



AMEL-0822-001C

SCOPE OF ACCREDITATION
The National Kidney and Transplant Institute
Medical Laboratory
 East Avenue, Quezon City

Medical Testing

Division: Anatomic Pathology and Special Diagnostic

Section: Anatomic Pathology

Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
Histopathology		
Immunohistochemical investigation	Breast Panel ER PR	Immunohistochemistry (IHC)
	General Immunohistochemistry P63 E-cadherin PSA P40 CK5/6	
Formalin Fixed Paraffin Embedded (FFPE) tissue	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Gross Examination Tissue Processing Embedding and Microtomy Automated or Manual H&E Staining APS-WI-002 Surgical Pathology APS-WI-011 Hematoxylin and Eosin (H&E) Stain
	Immunohistochemistry examination activities for the purposes of prognostication and diagnosis	Embedding and Microtomy Automated or Manual Immunohistochemistry staining APS-WI-003 Immunohistochemistry
	H. pylori	Giemsa Staining APS-WI-009 Giemsa Stain
	Fungal	Grocott's Staining APS-WI-010 Grocott's stain
	Reticulin fibers	Reticulin Staining APS-WI-014 Reticulin Stain
	Acid Fast Bacilli	Acid Fast Bacilli Staining, tissue APS-WI-007 Acid Fast Bacilli Stain, Tissue
	Amyloid fibrils	Congo Red Staining APS-WI-008 Congo Red Stain
Fresh/ Frozen Tissue	Examination of tissues in order to identify or exclude	Gross examination Freezing Microtomy



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Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
	morphological and cytological abnormalities for the purpose of diagnosis	Manual H&E Staining APS-W1-004 Frozen Section APS-W1-011 Hematoxylin and Eosin Stain (H&E)
Alcohol fixed smears and formalin fixed material for cell block	Examination of body fluid in order to identify or exclude morphological <i>and</i> cytological abnormalities for the purpose of diagnosis	Gross examination Tissue Processing Embedding and Microtomy Automated or Manual H&E Staining Papanicolaou staining APS-WI-001 Cytology
Formalin fixed paraffin embedded tissue and stained slides for review	Histopathological review of slides for the purposes of pathological diagnosis	Embedding and Microtomy Automated or Manual H&E Staining APS-WI-003 Immunohistochemistry APS-W1-011 Hematoxylin and Eosin (H&E) stain



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SCOPE OF ACCREDITATION
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Division: Anatomic Pathology and Special Diagnostics

Section: Renal Pathology and Electron Microscopy

Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
Histopathology		
Renal Biopsy	Renal biopsy sample preparation for the purposes of pathological diagnosis	Light Microscopy: APS-WI-011 Hematoxylin and Eosin Stain REM-WI-007 Periodic Acid Schiff Stain
		REM-WI-008 Periodic Acid Silver Stain (Gomori) Immunofluorescence Microscopy:
		REM-WI-010 Direct Immunofluorescence Technique (DIF)
Electron Microscopy		
Renal Biopsy	Examination by Electron Microscopy: Identifies ultrastructures that help in the diagnosis where light is microscopy apparently normal (minimal change disease, thin basement membrane nephropathy, hereditary nephropathy, fibrillary and Immunotactoid glomerulonephritis). Provides information to confirm or elucidate a diagnosis (immune-complex glomerulonephritis, amyloidosis, dense deposit disease and diabetes)	Manual/Automated method Electron Microscopy REM-WI-012 Electron Microscope Operation REM-WI-002 Manual Processing of Specimen



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SCOPE OF ACCREDITATION
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Division: Clinical Pathology

Section: Blood Donor Recruitment and
Apheresis

Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
Blood Transfusion Service	Collection of blood from donors, routine Collection of autologous blood donation Collection of directed/ dedicated blood donations Operation of a mobile collection unit Collection of Therapeutic Phlebotomy	BDR-WI-001 Physical Assessment of donor BDR-WI-002 Extraction of Sample for Testing BDR-WI-003 Blood Collection for Donation BDR-WI-007 Therapeutic Phlebotomy BDR-WI-009 Autologous Blood Donation BDR-WI-010 Coordination with Other Section for Mobile Blood Donation American Association of Blood Bank (AABB) International Society of Blood Transfusion (ISBT) Philippine manual of Standards for Blood Service Facilities (PMSBSF) World Health Organization (WHO) Manual on Blood Donor Selection and Counseling
	Apheresis Plateletpheresis Therapeutic Plasma Exchange White Blood Cell Collection Mononuclear Cell (MNC) Collection Dendritic Collection	BDR-WI-006 Single Donor Plateletpheresis BDR-WI-008 Therapeutic Plasma Exchange BDR-WI-011 Granulocytes Concentrate (WBC) Collection (+/- G-CSF) Spectra Optia American Association of blood Bank (AABB) American Society for Apheresis (ASFA)



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SCOPE OF ACCREDITATION
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Division: Immunology and Molecular Genetics

Section: Cellular Immunology and Flow Cytometry

Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
Tests for haemoglobin variants and thalassemias	Hemoglobin Electrophoresis	Capillary Electrophoresis CEL-WI-003 Hemoglobin Electrophoresis (HBE)
Immunophenotyping	Acute Lymphoblastic Leukemia Panel Acute Myelogeneous Leukemia Panel Basic Leukemia Panel Basic Lymphoma Panel Chronic Lymphocytic Leukemia Panel Comprehensive Leukemia Panel Hairy Cell Leukemia Panel Minimal Residual Disease Panel Plasma Cell / Multiple Myeloma Panel Comprehensive Lymphoma Panel	Flow Cytometry FLW-WI-015 Immunophenotyping of Leukemia and Lymphoma
	Absolutely CD34 Count	Flow Cytometry FLW-WI-020 Stem Cell Enumeration Assay (CD34 Count)



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Division: Immunology and Molecular Genetics

Section: FISH and Cytogenetics

Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
FISH and Cytogenetics		
Detection of defined, unbalanced chromosomal abnormalities by FISH	HER-2/neu FISH Bladder FISH	Fluorescence In-Situ Hybridization (FISH)Method
Formalin Fixed Paraffin Embedded (FFPE) tissue	HER-2/neu FISH	DNA Fluorescence In-Situ Hybridization (FISH)Method Reference: FCL-WI-001
		HER-2/neu Assay ASCO-CAP Breast Cancer HER@ Testing Guidelines



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SCOPE OF ACCREDITATION
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Division: Immunology and Molecular Genetics

Section: Transplant Immunology

Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
Immunopathology		
Human Leucocyte Antigen (HLA) Typing	HLA ABC Typing	Serology - Complement Dependent Cytotoxicity (CDC)
	HLA ABDRDQ typing	Polymerase Chain Reaction (PCR) based
HLA Single Antigen Tests Description required: HLA-B27HLA 51	HLA B27 Typing	Serology - (CDC)
Whole blood in ACD	Human Leucocyte Antigen (HLA) ABC Typing	Complement Dependent Cytotoxicity (CDC) TIS-WI-001 HLA ABC typing
	Human Leucocyte Antigen (HLA) B27Typing	Complement Dependent Cytotoxicity (CDC) TIS-WI-002 HLA B27 typing
Whole blood in EDTA	Human Leucocyte Antigen (HLA) ABDRDQ Typing	Polymerase Chain Reaction (PCR) based TIS-WI-015 HLA ABDRDQ and DRDQ Typing



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Division: Clinical Pathology

Section: Microbiology

Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
Preparation of films for microscopic examination	AFB stain (Routine and Modified) Cryptosporidium stain Giemsa stain Gram stain Toluidine Blue stain Wet Mount (India Ink and KOH)	Clinical and Laboratory Standards Institute (CLSI) Clinical Microbiology Procedure Handbook Kirby Bauer Method Manual of Clinical Microbiology
Inoculation of cultures	Culture of the following specimens: 1. Blood 2. Dialysate 3. Nocardia 4. Other Body Fluids 5. Sputum 6. Stool 7. Surveillance 8. Throat swab 9. Urine 10. Wound	
Microscopic examination of clinical specimens	a. AFB stain Routine AFB stain Modified b. Cryptosporidium Stain c. Giemsa Stain d. Gram Stain e. Toluidine Blue Stain f. Wet Mount (India Ink and KOH)	
Identification of organisms including antibiotic susceptibility testing	Culture and Sensitivity of the following specimens: Blood Dialysate Other Body Fluids Sputum Stool Throat Swab Urine Wound	



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Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
Microbiology (Microbiology Examination Activities for the Purpose of Clinical Diagnosis)		
Sputum Endotracheal Aspirate (ETA) Bronchial Alveolar Lavage (BAL) Body Fluids Urine	Detection of Acid Fast Bacilli AFB STAIN (Routine)	In-house documented procedure for staining Microscopy MIC-WI-001 Acid Fast Bacilli, Routine Clinical Microbiology Procedure Handbook Manual of Clinical Microbiology
Smear from lesion	Examination of the presence of typical basophilic intra cytoplasmic inclusion body and for examination of giant multinucleated cells Giemsa stain	In-house documented procedure for staining Microscopy MIC-WI-008 Giemsa stain Clinical Microbiology Procedure Handbook Manual of Clinical Microbiology
Sputum Endotracheal Aspirate (ETA) Bronchial Alveolar Lavage (BAL)	For rapid presumptive diagnosis of infectious agents and serves to assess the quality of clinical specimen	In-house documented procedure for staining Microscopy MIC-WI-009 Gram Stain Clinical Microbiology Procedure Handbook
Body Fluids Urine Blood	Gram Stain	
Blood Cerebrospinal Fluid (CSF) Hair, Nail, Skin Muco-cutaneous and subcutaneous tissue, lesion, Sputum Endotracheal Aspirate (ETA) Bronchial washings Urine, Vaginal and cervical samples	Visualization of fungal elements during microscopic examination Wet Mount (KOH)	In-house documented procedure for staining Microscopy MIC-WI-023 Wet Mount, KOH Clinical Microbiology Procedure Handbook Manual of Clinical Microbiology
Blood	Bacterial growth detection of pathogenic organisms and isolation of microorganisms of clinical significance Blood Culture and Sensitivity	Antimicrobial susceptibility testing of microorganisms using disc sensitivity testing, automated system and gradient strips, Manual and/or Automated biochemical method, Fluorescence Method MIC-WI-004 Blood Culture MIC-WI-014 Sensitivity Testing Clinical and Laboratory Standards Institute (CLSI)



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Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
Dialysate	Bacterial growth detection of pathogenic organisms and isolation of microorganisms of clinical significance Dialysate Culture and Sensitivity	Antimicrobial susceptibility testing of microorganisms using disc sensitivity testing, automated system and gradient strips, Manual and/or Automated biochemical method, Fluorescence Method MIC-WI-006 Dialysate Culture MIC-WI-014 Sensitivity Testing Clinical and Laboratory Standards Institute (CLSI)
Other Body Fluids (Ascitic fluid, Abscess, Peritoneal fluid, Pericardial fluid, Pleural fluid, CSF) Aspirates Cellular and fluid material contained on swabs, catheter tips Tissue	Bacterial growth detection of pathogenic organisms and isolation of microorganisms of clinical significance Other Body Fluid Culture and Sensitivity	Antimicrobial susceptibility testing of microorganisms using disc sensitivity testing, automated system and gradient strips, Manual and/or Automated biochemical method, Fluorescence Method MIC-WI-013 Other Body Fluid Culture MIC-WI-014 Sensitivity Testing Clinical and Laboratory Standards Institute (CLSI)
Sputum	Inoculation, isolation and Identification of different microorganisms causing lower respiratory tract infections	Antimicrobial susceptibility testing of microorganisms using disc sensitivity testing, automated system and gradient strips, Manual and/or Automated Biochemical method MIC-WI-016 Sputum Culture MIC~WI-014 Sensitivity Testing Clinical and Laboratory Standards Institute (CLSI)
Endotracheal Aspirate (ETA) Bronchial Alveolar Lavage (BAL) Transtracheal aspirate Lung aspirate Lung biopsy	Sputum Culture and Sensitivity	
Stool	Isolation of Enteric pathogen causing diarrhea	Antimicrobial susceptibility testing of microorganisms using disc sensitivity testing, automated system and Gradient strips, Manual and/or Automated Biochemical method



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Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
Rectal swab	Stool Culture and Sensitivity	MIC-WI-017 Stool Culture MIC-WI-014 Sensitivity Testing Clinical and Laboratory Standards Institute (CLSI)
Throat swab	Isolation and identification of usual pathogens causing Inflammation of the throat and tonsils Throat Swab Culture and Sensitivity	Antimicrobial susceptibility testing of microorganisms using disc sensitivity testing, automated system and gradient strips, Manual and/or Automated biochemical method MIC-WI-019 Throat Swab Culture MIC-WI-014 Sensitivity Testing Clinical and Laboratory Standards Institute (CLSI)
Urine	General isolation of microorganisms of clinical significance Urine Culture and Sensitivity	Antimicrobial susceptibility testing of microorganisms using disc sensitivity testing, automated system and gradient strips, Manual and/or Automated biochemical method MIC-WI-022 Urine Culture MIC-WI-014 Sensitivity Testing Clinical and Laboratory Standards Institute (CLSI)
Wound Punch skin biopsies Soft tissue aspirate	Isolation and identification of microorganisms associated with infection of the skin and subcutaneous tissues Wound Culture and Sensitivity	Antimicrobial susceptibility testing of microorganisms using disc sensitivity testing. automated system and gradient strips, Manual and/or Automated biochemical method MIC-WI-025 Wound Culture MIC-WI-014 Sensitivity Testing Clinical and Laboratory Standards Institute (CLSI)



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Division: Clinical Pathology

Section: Clinical Microscopy

Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
Parasitology		
Preparation and examination of films	a. Fecalysis	Philippine Textbook of Medical Parasitology CMI-WI- 007 Fecalysis (Macroscopic and Microscopic Examination)
Definitive identification of parasites	a. Fecalysis b. Formalin Ether Concentration Technique	Intestinal Direct Fecal Smear Parasite Identification Philippine Textbook of Medical Parasitology The Color Atlas of Intestinal Parasite CMI-WI-007 Fecalysis (Macroscopic and Microscopic Examination) CMI-WI-028 Formalin Ether Concentration Technique
Miscellaneous		
Miscellaneous test	Urinalysis: Urobilinogen, Blood, Protein, Glucose, Ketone, Bilirubin, Nitrite, Leucocytes, pH, Specific Gravity, Urine Color, Clarity Urine Particle Analysis (WBC, RBC, Epithelial cells, Bacteria, Hyaline casts) Urine Particle Digital Image	Colorimetric Flow Cytometry Urine Particle Digital Image CMI-WI-009 Urinalysis
Pregnancy	Pregnancy	Immunochromatography CMI-WI-005 Pregnancy Test
Fecal Occult Blood (FOBT)	FOBT	Immunochromatography CMI-WI-002 Fecal Occult Blood Test (FOBT)



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Division: Clinical Pathology

Section: Blood Bank

Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
Immunohematology		
Blood Bank (Blood Transfusion Examination Activities for The Purpose of Clinical Diagnosis)		
Whole Blood in EDTA (red cells and plasma) Serum Sample from donated blood units collected in CPD, CPDA1, SAGM or with ADSOL	Blood Typing A, Blood Typing B, Blood Typing O, Blood Typing AB, Blood Typing Rh (D) and Blood Typing Weak D Blood Typing Sub group of A	Tube Method and Column Agglutination Technology BBK-WI-003 Determination of ABO, Rh and Weak D Type (Tube Method) BBK-WI-001 Column Agglutination Technology BBK-GL-002 Type and Screen BBK-QP-001 - General Procedure in Blood Bank American Association of Blood Bank (AABB) Philippine Manual of Standards for Blood Service Facilities (PMSBSF) International Society of Blood Transfusion (ISBT) Modern Blood Banking and Transfusion Practices by Denise Harmening
Whole Blood in EDTA (red cells and plasma) Serum Sample from donated blood units collected in CPD, CPDA1, SAGM or with ADSOL	Screening of Antibodies Anti D, E, e, C, c, Cw, K, k, Kpa, Kpb, Fya, Fyb, Jka, Jkb, Lea, Leb, P1, M, N, S, s, Lua	Column Agglutination Technology BBK-WI-001 Column Agglutination Technology BBK-GL-002 Type and Screen BBK-QP-001 - General Procedure in Blood Bank American Association of Blood Bank (AABB) Modern Blood Banking and Transfusion Practices by Denise Harmening
Whole Blood in EDTA (red cells and plasma) Serum	Identification of Antibodies Anti D, E, e, C, c, Cw, K, k, Kpa, Kpb, Fya, Fyb, Jka, Jkb,	Column Agglutination Technology BBK-WI- 001 Column Agglutination Technology



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Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
Sample from donated blood units collected in CPD, CPDA1, SAGM or with ADSOL	Lea, Leb, P1, M, N, S, s, Lua	Modern Blood Banking and Transfusion Practices by Denise Harmening American Association of Blood Bank (AABB) International Society of Blood Transfusion (ISBT)
Whole Blood in EDTA (red cells and plasma) Serum Sample from donated blood units collected in CPD, CPDA1, SAGM or with ADSOL	a. Blood Crossmatching – compatibility testing between donor red cell antigens and patient plasma antibodies b. Indirect Antiglobulin Test	Tube Method and Column Agglutination Technology BBK-WI-001 Column Agglutination Technology BBK-WI-004 Blood Crossmatching BBK-WI-005 Antiglobulin Tests American Association of Blood Bank (AABB) Modern Blood Banking and Transfusion Practices by Denise Harmening
Whole Blood in EDTA	Red Cell Phenotyping E, e, C, c, Cw, K, k, Kpa, Kpb, Fya, Fyb, Jka, Jkb, Lea, Leb, P1, M, N, S, s, Lua	Tube Method and Column Technology Red cell Phenotyping (Tube method) BBK-WI-001 Column Agglutination Technology American Association of Blood Bank (AABB) International Society of Blood Transfusion (ISBT)
Whole Blood in EDTA	Antibody Elution Anti D, E, e, C, Cw, c, K, k, Kpa, Kpb, Fya, Fyb, Jka, Jkb, Lea, Leb, P1, M, N, S, s, Lua	Tube Method BBK-WI-008 Heat Elution BBK-WI-015 Acid Elution American Association of Blood Bank (AABB) International Society of Blood Transfusion (ISBT)
Whole Blood in EDTA	Adsorption Anti D, E, e, C, Cw, c, K, k, Kpa, Kpb, Fya, Fyb, Jka, Jkb, Lea,	Tube Method BBK-WI-009 Adsorption American Association of Blood Bank (AABB)



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Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
	Leb, P1, M, N, S, s, Lua	International Society of Blood Transfusion (ISBT)
Serum/plasma	Antibody Titration, anti D, Anti A and Anti B	Tube Method BBK-WI-011 Antibody Titration International Society of Blood Transfusion (ISBT) American Association of Blood Bank (AABB)
Whole Blood in EDTA (red cells and plasma) Serum	Pre-warm Technique	Tube Method BBK-WI-007 Pre-warm Technique International Society of Blood Transfusion (ISBT) American Association of Blood Bank (AABB)
Blood and blood components	Storage and distribution of blood and blood components	BBK-GL-001 Issuance of Blood and Blood Products Philippine Manual of Standards for Blood Service Facilities (PMSBSF) American Association of Blood Bank (AABB) Modern Blood Banking and Transfusion Practices by Denise Harmening
Whole Blood in EDTA	Blood grouping including ABO, Rh(D) Phenotyping by automated method Anti D, E, e, C, c, Cw, K, k, Kpa, Kpb, Fya, Fyb, Jka, Jkb, Lea, Leb, P1, M, N, S, s, Lua including subgroup of A	Column Agglutination Technology BBK-WI-001 Column Agglutination Technology Philippine Manual of Standards for Blood Service Facilities (PMSBSF) American Association of Blood Bank (AABB)
Whole Blood in EDTA (red cells and plasma)	Blood grouping including ABO, Rh(D) and other antigens and antibody screening by automated methods Anti D, E, e, C, c, Cw, K, k,	Modern Blood Banking and Transfusion Practices by Denise Harmening



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	Kpa, Kpb, Fya, Fyb, Jka, Jkb, Lea, Leb, P1, M, N, S, s, Lua including subgroup of A	
Whole Blood in EDTA (red cells and plasma) Serum	Blood grouping including ABO, Rh (D) and other antigens by manual methods Anti D, E, e, C, c, Cw, K, k, Kpa, Kpb, Fya, Fyb, Jka, Jkb, Lea, Leb, P1, M, N, S, s, Lua including subgroup A	
Whole Blood in EDTA (red cells and plasma) Serum	Blood grouping including ABO, Rh(D) and other antigens and antibody screening by manual methods Anti D, E, e, C, c, Cw, K, k, Kpa, Kpb, Fya, Fyb, Jka, Jkb, Lea, Leb, P1, M, N, S, s, Lua including subgroup of A	Tube Method and Column Agglutination Technology BBK-WI-003 Determination of ABO, Rh and Weak D Type (Tube Method) BBK-WI-001 Column Agglutination Technology BBK-GL-002 Type and Screen American Association of Blood Bank (AABB) Philippine Manual of Standards for Blood Service Facilities (PMSBSF) International Society of Blood Transfusion (ISBT) Modern Blood Banking and Transfusion Practices by Denise Harming
	Investigation of transfusion reaction	BBK-GL-007 Transfusion Reaction Work-up American Association of Blood Bank (AABB) Philippine Manual of Standards for Blood Service Facilities (PMSBSF) International Society of Blood Transfusion (ISBT) Modern Blood Banking and Transfusion Practices by Denise Harming



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Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
Whole Blood In EDTA	Direct antiglobulin test Polyspecific and monospecific	Tube and Column Agglutination Technology BBK-WI-001 Column Agglutination Technology BBK-WI-005 Antiglobulin Tests Philippine Manual of Standards for Blood Service Facilities (PMSBSF) International Society of Blood Transfusion (ISBT) Modern Blood Banking and Transfusion Practices by Denise Harmening
Blood and other blood products	Irradiation of Blood and Blood Products	BBK-WI-014 Irradiation of Blood and Blood Products Modern Blood Banking and Transfusion Practices by Denise Harmening American Association of Blood Bank (AABB)
Whole Blood in EDTA Serum	Examination of serum for Rh(D) and other blood group antibodies at reference laboratory level Anti D, E, e, C, c, Cw, K, k, Kpa, Kpb, Fya, Fyb, Jka, Jkb, Lea, Leb, P1, M, N, S, s, Lua	Tube Method and Column Agglutination Technology BBK-WI-003 Determination of ABO, Rh and Weak D Type (Tube Method) BBK-WI-001 Column Agglutination Technology BBK-GL-015 Difficult Crossmatching BBK-WI-052 Resolving ABO Discrepancies BBK-GL-002 Type and Screen American Association of Blood Bank (AABB) Philippine Manual of Standards for Blood Service Facilities (PMSBSF) International Society of Blood Transfusion (ISBT) Modern Blood Banking and



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Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
		Transfusion Practices by Denise Harmening
Blood Transfusion Service		
Whole Blood in CPD, CPDA1, SAGM or with ADSOL	Storage and distribution of blood autologous transfusions Storage and distribution of directed/dedicated blood donations	BBK-GL-001 Issuance of Blood and Blood Products BDR-WI-009 Autologous Blood Donation BDR-WI-003 Blood Collection for Donation BBK-GL-020 Blood Cold Chain Philippine Manual of Standards for Blood Service Facilities (PMSBSF) American Association of Blood Bank (AABB) Modern Blood Banking and Transfusion Practices by Denise Harmening
	Releasing of blood and blood components through Blood Bank Information System (BBIS)	BBK-GL-001 Issuance of Blood and Blood Products Philippine Manual of Standards for Blood Service Facilities (PMSBSF) American Association of Blood Bank (AABB) Modern Blood Banking and Transfusion Practices by Denise Harmening



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Division: Clinical Pathology

Section: Hematology

Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
Hematology		
Blood counts	Complete Blood Count (CBC)	Flow Cytometry, Impedance, Fluorescence, Spectrophotometry
	Reticulocyte Count	Fluorescence
Visual examination of blood films	Peripheral Blood Smear	Microscopic Examination
Erythrocyte sedimentation rate	Erythrocyte sedimentation rate (ESR)	Modified Westergren Method
Leucocyte differential counts	Leucocyte Differential Count	Flow Cytometry, fluorescence Manual
Examination for malarial parasites	Malarial screening	Immunochromatography and light Microscopy
Extended haemostasis related tests	Coagulation Tests 1. D-dimer Determination 2. DRVVT (Screen and Confirm) 3. Factor VIII 4. Factor IX 5. Fibrinogen Level 6. Kaolin Clotting Time (Lupus Anticoagulant) 7. Mixing PT and PTT 8. Prothrombin Time (PT) 9. Partial Thromboplastin Time (PTT)	Latex immunoassay Mechanical Clot Detection Mechanical Clot Detection Mechanical Clot Detection Mechanical Clot Detection Manual Method Mechanical Clot Detection Mechanical Clot Detection Mechanical Clot Detection
Hematology examination activities for the purpose of clinical diagnosis		
Whole Blood in EDTA	Complete Blood Count (CBC) Includes the following parameters: White Blood Cell count (WBC), Red Blood Cell Count (RBC), Hemoglobin (HGB), Hematocrit (HCT), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin	Flow Cytometry, Impedance, Fluorescence, Spectrophotometry HEM-WI-009 Rev1 Automated Complete Blood Count (CBC)



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	(MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Mean Platelet Volume (MPV), Red Cell Distribution Width (RDW), Platelet Count (PLT), Differential Count. Neutrophils Lymphocytes Monocytes Eosinophils Basophils	
	Peripheral Blood Smear	Visual examination of blood films Microscopic Examination HEM-WI-011 Peripheral Blood Smear Morphology
Whole Blood in EDTA	Reticulocyte count	Manual Method - Supravital stain HEM-WI-014 Reticulocyte Count Automated Method – Fluorescence HEM-WI-019 Automated Reticulocyte Count
	Erythrocyte sedimentation rate (ESR)	Modified Westergreen Method HEM-WI-012 Erythrocyte Sedimentation Rate Clinical and Laboratory Standard Institute (CLSI)
	Malarial Antigen screening for: Plasmodium falciparum and pan-detection for: Plasmodium malariae Plasmodium ovale Plasmodium vivax	Immunochromatography and Light Microscopy HEM-WI-013 Malaria Screening
Coagulation examination activities for the purpose of clinical diagnosis:		
Citratd Plasma	1. D-Dimer Determination	Latex Immunoassay HEM-WI- 007 D-Dimer
	2. Diluted Russell's Viper Venom (DRVVT) (Screen and Confirm)	Mechanical Clot Detection HEM-WI-002 DRVVT (Dilute Russell Viper Venom Test) Screen and Confirm



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	3. Factor VIII	Mechanical Clot Detection HEM-WI- 004 Factor VIII
	4. Factor IX	Mechanical clot Detection HEM-WI-005 Factor IX
	5. Fibrinogen Level	Mechanical Clot Detection HEM-WI-006 Fibrinogen Level
	6. Kaolin Clotting Time	Manual Method
	(Lupus Anticoagulant)	HEM-WI-015 Kaolin Clotting Time
	7. Mixing PT and PTT	Mechanical Clot Detection, Manual Method HEM-WI-008 Mixing PT and PTT
	8. Prothrombin Time (PT)	Mechanical Clot Detection HEM-WI-001 Prothrombin Time
	9. Activated Partial Thromboplastin Time	Mechanical Clot Detection HEM-WI-003 Partial Thromboplastin Time



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Division: Clinical Pathology

Section: Clinical Chemistry

Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
General Chemistry		
Serum	Albumin	Photometric CCH-WI-022 Albumin Determination
	Alanine Aminotransferase	Photometric CCH-WI-026 ALT Determination
	Alkaline Phosphatase	Photometric CCH-WI-023 ALP Determination
	Amylase	Photometric CCH-WI-025 AMYLASE
	Aspartate Aminotransferase	Photometric CCH-WI-014 AST Determination
	Bicarbonate	Photometric CCH-WI-053 Serum HCO ₃ Determination
	Bilirubin, Total	Photometric CCH-WI-029 Total Bilirubin Determination
	Bilirubin, Direct	Photometric CCH-WI-028 Direct Bilirubin Determination
Serum Urine (24-hour or random)	Calcium, Total	Photometric CCH-WI-030 Calcium Determination
	Chloride	Potentiometric using Ion Selective electrode CCH-WI-047 Sodium, Potassium, Chloride (Electrolytes) Determination
Serum	Cholesterol, Total	Photometric CCH-WI-031 Cholesterol Determination
	Creatinine Kinase	Photometric CCH-WI-033 Creatinine Kinase
Serum Urine (24-hour or random)	Creatinine	Photometric CCH-WI-034 Creatinine Determination
Serum	B2Microglobulin	Photometric CCH-WI-058 Beta 2 Microglobulin (B2MG) Determination



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Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
Serum Urine (24-hour or random)	Glucose	Photometric CCH-WI-037 Glucose Determination
Serum	GGTP	Photometric CCH-WI-036 Gamma-Glutamyl Transferase (GGT) Determination
	HDL Cholesterol	Photometric CCH-WI-027 HDL Determination
	LDH	Photometric CCH-WI-040 Lactate Dehydrogenase (LDH) Determination
	Lipase	Photometric CCH-WI-042 Lipase Determination
Serum Urine (24-hour or random)	Magnesium	Photometric CCH-WI-043 Magnesium Determination
	Osmolality	Freezing Point Method CCH-WI-017 Osmolality Determination
Serum	Phosphorus	Photometric CCH-WI-045 Phosphorus Determination
Serum Urine (24-hour or random)	Potassium	Potentiometric using Ion Selective Electrode CCH-WI-047 Sodium, Potassium, Chloride (Electrolytes) Determination
	Protein, Total	Photometric CCH-WI-048 Total Protein, Serum Determination CCH-WI-049 Total Protein, Urine/CSF Determination
Serum Urine (24-hour or random)	Sodium	Potentiometric using-Ion Selective Electrode CCH-WI-047 Sodium, Potassium, Chloride (Electrolytes) Determination
Serum	Triglycerides	Photometric CCH-WI-050 Triglyceride Determination



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Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
Serum Urine (24-hour or random)	Urea Nitrogen	Photometric CCH-WI-055 BUN / UREA Nitrogen Determination
	Uric Acid	Photometric CCH-WI-052 Uric Acid Determination
Urine (random)	Microalbumin	Photometric CCH-WI-044 Microalbumin Urine Determination
Urine (24-hour)	VMA	Anionic Exchange Resin CCH-WI-020 Vanilmandelic Acid (VMA) Determination, Urine
Drugs for therapeutic monitoring		
Serum	Digoxin	Chemiluminescence CCH-WI-077 Digoxin Determination
Biochemistry		
Hormone Assays and Tumour Markers:		
Serum	Cortisol	Chemiluminescence Technology CCH-WI-076 Cortisol Determination
	Estradiol	Chemiluminescence Technology CCH-WI-084 Estradiol Determination
	Free T3	Chemiluminescence Technology CCH-WI-087 Free T3 Determination
	FreeT4	Chemiluminescence Technology CCH-WI-088 Free T4 Determination
	FSH	Chemiluminescence Technology CCH-WI-080 Follicle Stimulating Hormone (FSH)Determination
	LH	Chemiluminescence Technology CCH-WI-079 Luteinizing Hormone (LH) Determination
	Prolactin	Chemiluminescence Technology CCH-WI-082 Prolactin Determination
	Progesterone	Chemiluminescence Technology CCH-WI-081 Progesterone Determination



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Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
	TotalT3	Chemiluminescence Technology CCH-WI-086 Total T3 (T3) Determination
	Total T4	Chemiluminescence Technology CCH-WI-089 Thyroxine (T4) Determination
	TSH	Chemiluminescence Technology CCH-WI-090 Thyroid Stimulating Hormone (TSH) Determination
	Testosterone	Chemiluminescence Technology CCH-W1-083 Testosterone Determination
	AFP	Chemiluminescence Technology CCH-WI-070 Alpha Feto Protein Determination
	CEA	Chemiluminescence Technology CCH-WI-075 Carcinoembryonic Antigen (CEA) Determination
	CA 125	Chemiluminescence Technology CCH- WI-073 CA 125 (OV-MA) Determination
	Total PSA	Chemiluminescence Technology CCH-WI-074 Total Prostate Specific Antigen (TPSA) Determination
	CA 15-3	Chemiluminescence Technology CCH-WI-071 CA 15-3 (BR-MA) Determination
	CA 19-9	Chemiluminescence Technology CCH-WI-072 CA 19-9 Determination
	Free PSA	Chemiluminescence Technology CCH-WI-091 Free Prostate Specific Antigen (FreePSA) Determination
Iron Studies		
Serum	Ferritin	Chemiluminescence Technology CCH-WI-078 Ferritin Determination



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Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
	Iron	Photometric CCH-WI-039 Iron Determination
	TIBC	Photometric CCH-WI-054 TIBC and UIBC Determination
	Markers for Bone Metabolism	
	Intact-PTH	Chemiluminescence Technology CCH-WI-085 Intact-Parathyroid Hormone (iPTH) Determination
	Diabetic Laboratory	
Whole blood in EDTA	HgbA1C	Photometric CCH-WI-038 Hemoglobin (HgbA1C) Determination
	Diabetic Laboratory	
Serology of Infection		
Limited serological testing	Anti-HAV IgM Anti- HCV HBsAg HIV	Chemiluminescence Microparticle Anti- HCV Immuno Assay (CMIA)



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SCOPE OF ACCREDITATION
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Division: Clinical Pathology

Section: Serology

Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
Blood Transfusion Service		
Preparation of Blood components		American Association of Blood Bank (AABB)
Preparation of leukocyte poor red cells		International Society of Blood Transfusion (ISBT)
		Philippine Manual of Standards for Blood Service Facilities (PMSBSF)
		World Health Organization (WHO)
Screening of donor blood for markers of transfusion transmitted disease	a. Anti-HCV	Electrochemiluminescence
	b. HBsAg	
	c. HIV	
	d. Syphilis	
	a. Malarial screening	Immunochromatography and Light Microscopy
	Treponema Pallidum Particle Agglutination (TPPA)	Particle Agglutination
Serology		
	Preparation of blood components	SER-GL-001 Use of the Blood Bank Information System for Donor Screening and Processing
Whole Blood	Preparation of leukocyte- poor red cells	SER-WI-010 Blood Component Preparation Methods
		American Association of Blood Bank (AABB)
		International Society of Blood Transfusion (ISBT)
		Philippine Manual of Standards for Blood Service Facilities (PMSBSF)
Serum	Screening of donor blood for markers of transfusion transmitted disease	Electrochemiluminescence
		SER-GL-001 Use of the Blood Bank Information System for Donor Screening and Processing
		SER-GL-002 Referral to RITM TTI-NRL
		SER-WI-003 Syphilis Test for Donor Screening
	a. Hepatitis C Antibody (Anti- HCV)	
	b. Hepatitis B Antigen (HBsAg)	
	c. HIV 1 & 2 Antibody/p24	
	d. Syphilis (IgM & IgG)	



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Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
		SER-WI-004 Treponema Pallidum Particle Agglutination SER-WI-005 Hepatitis B Surface Antigen (HBsAg) for Donor Screening SER-WI- 006 Antibody to Hepatitis C Virus (Anti-HCV) for Donor screening SER-WI- 007 Human Immunodeficiency Virus (HIV) for Donor Screening Philippine Manual of Standards for Blood Service Facilities (PMSBSF) DOH Department Circular No. 2012-0198
Whole Blood in EDTA	Malarial Antigen screening for: Plasmodium falciparum and pan-detection for: Plasmodium malariae Plasmodium ovale Plasmodium vivax	Immunochromatography and Light Microscopy SER-GL-002 Referral to RITM TTI- NRL SER-WI-008 Rapid Test for Malaria Donor Screening HEM-WI-080 Malaria - Parascreen and Microscopy
Serum	Treponema Pallidum Particle Agglutination (TPPA)	Particle Agglutination SER-QP-001 General Procedure in Serology SER-WI-004 Treponema Pallidum Particle Agglutination



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SCOPE OF ACCREDITATION
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Division: Immunology and Molecular Genetics

Section: Clinical Immunology

Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
Bacteriology		
Serum	Detection of bacterial antigen by non-cultural non- molecular technique Helicobacter pylori Immunoglobulin G (IgG)	Enzyme Linked Fluoro Assay (ELFA)
Parasitology		
Serum	Detection of parasitic antigen by non-cultural non- molecular technique a. Toxoplasma IgG b. Toxoplasma IgM	Enzyme Linked Fluoro Assay (ELFA)
Virology		
Serum	Detection of viral antigen by non-cultural non- molecular technique a. Cytomegalovirus (CMV) IgG b. CMV IgM c. Epstein Bar Virus (EBV) Viral Capsid Antigen (VCA) IgG d. EBV VCA IgM e. Rubella IgG f. Rubella IgM g. Varicella - Zoster IgG	Enzyme Linked Fluoro Assay (ELFA)
Mycobacteriology		
Plasma	Quantiferon TB	Enzyme Linked Immunosorbent Assay (ELISA)
Immunopathology		
Serum	Total IgE	Fluoro Enzyme Immunoassay (FEIA)



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Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
Miscellaneous		
Serum	Autoimmune Disease Assays 1. ANA 2. dsDNA 3. Anti-Sm 4. Anti-RnP 5. Anti-SSa (Ro) 6. Anti-SSb (La) 7. Anti-CCP 8. Anti-GBM 9. C-anca (PR3) 10. P-anca (MPO)	Fluoro Enzyme Immunoassay (FEIA) Enzyme linked immunoassay (ELISA)
	a. Anticardiolipin IgG b. Anticardiolipin IgM c. B2 Glycoprotein 1 IgG	Enzyme linked immunoassay (ELISA)



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Section: Molecular Laboratory

Classification of Scopes	Specific tests or Measurements	Standard Method/ Reference Standard
Hematology		
Molecular Genetic Studies	JAK2 Mutation Assay	Polymerase Chain Reaction (PCR) based
Molecular		
	JAK2 Mutation Assay	Polymerase Chain Reaction (PCR) based MOL-WI-001 JAK2 Mutation Assay (Qualitative)



JAMES E. EMPEÑO
 Director IV
 Philippine Accreditation Bureau



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