


**NO: SAMM 479**(Issue 1, 17 April 2025 replacement  
of SAMM 479 dated 17 April 2025)

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<b>LABORATORY LOCATION/ CENTRAL OFFICE:</b>	MAKMAL BIOSERASI, CENTRE FOR NATURAL AND PHYSICAL LABORATORY MANAGEMENT UKM (ALAF-UKM) UNIVERSITI KEBANGSAAN MALAYSIA , 43600, SELANGOR MALAYSIA
	
<b>ACCREDITED SINCE :</b>	17 APRIL 2025
<b>FIELD(S) OF TESTING:</b>	TOXICITY

This laboratory has demonstrated its technical competence to operate in accordance with MS ISO/IEC 17025:2017 (ISO/IEC 17025:2017).

This laboratory's fulfillment of the requirements of ISO/IEC 17025 means the laboratory meets both the technical competence requirements and management system requirements that are necessary for it to consistently deliver technically valid test results and calibrations. The management system requirements in ISO/IEC 17025 are written in language relevant to laboratory operations and operate generally in accordance with the principles of ISO 9001 (see Joint ISO-ILAC-IAF Communiqué dated April 2017).

<b>CENTRAL LOCATION:</b>	MAKMAL BIOSERASI, CENTRE FOR NATURAL AND PHYSICAL LABORATORY MANAGEMENT UKM (ALAF-UKM) UNIVERSITI KEBANGSAAN MALAYSIA , 43600, Selangor
<b>FIELD(S) OF TESTING :</b>	TOXICITY,

**SCOPE OF TESTING : TOXICITY**

<b>Material / Product Tested</b>	<b>Type Of Test / Properties Measured / Range Of Measurement</b>	<b>Standard Test Methods / Equipment / Techniques</b>
/ Cosmetic Formulations / Biologicals /	Acute toxicity effect (in vivo)	Acute Systemic Toxicity Study (Intravenous) based on ISO 10993-
/ Food Ingredients / Biologicals /	Acute toxicity effect (in vivo)	Acute Systemic Toxicity Study (Intraperitoneal) based on ISO
Biologicals /	None	Primary Skin Irritation Assay based
Chemicals / Cosmetic Formulations / Biologicals /	None	10993-10:2021
Formulations / Chemicals / Cosmetic Formulations / Pharmaceuticals	Cytotoxic effect (in vitro)	MEM Elution Assay based on ISO 10993-5:2009
Formulations / Pesticides /	Cytotoxic effect (in vitro)	Methods. (1983) 65:55-63

# Schedule

Issue date: 17 April 2025  
Valid Until: -



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Material / Product Tested	Type Of Test / Properties Measured / Range Of Measurement	Standard Test Methods / Equipment / Techniques
	None	10993-23:2021, Single-Exposure
Ingredients Formulations / Biologicals /	Genotoxicity effect - DNA	Alkaline Comet Assay based on
Medical Devices	Cytotoxic effect (in vitro)	MTT Assay (Annex C) based on ISO 10993-5:2009
	Intracutaneous reactivity of the skin (in vivo)	Animal Irritation Test by Intracutaneous (Intradermal) Administration ISO 10993-23:2021
	None	In-house Method [TM-500] Sterility
	In-vitro Cytotoxicity Test	ISO 10993-5:2009,
	Systemic Toxicity	ISO 10993-11:2017 Edition
	Haemolysis Study of Medical	Biological evaluation of medical
	In Vitro Cytotoxicity Test	Direct Contact Cytotoxicity
	Cytotoxicity	ISO 10993-5 (2013): Biological
	Bioburden Test- Microbial	USP 43 ,
	Sterility Tests	USP 43 ,
	Estimation of Product Bioburden	None
	Endotoxin	Test for Bacterial Endotoxin, BP
Medical Devices /	None	Rabbit Pyrogen Test based on USP.
Medical Devices / Chemicals	None	None
	None	None
Medical Devices / Herbal	None	MTT Assay based on J. /mmunol.
	None	Animal Irritation Test based on ISO
	None	None
Medical Devices / Herbal Formulations / Pesticides /	None	Skin Sensitization Test -" Guinea Pig Maximization Test based on ISO
Pharmaceuticals	damage, DNA strand breaks (in	Environ Mol Mutagen (2000) 35:206-
	None	on 16 CFR 1500.41 & 1500.3 (c)(4)
	None	Dermal Sensitization Assay -"
	None	11:2017
	None	10993-11:2017
	Raise in body temperature (in	General Chapter, Pyrogen
	Arsenic (as As)	None
	None	None
	None	None
Waste / Chemicals / Cosmetic Formulations /	Irritation effect of skin (in vivo)	Test
Waste / Chemicals / Food / Cosmetic	None	modification.

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