloride by Titration	USP Customer Protocol	Lower: 0.79 mg
	Medical Devices, Aqueous Solutions	Ethylene Oxide Residue Testing ppm Ethylene Oxide ppm Ethylene Chlorohydrin ppm Ethylene Glycol by GC	AAMI/ANSI/ISO USP Customer Protocol EN	Lower: 1 ppm
		ETOH by GC	USP Customer Protocol	Lower: 1 ppm



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Environmental Testing	Clean Room and Controlled Environments Particulate	Particle Count in Air	ISO 14644-1, 3 & 4	0 to 999 999 particles
	Clean Room and Controlled Environments Air Flow	Air Velocity	ISO 14644-1, 3 & 4	9 999 FPM
	Clean Room and Controlled Environments Microbial	CFU (Colony Forming Units) Enumeration and Identification	ISO 14644-1, 3 & 4	Lower: 0 CFU