National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :	AFFIGENIX BIOSOLUTIONS PRIVATE LIMITED, 265/1F, KSSIDC INDUSTRIAL AREA, BOMMASANDRA, ANEKAL TALUK, BENGALURU, KARNATAKA, INDIA
Accreditation Standard	ISO/IEC 17025:2017
Certificate Number	TC-8612
Validity	14/08/2022 to 13/08/2024

Last Amended on 02/12/2022

S.No	Discipline / Group	Materials or Products tested	Component, parameter or characteristic tested / Specific Test Performed / Tests or type of tests performed	Test Method Specification against which tests are performed and / or the techniques / equipment used
Permanent Facility				
1	BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS	Recombinant Proteins and antibodies	Protein quantification method - BCA	ABPL/SOP/QC/044 Version No.: 04 29.09
2	BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS	Recombinant Proteins. (Insulin & Analogs)	Cell based functional assay for insulin Phosphorylation assay	ABPL/SOP/QC/043 Version No.: 04 29.09
3	BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS	Recombinant Proteins. (Enzymes)	Quantification of impurities by sandwich ELISA	ABPL/SOP/QC/040 Version No.: 04 issue date 29.09
4	BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS	Recombinant Proteins. (Growth factors)	Quantification of HCDNA by using QPCR	ABPL/SOP/QC/041 Version No.: 04 29.09
5	BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS	Recombinant Proteins. (Insulin Aspart)	Immunogenicity assay – Bridge ELISA	ABPL/SOP/QC/045 Version No.: 04 29.09