**List of Regulations relevant to SAMM Medical Testing**

| **Scheme** | **Programme /Fields** | **Regulation / requirements** | **Regulatory Agency** | **Reference** | **Standards Malaysia Ref.** |
| --- | --- | --- | --- | --- | --- |
| SAMM | Medical Testing | It is mandatory for any fully registered medical practitioner who wishes to practice medicine in this country to apply for an Annual Practicing Certificate (APC) after the first year of his full registration. | KKM | Medical Act 1971 | SC 2 |
| SAMM | Medical Testing | The establishment of a National Accreditation Standard for medical testing laboratories based on ISO 15189, and the passing of the Pathology Laboratory Act in Parliament in mid-2007. The Pathology Laboratory Act 2007 seeks to ensure that the pathology laboratory is accountable to the public, meets required standards of practice, participates in Quality Assurance programmes, is run by qualified staff, complies with safety requirements and is subject to continuous audit. The Act is applicable to all private laboratories (stand alone or hospital) and laboratories in statutory bodies (Universities, foundations). | KKM | Pathology Laboratory Act 2007 | SC 2 |
| SAMM | Medical Testing | For licensing and monitoring of private healthcare facilities. | KKM | Private Healthcare Facilities and Services Act 1998  <https://www.mma.org.my/images/pdfs/Link-LawOfMsiaAct/private-healthcare-facilities-and-services-act-1998.pdf> | SC 2 |
| SAMM | Medical Testing | An Act to regulate medical devices, the industry and to provide matters connected thereto  Laboratory is required to used vendors/supplies of reagent which has registered with MDA. | MDA | Act 737 Medical Device Authority Act 2012  <http://www.federalgazette.agc.gov.my/outputaktap/20120209_737_BI_JW001759%20Act%20737%20(BI).pdf>  Surat pekeliling….  <https://portal.mda.gov.my/doc-list/circular-letter.html> |  |
| SAMM | Medical Testing | A Joint Committee of the College of Pathologists, Academy of Medicine Malaysia (CPath) and the Ministry of Health of Malaysia (MOH) was established in early 2004 to develop guidelines on the minimum requirements for retention of pathology records and materials for Pathology Laboratories in Malaysia. | CPATH  KKM | Guidelines on Retention of Pathology Records and Materials, Part I (VERSION 1/2005)  <http://mjpath.org.my/past_issue/MJP2005.1/10-guideline.pdf> | SC 2 |
| SAMM | Medical Testing | The proper human tissue management by the laboratory. | KKM | Akta 130 Akta Tisu Manusia 1974; Mengandungi Pindaan hingga 1 Januari 2006  <http://www.moh.gov.my/index.php/pages/view/403> |  |
| SAMM | Medical Testing | The participating laboratories must be accredited and certified with MS ISO 15189 for all laboratory tests identified under the Concession within twenty-four (24) months upon signing of the Agreement | FOMEMA | FOMEMA SOP -  SOP for Laboratories Registered with FOMEMA |  |