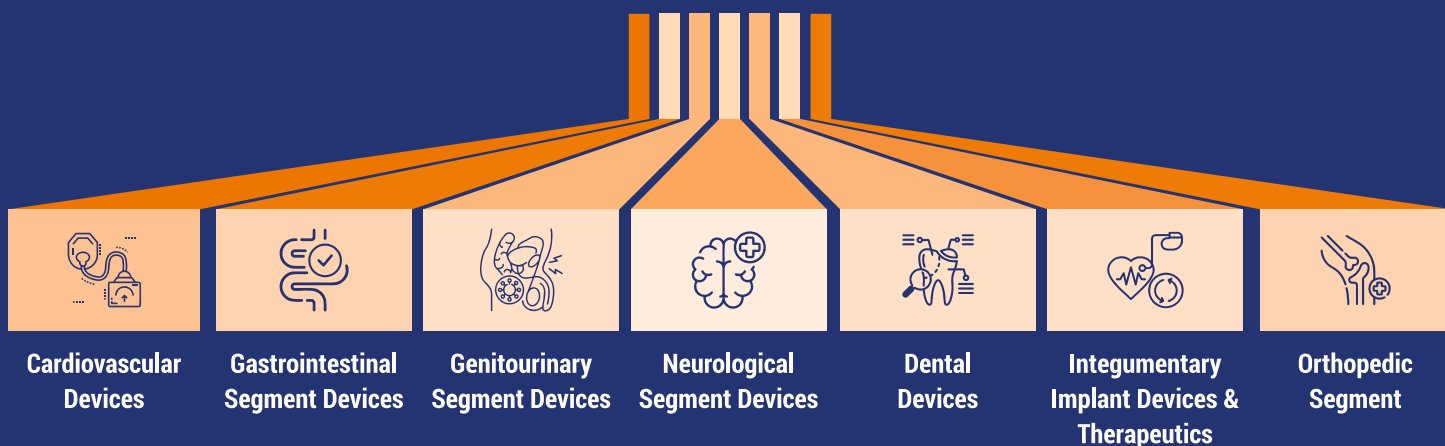


MEDICAL DEVICE TESTING SERVICES

ONE-STOP-SHOP FOR ALL YOUR
BIOCOMPATIBILITY & SAFETY
ASSESSMENT TESTING NEEDS



DEVICES WE TEST



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ANSI National
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Registered



DSIR Recognized



CDSCO Approved



STUDY TYPE

CATEGORY AND ISO NO.	STUDY TYPE
CYTOTOXICITY TESTS ISO 10993-5	• Elution method (qualitative) • Elution method [quantitative (NRU/MTT/XTT)] • Direct cell contact method • Agar diffusion method • Colony formation assay
SENSITIZATION TESTS ISO 10993-10	• Guinea pig maximization test (GPMT) • Buehler sensitization test • Local lymph node assay (LLNA)
IRRITATION TEST ISO 10993-23	• Intracutaneous reactivity test • Skin irritation test (in vivo and in vitro assay) • Ocular irritation test (in vivo and in vitro assay) • Buccal (mucosal) irritation test • Bladder irritation • Vaginal irritation • Rectal irritation • Penile irritation • Nasal irritation
SYSTEMIC TOXICITY TESTING (ISO 10993-11)	• Acute systemic toxicity test • Material mediated pyrogenicity testing • Subacute (28 days) systemic toxicity test • Subchronic (90 days) systemic toxicity test • Chronic systemic toxicity test (180 days)
IMPLANTATION TEST ISO 10993, PART 6 - INTRAMUSCULAR	• Intramuscular implantation test of varying period (1 week, 2 weeks, 4 weeks, 8 weeks, 13 weeks, 26 weeks, 52 weeks)
IMPLANTATION TEST ISO 10993, PART 6 - SUBCUTANEOUS	• Subcutaneous implantation test of varying period (1 week, 2 weeks, 4 weeks, 8 weeks, 13 weeks, 26 weeks, 52 weeks)
IMPLANTATION TEST ISO 10993, PART 6 - BONE	• Bone implantation test of varying period (1 week, 2 weeks, 4 weeks, 8 weeks, 13 weeks, 26 weeks, 52 weeks)
HEMOCOMPATIBILITY TESTS ISO 10993-4	• Haemolysis test (direct contact & extract method) • Platelet activation assay (PF4) • β Thromboglobulin assay (β-TG) • Complement activation test - (SC5b9) • Platelet leukocyte count (PLC)
GENOTOXICITY TESTS ISO 10993-3 AND 33	• Bacterial reverse mutation test (Ames test) • In vitro mammalian chromosomal aberration test in CHO cells • In vitro mammalian cell gene mutation test using the thymidine kinase gene (mouse lymphoma assay) • In vitro mammalian chromosomal aberration test in human peripheral blood lymphocytes • In vitro mammalian cell micronucleus test • In vivo micronucleus test • In vivo chromosomal aberration test

