National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name : VIPRAGEN BIOSCIENCES PRIVATE LIMITED, 67/B,HOOTAGALLI INDUSTRIAL AREA, MYSORE, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

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Validity 16/11/2021 to 15/11/2023 **Last Amended on** 18/01/2023

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-TOXICOLOGY	20G 6 Stripe Tube	Acute Systemic Toxicity Testing	ISO 10993-11
2	BIOLOGICAL-TOXICOLOGY	20G 6 Stripe Tube	Cytotoxicity test - Qualitative evaluation	ISO 10993-5
3	BIOLOGICAL-TOXICOLOGY	Angiographic Catheter	Cytotoxicity test - Qualitative evaluation	ISO 10993-5
4	BIOLOGICAL-TOXICOLOGY	Angiographic Catheter	Hemocompatibility Test	ISO 10993-4
5	BIOLOGICAL-TOXICOLOGY	Angiographic Catheter	Skin Sensitization test	ISO 10993-10
6	BIOLOGICAL-TOXICOLOGY	Angiography Guidewire	Acute Systemic Toxicity Test	ISO 10993-11
7	BIOLOGICAL-TOXICOLOGY	Angiography Guidewire	Cytotoxicity test - Qualitative evaluation	ISO 10993-5
8	BIOLOGICAL-TOXICOLOGY	Angiography Guidewire	Hemocompatibility Test	ISO 10993-4
9	BIOLOGICAL-TOXICOLOGY	Angiography Guidewire	Skin Sensitization test	ISO 10993-10
10	BIOLOGICAL-TOXICOLOGY	Bioresorbable Vascular Scaffold	Acute Systemic Toxicity Testing	ISO 10993-11
11	BIOLOGICAL-TOXICOLOGY	Bioresorbable Vascular Scaffold	Bacterial reverse mutation test	ISO 10993-3
12	BIOLOGICAL-TOXICOLOGY	Bioresorbable Vascular Scaffold	In vitro mammalian chromosome aberration test	ISO 10993-3
13	BIOLOGICAL-TOXICOLOGY	Bioresorbable Vascular Scaffold	In vivo mammalian-micronucleus test	ISO 10993-3
14	BIOLOGICAL-TOXICOLOGY	Bioresorbable Vascular Scaffold	Skin Sensitization test	ISO 10993-10
15	BIOLOGICAL-TOXICOLOGY	Bioresorbable Vascular Scaffold	Tests for Local Effects after Implantation	ISO 10993-06
16	BIOLOGICAL-TOXICOLOGY	Biosimilars	Innocuity	IP
17	BIOLOGICAL-TOXICOLOGY	Biosorbable Suture	Acute Systemic Toxicity Testing	ISO 10993-11
18	BIOLOGICAL-TOXICOLOGY	Biosorbable Suture	Irritation Test	ISO 10993-10

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19	BIOLOGICAL-TOXICOLOGY	Biosorbable Suture	Tests for Local Effects after Implantation	ISO 10993-6
20	BIOLOGICAL-TOXICOLOGY	Condom (Rubber)	Acute Systemic Toxicity Test	ISO 10993-17
21	BIOLOGICAL-TOXICOLOGY	Condom (Rubber)	Bacterial Reverse Mutation Test	ISO 10993:3
22	BIOLOGICAL-TOXICOLOGY	Condom (Rubber)	Cytotoxicity test - Qualitative evaluation	ISO 10993-5
23	BIOLOGICAL-TOXICOLOGY	Condom (Rubber)	Irritation Test	ISO 10993-10
24	BIOLOGICAL-TOXICOLOGY	Condom (Rubber)	Skin Sensitization test	ISO 10993
25	BIOLOGICAL-TOXICOLOGY	Copper T	Acute Systemic Toxicity Test	ISO 10993-11
26	BIOLOGICAL-TOXICOLOGY	Copper T	Cytotoxicity test - Qualitative evaluation	ISO 10993-5
27	BIOLOGICAL-TOXICOLOGY	Copper T	Hemocompatibility Testing	ISO 10993-4
28	BIOLOGICAL-TOXICOLOGY	Copper T	Irritation Test	ISO 10993-10
29	BIOLOGICAL-TOXICOLOGY	Coronary Stent	Acute Systemic Toxicity Test	ISO 10993-11
30	BIOLOGICAL-TOXICOLOGY	Coronary Stent	Bacterial Reverse Mutation Assay	ISO 10993:3
31	BIOLOGICAL-TOXICOLOGY	Coronary stent	Cytotoxicity test - Qualitative evaluation	ISO 10993-5
32	BIOLOGICAL-TOXICOLOGY	Formulation Sample (Film)	Irritation Test	ISO 10993-10
33	BIOLOGICAL-TOXICOLOGY	Formulation sample (film)	Skin Sensitization Test	ISO 10993-10
34	BIOLOGICAL-TOXICOLOGY	Formulation Sample (film)	Tests for Local Effects after Implantation	ISO 10993-6
35	BIOLOGICAL-TOXICOLOGY	Guiding Catheter	Acute Systemic Toxicity Testing	ISO 10993-11
36	BIOLOGICAL-TOXICOLOGY	Guiding Catheter	Cytotoxicity test - Qualitative evaluation	ISO 10993-5
37	BIOLOGICAL-TOXICOLOGY	Guiding Catheter	Hemocompatibility Testing	ISO 10993-4

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38	BIOLOGICAL-TOXICOLOGY	Heart Lung Pack	Cytotoxicity test - Qualitative evaluation	ISO 10993-5
39	BIOLOGICAL-TOXICOLOGY	Heart Lung Pack	Hemocompatability Testing	ISO 10993-4
40	BIOLOGICAL-TOXICOLOGY	Heart-lung Pack	Acute Systemic Toxicity	ISO 10993-11
41	BIOLOGICAL-TOXICOLOGY	Hypodermic Needle (Stain Less Steel)	Irritation Test	ISO 10993-10
42	BIOLOGICAL-TOXICOLOGY	Hypodermic Needle (Base of needle polypropylene silicone coated)	Bacterial reverse mutation test	ISO 10993-3
43	BIOLOGICAL-TOXICOLOGY	Hypodermic Needle (Base of needle polypropylene silicone coated)	Cytotoxicity test - Qualitative evaluation	ISO 10993-5
44	BIOLOGICAL-TOXICOLOGY	Hypodermic Needle (Base of needle polypropylene silicone coated)	Hemocompatibility Test	ISO 10993-4
45	BIOLOGICAL-TOXICOLOGY	Hypodermic Needle (Base of needle polypropylene silicone coated)	In-vitro mammalian chromosomal aberration	ISO 10993-3
46	BIOLOGICAL-TOXICOLOGY	Hypodermic Needle (Base of needle polypropylene silicone coated)	Irritation Test	ISO 10993-10
47	BIOLOGICAL-TOXICOLOGY	Hypodermic Needle (Base of needle polypropylene silicone coated)	Pyrogen Test	ISO 10993-11
48	BIOLOGICAL-TOXICOLOGY	Hypodermic Needle (Base of needle polypropylene silicone coated)	Skin Sensitization test	ISO 10993-10
49	BIOLOGICAL-TOXICOLOGY	Hypodermic Needle (Base of needle polypropylene silicone coated).	Acute Systemic Toxicity Test	ISO 10993-11
50	BIOLOGICAL-TOXICOLOGY	Hypodermic Needle (Base of needle polypropylene silicone coated).	In-vivo micro nucleus Test	ISO 10993-3
51	BIOLOGICAL-TOXICOLOGY	Introducer Needle	Acute Systemic Toxicity Test	ISO 10993-11
52	BIOLOGICAL-TOXICOLOGY	Introducer Needle	Cytotoxicity test - Qualitative evaluation	ISO 10993-5
53	BIOLOGICAL-TOXICOLOGY	Introducer Needle	Hemocompatibility Test	ISO 10993-4
54	BIOLOGICAL-TOXICOLOGY	Introducer Sheath kit	Acute Systemic Toxicity Testing	ISO 10993-11
55	BIOLOGICAL-TOXICOLOGY	Introducer Sheath kit	Cytotoxicity test - Qualitative evaluation	ISO 10993-5
56	BIOLOGICAL-TOXICOLOGY	Introducer Sheath kit	Hemocompatibility Testing	ISO 10993-4

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57	BIOLOGICAL-TOXICOLOGY	IVF consumables	Sperm Motility Assay	WHO
58	BIOLOGICAL-TOXICOLOGY	Liposomal amphotericin B injection	Acute Toxicity	IP
59	BIOLOGICAL-TOXICOLOGY	luteinizing	Bioassay	IP
60	BIOLOGICAL-TOXICOLOGY	Medical Devices in IVF	Mouse Embyo Assay	FDA
61	BIOLOGICAL-TOXICOLOGY	Menotrophin	Bioassay	IP
62	BIOLOGICAL-TOXICOLOGY	Processed Bovine Pericardial Patch	Acute Systemic Toxicity Test	ISO 10993-11
63	BIOLOGICAL-TOXICOLOGY	Processed Bovine Pericardial Patch	Bacterial Reverse Mutation Test	ISO 10993-3
64	BIOLOGICAL-TOXICOLOGY	Processed Bovine Pericardial Patch	Hemocompatibility Test	ISO 10993-4
65	BIOLOGICAL-TOXICOLOGY	Processed Bovine Pericardial patch	In vitro mammalian chromosome aberration test	ISO 10993-3
66	BIOLOGICAL-TOXICOLOGY	Processed Bovine Pericardial Patch	In vivo mammalian-micronucleus test	ISO 10993-3
67	BIOLOGICAL-TOXICOLOGY	PTCA Balloon Dilation Catheter	Acute Systemic Toxicity Testing	ISO 10993-11
68	BIOLOGICAL-TOXICOLOGY	PTCA Balloon Dilation Catheter	Cytotoxicity test - Qualitative evaluation	ISO 10993-5
69	BIOLOGICAL-TOXICOLOGY	PTCA Balloon Dilation Catheter,	Hemocompatibility Testing	ISO 10993-4
70	BIOLOGICAL-TOXICOLOGY	PTCA Guidewire	Acute Systemic Toxicity Test	ISO 10993-11
71	BIOLOGICAL-TOXICOLOGY	PTCA Guidewire	Cytotoxicity test - Qualitative evaluation	ISO 10993-5
72	BIOLOGICAL-TOXICOLOGY	PTCA Guidewire	Hemocompatibility Test	ISO 10993-4
73	BIOLOGICAL-TOXICOLOGY	Spinal implants	Bacterial Reverse Mutation test	ISO 10993-3
74	BIOLOGICAL-TOXICOLOGY	Spinal Implants	Cytotoxicity test - Qualitative evaluation	ISO 10993-5
75	BIOLOGICAL-TOXICOLOGY	Spinal Implants	Hemocompatibility Test	ISO 10993-4

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76	BIOLOGICAL-TOXICOLOGY	Spinal Implants	In vivo mammalian chromosome aberration test	ISO 10993-3
77	BIOLOGICAL-TOXICOLOGY	Spinal Implants	Tests for Local Effects after Implantation	ISO 10993-6
78	BIOLOGICAL-TOXICOLOGY	Stain less Steel cannula	Bacterial Reverse Mutation test	ISO 10993-3
79	BIOLOGICAL-TOXICOLOGY	Stainless Steel Cannula	Acute Systemic Toxicity Test	ISO 10993-11
80	BIOLOGICAL-TOXICOLOGY	Stainless Steel Cannula	Cytotoxicity test - Qualitative evaluation	ISO 10993-5
81	BIOLOGICAL-TOXICOLOGY	Stainless Steel Cannula	Hemocompatibility Test	ISO 10993-4
82	BIOLOGICAL-TOXICOLOGY	Stainless Steel Cannula	In vitro mammalian chromosome aberration test	ISO 10993-3
83	BIOLOGICAL-TOXICOLOGY	Stainless Steel Cannula	In vivo mammalian chromosome aberration test	ISO 10993-3
84	BIOLOGICAL-TOXICOLOGY	Stainless Steel Cannula	In vivo mammalian-micronucleus test	ISO 10993-3
85	BIOLOGICAL-TOXICOLOGY	Stainless Steel Cannula	Skin sensitization test	ISO 10993-10
86	BIOLOGICAL-TOXICOLOGY	Surgical Gloves	Cytotoxicity test - Qualitative evaluation	ISO 10993-5
87	BIOLOGICAL-TOXICOLOGY	Surgical Gloves	Irritation Test	ISO 10993-10
88	BIOLOGICAL-TOXICOLOGY	Surgical Tissue Heart Valve Components (without Tissue)	Acute Systemic Toxicity Test	ISO 10993-11
89	BIOLOGICAL-TOXICOLOGY	Surgical Tissue Heart Valve Components (Without Tissue)	Cytotoxicity test - Qualitative evaluation	ISO 10993-5
90	BIOLOGICAL-TOXICOLOGY	Surgical Tissue Heart Valve Components (without Tissue)	In vivo mammalian-micronucleus test	ISO 10993-3
91	BIOLOGICAL-TOXICOLOGY	Surgical Tissue Heart Valve Components (without Tissue)	Skin Sensitization test	ISO 10993-10
92	BIOLOGICAL-TOXICOLOGY	Surgical Tissue Heart Valve Components (without Tissue)	Tests for Local Effects after Implantation	ISO 10993-6
93	BIOLOGICAL-TOXICOLOGY	Surgical tissue heart valve components without tissue	Bacterial reverse mutation test	ISO 10993-3
94	BIOLOGICAL-TOXICOLOGY	Syringe	Intracutaneous Reactivity	ISO 10993-10

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95	BIOLOGICAL-TOXICOLOGY	Syringe	Systemic Toxicity	ISO 10993-11
96	BIOLOGICAL-TOXICOLOGY	Transcatheter Aortic valve	Acute Systemic Toxicity Testing	ISO 10993-11
97	BIOLOGICAL-TOXICOLOGY	Transcatheter Aortic Valve	Cytotoxicity test - Qualitative evaluation	ISO 10993-5
98	BIOLOGICAL-TOXICOLOGY	Transcatheter Aortic Valve	In vitro mammalian chromosome aberration test	ISO 10993-3
99	BIOLOGICAL-TOXICOLOGY	Transcatheter Aortic Valve	In vivo mammalian-micronucleus test	ISO 10993-3
100	BIOLOGICAL-TOXICOLOGY	Transcatheter Aortic Valve	Skin Sensitization test	ISO 10993-10
101	BIOLOGICAL-TOXICOLOGY	Transcatheter Aortic Valve	Tests for Local Effects after Implantation	ISO 10993-06
102	BIOLOGICAL-TOXICOLOGY	Urofollitropin	Bioassay	IP
103	BIOLOGICAL-TOXICOLOGY	Y Connecter	Hemocompatibility Testing	ISO 10993-4
104	BIOLOGICAL-TOXICOLOGY	Y Connector	Acute Systemic Toxicity	ISO 10993-11
105	BIOLOGICAL-TOXICOLOGY	Y Connector	Cytotoxicity test - Qualitative evaluation	ISO 10993-5