Schedule to

CERTIFICATE OF ACCREDITATION



Pathlab Rotorua Client Number 7551

Pathlab Lakes Ltd - Rotorua, PO Box 130, Seventh Avenue, Tauranga, 3140 Rotorua Hospital, Pukeroa Street, Rotorua, 3010

Telephone 07 349-7907 www.pathlab.co.nz

Authorised Representative

Michaela Head

Quality Officer/ Manager Taupo/Rotorua

Programme

Medical Testing Laboratory

Accreditation Number 1005 Initial Accreditation Date 30 September 2008

Conformance Standard

ISO 15189:2012

Medical Laboratories - Requirements for quality and competence

Laboratory Services Summary

Pathlab Rotorua, Rotorua Hospital

Biochemistry Haematology Microbiology

Patient Services Specimen Services Transfusion Medicine

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Pathlab Rotorua Medical Testing Laboratory SCOPE OF ACCREDITATION

Accreditation Number 1005

This laboratory is accredited for specific activities within the following disciplines:

Pathlab Rotorua, Rotorua Hospital

Biochemistry

General Biochemistry

Materials/Products

Blood; Plasma; Serum; Urine; CSF; Other body fluids

Types of Examination/Technical Field

Biochemical parameters by Beckman Coulter DxC AU700 and DxC AU480 autoanalyser(s) using the following techniques:

Automation ISE Indirect

Automation Kinetic

Automation Turbidometric

Automation Enzymatic

Endocrine parameters by Beckman Coulter Dxl 600 Autoanalyser using the following techniques:

Automation Chemiluminescent Immunoassay

Therapeutic drug monitoring by Beckman Coulter DxC700 autoanalyser using the following techniques:

Automation Kinetic

Automation Turbidometric

Automation Enzymatic

Osmolality Parameters by Osmo 1 using the following techniques:

Depression of freezing point

Biochemical and Blood Gas parameters by ABL90 Flex Plus using the following techniques:

ISE Direct

Absorbance and reflectance

Biochemical and Blood Gas parameters by Abbott iStat using the following cartridges:

CG4+ cartridge

CHEM8+ cartridge

cTnl cartridge

Specialist Biochemistry

Materials/Products

Other body fluids

Types of Examination/Technical Field

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Pathlab Rotorua Medical Testing Laboratory SCOPE OF ACCREDITATION

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Collection of sweat samples for iontophoresis testing

Other semi-quantitative, or qualitative parameters by manual or kit methodologies: Dipstick analysis (qualitative)

Haematology

General Haematology

Materials/Products

Blood

Types of Examination/Technical Field

Full blood count parameters by Beckman Coulter DxH 900 haematology analyser(s) using the following techniques:

Volume (impedance)

Conductivity (radio frequency)

Scatter (flow cytometry)

Photometry

Peripheral Blood film preparation and staining by the following technique:

Automated smear and stain using Beckman Coulter DxH SMS

Manual smear and stain baths/coplin jars

Special staining for malaria and other blood parasites

Blood film examination by light microscopy:

Automated digital method by Vision Haema

Manual conventional method

Malaria (thick and thin films) and other blood parasite screen

Erythrocyte Sedimentation Rate by the following technique:

Automated modified Westergren by Elitech Microsed

Manual modified Westergren method

Foetal Haemoglobin Estimation:

Acid elution (Kleihauer) stain and examination by light microscopy

Other semi-quantitative, or qualitative parameters by manual or kit methodologies:

Immunochromatographic technique

Bone marrow aspirate/trephine biopsy examinations (preparation only)

Haemostasis

Materials/Products

Plasma

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Medical Testing Laboratory
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Types of Examination/Technical Field

Haemostasis parameters/profiles by IL ACL350 analyser using the following techniques:

Routine haemostasis screen by optical clot detection

Fibrin Breakdown product(s) quantitation by Latex Immunoturbidimetric assay

Special Haematology

Materials/Products

Blood

Types of Examination/Technical Field

Blood film preparation and staining by the following technique:

Manual supravital stains and examination by light microscopy

Microbiology

Bacteriology

Materials/Products

Urine; Blood; Swabs; Sputum/Respiratory samples; CSF; Other body fluids; Aspirates; Tissue; Bone

Types of Examination/Technical Field

Urine and fluid cell counts by the following techniques:

Light microscopy

Phase contrast microscopy

Blood culture analysis by Bactec FX using:

Fluorescence

Bacterial culture using the following techniques:

Manual inoculation of agars and broths

Bacterial identification using the following techniques:

Manual stain and light microscopy

Rapid Antigen Test (ICT)

Antimicrobial susceptibility testing using the following techniques:

Disk diffusion (EUCAST / CLSI)

Molecular Pathology

Materials/Products

Sputum/Respiratory samples/Nasopharyngeal Swab

Types of Examination/Technical Field

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NAAT by GeneXpert using the following cartridges: Xpress CoV-2/Flu/RSV plus

Nucleic acid extraction and amplification for molecular testing using BD Max and the following techniques: Real Time PCR

Patient Services

Pathlab Rotorua	Type of Examination / Technical Field
Haupapa Street	Venepuncture collections Capillary collections Receipt of other specimens (urine, faeces, swabs) Collection of Mycology specimens (skin, nail, hair) Collection of specimens for Scabies investigations Collection of specimens for paternity testing Glucose Tolerance Tests Home visit collections Specimen preparation for transportation
Rotorua Hospital Outpatients	Venepuncture collections Capillary collections Collection of Mycology specimens (skin, nail, hair) Glucose Tolerance Tests Lactose Tolerance testing Skin Allergy Testing Therapeutic Venesections
Rotorua Hospital Wards	Venepuncture collections Capillary collections Collection of Mycology specimens (skin, nail, hair) Collection of specimens for Scabies investigations Glucose Tolerance Tests Skin Allergy Testing Therapeutic Venesections
Ngongotaha Medical Centre	Venepuncture collections Capillary collections Receipt of other specimens (urine, faeces, swabs) Collection of Mycology specimens (skin, nail, hair) Glucose Tolerance Tests
Te Ngae Medical Centre	Venepuncture collections Capillary collections Receipt of other specimens (urine, faeces, swabs) Collection of Mycology specimens (skin, nail, hair) Glucose Tolerance Tests

Specimen Services

Specimen reception

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Specimen preparation and storage - manual

Specimen preparation and storage - automated

Data registration

Specimen preparation for transport to alternative Pathlab Laboratories

Specimen preparation for transport to a national referral laboratory

Clinical Trials

Transfusion Medicine

Materials/Products

Red blood cells; Plasma; Fractionated products

Type of Examination/Technical Field

The following Transfusion related parameters by Immucore Echo and Immucore capture technology:

ABO/Rh Group

Antibody Screen

Antibody Identification

Full IAT Crossmatch

Direct Antiglobulin Test (monospecific and polyspecific)

Red cell antigen/Phenotyping

Antibody Elution

The following Transfusion related parameters by Ortho Workstation and Gel Cards:

Antibody Screen

Antibody Identification

Full IAT Crossmatch

Direct Antiglobulin Test (monospecific and polyspecific)

Red Cell Antigen Typing/Phenotyping

Antibody Elution

The following Transfusion related parameters by manual tube technique:

ABO/Rh Group

Abbreviated/Immediate Spin Crossmatch

Red Cell Antigen Typing

Full IAT Crossmatch

Direct Antiglobulin Test (monospecific and polyspecific)

Alkali Denaturation (Apt and Downey)

Antibody Elution

Transfusion Reaction Investigation

Storage and issue (including electronic) of blood components and products

Remote blood, product and storage equipment oversight:

Southern Cross Rotorua Hospital

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