Medical Laboratory Accreditation Programme

Schedule to

CERTIFICATE OF ACCREDITATION

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Pathlab Whakatane **Client Number 362**

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Whakatane Hospital, Stewart & Garaway Streets, Whakatane, 3120

Telephone 07 306-0823

Authorised Representative
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Quality Officer/ Manager Taupo/Rotorua
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Seventh Avenue
Tauranga 3140
New Zealand

Programme
Medical Testing Laboratory

Accreditation Number 680 **Initial Accreditation Date** 22 June 1998

Conformance Standard
ISO 15189:2022
Medical Laboratories - Requirements for quality and competence

Laboratory Services Summary

Pathlab Whakatane

Biochemistry
Haematology
Microbiology
Patient Services
Specimen Services
Transfusion Medicine

IANZ; Building 7, Central Park, 660-670 Great South Road, Ellerslie, Auckland 1051
Private Bag 28908, Remuera, Auckland 1541
Tel 09-525 6655 info@ianz.govt.nz ***ianz.govt.nz***

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

Pathlab Whakatane

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 autoanalyser using the following techniques:
- Automation ISE Indirect
- Automation Kinetic
- Automation Turbidimetric
- Automation Enzymatic

Therapeutic Drug monitoring by Beckman Coulter DxC AU700 autoanalyser using the following techniques:
- Automation Kinetic
- Automation Turbidimetric
- Automation Enzymatic

Biochemical parameters by Beckman Coulter DxC 500i autoanalyser (back-up) using the following techniques:
- Automation ISE Indirect
- Automation Kinetic
- Automation Turbidimetric
- Automation Enzymatic

Therapeutic Drug monitoring by Beckman Coulter DxC 500i autoanalyser (back-up) using the following techniques:
- Automation Kinetic
- Automation Turbidimetric
- Automation Enzymatic

Hormones and Cardiac parameters by Beckman Coulter Access 2 autoanalyser using the following techniques:
- Immune-enzymatic assay

Biochemical parameters by i-STAT Alinity Point of care analyser using the following techniques:
- Automation ISE Direct

Haematology

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General Haematology

Materials/Products
Blood

Types of Examination/Technical Field
Full blood count parameters by DxH 690t haematology analyser(s) using the following techniques:
- Volume (impedance)
- Conductivity (radio frequency)
- Scatter (flow cytometry)
- Photometry

Full blood count parameters by DxH 500 haematology analyser(s) using the following techniques:
- Photometry
- Impedance
- Axial light loss

Peripheral Blood film preparation and staining by the following techniques:
- Automated stain using Aerospray stainer
- Manual smear
- 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 techniques:
- Automated modified Westergren by Elitech MicroSED
- Manual modified Westergren method
- ESR analyser Mixrate x20

Foetal Haemoglobin Estimation
- Acid elution (Kleihauer) stain and examination by light microscopy

Haemostasis

Materials/Products
Plasma

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
- Stago Start 4 (back up coagulation instrument)

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Special Haematology

Materials/Products
Blood

Types of Examination/Technical Field
Blood film preparation and staining by the following techniques:
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
Gram Stain
WBC Differential on Aerospray Stainer

Blood culture analysis by Bactec FX using:
Fluorescence

Bacterial culture using the following techniques (put up only):
Manual inoculation of agars and broths

Antimicrobial susceptibility testing using the following techniques (put up only):
Disk diffusion (EUCAST / CLSI)

Molecular Pathology

Materials/Products
Sputum/Respiratory samples, Nasopharyngeal Swab

Types of Examination/Technical Field
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

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Pathlab Whakatane	Type of Examination / Technical Field
Whakatane Hospital Laboratory	Venepuncture collections Capillary collections Collection/receipt of other specimens (urine, faeces, swabs) Collection of Mycology specimens (skin, hair) Collection of specimens for paternity testing Glucose Tolerance Tests Skin Allergy Testing Therapeutic Venesections Home visit collections
Whakatane Hospital Wards	Venepuncture collections Capillary collections Collection/receipt of other specimens (urine, faeces, swabs) Collection of Mycology specimens (skin, hair) Glucose Tolerance Tests
Whakatane	Venepuncture collections Capillary collections Collection/receipt of other specimens (urine, faeces, swabs) Collection of Mycology specimens (skin, hair) Glucose Tolerance Tests Specimen preparation for transportation
Kawerau	Venepuncture collections Capillary collections Collection/receipt of other specimens (urine, faeces, swabs) Collection of Mycology specimens (skin, hair) Glucose Tolerance Tests Specimen preparation for transportation
Opotiki	Venepuncture collections Capillary collections Collection/receipt of other specimens (urine, faeces, swabs) Collection of Mycology specimens (skin, hair) Glucose Tolerance Tests Specimen preparation for transportation

Specimen Services

Specimen reception
24-Hour urine
Specimen preparation and storage - manual
Data registration
Specimen preparation for transport to alternative Pathlab Laboratories
Clinical Trials

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Transfusion Medicine

Materials/Products
Red blood cells; Plasma; Serum

Type of Examination/Technical Field
The following Transfusion related parameters by Immucor Echo and Immucor 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 manual 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 techniques:

- 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

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