Taranaki DHB Pathology and Laboratory Services

Purpose of this document:

Taranaki DHB has developing this draft service specification that sets out the services to be delivered by a single provider of pathology and laboratory (both community and hospital) services in the Taranaki DHB region. This document will form the basis of the service requirements within an agreement between TDHB and the successful supplier.

Process for developing the specification

There is no service specification for current hospital laboratory services, and this working draft has initially drawn on specifications from other New Zealand integrated hospital and community laboratory services as a starting point.

We are seeking your input to inform TDHBs service specification (the resulting output will be the property of TDHB).

Draft Service Specification – Work in Progress

1.1 Service definition

a) Laboratory services is the provision of diagnostic laboratory testing and associated services utilised for diagnostic, public health, screening programmes (excluding specific screening programmes separately funded by the Ministry of Health), infection prevention and control, and related monitoring purposes only.

b) Laboratory services are provided for Eligible People referred by a range of community and hospital registered Health Practitioners including general practitioners, private medical specialists, oral and maxillofacial surgeons, oral surgeons, midwives, nurse and allied health practitioners and certified cervical smear takers. Taranaki DHB previously had both Community and Secondary Laboratory services within the DHB and laboratory services to support these services are required to be maintained at the level that was in place prior to the Laboratory Services Start Date, and enhanced where appropriate.

c) Unless otherwise agreed in writing between us, all components within this Service Specification and in Parts B and C of this Schedule 2 are included in the Service Fee paid to you, and no additional payments will be made by us to you for your provision of these services.

1.2 Service objectives

a) **General**

Taranaki DHB wishes to fund, through this Agreement, hospital and community referred laboratory services:

(i) that provide Eligible People with high quality, accurate, cost effective and accessible services based on professional, contractual and statutory standards and codes of practice;

(ii) that ensure the safety of Eligible People and Personnel, and meet the quality and performance expectations of stakeholders and the quality standards specified in this Agreement;

(iii) that provide timely and quality test results and specialist pathology advice to Approved Referrers in both the hospital and community setting;

(iv) where you provide services efficiently and without unnecessary duplication;

(v) where you, independently or in conjunction with other health providers, identify and provide the specific requirements of high need groups;

(vi) where you provide advice to Approved Referrers on best practice utilisation of laboratory services;

(vii) that are clinically and financially sustainable, technically efficient and affordable for TDHB;

(viii) where you work collaboratively with other services and stakeholders;

(ix) that enable Approved Referrers to have access to a comprehensive range of tests that will enable accurate diagnosis and the management of patients in the hospital and the community;

(x) that provides an integrated service that spans primary and secondary/tertiary care seamlessly and is easily accessed by the community; and

(xi) that provides relevant summary data and reports to support service planning, clinical audit, infection prevention and control, and other quality systems.

b) **Māori health**

(i) An overarching aim of the health and disability sector is the improvement of health outcomes and reduction of health inequalities for Māori. Health providers are expected to provide health services that will contribute to realising this aim. This may be achieved through mechanisms that facilitate Māori access to services, provision of appropriate pathways of care which might include, but are not limited to:

(A) matters such as referrals and discharge planning;

(B) ensuring that the services are culturally competent;

(C) and that services are provided that meet the health needs of Māori.

(ii) It is expected that, where appropriate, there will be Māori participation in the decision making around, and delivery of, the Services, as further described in clause 1.8b) of Part B of this Schedule 2.

(iii) In addition you will develop and implement an annual plan that outlines how you will contribute to the Māori health gain through your provision of the Services, as further described in clause 1.8a) of Part B of this Schedule 2 (**Māori Health Plan**).Laboratory services will be delivered by you in a supportive manner that respects the dignity, rights, needs, abilities and cultural values of the Eligible Person, and their family and whānau as further described in clauses 1.8d) and 1.8e) of Part B of this Schedule 2.

(iv) The Treaty of Waitangi establishes the unique and special relationship between iwi, Maori and the Crown. As a Crown agency, we consider the principles of the Treaty of Waitangi concerning partnership, proactive protection of Maori health interests, co-operation and utmost good faith to be implicit conditions of the nature in which our internal organisation responds to Maori health issues.

(v) We require that these principles be explicitly expressed in contracts between us and service providers. Therefore, where your clientele includes Maori, you must demonstrate how the policies and practices of your organisation and service delivery benefit that Maori clientele.

1.3 Service users

a) **Patients**

(i) The client group for testing comprises Eligible People who have been referred by Approved Referrers.

(ii) For the avoidance of doubt, Laboratory Services are only funded by us for Eligible Persons.

b) **Approved Referrers**

Approved Referrers receive results and advice, and participate in multidisciplinary team meetings.

1.4 Access

a) Laboratory diagnostic services will be accessible to Eligible People. In the community, the collection of samples from Eligible People for the purpose of undertaking Laboratory Tests will be undertaken at locations practically situated for Eligible People. Provision of results of tests to Approved Referrers will be within a suitable timeframe for good quality patient care and in accordance with the required response times outlined in clause 1.6b) of these Service Specifications and as reflected in the relevant KPIs. Discussions with Approved Referrers regarding the most suitable investigations for specific problems and discussion of results in given specific clinical scenarios will happen in a timely manner. The development and use of clear referral pathways will support good practice, enhance patient care and help ensure timely access to laboratory diagnostic services. Clear referral pathways will also help support better management of testing.

b) **Eligible People and Services**

(i) You will provide laboratory diagnostic services, including undertaking all Laboratory Tests, at no charge to any Eligible Persons referred to your laboratory by Approved Referrers. It is the responsibility of the Approved Referrer to determine both the eligibility of the patient and of the service being requested, and to obtain the consent of the Eligible Person to the provision of the laboratory diagnostic services.

(ii) In accordance with clause 1.11a) of Part C of this Schedule 2, a declaration, as agreed to by both of us, as to the eligibility both of the Eligible Person being referred by the Approved Referrer and of the service being requested by the Approved Referrer is to be included in your Laboratory Test request forms within 1 month of the Laboratory Services Start Date or by any other date agreed to by both of us in writing. This declaration is to be signed by the Approved Referrer. Both of us agree to work with Approved Referrers to encourage them to sign this declaration.

(iii) Patients whom you know to be ineligible are excluded from receiving laboratory services funded by us under this Agreement.

(iv) The failure by the Approved Referrer to complete a declaration regarding a patient's eligibility does not, in itself, mean that the patient is ineligible.

c) **Eligibility of Approved Referrers**

(i) You will provide diagnostic laboratory services detailed in this Service Specification upon written or electronic referral from Approved Referrers only. For the avoidance of doubt, we are not funding the provision of diagnostic laboratory services under this Agreement if a health professional who is not an Approved Referrer directs a sample to you for laboratory analysis.

(ii) An Approved Referrer is any health practitioner lawfully entitled to request diagnostic tests and services for an Eligible Person including a hospital

inpatient, outpatient or community patient. Approved Referrers are eligible to request tests as described in 1.4 c (ii) (a) and (b):

(A) Tier One Tests – these are 'core tests' that any health practitioner registered under the HPCA 2013 with a current practising certificate and a relevant scope of practice may order.

(B) Tier Two Tests – these are considered to be specialist tests whereby the Approved Referrer needs appropriate vocational registration or credentialing to order the test. With pre-authorisation by a relevant specialist any Health Practitioner registered under the HPCA 2013 with a current practising certificate and a relevant scope of practice is able to order a Tier Twotest .. If in doubt, the referrer should consult a relevant pathologist at the laboratory for advice and authorisation.

(iii) Any changes to the list of Approved Referrers, including changes to introduce a new class of Approved Referrer will be determined by the TDHB following consultation with the Alliance.

1.5 Service components

a) **Processes**

You will carry out all Laboratory Tests appropriately referred to you by Approved Referrers.

b) **Services being funded**

You will provide the following laboratory diagnostic and related services in respect of all Laboratory Tests, requested by Approved Referrers and which you reasonably ought to know are not purchased by TDHB through another agreement in all cases, while ensuring that appropriate clinical and scientific expertise for best laboratory practice is implemented, including by undertaking the appropriate assessment and using new testing processes and technologies. These services include:

(i) ***Testing***

The analysis of inpatient, outpatient and community-referred specimens for diagnostic, public health and sexual health (excluding specific screening programmes separately funded by the Ministry of Health) and related monitoring purposes including surveillance (e.g. surveillance for multi-drug resistant organisms for infection prevention and control). The tests to be performed by you include all Laboratory Tests. You will be required to retain specimens for the purposes of further diagnostic testing if required according to the IANZ/NATA standards for retention of specimens.

For clarity, testing includes:

- *testing individual patient specimens for the purpose of assisting with individual case management:* To inform appropriate clinical management for an individual including confirmation of the need for appropriate infection control practices to prevent further spread e.g. isolation;

- *testing individual patient specimens for the purpose of assisting with contact management:* To confirm diagnoses in individuals that have specific time-limited effective interventions for their close contacts to decrease the likelihood of contacts developing the infection e.g. vaccination for measles or hepatitis A contacts; and

- *testing individual patient specimens for the purpose of assisting with individual contact management:* To confirm the immune or infectious status of contacts to inform appropriate decisions around prophylactic treatment, need for isolation or quarantine.

For clarity, the range of Laboratory Tests and associated services will include the following categories of pathology.

(A) haematology;

(B) biochemistry;

(C) anatomical pathology (histology and cytology, but excluding community-referred cervical cytology and cervical histology that are purchased under a separate contract managed by the Ministry of Health, Public Directorate);

(D) microbiology;

(E) immunology, including *in vivo* and *in vitro* testing;

(F) molecular diagnostics;

(G) point of care testing coordination and management;

(H) virology and serology;

(I) Blood grouping and transfusion services;

(J) the provision of therapeutic venesection; and

(K) other associated services such as bone marrow collection and sweat testing.

(ii) a mortuary service, which includes the operation of the mortuary facility, the employment of mortuary technicians, the provision of hospital post-mortems, return to patient services, and management of bereaved families within the mortuary complex. For the avoidance of doubt, coronial and forensic post-mortems are performed by your technical staff for the purpose of fulfilling the contractual requirements of the National Forensic Pathology Service and are outside the scope of the Services to be provided by you and funded by us under this Agreement although you acknowledge that you are required to contract separately with the Ministry of Justice and Auckland DHB to provide coronial and forensic post-mortems from the Laboratory Services Start Date that were provided by Taranaki DHB prior to the Laboratory Services Start Date.

(iii) For the avoidance of doubt, you are responsible for the supply and maintenance of equipment required to operate the mortuary.

(iv) ***Reflex testing***

Reflex testing is an integral aspect of laboratory medicine. You are required to use such patterns of reflex testing as were used by us in respect of laboratory testing prior to the Laboratory Services Start Date and any updated patterns of reflex testing as approved by us. These include undertaking both those tests

required for on-going management/diagnosis of individual patients and those required for surveillance purposes.

(v) ***Results & advice***

(A) The provision of laboratory test results and advice to Approved Referrers will be provided by electronic means unless we agree that there are legitimate reasons for the provision of hard copy results rather than electronic results, and may also be provided verbally where contemplated in this Schedule 2 or where you are responding to a verbal request for advice or results from an Approved Referrer.

(B) The provision of laboratory test results into the TDHB infection control information system to enable the provision of structured reports to aid infection control services to work in both the hospital and community sectors.

(C) You will participate in and contribute to multi-disciplinary meetings (**MDT**), clinical-pathological conferences (**CPC**), and committees such as Infection Prevention and Control Committee, Grand Rounds and clinical audit meetings. The frequency of MDT for each of Base and Hawera Hospitals as at the Laboratory Services Start Date is set out in the table below. Any proposed changes to the current meetings, programs and committee meetings detailed in the table below will be approved by us following consideration of a recommendation made by the Alliance.

Current meetings, programs and committees	Taranaki Base	Hawera
General Surgery – Oncology MDT	Monthly	
Breast – Oncology MDT	Monthly	
Gynaecology - Pathology CPC	Quarterly	
Orthopaedic - Pathology CPC	Twice a month	
Dermatology case review	As required	
Taranaki laboratory seminar	Twice per year	
Grand Round	Twice per year	
Point of care committee	Quarterly	
Infection control committee	Monthly	
Blood transfusion committee	Quarterly	
Allied Health Meeting	Monthly	
Quality/Risk Meeting	Monthly	Monthly
Health & safety	Monthly	Monthly
Mortality/ morbidity and perinatal mortality committee	Monthly	
Continuing medical education sessions on new tests, demand management with general practitioners.	Every six months	Every six months

Are there any other meetings e.g. medical or paediatrics, primary care?

(D) Provision for daily slide consensus meetings will be made.

(vi) ***Collection***

(A) You will collect samples that are taken at collection centres, and inpatient and outpatient phlebotomy services as detailed in clause 1.5c)(ii) of Part A of this Schedule 2.

(B) You will collect samples that are taken from home-based, hospice and rest-home based patients, in particular:

- home and after-hours collection services will be provided where these relate to bedridden patients or special medical cases as requested by the Approved Referrer. Samples may be taken by those caring for patients if they are competent to do so as agreed by you, otherwise by your laboratory representative, before collection by a laboratory courier;
- the provision of home based specimen collection for those patients not reasonably able to access specimen collection centres or medical centres,

as further described in clause 1.5c)(iii) of Part A of this Schedule 2.

(vii) ***Other specialist services***

You will also provide other specialist services, being:

(A) the provision of blood transfusion services in respect of Eligible Persons accessing such services in the Taranaki DHB Geographical Area, in accordance with guidelines as stipulated by the regulatory bodies – New Zealand Blood Service and International Accreditation New Zealand. The specific requirements for such services are outlined in Appendix 4 of this Schedule 2;

(B) the provision of a therapeutic venesection service(in respect of Eligible Persons accessing such). Referrals may be sent from Approved Referrers who are haematologists, consultants and general practitioners;

(C) the provision of fine needle aspirations and assistance at bone marrow collection;

(D) provision of other laboratory services relevant to secondary and community services including technical support to the sexual health clinic.

(viii) ***Supplies and other services***

You will:

(A) supply Approved Referrers with all materials or substances required for the purpose of providing diagnostic laboratory services, as further described in clauses 1.12c) and 1.12d) of Part A of this Schedule 2;

(B) provide medical services complementary to any diagnostic laboratory services, except medical services of a kind that are not ordinarily performed by Pathologists. These services include, but are not restricted to, direct advice to other services to support clinical management, participation in and contribution to MDT, data collection (for example, to assist audits and for public health purposes), quality improvement, quality assurance with IANZ participation, assistance with complaint processes and Official Information Act 1982 requests. A high level of integration is required between non-laboratory clinical services and Laboratory Services provided by you;

(C) establish and maintain a laboratory test database as an effective tool for all laboratory users. This will contain specimen requirements, expected

turnaround times and other appropriate information. You will make this database available to all Approved Referrers and such database must be kept up to date; and

(D) provide any other incidental services related to the provision of diagnostic laboratory services, including the collection and delivery of specimens from Approved Referrers, and where appropriate, cultural advice and support.

(ix) ***Information***

You will:

(A) meet all Information Standards and Reporting Requirements;

(B) report on a regular basis to the Alliance in accordance with all reporting requirements described in this Agreement;

(C) report to other groups and organisations as required by any applicable law, for example, the Cancer Registry, and National Cervical Screening Programme, bowel screening programme;

(D) provide direct notification of any notifiable organisms to Institute of Environmental Science and Research in accordance with legislative requirements;

(E) provide direct access to your laboratory information system results to all hospital clinical areas; and

(F) provide surveillance reports.

(x) ***Demand management and Approved Referrer education***

(A) You will put in place strategies to manage demand and limit unnecessary or inappropriate laboratory testing. Your strategies will include the following as appropriate in the circumstances:

- working collaboratively with Approved Referrers and clinical governance groups and facilitators to encourage evidence based test requesting;
- educating and giving feedback to Approved Referrers about appropriate test ordering based on the best available evidence, such as how to use new tests, on handling patients expectations of testing, giving feedback on test ordering through regular continuing medical education seminars or other methods;
- ensuring that the request form (electronic or paper) is appropriate for requesting tests and audit purposes;
- checking with Approved Referrers before completing a Laboratory Test where you believe the Laboratory Test is inappropriate in the circumstances;
- informing Approved Referrers of the costs and value of the tests they are ordering (either during the request build for computerised test orders or by giving feedback);

- making available a set of clinical guidelines on Laboratory Tests and Schedules;
- making Pathologists readily available to answer Approved Referrers' queries as quickly as practical, and making that availability known;
- providing updates/bulletins/news about changes in evidence-based practice etc. These would be best provided in electronic format with a way to look up specific topics;
- undertaking demand management planning for any surge in testing driven by an epidemic or community outbreak; and
- mechanisms to provide educational material, feedback regarding utilisation, and a way of making complaints or requests for information.

(B) You have responsibility for managing demand and cost for Laboratory Tests and associated services, as well as introducing evidence-based improvements or changes. This should be done in association with other clinical groups. We will support you in this through the activity of the Alliance. We will endeavour to consult with you in relation to any programmes run by us that might significantly alter laboratory testing in the Region.

c) **Settings**

(i) Laboratory services will be provided in both the hospital and community settings. In the hospital settings this will include inpatient and outpatient services, and in the community this will include community collection centres, aged residential care and the person's home.

(ii) ***Collection centres***

(A) There are a number of community and hospital laboratory collection centres in place as at the Agreement Start Date and we expect a pragmatic approach to the location of collection centres across the Taranaki DHB Geographical Area to facilitate access. For example:

- sample collection centres shall be aligned to the needs of the population: the choice of location should be based on evidence-, taking into account population, age and socio-economic status; and
- sample collection centres shall be designed for positive patient outcomes experience-based design should be used to determine factors that will improve patient access (for example, hours, parking, experience).

(B) One of the Strategy's high level outcomes is that the future configuration of laboratory services should seek to achieve improved health outcomes for our populations, provide equitable access to testing and deliver good value for money. Accordingly, your community collection centres will maintain, as a minimum, the levels of access for the community as a whole that existed prior to the Laboratory Services Start Date, with a particular focus on access for high needs populations.

(C) At least one community collection centre will be located in each territorial local authority (unless otherwise agreed in writing with TDHB), which will be open at a minimum from 7am to 5.30pm on week days and 8.30am to midday on Saturdays (excluding public holidays). The remainder of the specimen clinics will be open for various times as recommended by the Alliance and agreed by TDHB.

(D) The specimen collection clinics detailed below shall provide collection services free of charge to Eligible Persons. If collection services are not provided in an area, you shall contract with Approved Referrers in that area to provide the collection centre services at their premises, free of charge to all Eligible Persons. Any such arrangements must be approved in writing, in advance, by us.

(E) You are required to assist with up-skilling others to collect specimens, through running a minimum of two free training sessions per year during the Term. Māori health providers and others shall be encouraged, by you, to participate in these sessions, in order to reach those who may not otherwise follow through on test referrals.

(F) You will be responsible for transport and courier costs from the place of collection to the laboratory where the Laboratory Test will be undertaken.

(G) You may not make any changes to any existing collection centre's location or hours of service without our prior written approval. For the purpose of seeking our approval you shall refer any proposed changes relating an existing collection centre's location or hours of service to the Alliance which will be responsible for making a recommendation to us. Following receipt of our approval to such changes, you will ensure any changes are communicated appropriately to those affected in a timely manner.

(H) The following are the specimen collection clinics:

- Stratford;
- New Plymouth; and
- Hawera.

(iii) ***Collection from Approved Referrers/rest homes/residential homes/ hospice***

(A) Collection of samples from Approved Referrers that collect samples (including medical centres and rest homes) will occur at the frequency necessary to ensure that sample viability is not jeopardised, that patients are provided with a timely service and that enables you to meet the required response times. This will normally be a minimum of two collections per day staggered appropriately to meet the needs of Approved Referrers. Approved Referrers referring a smaller number of samples (less than 30 samples per day) may require fewer collections (for example once per day, plus an option to phone for additional tests).

(B) You will collect samples taken from home-based and rest-home based patients at least 5 days per week (excluding public holidays). This service will be available for the clinically indicated patients of any age. You may choose to impose written home-based testing guidelines to manage demand for this service. Any such guidelines shall be approved by us before use.

1.6 Service levels

a) Schedule of tests to be provided

(i) You will perform all Laboratory Tests, which must be undertaken in accordance with the Laboratory Test Referral Guidelines set out in Appendix 2 of this Schedule 2 (where applicable). You will also provide any additional tests to

support national service specifications where appropriate where funding from the Flexifund is made available to you for the purpose of performing such tests (as contemplated in this Agreement), or as otherwise agreed between the parties.

b) **Required response times**

(i) You are required to provide:

(A) laboratory services described in this Service Specification on a 24 hours per day, 7 days per week basis at Taranaki Base Hospital, and on the basis set out in clause **Error! Reference source not found.** of Part A of this Schedule 2 at Hawera Hospital. The turn-around time for all Urgent Laboratory Tests shall meet the reasonable clinical needs of the Approved Referrer and the Eligible Person and shall comply with the turn-around times set out in clause 1.6b)(iv) of Part A of this Schedule 2;

(B) specialist advice on a 24 hours per day, 7 days per week basis to Approved Referrers and be available for consultation with Approved Referrers; and

(C) advice to all Approved Referrers for significant abnormal results, with critical results (being those results which fall outside of critical limits defined for each discipline as set out in Appendix 6 of this Schedule 2) being advised to Approved Referrers immediately.

(ii) The Approved Referrer is to be informed of expected turn-around times for Laboratory Tests at, or in advance of, the time the Laboratory Test(s) are referred to you so that patients can be informed.

(iii) For the avoidance of doubt, the required response times apply to Laboratory Tests referred by both hospital and community Approved Referrers although the actual required response time in each setting may differ, as set out in this Service Specification.

(iv) You will use your best endeavours to immediately inform the relevant Approved Referrer by telephone of any abnormal results with significant implications Abnormal results with significant implications will include, but is not limited to:

(A) Life threatening results;

(B) Results outside critical limits defined for each discipline as agreed through consultation as per IANZ requirements such as panic values.

(v) The required response times for Urgent and non-Urgent hospital Laboratory Tests is calculated from receipt of the sample in the laboratory where the sample was taken from the Eligible Person and are as set out in the table in clause 1.6b)(vii) of these Service Specifications.

(vi) The required response times for Urgent and non-Urgent community Laboratory Tests are:

(A) 90% of routine biochemistry and haematology Laboratory Tests need to be reported within 24 hours of collection (being any biochemistry and haematology Laboratory Test that is to be performed on a sample that is not an Urgent sample) (by volume), except microbiology, histology and cytology Laboratory Tests, are completed and the results communicated to Approved Referrers within 24 hours of receipt of the Laboratory Test

sample at the specimen collection clinic or from a home or rest home, as applicable (excluding weekends and public holidays);

(B) routine histology and cytology Laboratory Tests (being any histology and cytology Laboratory Test that is to be performed on a sample that is not an Urgent sample) are completed and the results communicated to Approved Referrers within the required timeframes (calculated from receipt of the Laboratory Test sample at the specimen clinic or from a home or rest home, as applicable (excluding weekends and public holidays)) in accordance with the required response times specified for such tests in the table in clause 1.6b)(vii) of this Service Specification;

(C) 90% of routine microbiology Laboratory Tests (being any microbiology Laboratory Test that is to be performed on a sample that is not an Urgent sample) (by volume), are completed and the results communicated to Approved Referrers within 72 hours of receipt of the Laboratory Test sample at the specimen collection clinic or from a home or rest home, as applicable (excluding weekends and public holidays); and

(D) 80% of Laboratory Tests to be performed on Urgent samples are completed and the results communicated to Approved Referrers by phone/fax/electronic format within 3 hours of receipt of the Laboratory Test sample at the specimen collection clinic or from a home or rest home, as applicable.

(vii) The required response times for selected routine and Urgent Laboratory Tests are shown in the table below. Required reporting time is defined as time from receipt of sample (or collection of sample) by you to the time the result is reported to the Approved Referrer.

Test (or group)	**Urgent Hospital (from receipt)**	**Routine Hospital (from receipt)**	**Urgent Community (from time sample taken)**	**Routine Community (from time sample taken by you)**
Electrolytes, LFT, hCG, Therapeutic drugs	90% in 1 hr	90% in 2 hrs	80% in 3 hrs	90% in 24 hrs
Troponin	90% in 1 hr		90% <3 hr	
Blood Gas	90% in 15 mins	90% in 30 mins		
FBC	90% in 45 mins	90% in 2 hrs	80% in 3 hrs	90% in 24 hrs
Coagulation (INR, APTT, Fibrinogen)	90% in 1 hr	90% in 2 hrs	80% in 3 hrs	90% in 24 hrs
Urine Culture		90% in 24 hrs		90% in 24 hrs
Histology		80% <5 days		80% <5 days
		90% < 10 days		90% < 10 days
		98% <15 days		98% <15 days
Frozen section	Verbal report within 20 mins of receipt			
Cytology		90% within 2 Working Days		90% within 2 Working Days
		95% within 3 Working Days		95% within 3 Working Days

D-dimer	1 hr	24hrs	90% <3 hr	

(viii) In respect of Laboratory Tests that are not captured in the table directly above, required response times for some such additional "specialist" Laboratory Tests will be set by us in the First 12 Months following consideration of recommendations made by the Alliance as to the appropriate required response times for such specialist Laboratory Tests. Once set by us, the required response times for those specialist Laboratory Tests will be notified to you in writing and you must, from the date of receiving notice from us, begin performing those Laboratory Tests within the required response times set by us.

1.7 Training and development

a) From time to time there may be a requirement to train Pathology registrars (including those Pathology registrars employed by TDHB or you)[1], other specialty registrars, medical laboratory scientists, trainees and medical students. The training includes providing adequate supervision of pathology, pathology registrars and resources required for their training, writing and making examinations.

b) From time to time you may be required to train Pathology registrars at the level necessary for the training Hospital (being the Taranaki Base and Hawera hospitals) to maintain accreditation from the appropriate colleges to train registrars. For the avoidance of doubt, if other non-laboratory hospital services require a laboratory discipline's location to be on-site and/or maintained to a specific level for them to be able to maintain accreditation from the appropriate colleges to train registrars, then the level of service you must maintain will be the level of service required by the appropriate colleges so that accreditation is maintained.

c) You will participate in the training scheme for 4th year Bachelor of Medical Laboratory Science (BMLS) students. If requested from the training institutions you will train not less than one per year per discipline per year.

d) You will provide phlebotomy training/education for Approved Referrers, nursing, midwives, pharmacists and other staff in the hospital and community.

e) You will have policies and procedures in place for the continuing education of Personnel, to enable maintenance of professional registration, to enhance clinical practice and service delivery and to ensure current practice reflects awareness of recent developments in service delivery, and at a minimum it meets the relevant national professional bodies' current recommendations.

f) Skill sets will be maintained amongst your Personnel for the provision of all services including secondary hospital services, for example in renal, paediatric and breast.

g) You will work with relevant medical services organisations (MSOs) Primary Health Organisations (PHOs), community groups and hospital doctors and other hospital referrers to develop and run a regular annual schedule of Continuing (Medical) Education sessions for Approved Referrers

1.8 Infection prevention and control

[1] Including but not limited to anatomic pathology, haematology, microbiology, biochemistry and immunology.

a) You will develop and implement health and safety and infection control policies and procedures for your laboratory/ies (including any phlebotomy centres). These shall be consistent with nationally accepted guidelines, which set out defined Personnel responsibilities in this area, pre-employment and in-service screenings, employee training, appropriate management and response procedures and a process for the regular review of these policies and procedures.

b) You are expected to contribute to infection control management within the hospitals and communities within the Region. You are required to:

(i) provide at least one appropriate person to sit on the TDHB' Infection Control Committee; and

(ii) provide the TDHB with access to the following information relating to infection control:

(A) laboratory results;

(B) summary data;

(C) current best practice; and

(D) microbiology information;

(iii) ensure your laboratory information system connects to DHB information systems for infection control purposes including the patient management system and clinical data repository, such that the level of functionality at the Contract Start Date is maintained or improved.

(iv) provide clinical expertise in conjunction with hospital infection control staff in risk assessment of blood and body fluid exposure (BBFE) events and have developed, a pathway for management of exposed Personnel including urgent availability of serological testing and interpretation and follow up of those results;

(v) provide appropriate clinical support for the DHBs' Infection Control Teams;

(vi) perform surveillance for detection of multi-drug resistant organisms of infection control importance, including both active surveillance and passive surveillance, as recommended by the TDHB' infection control committee;

(vii) inform the relevant Infection Control Team at TDHB of who is available to provide support (in line with NZIC Standard C3.1);

(viii) continue to assist with the development of improved reporting mechanisms regarding isolates and infections in the hospital and long term care facility populations;

(ix) perform required tests such as those for multi-drug resistant organisms; and

(x) assist in other ways as requested by the relevant Infection Control Team at each of the TDHB.

1.9 Point of care testing outside of the laboratories

a) You will contribute to point of care testing quality assurance systems within the hospital and community within the Region. In general you will be required to:

(i) provide an appropriate person/s to sit on TDHB's committee;

(ii) provide expertise on quality systems and accreditation in accordance with point-of-care testing polices within the TDHB;

(iii) where necessary, provide training in the use of point of care testing equipment;

(iv) where appropriate, provide troubleshooting and maintenance on point of care testing equipment;

(v) provide evaluation and implementation of, point of care testing devices;

(vi) provide ongoing quality management of implemented point of care testing devices; and

(vii) participate in the New Zealand Point of Care Advisory Group.

(viii) where appropriate, you are required to provide troubleshooting and maintenance support on blood gas equipment on a 24/7 basis across the DHB sites.

b) For the avoidance of doubt, with respect to point of care testing devices within the DHB, we are responsible for:

(i) initial point of care testing device purchase cost;

(ii) on-going purchase reagent/quality control/calibration/maintenance supplies;

(iii) entering into preventative maintenance contracts;

(iv) ad hoc point of care testing device maintenance and troubleshooting costs;

(v) ICT costs associated with implementing, maintaining point of care testing software and interfacing with any electronic patient clinical record;

(vi) maintaining the point of care testing governing body i.e. the point of care testing committee responsible for approval of new point of care testing equipment and monitoring the quality of point of care testing within the TDHB; and

(vii) initial and on-going cost for ISO:22870 accreditation for point of care testing – IANZ and registration costs and compliance costs.

c) You are responsible for maintaining a point of care testing quality management system in accordance to ISO:22870 by:

(i) appointing appropriately experienced and trained point of care testing co-ordinators and laboratory Personnel to provide management and technical expertise to point of care testing;

(ii) providing representation on the TDHB' point of care testing governing body;

(iii) being responsible for the documentation of the quality management system in conjunction with clinical areas as required;

(iv) maintaining appropriate policies and procedures;

(v) identifying and controlling “patient events” (collection, analysis, correction and escalation);

(vi) taking preventative action and undertaking continual improvement;

(vii) defining the requirements of technical and clinical records;

(viii) conducting internal audits;

(ix) Undertaking yearly management reviews of point of care testing within the TDHB;

(x) providing documented technical training to users of point of care testing in conjunction with vendors and clinical areas;

(xi) providing operator and super user competency review programmes for point of care testing devices;

(xii) evaluating, validating and implementing new point of care testing devices;

(xiii) maintaining records of point of care testing devices including maintenance records, reagent and quality control/calibration data to ensure an auditable trail of any test performed;

(xiv) implementing and maintaining internal quality control and external quality control programmes for all point of care testing devices;

(xv) providing advice and support to Approved Referrers in regard to point of care testing. This includes implementation, on-going external quality control or sample comparisons, auditing; and

(xvi) participating in the New Zealand Point of Care Advisory Group.

d) The equipment that your laboratories needs to support on a 24/7 basis are located in:

(i) Taranaki Base Hospital Laboratory;

(ii) Hawera Hospital Laboratory;

1.10 Facilities

a) **Laboratory locations and hours of operation**

You will provide laboratory services at Hawera Hospital and Taranaki Base Hospital. The location of relevant laboratory services shall appropriately support clinical specialities and maintain the efficiency and quality of these services at each of the two hospitals.

b) **The minimum hours of operation for the Hospital laboratories**

You shall ensure that you have a hospital laboratory established at each of the following hospitals and that each hospital laboratory is operational during the following minimum hours of operation, noting that any change to these hours, including increased use of point of care for out of hours cover, must be approved by the DHB following a recommendation from the Alliance:

(i) **Taranaki Base Hospital laboratory:**

(A) 24 hours per day, 7 days per week for chemical pathology, haematology microbiology and blood bank;

(B) Anatomical pathology 0800-1700 Monday to Friday. On-call Pathologists available after-hours primarily for frozen sections and other advice as appropriate;

(C) phlebotomy services: Outpatient phlebotomy services 0730-1700 hours Monday to Friday and one in-patient ward round service every day of the week; and

(D) other services such as therapeutic venesection 0800-1700 hours, Monday to Friday with on-call as required.

(ii) **Hawera Hospital laboratory:**

(A) biochemistry, haematology, microbiology, transfusion medicine 0800-1700rs Monday to Friday, 0800 – 1200 weekends and public holidays, on-call for all other hours;

(B) phlebotomy services: Outpatient phlebotomy services 0800-1700 hours, Monday to Friday and one in-patient ward round service every day of the week; and

(C) other services such as therapeutic venesection 0800-1700 hours, Monday to Friday with on-call as required.

(D)

1.11 After hours work

a) Essential Tests are Laboratory Tests that are required to be performed by you on a 24 hours per day, 7 days per week basis. This should not preclude the processing of routine samples as staffing and time allows.

b) If a sample is labelled “urgent” by an Approved Referrer and the Laboratory Test is an Essential Test, then it shall be analysed on a 24 hours per day, 7 days per week basis. If it is not labelled as “urgent” and is an Essential Test that is also a community Laboratory Test, then it may be analysed on the next day.

c) Tests which are not Essential Tests may be performed out of standard operating hours by special arrangement and by agreement with a pathologist.

1.12 Key inputs

a) This Service Specification includes provision and administration of any laboratory services, substances and supplies incidental to the procedure including, where appropriate, cultural advice and support. Pathology tests shall be performed by, or under the direction of a recognised Pathologist.

b) Provision of Pathology services will include, but is not limited to:

(i) Consultation and liaison with sub speciality pathologists which will be available to referrers as and when required;

(ii) Case review, presentation and follow up of clinical issues; and

(iii) Clinical director role for Pathology with senior management attendance and input into DHB services, protocols, quality assurance, meetings, and hospital credentialing as and when required by TDHB.

c) **Equipment/consumables**

You will supply Approved Referrers with equipment and consumables related to the collection of samples free of charge, in reasonable quantities to support sample collection from primary care centres, hospital wards,,,outpatient clinics, residential care facilities, and patient homes and including materials for public health testing. This equipment includes but is not limited to:

(i) vacutainer tubes and needles;

(ii) needle disposal units (and units appropriate for vacutainer needle disposal);

(iii) specimen swabs, e.g. transport media, chlamydia, herpes;

(iv) urine and faeces pots;

(v) specimen bags;

(vi) formalin;

(vii) hard copy Laboratory Test request forms if required;

(viii) chilly bins for transport; and

(ix) blood culture bottles.

d) You are not required to supply hardware or other electronic or medical equipment such as computers, printers, telephones or facsimiles to Approved Referrers. You are not required to supply disposal of medical waste, specula and winged infusion (Butterfly) needles to Approved Referrers. However you shall provide needle disposal units and organise the regular removal of these where this is for the sole purpose of venepuncture.

e) **Personnel**

You will ensure you have employed or otherwise engaged all Personnel required to provide a laboratory service and otherwise provide the laboratory services described in this Schedule 2, including Pathologists, scientists, technicians, phlebotomists, specimen reception staff, pathology registrars administrative and management Personnel.

f) **Access to advice from Pathologists**

You will provide 24 hours per day, 7 days per week access to advice from Pathologists.

g) **Pathologist oversight**

You will ensure a supervising Pathologist or supervising Pathologists is/are responsible at all times in respect of laboratory services provided by you under this Schedule 2 for:

(i) the service specific quality standards;

(ii) the ethical standards; and

(iii) the provision of advice to and for Approved Referrers and the reporting of the results of Laboratory Tests to them.

h) Any changes in your supervising Pathologist(s) shall be notified to us within 7 days of any such change. Such notification is to include the details of the qualifications and experience of any additional supervising Pathologist.

i) Any dispute over the eligibility of a supervising Pathologist is to be referred to the Medical Council for a ruling, which will be binding on both of us.

1.13 Service linkages

In providing the diagnostic laboratory testing and associated services you will provide evidence of effective relationships in the TDHB Region with the following associated services as demonstrated by the nature of the linkage column:

Linked Provider	Nature of Linkage
Primary community based medical and nursing services	Accept referrals from and provide results to, liaise with and provide appropriate specialist advice and education to other health professionals and support services.
Hospital inpatient and outpatient services secondary medical and surgical services, in particular senior medical staff	Provide appropriate specialist advice, education utilisation data, audit and surveillance to other health professionals and support services. Provide pathology leadership in DHB clinical governance structures.
Public and private specialists	Provide appropriate specialist advice and education to other health professionals and support services.
Midwifery services	Provide appropriate specialist advice and education to other health professionals and support services.
Māori primary and community services	Provide appropriate specialist advice and education to other health professionals and support services.
Pacific Peoples primary and community services	Provide appropriate specialist advice and education to other health professionals and support services.
Approved Referrers	Accept referrals from and provide results to, liaise with and provide appropriate specialist advice and education to other health professionals and support services.
Primary Health Organisations	Provide appropriate specialist advice and education to other health professionals and support services.
Other diagnostic laboratories from which tests or to which tests are referred.	Send away Laboratory Tests not done locally, and results entered into local database, liaison.

Regional and Māori Cervical Screening Co-ordinator and the National Cervical Screening Register	Liaison.
Public and private diagnostic laboratories	Send away Laboratory Tests not done locally, and results entered into local database, liaison.
Consumer advocacy services, including Māori and Pacific Peoples advocacy services	Liaison.
Other appropriate organisations, including Māori and Pacific Peoples organisations.	Liaison.
Ministry of Health	Notification, being responsive in public health emergencies, requests for information.
Sexual Health Services	Provide technical support and liaison
Public Health	Referral and liaison.
ESR	National surveillance activities.
Management information unit	Audit and reporting.
Community pharmacies	Monitoring and oversight of point of care equipment and processes

1.14 Exclusions

The laboratory services you provide under this Service Specification, does **not** include the provision of:

a) medical genetics services which are purchased under the Specialist Medical and Surgical Services service description;

b) examination of environmental specimens for public health purposes;

c) the preparation of sera and vaccines;

d) laboratory diagnostic services provided for the purpose of obtaining immigration permits, or visas issued in New Zealand;

e) laboratory diagnostic services provided for the purpose of life insurance, superannuation or other similar benefit;

f) laboratory diagnostic services provided for the sole or primary purpose of a scientific study;

g) laboratory diagnostic services provided for the purpose of staff employment health and safety check;

h) laboratory diagnostic services provided for veterinary clinics;

i) laboratory diagnostic services provided for the purpose of a drug trial (unless the test would be performed as part of routine clinical testing in non-trial patients);

j) laboratory diagnostic services provided for screening purposes related to education or work experience; and

k) laboratory testing to establish immune status pre and post vaccination.

PART B: Organisational and Service Specific Quality Standards

1.1 Introduction

a) You will provide all Laboratory Services covered by this Agreement according to the organisational and service specific quality standards set out in this Part B of this Schedule 2. These standards are auditable but are not subject to regular reporting unless required under this Part B of this Schedule 2. Where an organisational standard refers to the requirement for a written policy, procedure, programme, information or plan, you will provide us with a copy on request.

b) These organisational and service specific quality standards shall apply to all Eligible People whether referred to as patients, customers, Eligible People or residents.

1.2 Needs of specific groups and individuals

a) **Facilities accessible**

The Laboratory Services, and facilities from which the Laboratory Services are provided, shall be accessible to Eligible People irrespective of their age, physical or mental disability. Facilities for Eligible People with a disability shall be clearly indicated.

1.3 Safety/hygiene

a) **Compliance with laws and regulations**

You shall comply with any laws and regulations regarding the provision of the Laboratory Services. In particular, you shall obtain all licences and consents you need to properly carry on your business. Having obtained the necessary licences and consents, you shall keep them current and not do anything which could result in any of them being cancelled or not renewed.

b) **Security**

You shall take all reasonable steps to ensure that the facilities from which the Laboratory Services are provided, equipment, chemical supplies and drugs are secure, that waste management programmes are implemented, and that the safety of Eligible People, staff and visitors is assured.

c) **Incident Reporting**

You will develop and implement incident reporting policies and procedures which set out guidelines for reporting incidents, definitions of “an incident”, a monitoring process, a corrective action process, and a process for the regular review of these policies and procedures.

d) **Personnel qualifications**

You will ensure that your Personnel are, where relevant, registered with the appropriate statutory body, and hold a current practising certificate. Personnel should only work on tasks and procedures for which appropriate training has been given. You will ensure that assistants and other relevant support Personnel have appropriate supervision.

e) **Physical and chemical hazards**

You will develop and implement physical and chemical control policies and procedures, consistent with appropriate guidelines and standards, which set out defined Personnel responsibilities in this area, employee training, appropriate management and response procedures and a process for the regular review of these policies and procedures.

1.4 Quality management systems

a) **Quality standards, equipment and facilities**

(i) ***Quality standards***

(A) You are expected to provide a high quality service to all Approved Referrers. You shall comply with the following policy, quality and service standards and other requirements as they existed as at the Agreement Start Date (as a minimum), or those same standards and other requirements as varied from time to time following consultation with you where the quality and service standards as varied, are set at a higher threshold than what existed as at the Agreement Start Date:

- Quality and Service Standards for Medical Testing Laboratories used by IANZ;
- IANZ Point of Care ISO Standards;
- QHNZ accreditation standards;
- the National Cervical Screening Programme Quality Standards, to the extent applicable;
- the National Breast Screening Quality Standards, to the extent applicable;
- the New Zealand Blood Service standards;
- Ministry of Health certification requirements;
- the reasonable requirements of the TDHB and/or the Alliance, to the extent that those requirements are applicable to the provision of the Laboratory Services;
- standards pertaining to health and safety within New Zealand laboratories and hospitals, in particular those pertaining to meeting the Pc2 standard;
- DHB quality plans and systems;
- Tikanga Māori as per DHB policy;
- the Health and Disability Services (Safety) Act 2001;and
- all other legislative and regulatory requirements regarding the provision of the Laboratory Services.

(B) Where we intend to vary any of the policy, quality and service standards and other requirements specified in this clause, we will discuss with you whether such variation will affect the cost to you of providing the Services and, if so, both of us will endeavour to agree on any price changes that should occur, provided that any failure to agree to price changes will not detract in any way from your obligation to comply with this clause and to provide the Services in accordance with the terms and conditions in this Agreement.

(C) Any and all subcontractors that you refer Laboratory Tests to shall also meet the applicable or equivalent quality standards.

(ii) ***Equipment and facilities***

(A) Any laboratory that you operate shall be IANZ accredited for specimen collection and medical testing.

(B) Subject to sub-clause (H) below, we will fund only those Laboratory Tests which have IANZ (or equivalent, as determined by us in consultation with appropriate organisations) accreditation and subsequent IANZ registration. You shall ensure that any Laboratory Test which you do not provide is subcontracted to a laboratory which has IANZ (or equivalent, as determined by us in consultation with appropriate organisations) accreditation and IANZ registration for that Laboratory Test.

(C) You shall notify us within 48 hours if you or your subcontractor are denied IANZ (or equivalent, as determined by us in consultation with appropriate organisations) accreditation and registration or if, for any reason, your subcontractor or your IANZ (or equivalent, as determined by us in consultation with appropriate organisations) accreditation or registration is suspended or cancelled. Where your subcontractor's or your IANZ (or equivalent, as determined by us in consultation with appropriate organisations) accreditation or registration is suspended or cancelled in respect of a particular Laboratory Test, a group of Laboratory Tests or all of the Laboratory Tests, we may suspend payments to you under this Agreement in respect of such Laboratory Tests until such time as we are satisfied that you or your subcontractor have regained your IANZ (or equivalent, as determined by us in consultation with appropriate organisations) accreditation and registration in respect of the relevant Laboratory Tests.

(D) You will provide us with a copy of your audit reports from IANZ, which specify your accreditation reviews, no less than annually, and more frequently if required by us if any significant issue arises.

(E) You agree that IANZ may provide to us with information about your accreditation status.

(F) You agree to notify us before you begin to operate a new laboratory for the provision of Laboratory Tests or provide a particular Laboratory Test(s) for the first time or close an existing laboratory.

(G) You agree to use all reasonable endeavours to gain IANZ (or equivalent, as determined by us in consultation with appropriate organisations) accreditation and registration, in respect of any new laboratory that you operate or any particular Laboratory Test(s) that you provide for the first time, by no later than 6 months after the date when you begin to operate the new laboratory or provide such Laboratory Test(s).

(H) We agree to fund the relevant Laboratory Test(s) during the 6 month period specified in sub-clause (G) above only on the basis that, during such period, you will operate the new laboratory and/or provide the relevant Laboratory Test(s) to the standards necessary to meet the IANZ (or equivalent, as determined by us in consultation with appropriate organisations) accreditation and registration requirements (as if such accreditation and registration had been gained).

(I) Where you are denied IANZ (or equivalent, as determined by us in consultation with appropriate organisations) accreditation and registration within 6 months in terms of sub-clause (G) above or fail, in the interim, to meet the IANZ (or equivalent, as determined by us in consultation with appropriate organisations) accreditation and registration standards in terms of sub-clause (H) above, and are unable to either meet the Service Specifications or undertake Laboratory Tests at an alternative site (approved by us), we will immediately reduce the amount of the Service Fee, in proportion to the value which both of us agree should be attributed to the amount of those Laboratory Test(s) that we would expect you to provide over a one-year period and you agree to refund to us an equivalent proportion of the amount previously paid to you by us over the relevant period in respect of such Laboratory Test(s).

b) **Quality Plan**

(i) You will develop and implement within 3 months of the Agreement Start Date, a written Quality Plan that incorporates the following elements:

(A) a commitment to develop a total quality management system, including a quality improvement programme;

(B) a statement of the purpose and values of your organisation and of each operational unit within your organisation;

(C) designated Personnel responsibilities for implementing your quality procedures within each operational unit;

(D) auditable standards of performance; and

(E) integration and compliance with DHB plans and systems where sensible and practical.

(ii) Thereafter, you will submit a draft Quality Plan to us by 1 October each year for the Term of this Agreement. Within four weeks of receipt of the draft Quality Plan, we will:

(A) approve the draft Quality Plan as being ready for finalising; or

(B) provide comments on the draft Quality Plan to you and require you to incorporate our comments into the draft within 20 Working Days before the draft is finalised.

(iii) From 1 December each year, you will implement the Quality Plan approved by us.

(iv) You will ensure that current best practice guidelines for clinical practice by Approved Referrers will underpin any demand management. You will ensure that the management of the Laboratory Services does not impact adversely on clinical decision making and will not lead to adverse health outcomes.

(v) You will seek regular feedback from Eligible People, Approved Referrers and other relevant stakeholders in relation to your performance against the Quality Plan. This will include carrying out feedback surveys with these stakeholders on an annual basis.

c) **Personnel, including subcontractors aware of this Agreement**

You will ensure that your Personnel are aware of your responsibilities under this Agreement as they relate to service delivery.

1.5 Eligible People and referrer focus

a) **Complaints policies and procedures**

You will enable Eligible People, families and other people to make complaints through a procedure for the identification and management of complaints. This procedure will comply with the Code of Health and Disability Services Consumers' Rights and will ensure that:

(i) the complaints procedure itself is made known to and easily understandable by Eligible People;

(ii) all parties have the right to be heard;

(iii) the person handling the complaint is impartial and acts fairly;

(iv) complaints are handled at the level appropriate to the complexity or gravity of the complaint;

(v) any corrective action required following a complaint is undertaken;

(vi) the complaints procedure sets out the various Complaints Bodies to whom complaints may be made and the process for doing so. Eligible People will further be advised of their right to direct their complaint to the Health and Disability Commissioner and to us, particularly in the event of non-resolution of a complaint;

(vii) complaints are handled sensitively with due consideration of cultural or other values;

(viii) Māori Eligible People and their whānau have access to a Māori advocate to support them during the complaints process;

(ix) Eligible People who complain, or on whose behalf families complain, shall continue to receive services which meet all contractual requirements;

(x) complaints are regularly monitored by the management of the service and trends identified in order to improve service delivery; and

(xi) the complaints procedure is consistent with any of our complaints policies as notified from time to time.

b) **Code of Health and Disability Services Consumers' Rights**

You will ensure you comply with your obligations in the Code of Health and Disability Services Consumers' Rights and that a written copy of the Code of Health and Disability Services Consumers' Rights is available to Eligible People who visit your laboratory. This should be in accordance with the recommendations of the Health and Disability Commissioner.

c) **Eligible Person advocates**

You will inform Eligible People, in a manner appropriate to their communication needs, of their right to have an advocate, including to support the resolution of any complaint. You will allow advocates reasonable access to facilities, Eligible People, employees and information to enable them to carry out their role as an advocate. The right of advocates to promote advocacy services to Eligible People is to be protected.

d) **Informed choice and consent**

You will develop policies and procedures for obtaining Eligible People's informed consent to the Laboratory Services you provide under this Agreement. You will ensure that Personnel are properly trained in respect of these policies and procedures and that they are followed at all times.

e) **Service information**

You will have available for Eligible People and Approved Referrers appropriately written information, which describes:

(i) the services you offer;

(ii) the location of these services;

(iii) the hours of access;

(iv) how to access these services (i.e. whether a referral is required); and

(v) any other information to enable Eligible People to access these services.

f) **Personal identification**

You will have, and implement, a written policy that will ensure all Eligible People and Approved Referrers are informed, where relevant, of the identity and status of all Personnel, volunteers, students or subcontractors undertaking or observing service delivery.

g) **Respect for privacy, dignity, religion and culture**

(i) You will ensure that there is respect for the personal privacy and dignity of Eligible People during service delivery and that Laboratory Services are provided in a manner which shows respect for Eligible People's religious and cultural beliefs and practices.

(ii) Both of us shall, and shall cause all of our employees and personnel to, at all times, respect the confidentiality of any health or personal information relating to any patient (including any former patient) of our or any personal information relating to any our personnel and shall not do or omit to do any act, matter or thing which might result in our or our employees, your or your employees or any subcontractor or any employees of any subcontractor, being in breach of any of the provisions of the Health Information Privacy Code 1994, the Privacy Act 1993 or any code of practice issued under the Privacy Act 1993 or any other act, regulation or other law which relates to the privacy of health information or personal information.

(iii) You shall make compliance with the provisions of sub-clause g)(ii) a condition of any subcontract.

1.6 Ethical standards

a) **Ethical standards**

You will comply with the ethical guidelines of your relevant professional bodies and uphold the ethical standards generally expected of providers of health and disability support services.

b) **Duty to provide care**

You will provide and uphold at all times appropriate standards of care.

1.7 Service delivery

Health promotion, health education and disease prevention

You will incorporate within your services, where appropriate, support for health promotion, health education, disease prevention and support for the goals of the New Zealand Health Strategy and the New Zealand Disability Strategy.

1.8 Māori health policy

a) **Māori Health Plan**

(i) You will develop a Māori Health Plan as required by the terms of this Agreement within 3 months of the Agreement Start Date. You will work towards ensuring that the Laboratory Services will meet the diverse needs of Māori. You will have written, implemented and at least annually reviewed the Māori Health Plan designed to improve outcomes for Eligible People. The Māori Health Plan will also describe how you manage any risks associated with the provision of Laboratory Services to Māori. The Māori Health Plan will outline a clear strategy and will identify the organisational arrangements and the policies necessary to implement it.

(ii) The Māori Health Plan will be of a size and scope appropriate to the size of your organisation and the Laboratory Services to be provided by you in accordance with this Agreement. The Māori Health Plan will include how you will address Māori issues including recognition of:

(A) Māori participation, where appropriate, in strategic, governance, management and service delivery planning, implementation and review functions;

(B) Māori as a government health gain priority area;

(C) Māori health priority areas; and

(D) our Māori health policy and strategies.

(iii) The Māori Health Plan should also include the following objectives (as a minimum):

(A) how the provider will ensure that Māori utilisation is targeted to meet need;

(B) how links with primary care – general practice, community providers, Māori providers will be established and enhanced for Māori health gain;

(C) and how these objectives will be monitored and measured for Māori health gain.

(iv) You will actively seek feedback from Māori by appropriate methods to improve organisation responsiveness to Māori. The method of obtaining feedback will be specified in the Māori Health Plan.

(v) You will report to us on an annual basis on the performance measures and milestones agreed as part of the Māori Health Plan in hard copy form, including progress towards implementation.

b) **Māori participation**

(i) Māori participation will, where appropriate, be integrated at all levels of strategic and service planning, development and implementation within your organisation at governance, management and service delivery levels.

(ii) This will include:

(A) consultation with, and involvement of, Māori (where appropriate) in your strategic, operational and service processes;

(B) development of a monitoring strategy in partnership with Māori that reviews and evaluates whether Māori needs are being met by your organisation;

(C) reduction of barriers to accessing your services;

(D) facilitation of the involvement of whānau and others;

(E) integration of Māori values and beliefs and cultural practices;

(F) availability of Māori Personnel to reflect the Eligible Person population;

(G) existence, knowledge and use of referral protocols with Māori service providers in your locality;

(H) education and training of Personnel in the requirements of our Māori health policy and strategies;

(I) incorporation of Māori health policy expectations in employment contracts;

(J) education and training of Personnel in Māori values and beliefs and cultural practices; and

(K) support and development of a Māori workforce.

c) **Employees registration, education and training**

Your employment policies and practices will support professional career pathway development for Māori health workers, Māori service advisory positions, Māori management positions, and the recruitment and retention of Māori employees at all levels of your organisation to reflect the consumer population. As part of your support for Māori employees and Eligible People, you will support the introduction of appropriate Māori principles/tikanga within your organisation.

d) **Support for Māori**

You will facilitate support from whānau/hapu/iwi, kuia/kaumatua, rongoa practitioners, spiritual advisors, Māori Personnel and others, as appropriate, for Māori accessing your service.

e) **Cultural values**

You will deliver the Laboratory Services in a culturally appropriate and competent manner, ensuring that the integrity of each Eligible Person's culture is acknowledged and respected. You will take account of the particular needs within the community served so that there are no barriers to access or communication, and that your provision of Laboratory Services are safe for all people. You will include significant local or service specific ethnic and other cultural groups in assessing satisfaction with services. You will incorporate Māori principles/tikanga into your organisation. Some explanation of these principles/tikanga are set out in sub-clause g) below. Reference to "Māori" includes the development of a relationship with local tangata whenua and if appropriate, regional tangata whenua, Māori personnel, Māori providers, and Māori community organisations to achieve the required Māori input.

f) **Ethical review**

You will consult and receive approval from Māori for any research or innovative procedures or treatments that will impact on Māori.

g) **Explanation of some Māori principles/tikanga**

Explanations of Māori principles/tikanga include:

(i) **aroha** (compassionate or love) is the unconditional acceptance which is at the heart of care and support;

(ii) **kawa** (protocol of the marae, land, iwi) determines how things are done in various circumstances. Respect for kawa is important. If the kawa is not known, the tangata whenua should be consulted;

(iii) **manaaki** is to care for and show respect. The Laboratory Services shall show respect for Māori values, traditions and aspirations;

(iv) **mana** is the authority or standing of a person. The Laboratory Services shall recognise the mana of Māori consumers;

(v) **tapu/Noa** (sacred/profane) is the recognition of the cultural means of social control envisaged in tapu and noa, including its implications for practices in working with Māori consumers;

(vi) **turangawaewae** (a place to stand) is the place a person calls home or where their origins are. This shall be identified for all Māori consumers who wish it;

(vii) **wairua** (spirit or spirituality) is a recognition that the Māori view of spirituality is inextricably related to the well-being of the Māori consumer; and

(viii) **whanaungatanga** (the extended family) is the family or group that takes responsibility for its members and who shall be informed of where its member is.

PART C: Information Standards and Reporting Requirements

1.1 Principles

a) You will be committed to the extension and further development of electronic processes to support all aspects of laboratory services, with particular emphasis on ordering, reporting and effective linkages to DHB systems.

b) You agree to cooperate with us in good faith on any initiative we undertake to achieve improvements in laboratory information processes or content.

1.2 Information standards and reporting requirements

a) You will have a consistent methodology for all Approved Referrers (in hospital and community care) to access and process Laboratory Test results. Your methodology will facilitate seamless and integrated care for all patients.

b) You shall ensure primary referred Laboratory Test results:

(i) are reported back to the Approved Referrer; and

(ii) the DHB clinical data repository, and when established the regional data repository, except where the patient requests to opt out of their information being included in the clinical record.

c) You will ensure Laboratory Test results are available to health practitioners requiring access to results.

1.3 Information process requirements

a) Your laboratory information system processes will adhere to the information requirements set out in this Agreement, including the Laboratory System Requirements described in Appendix 5 of this Schedule 2, and IANZ and HISO standards. Your laboratory information system will support electronic information processing, interfaces and workflows.

b) You will ensure your information systems capability includes:

(i) fully functional information systems and other IT capability and infrastructure. Where computer systems are changed or upgraded, access to the patient information on previous systems will be retained in accordance with IANZ standards, such access to be electronic or hard copy in accordance with current practice in place at the date of this Agreement, including;

(A) your information system is fully functional and compatible with other information systems used by referrers;

(B) your information system is configured to receive electronic orders from referrers within twelve months from the Contract Start Date;

(C) your electronic ordering system must be approved by the DHB through the Alliance process prior to installation; and

(D) where your information system or technology are changed or upgraded, access to the patient information on previous systems will be retained in accordance with IANZ standards.

(ii) clearly identified responsibilities of Personnel, for example in advising Approved Referrers of urgent results;

(iii) appropriately skilled Personnel to manage the supporting information systems;

(iv) procedures clearly identifying maintenance routines, installation, security management, data definitions and documentation of the sources of each data item reported;

(v) an audit trail for users performing updates or inquiries, and version control on changes to results; and

(vi) delivery of results electronically to Approved Referrers, other required recipients and appropriate clinical data repositories.

c) All Laboratory Test data for community Laboratory Tests performed will be supplied to Sector Services and/or NZHIS for inclusion in the Laboratory Warehouse, and this will be extended to included hospital Laboratory Tests when Sector Services systems are able to receive this information.

d) You will undertake with us a quarterly reconciliation of all the information relating to community Laboratory Tests included in your information systems and the information held in the Laboratory Warehouse.

1.4 Key information requirements

a) You will maintain the following information and provide it to us upon request:

(i) a copy of all Laboratory Test request forms;

(ii) an electronic copy of each report that you make on any Laboratory Test;

(iii) a record of all Laboratory Tests (including reports on any Laboratory Test) undertaken at your initiative; and

(iv) the following information for each Laboratory Test undertaken:

(A) a unique identification number;

(B) referral identification;

(C) a test code;

(D) the date of service;

(E) the number of tests;

(F) Eligible Person date of birth;

(G) Eligible Person gender;

(H) Eligible Person NHI number;

(I) Approved Referrer identifier;

(J) practitioner – pathologist; and

(K) PIN/PAN number if applicable.

b) You will keep this information for a period of time that is consistent with IANZ policies and that complies with any relevant legislative requirements and in any event for a period of not less than one year from the date on which receive payment under this Agreement in respect of the month in which you carried out the Laboratory Test.

1.5 Interfaces

a) You will use all reasonable endeavours to meet your obligations under clauses 1.5b) to 1.5g) of Part C of this Schedule 2 as soon as practicable following the Agreement Start Date.

b) You will use HL7 messaging format and protocols in line with HISO standards.

c) Your laboratory information system will support the following interfaces to other systems:

(i) electronic delivery of processed Laboratory Test results to the Approved Referrer;

(ii) electronic processing of request to send copies of patient Laboratory Test results to other authorised parties; and

(iii) electronic orders, including the receiving, validating, processing and status reporting of Laboratory Test requests from practitioners electronically and according to HISO standards; and

(iv) electronic receipt of patient test results from point of care equipment and from other laboratory information systems to whom you subcontract Laboratory Tests.

d) In accordance with the interface requirements set out in clause 1.5c) above, you will ensure that as a minimum your laboratory information system complies with any technical specifications, information and field requirements that we specify from time to time.

e) You will ensure message formats are consistent with commonly accepted New Zealand standards, including, as appropriate:

(i) HL7 v2.1 (“HealthLink”) – current HealthLink format supported by Practice Management Systems such as Medtech;

(ii) HL7 v2.4 – to support copying results into the regional repository; and

(iii) other HL7 message formats as ratified by HISO from time to time.

f) We may require you to, and you shall where we so require, support HL7 v3 XML or other relevant XML protocol if this becomes industry standard.

g) You will code Laboratory Test results using LOINC codes (either the New Zealand Pathology Observation Code Sets (**NZPOCS**) as prescribed by HISO or the particular codes recommended by the Alliance and approved by us).

1.6 Reporting of results

a) You will report the results of Laboratory Tests carried out to the Approved Referrer, the DHB Patient Management system unless the patient has declined permission and other authorised parties.

b) You will consult with Approved Referrers on, and seek approval from us in writing of, any significant changes in your method of reporting of results prior to any such changes taking effect.

c) You will provide to us, in electronic form approved by us, a monthly report of test volumes by test type, Approved Referrer, and by hospital department or speciality for hospital referred tests.

d) You will provide additional data as required to ensure that we are able to meet our reporting requirements to the Ministry of Health.

e) You will ensure that the patient's NHI number is used as the patient identifier in a manner consistent with current practice at the date of this Agreement. When a NHI number is not available, all reasonable endeavours shall be used to obtain one.

f) You will transmit a complete set of data with a Laboratory Test result to ensure data integrity is maintained.

g) You will include the following minimum data elements in an electronically transmitted Laboratory Test result to an Approved Referrer:

(i) a unique specimen number identifier;

(ii) text for Laboratory Tests that are text based;

(iii) comments in free text format;

(iv) patient NHI number;

(v) specimen receipt date;

(vi) specimen receipt time of day;

(vii) class (category of test such as haematology, histology);

(viii) Laboratory Test identification;

(ix) results as a numeric value (where applicable) of Laboratory Test ;

(x) a status indicator (a descriptive terms including "high" and "low");

(xi) where the result origin is from histology the specimen type;

(xii) Approved Referrer (HPI format when available); and

(xiii) test reference ranges, where applicable.

h) You will provide back-up paper reporting to Approved Referrers of the information specified in sub-clause g) above when required.

i) You will ensure that all off site communications use a secure network environment, which is in conformance with any Health Network Code of Practice standard or HISO standard that applies.

j) You will ensure that successful and unsuccessful messages are tracked and acknowledged.

k) You will ensure that messages (results) that are rejected by an Approved Referrer's mailbox are corrected within a clinically acceptable timeframe.

l) You will establish and maintain a website, on which Approved Referrers can access details, including results, of all Laboratory Tests performed under this Agreement, requirements for sample collection, and clinical advice and guidelines.

m) You will use your reasonable endeavours to provide us with the capability to access results on-line using an enquiry system as soon as practicable after the Agreement Start Date.

n) The laboratories should allow for the eventual development of paperless laboratories in the future.

o) You will encourage and facilitate the research process by providing ready access to patient results where appropriate privacy approval has been obtained.

1.7 Regional repository

a) You will provide Approved Referrers with information about the privacy implications of making patients' Laboratory Test results available via a regional clinical data repository. You will provide Approved Referrers with signs to be posted in their offices informing patients of this, and the availability of brochures offering more information. Your collection and use of this information shall comply with the Health Information Privacy Code 1994.

b) You will place all Laboratory Test results into the regional clinical repository in the format specified by us. It will be the patients' responsibility to opt out of having their results generally available.

c) You will work with us, other Providers and Approved Referrers to implement an information sharing policy.

1.8 Backup and disaster recovery procedures

You will have in place back-up and disaster recovery procedures which are acceptable to us to protect against the loss of information. If requested by us, you will provide details of such procedures.

1.9 Response to enquiries

We both will respond within 5 Working Days to all enquiries from each other where such enquiries relate to the health or well being of an Eligible Person or to any aspect of performance under this Agreement as long as the request complies with law.

1.10 Payment for information

For the avoidance of doubt, the Service Fee includes payment for you complying with all the information requirements specified in this Agreement within the specified times, and having

in place all of the information systems which are specified in this Part C of this Schedule 2 of the Agreement.

1.11 Approved Referrer Laboratory Test request forms

a) Laboratory Test request forms which you must ensure are provided to you by Approved Referrers when referring a sample to you to perform Laboratory Tests in respect of, will include:

(i) provision for an Eligible Person's NHI, date of birth and gender data. This is the responsibility of the Approved Referrer to complete;

(ii) provision for the Approved Referrer's Approved Referrer Identifier and PAN/PIN number data. This will be completed by the Approved Referrer; and

(iii) a declaration by the Approved Referrer of the eligibility of the Eligible Person and the services being referred, and provision for the declaration to be signed by the Approved Referrer.

b) You will consult with the Alliance, through us, over the layout of your Laboratory Test request forms and the Laboratory Tests that are included on it.

c) You shall use all reasonable endeavours to ensure you have systems in place from the Agreement Start Date to enable you to provide information on Laboratory Test results to any Approved Referrer in an electronic form that is compatible with the reasonable needs of the Approved Referrer and you shall provide that information in such form where requested to do so by the Approved Referrer.

Appendix 1: Laboratory Test Schedule

Insert Laboratory Test Schedule v1.0 found at this link: http://www.dhbsharedservices.health.nz/Site/Laboratory/Laboratory-Schedule-Review-Project.aspx]

Appendix 2: Laboratory Test Referral Guidelines

Insert Laboratory Test Referral Guidelines v1.0 found at this link: http://www.dhbsharedservices.health.nz/Site/Laboratory/Laboratory-Schedule-Review-Project.aspx]

Appendix 3: Essential Tests

The following are Essential Tests that must be performed by you on a 24 hour per day 7 days per week basis across the Taranaki DHB region:

Microbiology – Taranaki Base

- CSF,
- Joint Aspirate,
- Abscess pus
- corneal scrapes and vitreous fluid samples,
- sterile fluids (pleural, peritoneal and pericardial),
- tissue from theatre,
- positive BC

Haematology – both Taranaki Base and Hawera

- FBC
- ESR
- RETIC
- INR
- COAG SCREEN (PT, APTT, -TCT)
- D-DIMER
- fibrinogen
- Malarial Parasite Testing
- Factor VIII (Urgent only; i.e. post-op known deficiency (Taranaki Base hospital only)
- Acute blood films

Transfusion medicine (Taranaki Base only)

- ABO groups, Rh (D) types
- Patient group confirmation
- Cord/Neonatal group & DAT
- Apt & Downey
- Antibody screens
- Antibody ID
- Red Cell antigen typings
- Crossmatch
- RBC unit group confirmation
- DAT Poly/Mono
- Antibody Elution
- Kleihauer (if required))
- Auto absorption (if required)
- Transfusion Reaction Investigation

Biochemistry

- Electrolytes (Na, K, Cl Creat, eGFR)
- Urea, Uric Acid
- Glucose
- Ketones

- Calcium (Ionised and corrected), Phosphate, Magnesium
- LFT: **(**Tbil, ALP, ALT, TP, ,GGT, ALB)
- Conjugated bilirubin
- Neonatal bilirubinl
- AST,
- TLDH
- TCK
- LIPID Profile (Chol, Trig, HDL, calculated LDL)
- LDL
- Iron(Taranaki Base only)
- Transferrin(Taranaki Base only)
- Ferritin(Taranaki Base only)
- CRP
- Lipase(Taranaki Base only)Amylase
- Ammonia(TBase only)
- Ethanol (serum and urine)(Taranaki Base only)
- TDM (Lithium, Digoxin, Phenytoin, Valproate, Vancomycin (excluding Wairarapa DHB's hospital), Gentomycin, Tobramycin, Carbamazepine, Paracetamol, Salicylate(TBase only)
- Urine Chemistry (UNa, UrK, UrCl, UrUA, UrCreat, UrCa, UrPhos, UrMg, UrGlucose, Ur Total protein, Ur Microalbumin
- Urine drugs of abuse: Cannabinoids, Amphetamines, Methadone, Benzodiazepines , Opiate(Taranaki Base only)
- CSF: Total Protein, Glucose.
- Blood Gases: pCo2,O2, pH, HCO3, tHB, sO2, p50c, O2Hb, COHb, MetHb, Na, K, iCa, Cl, Glu, Lac.
- Lactate (blood, CSF, fluid)
- Osmolality (serum and urine)(Taranaki Base only)
- Plasma HCG(TBase only)
- Cardiac Markers, (CKMB, hsTNT, NT-proBNP/BNP)(Taranaki Base only)
- Hormones (Cortisol, FT4, TSH
- Procalcitonin(TBase only)
- **Serology tests (**HepB (Ag & Ab), HepC**,** HIV) (Taranaki Base only)
- **Miscellaneous and manual tests: (**pH, Pregnancy Test, (Taranaki Base only)

Appendix 4: Blood Transfusion Service Requirements

a) You will provide a transfusion medicine service, following guidelines as stipulated by the regulatory bodies – New Zealand Blood Service (NZBS) and International Accreditation New Zealand for the Taranaki DHB Geographical Area. Service requirements include:

(i) the provision of suitably trained and competent Personnel and necessary validated equipment to provide a complete transfusion medicine service;

(ii) red cell transfusions will be preceded by appropriate pre-transfusion testing processes as defined in the ANZSBT Pretransfusion Guidelines. Where necessary, advice on the implications of results will be obtained from NZBS;

(iii) the management, ordering, storage and distribution of all blood and blood products for Taranaki Base and Hawera Hospital. Appropriate stock levels will be determined in conjunction with NZBS;

(iv) The management of the Bone Bank including storage and administration requirements;

(v) the entry of results of transfusions and positive antibody findings at Taranaki Base Hospital laboratories into eProgesa Blood Management System and the TDHB' clinical information systems. Reports of positive antibody findings will be provided as required;

(vi) the provision of all antenatal/postnatal associated testing on mothers and babies both within the DHB hospitals and communities;

(vii) the provision of transfusion medicine services to Southern Cross Hospital;

(viii) Being a participant in and providing support to the DHB Transfusion Committees, based at Taranaki Base Hospital;

(ix) participation in the haemovigilance and oversight programme as required by the New Zealand Blood Service (NZBS);

(x) participation in appropriate external quality assurance programmes according to NZBS and IANZ requirements;

(xi) offering advice and input to transfusion product availability, correct usage of products and any recalls;

(xii) provision of support and advice for transfusions 24 hours a day, 7 days a week; and

(xiii) weekly, monthly and yearly monitoring of refrigeration equipment for the storage of blood and blood products, including external alarms monitoring to ensure compliance with the following standard – Australian Standard AS3864 as documented in the NZBS Blood Refrigeration Guidelines is required.

b) You will also ensure that less than five percent of NZBS products are wasted. Performance to this measure will be monitored by the DHBs using reports provided by NZBS and escalated as required to the relevant DHBs Portfolio Manager.

c) This service excludes the cost of blood products as those costs sit directly with the TDHB.

Appendix 5: Laboratory System Requirements

1.1 Electronic data format

a) Laboratory Test data is received electronically in a form specified by Sector Services.

b) Volume labels are optional.

c) Data is in ASCII format with fixed length fields, no field delimiters, and an ASCII 'end of record' delimiter after each record. Each record is 81 bytes long. Numeric fields are not 'packed' nor any other non-ASCII format.

1.2 Input record format

Field Name	Data Type	Length in Bytes	Start Position	Mandatory Data
Unique identification	Alphanumeric	8	0	Yes
Referral identification	Alphanumeric	10	8	Yes
Test Code	Alphanumeric	3	18	Yes
Date of Service	DDMMCCYY	8	21	Yes
Number of Tests	Numeric	2	29	Yes
Date of Birth	DDMMCCYY	8	40	*1
Gender	Alphanumeric	1	48	*1
NHI Number	Alphanumeric	7	49	2
CSC Card	Alphanumeric	2	56	*2
HUHC Card	Alpha	1	58	*2
Approved Referrer Identifier	Alphanumeric	8	59	Yes
PAN/PIN Number	Numeric	6	67	*2
Practitioner - Pathologist	Alphanumeric	8	73	*3
Funded	Alphanumeric	1	81	*4

*1 Mandatory for specified Laboratory Tests otherwise mandatory if supplied by the Approved Referrer

*2 Mandatory if supplied by the Approved Referrer

*3 Mandatory if pathologist performing additional Laboratory Test(s)

*4 Mandatory if specified by the TDHB, otherwise to be omitted

A record will comprise of one record for each Laboratory Test requested on a Laboratory Test referral form. Repeats of the same Laboratory Test are submitted as a single record with 'Number of Tests' (previously known as Unit of Service) set to the number of times the test was performed.

1.3 Detailed Description and Format of Fields

a) **Specimen Number**

(i) A unique code that identifies a particular specimen.

(ii) Format is XXYY9999 where XX is laboratory identifier, YY is financial year, 9999 is a sequential number to identify a specimen within a financial year.

b) **Referral Identification**

(i) A unique identification code for each Laboratory Test referral.

(ii) Format is XXnnnnnnnn where XX is the Laboratory identification and nnnnnnn is the unique number assigned to the referral, filled with leading zeros.

c) **Test Code**

(i) The unique 3 alphanumeric characters identifying a clinical test as defined in the Laboratory Test Schedule.

(ii) Only one record may exist for a particular Laboratory Test in a referral.

d) **Date of Service**

(i) The date the referred specimen was initially submitted to the laboratory. There can only be one date of service for a Laboratory Test referral.

(ii) Shall be a valid date.

(iii) Format is DDMMCCYY where DD is day of month, insert leading zero, MM is month of the year, insert leading zero, CC is century e.g.19, and YY is the last two digits of the year.

e) **Number of Tests**

(i) Used to record the number of times a particular clinical test requested on a referral was performed.

(ii) Format is 2 numeric characters with a leading zero inserted where necessary.

f) **Date of Birth**

(i) The patient's date of birth shall be a valid date.

(ii) Format is DDMMCCYY where DD is day of month, insert leading zero, MM is month of the year, insert leading zero, CC is century e.g.19, and YY is the last two digits of the year.

g) **Sex**

(i) The gender of the patient clinically tested.

(ii) F = Female, M = Male, U = Unknown

h) **NHI**

The National Health Index identifier for the patient being clinically tested. Format is 7 alphanumeric characters (ABC1234), left justified with spaces inserted if NHI is not available.

i) **CSC Card**

The community services card (CSC) as assigned by Work and Income New Zealand for the patient being clinically tested. Format is 2 alphanumeric characters (A1), left justified. The data required for this field is currently non-mandatory unless supplied by the Approved Referrer, but the field shall be included in each record.

j) **HUHC Card**

The high use health card number (HUHC) is assigned by our Payment Agent for the patient being clinically tested. Format is 1 alpha character (Y = yes patient has HUHC, N = no patient does not have HUHC). The data required for this field is currently non-mandatory unless supplied by an Approved Referrer, but the field shall be included in each record.

k) **Approved Referrer Identifier**

(i) The MCNZ code, NCONZ code, Cervical Smear Taker or other referrer types, associated with the medical practitioner who requested the clinical test. The first character identifies the registration code as shown below. For instance

M Medical Council of NZ

N Nursing Council of NZ

L Lay smear taker (as defined by the National Cervical Screening Programme)

D Dental Council of NZ

(ii) The following 7 digits are the actual registration number assigned. Where a cervical smear taker has an assigned MCNZ or NCONZ registration, this shall be used to identify the referrer, using the format indicated above.

(iii) Format is 8 alphanumeric characters, left justified, with trailing spaces inserted.

l) **PAN/PIN Number**

(i) The Practice Identifier Number allocated by us to the Primary Health Organisation or other referring group to indicate budget holding practices.

(ii) Format is up to 6 numeric characters, left justified with trailing spaces inserted, and spaces inserted if PAN/PIN is not available.

m) **Practitioner – Pathologist**

(i) The MCNZ code associated with the contracting laboratory's pathologist when performing additional tests on behalf of the Approved Referrer. This code to be inserted in association with the Approved Referrer's details when additional tests are ordered by the pathologist.

(ii) Format is 8 alphanumeric characters and spaces inserted if not applicable. This is exactly the same format as the Approved Referrer's ID.

n) **Funded**

(i) The Funded field is provided by the laboratory for each Laboratory Test to identify the source of funding for the referred Laboratory Test. The following types of funding are recognised:

(A) ACC

(B) VoteHealth / DHBs / MoH

(C) Private

(ii) This field is mandatory for laboratories that have been so instructed by their parent DHB. Otherwise it is to be omitted.

(iii) The format of this field is 1 alpha character with the following values:

(A) **A** indicates the test is funded by ACC

(B) **D** indicates the test is funded by a DHB

(C) **P** indicates the test is privately funded

(D) **blank** indicates the test is funded by a DHB

Appendix 6: Critical Limits

These are the categories of results that are always required to be phoned as critical results with the relevant critical limits applying to each result. It is expected that the phoning through of critical results would be performed by your technical Personnel, Registrars or Consultants. These critical limits will be updated from time to time through the Alliance.

You may reach agreement with individual service areas for critical limits that more specific to their area of speciality, i.e where the result falls outside these limits but is an expected result.

1 Biochemistry

- Blood Gas pH: ≤ 7.1 or ≥ 7.55
- Lactate > 5.0 mmol/L
- Sodium: <120 or >155mmol/L
- Potassium: <3.0 or >6.0mmol/L
- Corrected Calcium: <1.80 or >3.00mmol/L
- Magnesium <0.50 or >2.00mmol/L
- Phosphate <0.50 or >3.00mmol/L
- Glucose <2.5 or >20.0mmol/L (and whenever ketones present. Check for ketones when glucose<3.0 or >19 mmol/L)
- Total Bilirubin (baby's SBR) ≥ 250µmol/L *(if result is the first or inconsistent with previous).*
- FT4 <6.5 or >30pmol/L
- Cortisol <30 nmol/L (Check that the result is not due to dexamethasone suppression, look up request form)
- Lithium >1.2mmol/L
- All detectable Paracetamol and Salicylate results,
- Ethanol >40mmol/L.
- Any TDM levels above therapeutic ranges.

2 Haematology

- White Count: < 2.0 x 10^9/L or >30.0 x 10^9/L
- Haemoglobin :
  - If > 3yr <70.0 g/L or >190.0 g/L
  - If 0 – 3yr, 50 g/L below reference range or 20 g/L above reference range
- Platelets: <25.0 x 10^9/L or >900.0 x 10^9/L
- Neutrophils: <1.0 x 10^9/L
- INR >1.5 (If patient not on warfarin)
- INR >5.0 (If patient on warfarin)
- APTT >40 seconds (If patient not on Heparin)
- APTT >120 seconds (If patient on Heparin)
- Fibrinogen <1.0 g/L
- Fibrinogen: <0.7g/l need to be referred to a Haematologist as well.
- D-Dimers >500 ng/mL to requesting ward except urgent care

Patients on Warfarin

- INR >5.0
  - Out of hours, weekends or public holiday contact O/C Haematologist about all NON ward INR's >5.0

3 Transfusion Medicine

- Positive Transfusion Reaction Investigation
- Positive antibody screen which would result in the delay in providing compatible blood.
- Positive Kleihauer results > 6ml foetal bleed
- Unexpected antenatal antibody titre increase

4 Microbiology

- All positive blood cultures
- Gram stain positive CSF
- Results notified to infection control
    - Positive Clostridium difficile toxin
    - Positive MDRO/MRSA/ESBL organisms

5 Histology

- Unexpected results; including malignancy and infection.
- Uterine curetting specimens for products of conception when products of conception are absent.