



Accredited Laboratory

A2LA has accredited

ACCUPREC RESEARCH LABS PVT LTD

Ahmedabad, INDIA

for technical competence in the field of

Biological 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 laboratory also meets the A2LA R256 – *Specific Requirements – FDA ASCA Program*. 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 19th day of December 2024.

A blue ink signature of Mr. Trace McInturff, written over a horizontal line.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 7320.01
Valid to December 31, 2026

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



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

ACCUPREC RESEARCH LABS PVT. LTD.
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BIOLOGICAL

Valid To: December 31, 2026

Certificate Number: 7320.01

In recognition of the successful completion of the A2LA evaluation process (including an assessment of the laboratory’s conformance with A2LA’s FDA ASCA Accreditation Program), accreditation is granted to this laboratory to perform the following tests on medical devices:

<u>Test Name</u>	<u>Test Method(s)</u>	<u>SOPs</u>
Hemolytic Properties	ISO 10993-4 and ASTM 756: Direct and Indirect Hemolysis	ARL/SOP/GLP/PT/085
Interactions with Blood	ISO 10993-4: Complement Activation using a U.S. marketed ELISA kit	ARL/SOP/GLP/PT/091
In-Vitro Cytotoxicity	ISO 10993-5 MEM Elution Cytotoxicity	ARL/SOP/GLP/PT/056
Irritation	ISO 10993-23: Dermal Irritation, Intracutaneous Reactivity Irritation	ARL/SOP/GLP/PT/090 ARL/SOP/GLP/PT/020
Pyrogen	ISO 10993-11 and USP 151: Material-Mediated Pyrogenicity	ARL/SOP/GLP/PT/083
Sample Preparation	ISO 10993-12: Sample preparation for all test types	ARL/SOP/GLP/PT/096
Skin Sensitization	ISO 10993-10 and ASTM F720: Guinea Pig Maximization Sensitization	ARL/SOP/GLP/PT/017
	ISO 10993-10: Closed Patch Sensitization	
Systemic Toxicity	ISO 10993-11: Acute Systemic Toxicity	ARL/SOP/GLP/PT/014

Testing Activities performed under the scope of the U.S FDA ASCA Pilot Program Specifications: *Biocompatibility Testing of Medical Devices – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program* published on September 25th, 2020, and in accordance with all requirements of A2LA R256 *Specific Requirements - FDA ASCA Program*

FDA Recognition Number	Test Name	Standard Method¹	Internal SOP
2-248 2-250	Hemolytic Properties	ISO 10993-4 Third edition 2017-04 and ASTM F756-17	ARL/SOP/GLP/PT/085
2-248	Interactions with Blood	ISO 10993-4 Third edition 2017-04	ARL/SOP/GLP/PT/091

FDA Recognition Number	Test Name	Standard Method¹	Internal SOP
2-245	In-Vitro Cytotoxicity	ISO 10993-5 Third edition 2009-06-01	ARL/SOP/GLP/PT/056
2-291	Irritation	ISO 10993-23 First edition 2021-01	ARL/SOP/GLP/PT/090 ARL/SOP/GLP/PT/020
2-255 2-295	Pyrogen Test	ISO 10993-11 Third edition 2017-09 and USP<151>: Material-Mediated Pyrogenicity	ARL/SOP/GLP/PT/083
2-289	Sample Preparation	ISO 10993-12 Fifth edition 2021-01	ARL/SOP/GLP/PT/096
2-296 2-256	Skin Sensitization	ISO 10993-10 Fourth edition 2021-11 and ASTM F720-17: Guinea Pig Maximization Sensitization	ARL/SOP/GLP/PT/017
		ISO 10993-10 Fourth edition 2021-11: Closed Patch Sensitization	
2-255	Systemic Toxicity	ISO 10993-11 Third edition 2017-09	ARL/SOP/GLP/PT/014

¹These methods have been assessed by A2LA according to A2LA's FDA ASCA Program requirements. Accreditation by A2LA does not imply FDA ASCA-Accreditation. All ASCA-accreditation decisions for testing laboratory applications are made solely by the FDA. A list of approved laboratories can be found at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/asca-accredited-testing-laboratories.cfm>.

