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Class of Test Structure – Medical Testing

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Introduction

Accreditation in the field of Medical Testing is described into classes and sub-classes of test. Accreditation maybe made for one or more classes of test, or for one or more sub-classes or specific tests within a single class of test, whenever possible, accreditation should be specific and in the form of the list of classes of test provided below.

Most accreditation is described in more detail and usually includes reference to specific determinations, relevant standard test methods and specification, or in-house test method.

The scope of accreditation may be reviewed and extended on request, provided that the laboratory complies with condition for accreditation for the classes of tests or specific test involved.

6.1 Microbiology

6.2 Bacteriology

- .01 Preparation of films for microscopic examination
- .02 Inoculation of cultures
- .03 Microscopic examination of clinical specimens
- .04 Identification of organisms including antibiotic susceptibility testing
- .05 Identification of organisms excluding antibiotic susceptibility testing
- .06 Detection of bacterial antigens by non-cultural non-molecular techniques
- .07 Specialized antibiotic procedures
- .08 Miscellaneous tests

6.3 Parasitology

- .01 Preparation and examination of films
- .02 Definitive identification of parasites
- .03 Limited identification of parasites
- .04 Detection of parasitic antigens by non-cultural non-molecular techniques
- .05 Miscellaneous tests


6.4 Virology

- .01 Isolation of viruses
- .02 Definitive identification of viruses
- .03 Limited identification of viruses
- .04 Detection of viral antigens by non-cultural non-molecular techniques
- .05 Miscellaneous tests


6.5 Mycology

- .01 Microscopic examination of clinical specimens
- .02 Culture of specimens
- .03 Limited identification of fungi
- .04 Definitive identification of fungi
- .05 Susceptibility to antifungal agents
- .06 Detection of fungal antigens by non-cultural non-molecular techniques
- .07 Miscellaneous tests

6.6 Mycobacteriology

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- .01 Microscopic examination of clinical specimens
 - .02 Culture for isolation of mycobacteria
 - .03 Limited identification of isolates
 - .04 Definitive identification of isolates
 - .05 Susceptibility testing
 - .06 Miscellaneous tests
- 6.7 Serology of infection
- .01 Limited serological testing
 - .02 General serological testing
 - .03 Specialized or uncommon serological testing procedures
 - .04 Miscellaneous tests
- 6.8 Detection and characterization of microbial DNA/RNA
- .01 Detection and characterization of bacterial DNA/RNA
 - .02 Detection and characterization of parasitic DNA/RNA
 - .03 Detection and characterization of viral DNA/RNA
 - .04 Detection and characterization of fungal DNA/RNA
 - .05 Detection and characterization of mycobacterial DNA/RNA
 - .06 Genotyping for infectious diseases
 - .07 Sanger sequencing
 - .08 Massively parallel sequencing
 - .09 Miscellaneous tests
- 6.9 Tests on clinical non-human specimens
- .01 Environmental investigations
 - Spore strips/capsules, Air strips
 - .02 Investigation of nosocomial infections in outbreaks and/or individuals
 - MRSA/VRE/Acinetobacter/Other resistant organisms
 - Gastrointestinal endoscopes
 - Vascular catheter tips
 - Transfusion bags
 - .03 Dialysis waters
- 6.10 Miscellaneous
- .01 Semen analysis (Screening Test)
 - .02 Miscellaneous tests
- 6.11 Immunohaematology
- . 01 Blood grouping including ABO, Rh(D)
 - . 02 Blood group antibody screening
 - . 03 Identification of blood group antibodies
 - . 04 Determination of compatibility of donor units
 - . 05 Red cell phenotyping
 - . 06 Antibody elution
 - . 07 Antibody titration
 - . 08 Storage and distribution of blood and blood components
 - . 09 Blood grouping including ABO, Rh(D) and other antigens by automated methods
 - . 10 Blood grouping including ABO, Rh(D) and other antigens and antibody screening by automated methods
 - . 11 Blood grouping including ABO, Rh(D) and other antigens by manual methods

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- . 12 Blood grouping including ABO, Rh(D) and other antigens and antibody screening by manual methods
- . 13 Investigation of transfusion reactions
- . 14 Direct antiglobulin test (Poly and monospecific)
- . 15 Identification of platelet antibodies
- . 16 Identification of platelet antigens
- . 17 Identification of granulocyte antibodies
- . 18 Identification of granulocyte antigens
- . 19 Detection of anti-IgA antibodies in transfusion recipients with low IgA levels
- . 20 Molecular genetic studies
- . 21 Miscellaneous tests

6.12 Haematology

- . 01 Blood counts
- . 02 Visual examination of blood films
- . 03 Erythrocyte sedimentation rate
- . 04 Automated differential leucocyte counts
- . 05 Automated reticulocyte counts
- . 06 Blood film examinations involving special staining procedures
- . 07 Examination for malarial parasites
Thick and thin film examination, ICT kit
- . 08 Bone marrow examination
- . 09 Human progenitor cell collection
- . 10 Progenitor cell transplantation procedures
- . 11 Tests for haemoglobin variants and thalasseмии
- . 12 Tests for foetal Hb
- . 13 Tests to investigate haemolysis
- . 14 Screening tests for G6PD deficiency
- . 15 Red cell enzyme assays 10.71
- . 16 Limited haemostasis related tests
- . 17 Extended haemostasis related tests
- . 18 Point of care testing
- . 19 Mobile/ Filed PoCT
- . 20 Tests of platelet function
- . 21 *In vivo* radioisotopic haematological tests
- . 22 Iron studies
- . 23 Screening test for infectious mononucleosis
- . 24 Vitamin B₁₂ and folate (serum and red cell)
- . 25 Cryoglobulins . cryofibrinogens
- . 26 β₂-microglobulin
- . 27 Plasma viscosity
- . 28 Immunophenotyping
- . 29 Molecular genetic studies
- . 30 Electron microscopy
- . 31 Miscellaneous tests

6.13 Immunopathology

- . 01 Quantitative investigation of immunoglobulins G, A, M and D in body fluids
- . 02 Qualitative investigation of immunoglobulins G, A, M and D in body fluids including paraprotein typing, CSF oligoclonal bands and Bence Jones proteins

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- . 03 Investigation of complement
- . 04 Rheumatoid factor - quantitative assays
- . 05 Detection of autoantibodies in body fluids and biopsy material
- . 06 Tests of cellular immunity - quantitation of lymphocytes
- . 07 Tests of cellular immunity - *in vitro* lymphocyte function tests
- . 08 Tests of cellular immunity - cytokine assays
- . 09 Assessment of neutrophils - quantitation
- . 10 Assessment of neutrophils - *in vitro* functional tests
- . 11 Natural killer cell assay by flow cytometry or radioisotope release from target cells
- . 12 Immunophenotyping
- . 13 Human Leucocyte Antigen (HLA) typing
- . 14 HLA Single Antigen Tests
 Descriptore required: HLA – B27, HLA B51
- . 15 Total IgE
- . 16 Allergen - specific IgE
- . 17 Eosinophil cationic protein
- . 18 Tryptase
- . 19 Simple slide tests for biochemical and immunological analytes
- . 20 Cytokines
- . 21 Molecular genetic studies
- . 22 Killer-cell immunoglobulin-like receptors (KIR) typing
- . 23 β_2 -microglobulin
- . 24 Miscellaneous tests

6.14 Anatomical pathology

6.15 Histopathology

- . 01 Histopathology of biopsy material
- . 02 Immediate frozen section diagnosis
- . 03 Immunohistochemical investigation
- . 04 Paraffin-ISH (Chromogenic)
- . 05 Paraffin-ISH

6.16 Cytopathology

- . 01 Gynaecological (cervical)
- . 02 Non-gynaecological
- . 03 Fine needle aspiration biopsy specimens
- . 04 Gynaecological (other than cervical)

6.17 Examination by electron microscopy


6.18 Autopsy service

6.19 Mortuary facilities


6.20 Chemical pathology

6.21 General chemistry

- . 01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies

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- . 02 Proteins, quantitative analysis
- . 03 Proteins, qualitative and semi-quantitative analysis; including by electrophoresis and immunoelectrophoresis
- . 04 Point of care testing for blood gases, glucose and other profiles
- . 05 CO-oximetry
- . 06 Blood pH and gas tensions
- . 07 Other analytes performed on a blood gas analyzer
- . 08 Haem-related pigments and precursors
- . 09 Trace elements
- . 10 Drugs for therapeutic monitoring
- . 11 Alcohol for non-legal purposes
- . 12 Drugs for toxicological purposes
- . 13 Drugs for toxicological purposes to AS/NZS 4308:2001
- . 14 Drugs for toxicological purposes in urine to AS/NZS 4308:2008
 Descriptors available:
 - Section 2 Specimen collection, storage, handling and dispatch
 - Appendix A On-site screening procedure
 - Section 3 General laboratory requirements
 - Section 4 Laboratory screening procedures
 - Section 5 Laboratory confirmatory procedures
- . 15 Drugs for toxicological purposes in oral fluid to AS 4760:2006
 Descriptors available:
 - Section 2 Collection, storage, handling and dispatch
 - Section 3 On-site initial testing
 - Section 4 Laboratory initial testing
 - Section 5 Confirmatory testing procedures
- . 16 Hormones
- . 17 Hormone receptor assays
- . 18 Sweat electrolytes
- . 19 Maternal markers of foetal wellbeing
- . 20 Amniotic fluid analytes for foetal lung maturity
- . 21 Amniotic fluid analytes for foetal abnormalities
- . 22 Iron studies
- . 23 Vitamin B₁₂ and folate
- . 24 Vitamin assays
- . 25 Protein and peptide tumour markers
- . 26 C-1 esterase inhibitor
- . 27 Markers of bone metabolism
- . 28 Solid tissue enzymes
- . 29 Trace elements in solid tissues
- . 30 Biogenic amines
- . 31 Glycohaemoglobins
- . 32 Point of care testing for Hb A_{1c}
- . 33 pH of urine and fluids by electrode
- . 34 Breath tests
- . 35 Pregnancy tests - qualitative
- . 36 Faecal fats
- . 37 Faecal occult blood
- . 38 Faecal α₁-antitrypsin
- . 39 Reducing substances and/or other sugars in urine or faeces
- . 40 Malabsorption tests, not otherwise specified

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- . 41 Simple slide tests for biochemical and immunological analytes
- . 42 Calculi
- . 43 Intermediary metabolites
- . 44 Special enzyme assays
- . 45 Chemicals for toxicological purposes
- . 46 Automated detection of autoantibodies in body fluids
- . 47 Snake Venom Detection
- . 48 Mobile/ Field PoCT
- . 49 Miscellaneous tests

6.22 Biochemical genetics

- . 01 Metabolite analysis
- . 02 Enzymology
- . 03 Tissue culture and long term storage


6.23 Newborn Screening

- . 01 Immunoassays
- . 02 Colorimetric/fluorescence assays
- . 03 Tandem mass spectrometry
- . 04 DNA assays for a defined mutation or polymorphism


6.24 Genetic testing

6.25 Cytogenetics

- . 01 Blood
- . 02 Bone marrow
- . 03 Amniotic fluid
- . 04 Chronic villus tissue
- . 05 Other tissues – non malignant
- . 06 Other tissues - malignant
- . 07 Detection of defined, unbalanced chromosomal abnormalities by FISH
- . 08 Karyotype detection of unbalanced chromosome abnormalities by a microarray based method
 Descriptor required for sample type from:
 - Blood
 - Bone Marrow
 - Amniotic fluid
 - Chorionic villus tissue
 - Other tissues – non-malignant
 - Other tissues – malignant
- . 09 Karyotype detection of balanced and unbalanced chromosome abnormalities by a microscopy based method
 Descriptor required for sample type from:
 - Blood
 - Bone Marrow
 - Amniotic fluid
 - Chorionic villus tissue
 - Other tissues – non-malignant
 - Other tissues – malignant
- . 10 Miscellaneous tests


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- 6.26 Molecular genetics
- . 01 Sanger sequencing
 - . 02 Prenatal genetic testing
 - . 03 Pre-implantation genetic testing
 - . 04 Genetic testing for constitutional gene variants (diagnostic and carrier testing)
 - . 05 Predictive genetic testing
 - . 06 Pharmacogenetic testing (results influence drug prescribing decisions)
 - . 07 Genetic testing for mosaic gene variants (cancer and somatic mosaicism)
 - . 08 Screening for an unknown mutation
 - . 09 Assay for a defined mutation or polymorphism
 - . 10 Assaying heterozygous loci
 - . 11 Calculated estimate of risk of inheritance of an unknown mutation (Bayesian and linkage calculations)
 - . 12 Massive parallel sequencing
 - . 13 Non-invasive prenatal screening
 - . 14 Detection and characterization of cell free DNA in cancer screening
 - . 15 Miscellaneous tests
- 6.27 Blood transfusion service
- . 01 Collection of blood from donors, routine
 - . 02 Collection and storage of autologous blood donations
 - . 03 Collection and storage of directed/dedicated blood donations
 - . 04 Collection of cells or plasma by automated means
 - . 05 Operation of a mobile collection unit
 - . 06 Preparation of blood components
 - . 07 Storage and distribution of blood and blood components
 - . 08 Freezing and thawing of cellular components for transfusion
 - . 09 Preparation of leucocyte-poor red cells
 - . 10 Screening of donor blood for markers of transfusion transmitted disease
 - . 11 Tissue typing – donor specific antibody detection and antibody identification
 - . 12 Miscellaneous tests
- 6.28 Medical practice pathology
- . 01 Microbiology
 - . 02 Immunohaematology
 - . 03 Haematology
 - . 04 Immunology
 - . 05 Chemical pathology
 - . 06 Miscellaneous tests
- 6.29 Assisted reproduction procedures
- . 01 Semen analysis
 - . 02 Sperm antibodies
 - . 03 Detection of leucocytes in semen
 - . 04 Sperm preparation for In Vitro Fertilization
 - . 05 Embryo cryopreservation
 - . 06 Semen cryopreservation
 - . 07 Tests for semen/sperm-cervical mucus interaction
 - . 08 Sperm chromatin structure assays
 - . 09 Hormones

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- . 10 Serology testing
- . 11 Miscellaneous

ISSUE AND AMENDMENT RECORD

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Title	Issue	Date	Amendments
Class of Test Structure – Medical Testing	01	January 2015	Initial Issue
	01 rev. 01	January 2017	Change the code number to 6 and update the numbering system in ascending order. Also, classifications were aligned based on arrangements of other accreditation bodies.