

Agreement

between

**HER MAJESTY THE QUEEN IN RIGHT OF HER
GOVERNMENT IN NEW ZEALAND
(acting by and through the Ministry of Health)**



650 Great South Road
Private Bag 92-522
Auckland
Ph: 09-580 9000
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Contact: «CONTRACTDEPUTY_NAME»

and

«PROVIDER_NAME»

**National Cervical Screening Programme Laboratory
Services**

«PROVIDER_ADDRESS»
«PROVIDER_ADDRESS2»
«PROVIDER_CITY»
Ph: «PROVIDER_PHONE»
Fax: «PROVIDER_FAX»

Contact: «PRVDRCONTACT_NAME»

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Section A. Guide to this Agreement

1 This Section not legally binding

This Section A provides a guide to the nature and structure of this Agreement and to the location of some important provisions. It is intended that you will use this Section A to obtain an overall sense of how this Agreement works before considering each of the other Sections in detail. Notwithstanding anything else in this Agreement, nothing in this Section A constitutes a legally binding commitment.

2 Introduction

2.1 Parties to this Agreement

We are the Ministry of Health (“the Ministry”), responsible for funding National Cervical Screening Programme laboratory services for Eligible People. You are a Provider of National Cervical Screening Programme (“NCSP”) laboratory services.

2.2 Funding and provision of services

In this Agreement, we agree to fund, and you agree to provide, the Services for Eligible People in accordance with the terms and conditions set out under the various Sections and Schedules in this Agreement.

2.3 Interpretation of this Agreement

Some of the expressions used in this Agreement have defined meanings. Section E of this Agreement sets out the definitions of these expressions. These expressions will be shown with initial capital letters in the text of the Agreement. This Section A, however, mostly avoids using these defined expressions to provide you with an informal overview of the Agreement.

3 Basic structure of this Agreement

3.1 Modular Approach

This Agreement has been divided into Sections. Each Section deals with a particular topic or with closely related topics. It is envisaged that this “modular” approach will enable amendments to be more readily incorporated into the Agreement because entire Sections can be replaced without disruption to the integrity of the document.

3.2 Sectional Analysis

Section B sets out certain key terms of this Agreement. It deals with the basic scope and duration of this Agreement and provides a space for signing. Generally, the first clause of each Section will identify the key obligations associated with the subject matter of that Section. Sometimes a clause within a Section will refer you to a Schedule. The Schedules are located at the end of this Agreement. The Schedules tend to contain the more technical or specialised information.

4 Our respective responsibilities

4.1 The responsibilities of us both

Some Sections of this Agreement focus on the responsibilities of us both. In general terms, **we both agree to:**

- (a) be guided in our dealings by the purposes and principles set out in Section D of this Agreement;
- (b) comply and co-operate with the procedure for risk management set out in Section H of this Agreement and the dispute resolution procedure set out in Section J of this Agreement;
- (c) accept and comply with the variation and renewal provisions set out in Section K of this Agreement and the failure to perform and termination provisions set out in Section N of this Agreement; and
- (d) comply with the miscellaneous provisions governing our relationship set out under Section M of this Agreement.

4.2 Your responsibilities

Some Sections of this Agreement focus on your responsibilities. In general terms, **you agree to:**

- (a) provide the Services described in Section C and Schedule C1 of this Agreement according to the quality standards set out in Section F of this Agreement;
- (b) claim for payment only in accordance with the claiming requirements, rules and procedures set out in Section G of this Agreement;
- (c) comply and co-operate with the reporting requirements set out in Section H and the monitoring, auditing and evaluation procedures set out in Section I of this Agreement; and
- (d) deal with third parties according to the provisions set out under Section L of this Agreement.

4.3 Our responsibilities

Some Sections of this Agreement focus on our responsibilities. In general terms, **we agree to:**

- (a) pay you for providing the Services to Eligible People in accordance with the terms and conditions set out in this Agreement and on the funding, claiming and payment terms set out in Section G of this Agreement; and
- (b) undertake the monitoring, auditing and evaluation functions set out in Section I of this Agreement.

5 Special terms

Section O of this Agreement contains special terms that are departures from, or additions to, the standard terms in the remainder of this Agreement. These special terms are terms specific to you or the type of services you provide. The provisions of Section O apply notwithstanding anything in the remainder of this Agreement. Where there is a conflict between these special terms and any other terms in this Agreement, these special terms take precedence and apply over any other terms. Because these special terms override what you may have already read in the remainder of the Agreement, you should check Section O of this Agreement every time you refer to this Agreement.

6 Summary and history of this Agreement

A summary of this Agreement and a list of variations to it are recorded in Schedule B1 of this Agreement. As variations occur from time to time, we will provide you with replacement pages to update the information in Schedule B1 of this Agreement.

Section B. Key terms and execution

1 Scope

We agree to fund, and you agree to provide, the Services for Eligible People in accordance with the terms and conditions set out in this Agreement.

2 Duration of the Agreement

2.1 Commencement

This Agreement comes into effect on the Commencement Date, which is «CONTRACT_STARTDATE».

2.2 Termination

This Agreement ends on the Termination Date, which is either:

- (a) the Set Termination Date of «CONTRACT_ENDDATE», subject to any variation or renewal in accordance with Section K of this Agreement; or
- (b) the date of any earlier termination in accordance with Section N of this Agreement.

3. Rights not exclusive

This Agreement gives you the right to provide the Services to us but does not give you any right to provide those Services to the exclusion of other Providers. We have the right to contract with other Providers, including those in your area of expertise or in your vicinity, for the provision of the Services. Equally, but subject to clause 1 of Section L of this Agreement, you have the right to provide Services of a similar nature to the Services, to women where such services are not funded by us.

4. Execution

By our respective authorised signatories signing below, we both agree to comply with and be bound by the terms and conditions of this Agreement.

Ministry of Health by:

«PROVIDER_NAME» by:

Signature

Signature

Name

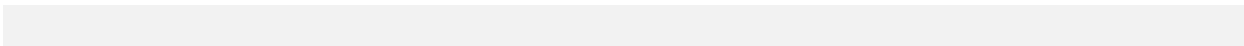
Name

Position

Position

Date

Date



Section C. Summary of Services to be provided

1 Agreement to provide Services

You agree to provide to Services for Eligible Persons as detailed in, and in accordance with, this Section C and Schedule C1 of this Agreement.

2 Description of the Services

2.1 Services funded

We agree to fund the following Services that you will provide at no charge to an Eligible Person referred to your laboratory by Referring Practitioners:

- (a) the services set out in Schedule C1 of this Agreement, in accordance with the Service Specifications set out in Schedule C1 of this Agreement;
- (b) the analysis of Specimens for cervical screening laboratory diagnostic purposes from a laboratory;
- (c) the supply of all materials or substances, including sampling devices, liquid based cytology mediums, required for the purpose of providing cervical screening laboratory diagnostic services, including containers;
- (d) the provision of laboratory services incidental to any cervical screening laboratory diagnostic services, except medical services of a kind that are not ordinarily performed by Pathologists as such (whether in any particular case the services are performed by the Pathologist or any other registered medical practitioner);
- (e) the provision of any other incidental services for the purposes of cervical screening laboratory diagnostic services, including the collection, delivery and storage of Specimens;
- (f) the provision of specialist advice for Referring Practitioners and availability of Pathologists and other staff for consultation by Referring Practitioners;
- (g) reporting back to other groups and organisations as required by statute;
- (h) subject to clause 3.3 in Schedule C1 of this Agreement, the provision of NCSP Test results and information to Referring Practitioners;
- (i) the provision of cervical cytology, HrHPV testing and histology test results and information to:
 - (i) the National Cervical Screening Programme Register pursuant to the Health (National Cervical Screening Programme) Amendment Act 2004; and
 - (ii) the Cancer Registry pursuant to section 5 of the Cancer Registry Act 1993;

- (j) the provision of such advice as we may reasonably request to the relevant NCSP Regional Service.

2.2 Services and costs excluded from funding

Under this Agreement, we will not fund any services other than the Services in this Agreement and in particular we will not fund:

- (a) laboratory tests that are not NCSP Tests;
- (b) laboratory tests that are equivalent to NCSP Tests but are outside the scope of this Agreement, including tests that are funded separately as part of DHB colposcopy services.
- (c) For the avoidance of doubt,
 - (i) the amounts paid under this Agreement for the Services cover all costs related to the provision of the Services and no additional money will be paid to you including no additional money to assist with the acquisition of capital items required for the delivery of the services
 - (ii) you will fund all costs associated with acquiring the resources necessary to provide the Services.

Section D. General purposes, objectives and principles

1 Nature of this Section

This Section D clarifies the intentions of the parties and provides a broad context, which is intended to assist interpretation of all other provisions of this Agreement. Notwithstanding anything else in this Agreement, the provisions of this Section D do not constitute legally binding commitments.

2 Purposes of this Agreement

This Agreement has the following general purposes:

(a) **Provision of best quality and cost-effective Services**

To ensure Eligible People are provided with the best quality, accurate and most cost-effective Services based on professional, contractual and statutory standards and codes of practice.

(b) **Safety, quality and performance expectations**

To promote:

- (i) the safety of Eligible People and staff, and
- (ii) to meet the quality and performance expectations of all stakeholders and
- (iii) the quality standards specified in this Agreement.

(c) **Timely and quality test results**

To provide timely and quality results of NCSP Tests and specialist pathology advice to Referring Practitioners and to the National Cervical Screening Programme Register in accordance with Schedule C1 of this Agreement.

(d) **Best practice utilisation**

To ensure the provision of advice from Staff to Referring Practitioners on best practice utilisation of the Services.

(e) **Sustainable Services**

To ensure that the Services are sustainable in relation to the amount of public funding available.

(f) **Fair contract**

To ensure the Services are provided under a fair contract with quality provisions.

(g) **Create good working relationship**

To create a relationship between us which enables us to work together to achieve the best possible health outcomes while recognising each other's legitimate interests.

3 Objectives of the NCSP

The aim of the NCSP is to reduce the incidence and mortality rates of cervical cancer among women within New Zealand by the detection and treatment of precancerous cell changes.

The objectives of the NCSP, as set out in section 112D of the Health (National Cervical Screening Programme) Amendment Act 2004 are to:

- (a) promote high quality cervical screening, assessment and treatment services, while recognising and managing the differences between the various types of cervical cancer, with a view to reducing the incidence and mortality rate of cervical cancer; and
- (b) inform women and the community of the risks, benefits and expected population health gains from participation in the NCSP; and
- (c) ensure a commitment to maximising coverage and participation for Priority Group Women throughout the screening pathway; and
- (d) facilitate continuous quality improvement by allowing and performing regular evaluations of the NCSP; and
- (e) ensure that information that is collected for the purposes of the NCSP is-
 - ii. available, in a reliable, accurate and timely manner, to persons authorised under this Pat, or any other enactment, to have access to it; and
 - iii. safely stored, including on the NCSP Register; and
- (f) provide information to women about the quality and effectiveness of the NCSP including, if it is appropriate, information based on the results of evaluations.

4 Service Delivery Principles

We both recognise the importance of the following Service delivery principles:

(a) **Quality services**

Eligible People have a right to expect high quality service provision. We have a responsibility to keep under review the agreed service quality provided by you through audit, monitoring and evaluating your quality policies, procedures and systems.

(b) **Equity of access**

Subject to recognised medical ethics and geographical limitations, all Eligible People should have equitable access to quality laboratory services according to their needs and their decisions about screening.

(c) **Equity of outcome for Māori**

The health of Māori is a priority area. Strategies to ensure the health of Māori is improved are essential to equity of health outcome for all New Zealanders.

(d) **Finite health resources**

Health resources are finite and preferred solutions are those that maximise health outcomes within the limits of available resources.

(e) **Informed consent**

Informed consent is the appropriate basis of all decisions made between a Referring Practitioner and any Eligible Person.

(f) **Professional standards**

Appropriate professional standards groups and/or the National Screening Unit will determine minimum clinical quality standards for laboratories providing Services, following consultation with Providers.

(g) **Information sharing**

Timely and accurate communication and information sharing among Providers is essential to good quality care. Timely and accurate communication and information sharing between us both is essential to good quality health planning. Both of these need to occur with appropriate authorisation and subject to the requirements of the Health Act 1956, the Health (National Cervical Screening Programme) Amendment Act 2004, the Privacy Act 1993 and the Health Information Privacy Code 1994.

(h) **Constructive working relationships with others**

Creating and maintaining constructive working relationships with all Referring Practitioners is essential to delivering the Services effectively.

4 Relationship principles

We both recognise that the following relationship principles are important and intend that they will guide each of us in our dealings with each other under this Agreement:

(a) **Recognition of each other's skills**

We both recognise and value the others' skills and expertise where required quality standards are met.

(b) **Good faith negotiations**

We both agree to conduct all negotiations and implement agreements in good faith.

(c) **Setting reasonable timeframes**

We both recognise the importance of fixing mutually acceptable timeframes for negotiation, which include reasonable progress milestones.

(d) **Future funding strategies**

We both recognise that we will continue to develop future funding strategies for delivery of the Services to ensure the effective and efficient use of public money.

(e) **Freedom from interference**

We both recognise the right of a Provider to manage their own business, including having the freedom to contract with other funders and providers.

(f) **Continuous quality improvement**

We both acknowledge that additional quality requirements may be required of Providers during the term of this Agreement to allow for continuous quality improvement.

(g) **Open and transparent dealings**

We both agree to act in an open and transparent manner with each other.

(h) **Developments in provision of Laboratory Services**

We both recognise that there may be developments and/or changes that occur in the provision of laboratory services beyond the scope of the Services funded under this Agreement, which may need to be reflected in our actions under this Agreement.

Section E. Construction and general definitions

1 Definitions

1.1 Nature of this clause

This clause 1 sets out the definitions of expressions that are used throughout this Agreement. These defined expressions will be shown using the first letter of the word/s in upper case in the text of the Agreement.

1.2 References to the parties

We, us, our means the Ministry of Health (and, in particular, the National Screening Unit that operates within the Ministry of Health);

You, your means «PROVIDER_NAME»;

We both, us both means both you and we;

Each or us means both you and we;

Either of us means either you or we;

Neither of us means neither you nor we.

1.3 Definitions applying to all Sections

In this Agreement, unless the context requires otherwise:

Act means the New Zealand Public Health and Disability Act 2000, as amended from time to time, or any enactment relating to the funding and provision of health and disability services that replaces or succeeds the Act, and references to sections of the Act are to be read as references to equivalent sections of a replacement or successor enactment, as applicable.

Agreement means this Agreement between us both for the funding and provision of the Services and includes each Section and Schedule and all documents incorporated by reference pursuant to this Agreement.

Agreement Number means the unique identification number that relates to this Agreement, which is printed on the cover of this Agreement.

Audit includes inspection, surveillance, assessment, investigation, Monitoring, and Evaluation of the provision of Services and the performance of your obligations under this Agreement, and the performance of the NCSP.

Auditor means an auditor appointed to carry out an Audit under clause 2.2 of Section I of this Agreement.

Author's Rights has the same meaning as set out in clause 4.1 of Section M of this Agreement.

Business Day means a day on which your bank, our bank and our payment agent's bank are open for business.

Cancer Registry means the registry maintained in accordance with section 4 of the Cancer Registry Act 1993.

Claim Period means a single calendar month as described in clause 5.1 of Section G of this Agreement.

Code of Health and Disability Services Consumers' Rights 1996 means the code issued under the Health and Disability Commissioner Act 1994, including the Code's 2004 amendment.

Commencement Date means the date the Agreement commences, as set out in clause 2.1 of Section B of this Agreement.

Compulsory Variation means a variation to this Agreement described in clause 2.1 (c), (d), (e) (f) or (g) of Section K of this Agreement.

Confidential Information means any information, data or knowledge disclosed by us to you or by you to us, either before or during the course of the Agreement, or arising out of the operation of the Agreement:

- (a) that is agreed by us both as being confidential; or
- (b) that may reasonably be considered to be confidential taking into account all the circumstances, including without limitation, the manner of and circumstances in which disclosure occurred,

but excludes prices and funding amounts unless agreed by both of us as being Confidential Information.

Consult means the consultation process, to be carried out within a reasonable time frame, where by the party consulting:

- (a) fully states its proposals and views to the other party;
- (b) carefully considers each response from the other party to its proposals and views;
- (c) acts in good faith and does not predetermine any matter; and
- (d) gives the other party adequate opportunity to consult with any other interested party,

provided that the obligation on either of us to carry out this process ceases to exist if the other party refuses or fails to take part in this Consultation process; and **Consultation** has a corresponding meaning.

Crown has the meaning given in the Act.

Crown Direction means any direction or notice given to a DHB or its successors by the Minister of Health under section 32 or section 33, as applicable, of the Act or any other direction or notice given by or on behalf of the Crown pursuant to a statute.

DHB means a District Health Board established under section 19 of the Act.

Due Date means the date on which your claims for payment must be received by us, which is the tenth Business Day following the Claim Period, as also described in clause 5.3 of Section G of this Agreement.

Eligible Person means any individual who is in need of the Services and is eligible to receive Services funded under the Act, as specified in a Ministerial direction issued under section 32 of the Act; and **Eligible Persons** or **Eligible People** have a corresponding meaning.

Evaluation means the consideration of available information to assess the provision of Services and the performance of your obligations under this Agreement, and the performance of the NCSP; and **Evaluate** has a corresponding meaning.

GST means the tax imposed under the Goods and Services Tax Act 1985.

Guidelines for Cervical Screening in New Zealand means the clinical management guidelines developed for the NCSP in 2008 and any revisions and updates; and **Guidelines** has a corresponding meaning.

Health and Disability Commissioner means the Commissioner appointed under the Health and Disability Commissioner Act 1994.

Health Education means those activities that seek to support, improve and maintain knowledge about these services for Referring Practitioners specified under this Agreement.

Health Education Resources means pamphlets, posters, stickers, cards, manuals, resource kits, training kits, DVDs or other similar materials, (excluding newsletters) which are about promoting health for general distribution or for people in a specified group provided for under this Agreement.

Health Information Privacy Code 1994 means the code issued under section 46 of the Privacy Act 1993.

HL7 means Health Level Seven pathology messaging standard, version 2.4.

HrHPV means high-risk (oncogenic) human papillomavirus.

HrHPV testing means testing for the presence or absence of a pool of high-risk types of human papillomavirus in the following circumstances:

- (a) the triage of women 30 years and over with atypical squamous cells of undetermined significance (ASC-US) or low-grade squamous intra-epithelial lesion (LSIL) cytology D (without an abnormal smear in the last five years); or
- (b) the follow up of women who have been treated for, or have a history of, a high-grade lesion as documented on the NCSP-Register and according to the Guidelines for Cervical Screening in New Zealand;
- (c) post colposcopy management of women with discordant results: eg high-grade cytology and negative, satisfactory colposcopy.

Hung Parliament means when the party or parties who form the current government do not have sufficient numbers in Parliament to support and pass the relevant appropriation Bill.

IANZ means International Accreditation New Zealand.

IANZ Quality and Service Standards for Medical Testing Laboratories means the publication entitled “IANZ Quality and Service Standards for Medical Testing Laboratories” (ISO 15189:2007) as varied from time to time.

Insufficient Appropriation means where Parliament provides no, or insufficient, appropriation under the Public Finance Act 1989 to cover funding of services of the type covered by this Agreement.

Laboratory means each individual fixed laboratory site, which may be a community laboratory or a hospital laboratory that conducts Services performed under this Agreement.

Liquid based cytology (LBC) means an approved method for preparing cells taken from the cervix for cytology testing by putting those cells into a liquid preserving solution.

Ministry means the Ministry of Health and its legal successors.

Medical Laboratory Scientist means a registered health practitioner holding a current annual practising certificate issued by the New Zealand Medical Laboratory Science Board (NZMLSB) (Te Poari Mātai Oranga), with a scope of practise of Medical Laboratory Scientist with sub-specialty training in cytology or histology, if practising within cytology or histology (respectively)

Medical Laboratory Technician means a registered health practitioner holding a current annual practising certificate issued by the NZMLSB, with a scope of practise of Medical Laboratory Technician with sub-specialty training in cytology or histology, if practising within cytology or histology (respectively).

Monitoring means the continuous and/or intermittent checking of Service deliverables for the purposes of assessing the provision of Services and the performance of your obligations under this Agreement, and the performance of the NCSP; and **Monitor** has a corresponding meaning.

National Indicators means the set of indicators and targets and their specifications used to assess the performance of the NCSP.

National Screening Unit means the National Screening Unit within the Ministry that is responsible for overseeing the delivery of the NCSP.

NCSP means the National Cervical Screening Programme.

NCSP Case Review Protocol means the NSU processes and procedures for review of cancer cases and other case and/or slide reviews, which may be amended from time to time

NCSP Laboratory Reporting Template means the template, as amended from time to time. containing all of the regular reporting to the NSU against the NCSP OPQS and National Indicators.

NCSP Monitoring Technical Specification for Laboratories means the definitions, specifications and calculations used for laboratories to report against the NCSP OPQS and National Indicators, as published by the NSU, and which may be amended from time to time.

NCSP Operational Policy and Quality Standards (NCSP OPQS) means the NCSP Operational Policy and Quality Standards, as published by the NSU, and which may be amended from time to time.

NCSP Register means the information system, data repository and management tool of the NCSP maintained in accordance with the Health (National Cervical Screening Programme) Amendment Act 2004.

NCSP Technology means any new technique, methodology or technology which is used in association with the processing and reporting of NCSP Tests to Referring Practitioners.

NCSP Test means any of the individual NCSP laboratory tests listed in clause 5 of Schedule G1 of this Agreement.

NCSP Test Purchase List means the list of NCSP Tests funded by us, as set out in the table in clause 5 of Schedule G1 of this Agreement.

New Zealand Code of Laboratory Management Practice 1998 means the publication entitled “New Zealand Code of Laboratory Management Practice 1998” dated December 1998, as varied from time to time.

NHI means the National Health Index number which refers to the unique number allocated to a person by the New Zealand Health Information Service or its successors to help identify their use of health and disability services.

NSU HL7 Implementation Guide means the National Screening Unit HL7 Implementation Guide, August 2008, version 1.5d as varied from time to time .

Pathologist means a medical practitioner:

- (a) whose name appears in the New Zealand Medical Council register of practitioners and who is either a Fellow of the Royal College of Pathologists of Australasia (provided that such fellowship must cover the sub-speciality in which the pathologist is working) or is the holder of an equivalent qualification that is recognised by the New Zealand Medical Council; and
- (b) who has trained in either general pathology or anatomical pathology.

Payment Agent means an agent employed by us to make payment to you on our behalf as described in clause 24 of Section G of this Agreement.

Provider means a person or entity, other than you, who has agreed to provide services equivalent to the Services, to Eligible People, which we have agreed to fund pursuant to an equivalent agreement with us.

Quality Plan means a plan that relates to the quality of Service delivery as required under clause 8 of Section F of this Agreement.

Quality Standards means the quality standards set out in Section F and Schedules F1 and F2 of this Agreement.

Records means:

- (a) all written and electronically stored material;
- (b) all records and information held by you, or on your behalf, or by your employees (including financial, administrative and health-related records and information); and
- (c) all slides, smears and histological blocks,

which are relevant to the provision of the Services or the condition and maintenance of the sites, supplies and equipment used for providing the Services.

Referring Practitioner means a health practitioner of a type described in clause 4.1 of Schedule C1, who may refer samples to you for laboratory analysis.

Sector Services means Sector Services, an operating unit within the Ministry that receives claims from you and pays you for the Services you provide under this Agreement and its successors.

Sentinel Event is an event that signals something serious has occurred which may result in actual or potential harm to an Eligible Person or the NCSP and warrants in-depth investigation.

Services mean the services specified in clause 2.1 of Section C and in Schedule C1 of this Agreement. Service has a corresponding meaning and applies to a single service.

Service User means a user of any Service (including Eligible People, Referring Practitioners and other health professionals, as applicable).

Set Termination Date means the date the Agreement ends, as set out in clause 2.2 of Section B of this Agreement.

Site means the location (whether a building or facility at a specific location) from where you or your sub-contractor perform the Services or where anything relating to the Services occurs or is kept, including the location of the Records.

Specimen means a bodily sample or tissue sample taken from an Eligible Person for the purpose of a screening test or a diagnostic test, and includes:

- (a) a liquid based sample taken for the purpose of cervical cytology and HrHPV testing and other ancillary testing that may be approved,
- (b) a tissue sample for cervical/vaginal histology and other ancillary testing that may be approved.

Specimens has a corresponding meaning.

Staff includes your employees, sub-contractors, contractors, agents and other personnel connected with the delivery of the Services.

Termination Date means the date on which this Agreement ends.

Uncontrollable Event means an event that is beyond the reasonable control of the party immediately affected by the event and includes:

- (a) where there is Insufficient Appropriation,

but does not include:

- (b) any risk or event which the party claiming could have prevented or overcome by taking reasonable care, including having in place a reasonable risk management process; or
- (c) subject to paragraph (a) above, a lack of funds for any reason (other than where we have failed to make due payment).

Voluntary Variation means a variation to this Agreement described in clauses 2.1(a) or (b) of Section K of this Agreement.

2 Construction

2.1 Construction of general references

(a) **Headings:**

Headings have been included in this Agreement for convenience only and are to be ignored when interpreting this Agreement;

(b) **Clause, schedule, annexure:**

a reference to a section, clause, schedule or annexure is a reference to a section of, clause of, schedule to, or annexure to this Agreement;

(c) **Varied document:**

a reference to this Agreement or another document includes any variation, novation, or replacement of it;

(d) **Statutes:**

a reference to a statute or other law includes regulations and other rules made under it and consolidations, amendments, re-enactments or replacements of any of them (whether before or after the date of this Agreement);

(e) **Financial references:**

references to and expressions used in connection with financial calculations, valuations, accounting or financial reporting functions or their description in this Agreement bear the respective meanings ascribed to like expressions or expressions of similar intent under generally accepted accounting practice (**GAAP**);

(f) **Singular includes plural:**

the singular includes the plural and vice versa;

(g) **Person includes groups:**

the word person includes an individual, a body corporate, an association of persons (whether corporate or not), a trust, a state and an agency of state, in each case, whether or not having a separate legal personality;

(h) **Person includes successors:**

subject to clauses 4.1 and 4.5 of Section L of this Agreement, a reference to a person includes a reference to the person's executors, administrators, successors, substitutes (including, but not limited to, persons taking by novation) and permitted assigns;

(i) **Joint and several:**

an agreement, representation or warranty in favour of two or more persons is for the benefit of them jointly and severally and an obligation of two or more persons binds them jointly and severally;

(j) **Currency:**

a reference to \$ or dollars is a reference to the lawful currency of New Zealand and, unless otherwise specified, all amounts payable by a party under this Agreement are to be paid in that currency;

(k) **Notice:**

all periods of time for notice exclude the days on which they are given and include the days on which they expire;

(l) **Business Day:**

anything required by this Agreement to be done on a particular day that is not a Business Day may be done on the next Business Day; and

(m) **Including without limitation:**

any reference to "including", "include", "includes" or "in particular" does not limit the generality of the relevant statement.

Section F. Quality Standards

1 Agreement to adhere to Quality Standards

You agree to provide the Services and to conduct your activities, in so far as they are associated with the performance of and compliance with your obligations under this Agreement, in accordance with the quality standards set out in this Section F (the **Quality Standards**). Where a Quality Standard refers to a requirement for a written policy, procedure, programme, information or plan, you must provide us with a copy on our request. You must provide evidence of IANZ accreditation for ISO 15189:2007 on request.

2 IANZ accreditation and NCSP quality standards and legislation

2.1 Compliance with standards and other requirements

You must comply with the following policy, quality and service standards and other requirements, as varied from time to time in accordance with clause 2.10 of Section F below:

- (a) all legislative and regulatory requirements relating to quality and service standards in respect of the provision of the Services, and in particular those listed in clause 2.2 of Section F below;
- (b) any quality standards or requirements set out in this Agreement;
- (c) the NCSP Operational Policy and Quality Standards in Schedule F2 of this Agreement;
- (d) the IANZ General Criteria for Medical Laboratories – NZS/ISO 15189:2007 Medical Laboratories – Particular requirements for quality and competence;
- (e) the New Zealand Code of Laboratory Management Practice 1998;
- (f) the Health and Disability Sector Standards (NZS 8134:2001);
- (g) the Health Records Standard NZS 8153:2002;
- (h) the Code of Practice for Information Security Management AS/NZS ISO/IEC 17799:2006; and
- (i) any other policy, quality and service standards and other requirements that may be developed, from time to time, and accepted by us, in respect of the provision of Services.

If any issue arises regarding whether a policy, quality or service standard or other requirement in the NCSP OPQS has been complied with, we or our Auditor(s) will determine the issue after Consultation with you.

2.2 Compliance with legislation

You must comply with all applicable legislation, including:

- (a) the New Zealand Public Health and Disability Act 2000;
- (b) the Health Act 1956, and any subsequent amendment to that Act;
- (c) the Privacy Act 1993;
- (d) the Health Information Privacy Code 1994;
- (e) Code of Health and Disability Services Consumers' Rights 1996 and any subsequent amendments
- (f) the Health Practitioners Competence Assurance Act 2003; and
- (g) the Public Records Act 2005.

2.3 Order of precedence

The Quality Standards contained in paragraphs (a), (b), (c), (d), (e) (f) and (g) in clause 2.1 of Section F above are set out in descending order of precedence from (a) to (g), provided that the highest quality standard is to be applied in any given situation regardless of this order of precedence.

2.4 Application to individual Laboratories

We both acknowledge and agree that in providing the Services under this Agreement we may exercise any right or remedy available to us under this Agreement or otherwise, relating to your compliance with any policy, quality and service standards and other requirements relating to quality under this Agreement, against you as we consider appropriate.

2.5 IANZ accreditation

Any Laboratory that you operate for NCSP laboratory testing must be IANZ accredited with a current issue for the NCSP Services and Tests performed in accordance with section 2.1.d of Section F of this Agreement.

2.6 IANZ accreditation and registration denied or cancelled

You must notify us within 48 hours if you are denied IANZ accreditation and registration or if, for any reason, your IANZ accreditation or registration is suspended or cancelled.

2.7 Information about accreditation status

You agree that IANZ may provide to us (or our successors) information relating to your accreditation and registration status or any potential change in that status.

2.8 New Laboratory or new NCSP Technology

You agree to notify us before you begin to operate a new Laboratory for the provision of the Services or to provide a particular NCSP Technology for the first time. You are required to

ensure that the new NCSP Technology has been appropriately validated. You will require approval from us prior to using the new NCSP Technology.

2.9 Accreditation and registration for new Laboratory and test

You agree to use your best endeavours to gain IANZ accreditation and registration, in respect of any new Laboratory that you operate or any particular Service or Test(s) that you provide for the first time, by no later than 4 months after the date when you begin to operate the new Laboratory or provide such test(s). If accreditation is not gained within that time, you must notify the Ministry as to why accreditation has not been obtained, steps being taken to gain accreditation and anticipated date of accreditation. The Ministry reserves the right to monitor your progress and request information on compliance with other Quality Standards. If accreditation is not obtained within 6 months, clause 2.4 applies.

2.10 Variations to Quality Standards

We may amend or vary the Agreement to give effect to any variation of the policy, quality and service standards and other requirements specified in clause 2.1 of Section F above after Consultation with you. If you consider that there will be any cost or resource consequences arising as a result of such amendment or variation you must raise these issues during the Consultation process and we will consider those issues before amending or varying the Agreement to give effect to any variation of the policy, quality and service standards and other requirements specified in clause 2.1 of Section F above.

Such amendments or variations shall apply nationally to all providers of similar Services and shall take effect from the first 1 July date following Consultation on those amendments or variations, unless we agree on an earlier implementation date.

3 Accessibility standards

Continuous Services

Subject to clause 6 of Section N of this Agreement, you agree to provide the Services without material interruption from the Commencement Date until the Termination Date, or between such other dates as are determined in accordance with the variation, renewal and termination provisions of Sections K or N of this Agreement. However, you may provide certain Services for a shorter period than the term of this Agreement where so specified in the Agreement or otherwise agreed in writing by the parties.

4 Qualifications and standards of conduct

4.1 Good practice and care

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

4.2 Staff qualifications

You must:

- (a) ensure that Services are provided by sufficient numbers of suitably skilled and qualified personnel;

- (b) ensure that your Staff are, where relevant, registered with the appropriate statutory body, and hold a current practising certificate;
- (c) implement and maintain systems for ensuring the sighting and recording of qualifications and all professional practice certificates and requirements, including in respect of new appointments and new qualifications;
- (d) clearly define and document the responsibilities and accountabilities for all Staff;
- (e) ensure that Staff only work on tasks and procedures for which appropriate training has been given;
- (f) ensure that Staff are competent to meet the requirements of their positions, including through clinical audits and peer reviews;
- (g) ensure that assistants and other relevant support Staff have appropriate supervision.

4.3 Staff training and development

You must have policies and procedures in place to ensure the continuing education of Staff to enable maintenance of professional registration, to enhance clinical practice and Service delivery quality standards and to ensure current practice reflects awareness of recent developments in Service delivery quality standards.

4.4 Professional and ethical standards

You and your Staff must comply with the ethical guidelines of any relevant professional bodies and uphold the ethical standards of Providers generally.

4.5 Health Education

You will incorporate within your Services, where appropriate, support for Health Education.

4.6 Co-ordination with others

You must ensure a range of linkages and co-operation is maintained with other Providers and community agencies to promote effective Service delivery.

5 Sites and safety standards

5.1 Sites and equipment

You must ensure that:

- (a) all buildings and equipment used in Service delivery are fit for their purpose and are maintained adequately and in safe working order;
- (b) all equipment and supplies required to provide the Services are available, including necessary provisions for management of emergencies;

- (c) safety and emergency equipment and related information is clearly displayed and accessible; and
- (d) all legislative, regulatory and any other relevant requirements that relate to the accessibility and standards of the sites used in Service delivery are met.

5.2 Security

You must take all reasonable steps to ensure that within the sites from which the Services are delivered that the safety of Service Users, Staff and visitors is assured. All chemical supplies, drugs, equipment and buildings must be appropriately secure and appropriate waste management programmes must be implemented.

5.3 Hygiene and infection control

You must take all reasonable steps to ensure that within the sites from which the Services are delivered all Service Users, Staff and visitors are safeguarded from infections. You will develop and implement infection control policies and procedures, consistent with nationally accepted guidelines, which set out defined Staff responsibilities in this area including 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.

6 Service User focus standards

6.1 Service information

You must have available for Eligible People and Referring Practitioners appropriately written information, which describes (without limitation):

- (a) the Services you offer;
- (b) the location of these Services;
- (c) the hours of access;
- (d) how to access the Services (i.e. whether a referral is required); and
- (e) any other information to enable Service users to access the Services.

6.2 Personal identification

You must have, and implement, a written policy that will ensure all Eligible People and Referring Practitioners can be informed, where relevant, of the identity and status of all Staff or students undertaking the delivery of the Services.

6.3 Privacy

You must establish and maintain processes to ensure the confidentiality of Eligible People information in compliance with the Health Act 1956, the Privacy Act 1993 and the Health Information Privacy Code 1994, as applicable.

6.4 Respect for privacy, dignity, religion and culture

You must ensure that there is respect for the personal privacy and dignity of Service Users during Service delivery and that Services are provided in a manner which shows respect for Service Users' religious and cultural beliefs and practices. You must deliver the Services in a culturally appropriate and competent manner. You must take account of the particular needs within the community served so that there are no barriers to access or communication and that the Services are safe for all people. You must include significant service specific ethnic and other cultural groups in assessing satisfaction with the Services.

6.5 Code of Health and Disability Services Consumers Rights

You must provide the services in accordance with all requirements of the Health and Disability Commissioner (Code of Health and Disability Services Consumer Rights) Regulations 1996 including the Code's 2004 amendment.

6.6 Service user advocates and support people

You must inform Service Users, in a manner appropriate to their communication needs, of their right to have an advocate or support person, including supporting the resolution of any complaint. You must allow advocates and supports people reasonable access to facilities, Service Users, employees and information to enable them to carry out their role as an advocate or support person. You must know of, and be able to facilitate access to, a Māori advocate or support person for Service Users who require this Service.

6.7 Complaints policies and procedures

You must enable Service Users, 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 1996, including the Code's 2004 amendment to the Code, and will ensure that:

- (a) the complaints procedure itself is made known to and easily understandable by Service Users;
- (b) all parties have the right to be heard;
- (c) the person handling the complaint is impartial and acts fairly;
- (d) complaints are handled at the level appropriate to the complexity or gravity of the complaint;
- (e) where a complaint is made or incident recorded, where there is identifiable risk to the Service User, the laboratory will provide the NSU with details of the complaint and all contacts made with health professionals and consumers of the Service;
- (f) any corrective action required following a complaint is undertaken;
- (g) the complaints procedure sets out the various complaints bodies to whom complaints may be made and the process for doing so. Service Users 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;
- (h) complaints are handled sensitively with due consideration of cultural or other values;

- (i) Service Users who are Māori and their whanau have access to a Māori support person to support them during the complaints process;
- (j) Service Users who complain, or on whose behalf families complain, shall continue to receive Services; and
- (k) complaints are regularly monitored by the management of the Service and trends identified in order to improve Service delivery.

6.8 NSU to be advised of complaints

You must advise the NSU immediately if you:

- (a) receive a complaint:
 - i. from the media;
 - ii. from a Member of Parliament;
 - iii. from a lawyer;
 - iv. that is a potential Sentinel Event; or
 - v. is an actual Sentinel Event.
- (b) are notified by either the Accident Compensation Corporation (ACC) or the Health and Disabilities Commissioner (HDC), that one or both of these agencies is undertaking an investigation of Services provided by you or that you are required to provide information to either ACC or HDC.

7 Records and administration

7.1 Service User Records

Service User Records and related administrative processes must meet legislative and accepted professional and/or sector standards. Formal documented processes must be maintained to enable the Referring Practitioner to plan and implement safe and timely referral, treatment or transfer.

7.2 Administration standards and record keeping

(a) Operation of business

You must operate under sound financial and business management principles, procedures and practices.

(b) Accounting Records

You must maintain full and proper financial and business Records in accordance with generally accepted accounting principles, procedures and practices and best business practice generally and any legal obligations applicable to you. You must account financially for any Services you provide in a way that ensures financial separation between those Services and any other activities you are engaged in.

7.3 Security and preservation of Records

- (a) You must retain the Records, and preserve and protect the safety, security and confidentiality in accordance with:
 - (i) the retention requirements in Section 5 of the NCSP Operational Policy and Quality Standards;
 - (ii) clauses 5.1, 5.2 and 5.5 of Section H of this Agreement;
 - (iii) any other legal obligations applicable to you; and
 - (iv) best business practice.
- (b) You must ensure that the Records are properly archived and readily accessible, and have in place appropriate back-up and disaster recovery procedures to protect against loss of electronically stored information.
- (c) Where you cease to provide the Services under this Agreement or where there is any change in your ownership or any sale of your business or other transfer in terms of clause 4.1 of Section L of this Agreement, then you will remain primarily liable for ensuring the performance of your obligations under paragraphs (a) and (b) above, provided that those obligations may be transferred to any replacement Provider with our prior written consent, which may not be unreasonably withheld.
- (d) For the avoidance of doubt, this clause 7.3 survives termination of this Agreement.

7.4 Information provision

Where you are required to provide us with any information under this Agreement, including under:

- (a) Section G of this Agreement in relation to claiming for payment;
- (b) Section H of this Agreement in relation to reporting and risk management;
- (c) Section I of this Agreement in relation to Audit, Monitoring and Evaluation; and
- (d) Schedule C1 of this Agreement,

you must ensure that such information is accurate and complete to the best of your knowledge and belief and you must identify any material inaccuracies or uncertainties at the time you submit this information or at such time as you discover the inaccuracy or uncertainty.

7.5 Response time to enquiries

We must each respond to enquiries from the other as soon as is practicable but in no case later than 10 Business Days.

8 Quality management systems

8.1 Quality Plan

You must develop and implement, within 3 months of the Commencement Date, a written quality plan (which will be updated on an annual basis) (the **Quality Plan**) that incorporates the following elements:

- (a) a statement of your organisation’s principles and objectives regarding Service quality;
- (b) assigned responsibilities and accountabilities for meeting all Quality Standards set out in Section F of this Agreement;
- (c) systems and processes for maintaining and developing the quality assurance of ongoing Service delivery and for defining priorities and new initiatives for quality development;
- (d) systems and processes for monitoring against the NCSP OPQS, including National Indicators for laboratories, and other measures and targets as specified from time to time by the NCSP (e.g. screener sensitivity);
- (e) systems and processes for identifying risks to health and safety that relate to the provision of the Services, the corresponding mitigation strategies and progress reviews;
- (f) incident reporting policies and procedures that set out guidelines for reporting incidents, including the definition of “an incident”;
- (g) monitoring and measuring systems and processes, which includes at least an annual internal audit, to evaluate the effectiveness of quality activities and progress against the Quality Plan; and
- (h) a corrective action process.

8.2 Further requirements

You must ensure that the quality systems and processes developed under clause 8.1(c) of Section F above:

- (a) provide for the development of multidisciplinary internal audit and peer review processes, as appropriate, to assure and develop the quality of service delivery;
- (b) require your compliance with appropriate professional and other standards relevant to the Services;
- (c) provide for Staff and Service Users input into quality development activities; and
- (d) provide for the development of documented policies and procedures wherever such documentation is necessary to support effective and safe service delivery, including processes for regular review and updating of such documents and for ensuring that they are readily accessible, known to and implemented by Staff.

8.3 Staff aware of this Agreement

You must ensure that your Staff, including sub-contractors, comply with your responsibilities under this Agreement as they relate to service delivery Quality Standards.

8.4 We may request a copy of Quality Plan

We may request, and you must provide within 10 Business Days of our request, a copy of the Quality Plan or of certain specified parts of it. We may require you to make amendments or improvements to the Quality Plan if we do not consider it meets the requirements of clause 8.1 and 8.2. Where we request amendments, you must work with us to complete necessary amendments to the Quality Plan.

8.5 Exception where similar Quality Plan already exists

Notwithstanding anything else in this clause 8, you will not be required to submit a Quality Plan if you can demonstrate to our satisfaction by submission in writing that you have an existing plan of a similar nature that already meets the requirements of clauses 8.1 and 8.2 of Section F above.

9. Health Education Resources

You have a responsibility to ensure that new Health Education Resources are technically accurate, have been developed in an appropriate way, and support Ministry of Health policy.

Section G. Funding for Services, claiming procedure and payment terms

Funding for Services

1 Funding for the Services

- 1.1 You may claim, and we will pay you, for having delivered the Services in accordance with this Agreement, on the basis of the prices set out in the NCSP Test Purchase List in Schedule G1 of this Agreement, subject to any further requirements, rules and procedures as to claiming and payment as set out in:
- (a) this Section G;
 - (b) claiming restrictions on NCSP Tests in Schedule G2 of this Agreement;
 - (c) the laboratory system requirements in Schedule G3 of this Agreement; and
 - (d) the business rules for laboratory system in Schedule G4 of this Agreement.
- 1.2 Nothing in this Section G precludes either of us from varying this Agreement in accordance with the provisions in Section K of this Agreement, or from terminating this Agreement in accordance with provisions in Section N of this Agreement.

2 Goods and Services Tax

Under this Agreement:

- (a) all prices are quoted exclusive of GST, unless this Agreement expressly provides otherwise;
- (b) all payments will be made inclusive of GST, unless this Agreement expressly provides otherwise; and
- (c) all claims must comply with the Goods and Services Tax Act 1985.

Claiming procedure

3 Your ability to claim for payment

You may claim payment from us (on the basis of the prices set out in the NCSP Test Purchase List in Schedule G1 of this Agreement) for the Services if you have delivered the Services during the Claim Period in accordance with this Agreement, including the requirements, rules and procedures set out in:

- (a) this Section G;
- (b) claiming restrictions on NCSP Tests in Schedule G2 of this Agreement;
- (c) the laboratory system requirements in Schedule G3 of this Agreement; and
- (d) the business rules for laboratory system in Schedule G4 of this Agreement.

4 Claiming allowances and restrictions

4.1 Ineligible persons and services excluded

You may not claim or use the funding provided under the Agreement for Services performed in respect of a person whom you know is not an Eligible Person and you may not claim for a service which is excluded under clause 2.2 of Section C of this Agreement. If we discover that you have claimed for NCSP Tests performed on a patient whom you know is not an Eligible Person, or that you have claimed for a service which is excluded under clause 2.2 of Section C of this Agreement, we may reduce the amount of any payment owing to you under this Agreement by the amount inappropriately claimed, or require a refund from you of the amount inappropriately used by you.

4.2 Services must have been provided in New Zealand

You may not claim for having delivered the Services to any Eligible Person who was not in New Zealand at the time those Services were initiated by a Referring Practitioner, unless there has been prior agreement with the NCSP. We must be notified of any NCSP Tests for persons outside of New Zealand if claims are being made.

4.3 Services must meet Quality Standards

Subject to clause 4.5 of Section G below, we will fund only those NCSP Tests in respect of which you have IANZ accreditation and subsequent IANZ registration and only where you meet or exceed the policy, quality and service standards and other requirements set out in Section F of this Agreement.

4.4 IANZ accreditation and registration denied or cancelled

Where your IANZ accreditation or registration is suspended or cancelled in respect of a particular NCSP Test, a group of NCSP Tests or all of the NCSP Tests, we may suspend

payments to you under this Agreement in respect of such tests until such time as we are satisfied that you have regained your IANZ accreditation and registration in respect of the relevant tests.

4.5 Funding pending accreditation and registration

We agree to fund the relevant NCSP Test(s) in respect of any new Laboratory that you operate or any particular NCSP Test(s) that you provide for the first time during the 4 month period specified in clause 2.8 of Section F of this Agreement only on the basis that, during such period, you will operate the new Laboratory and/or provide the relevant NCSP Test(s) to the standards necessary to meet the:

- (a) IANZ accreditation and registration requirements (as if such accreditation and registration had been gained); and
- (b) other policy, quality and service standards and other requirements set out in clause 2.1 of Section F of this Agreement.

4.6 Funding ceased

Where you are denied IANZ accreditation and registration within 4 months in terms of clause 2.8 of Section F of this Agreement or fail to meet the IANZ accreditation and registration standards or other policy, quality and service standards and other requirements set out in clause 2.1 of Section F of this Agreement, we will immediately cease funding the relevant NCSP Test(s) and you agree to refund to us the total amount paid to you by us over the relevant period in respect of such NCSP Test(s).

4.7 No cost or volume shifting

You must not engage in any cost or volume shifting activity. For the purposes of this clause 4.7, cost or volume shifting includes activities where you gain a financial advantage or we suffer a financial disadvantage because you have:

(a) **Cost shifting**

In the case of cost shifting, shifted a cost that is properly incurred by you under some other agreement, whether that agreement is with us or another funder, and as a result inflated the real costs of the Services under this Agreement, or incurred a cost which was or is properly incurred by another Provider under contracting arrangements with us;

(b) **Volume shifting**

In the case of volume shifting, shifted all or part of a Service that you have agreed to provide under this Agreement, or any other Agreement you have with us or another funder, to another Provider, carried out all or part of a Service that another Provider has been contracted to provide to us or another funder or switched the carrying out of a service between this Agreement and another agreement you have with us or another funder.

4.8 Further clarification

Without limiting the generality of clause 4.7 of Section G above, you must not:

- (a) claim payment from us for having delivered any Service that you have carried out for any Provider who is contracted to provide us with that Service;

- (b) refer to any Provider in part or in total, the Services that you have been contracted to provide to us under this Agreement;
- (c) act in a way that enables you to claim or recover payment twice under this Agreement, or any other agreement you have with us or another funder, for providing services of a similar nature to the services;
- (d) claim in respect of one Laboratory for Services that are not carried out by that Laboratory; or
- (e) inflate the cost of providing the Services by entering into sub-contract arrangements with related parties for the provision of those Services in part or in total where the prices agreed to be paid for sub-contracted Services are not comparable with prices paid for similar services by other Providers.

5 Claiming generally

5.1 Service Period

The Service period is to be a single calendar month, for example, beginning 1 March and ending 31 March (Service Period).

5.2 All Services must be claimed for

Any claim you make for payment must relate to all of the Services that you have delivered, and intend to claim for, during that Service Period, provided that you may make more than one claim in respect of a particular Claim Period, in which case your claims collectively must relate to all of the Services that you have delivered, and intend to claim for, during that Claim Period. However, where there is a good reason why you are unable to include some of the Services you provided in the Service period within the claim for that Service Period, you may claim for those Services in the following Service Period.

5.3 Due date for claim

Any claim you make for payment must be submitted so that we receive it by the tenth Business Day of the calendar month that follows the Claim Period (**Due Date**).

6 Charges to Eligible People

6.1 Eligible Persons

Subject to clause 6.3 of Section G below, where you provide the Services to Eligible Persons you must not charge Eligible Persons for the Services they use which are funded or partially funded by us, except as otherwise agreed in writing with us.

6.2 Additional charges for the Services

Subject to clause 6.3 of Section G below, you will not charge us, or any other person, additional fees for the provision of the Services that are funded by us under this Agreement.

6.3 Eligible Persons to pay additional charges

Nothing in clauses 6.1 and 6.2 of Section G above shall apply where an Eligible Person or a person acting on behalf of an Eligible Person notifies you in writing that he or she does not wish to accept the benefits available under this Agreement, in which case the whole amount of your fee may be charged to, or on account of, the Eligible Person and no amount of your fee will be payable by us under this Agreement.

6.4 Persons not Eligible

Where you provide Services to persons who you know are not Eligible Persons you are not entitled to claim payment from us in relation to the provision of those Services and you must use your best endeavours to charge and recover from, or on behalf of, those persons the cost to you of providing those Services.

7 Form of claim and information to be provided

7.1 Format and information

You must submit each claim by invoicing us in an electronic format in accordance with Schedule G3 of this Agreement. All fields specified in the table in clause 3 of Schedule G3 of this Agreement must be completed by you. Each claim must state the Agreement Reference Number and include the information set out in the following table:

| Claim information | Comment |
|-----------------------------------|--|
| Claim identification | |
| Referral identification | |
| NCSP Test code | |
| Date of Service | |
| Number of tests | |
| Claimed fee | |
| Date of birth | Date of birth is a non-mandatory requirement for payment of a claim, apart from tests which patient age restrictions apply, as specified in Schedule G2 of this Agreement. |
| Gender | It is non-mandatory for payment of a claim to identify the gender of a patient apart from tests to which gender restrictions apply, as specified in Schedule G2 of this Agreement. |
| NHI number | It is non-mandatory for payment of a claim to identify the NHI for a patient. However, where a Referring Practitioner includes details of any non-mandatory information for a NCSP Test you will include this information as part of your claim for the NCSP Test. |
| Referring Practitioner identifier | |
| PAN/PIN number | |

| | |
|----------------------------|--|
| | |
| Practitioner – pathologist | |
| Agreement Reference Number | |
| Payee Number | |

7.2 Claim summary

Each claim submitted by you must be accompanied by a claim summary in the form set out in Schedule G3 of this Agreement.

7.3 Certification of Claims

Each claim submitted by you must be signed by your duly authorised officer certifying that:

- (a) the claim being made is an accurate claim;
- (b) the Services referred to in the claim have been completed and provided in accordance with the Quality Standards set out in Section F of this Agreement;
- (c) consultation has occurred with Referring Practitioners, where necessary;
- (d) the NCSP Test results have been sent to the Referring Practitioner;
- (e) all required information about the NCSP Test, Referring Practitioner, Eligible Person, and NCSP Test results has been supplied to the National Cervical Screening Programme Register in accordance with the Health (National Cervical Screening Programme) Amendment Act 2004; and
- (f) the Services referred to in the claim have been carried out by the Laboratory in respect of which the claim is being made.

7.4 Changes to content and form

We both commit to streamlining claiming requirements as appropriate. After we have Consulted with you and given you reasonable notice of the nature of any changes to the content and form of claims, we may vary the content of any claims and the form in which claims must be submitted. We agree that changes to the content and form will not impose unreasonable cost on you, unless you agree in writing.

7.5 Change to address

We may change the address for the submission of claims on 10 Business Days' written notice.

8 Rejection of Claim

8.1 Rejection of Claim

We reserve the right to reject any claim or part claim where we believe on reasonable grounds that you have submitted incomplete or inaccurate information or where you have not complied with claiming restrictions. We will notify you that your claim or a part of your claim has been rejected, where applicable, and the reason for it within 10 Business Days' of us having received your claim.

8.2 Resubmission of Claim

Notwithstanding clause 8.1 of Section G above, you may resubmit that claim or part claim, duly corrected, within 1 month after having received the rejection notice from us.

9 Late Claims

9.1 Submission within 3 months

Where you have failed to submit your claim by the Due Date, you may submit it within 3 months after the date of the completion of the Service.

9.2 Submission outside 3 months

Where you have failed to submit your claim within the 3 month period specified in clause 9.1 of Section G above, you may submit it out of time together with an explanation of the reason for the delay. Where, in our reasonable opinion, you have established reasonable grounds for late submission, we will consider that claim for payment.

9.3 No Submission after 12 months

In no circumstances will any claim submitted for the first time more than 12 months after the date of the completion of the Service qualify for payment.

10 Verification of Claim

In relation to any claim, we may require you to, and you must, substantiate the claim after giving you 15 working days' prior written notice.

Payment terms

11 Our obligation to pay

We agree to pay you for providing the Services on the payment terms set out in clauses 11 to 24 of Section G of this Agreement where you comply with this Agreement and the claiming rules and procedures set out in clauses 3 to 10 of Section G above.

12 Payment time frames

Where we have received a valid claim, we will pay you for that claim no later than 20 Business Days from the Due Date. Where a claim is not submitted by the Due Date, but has been accepted by us under clause 9 of Section G above, we will pay you for that claim no later than 20 Business Days from the next Due Date that arises.

13 Form of payment

We will pay you by lodging funds into the bank account that you specify. You may change the bank account into which your funds are to be lodged on 10 Business Days prior written notice to us.

14 Payment variations

Where we believe on reasonable grounds that a claim is partially valid and partially invalid, we will pay you for the valid portion only and reject the invalid portion.

15 Reasons for payment variations

We will inform you of the reasons why we have amended any amount claimed by you, and any disputes that may arise in relation to this matter will be dealt with in accordance with the provisions in Section J of this Agreement.

16 No payment where referring practitioner identifier omitted

No payment will be made for any test where the claim for that test does not include the Referring Practitioner's Referring Practitioner Identifier, as specified in Schedule G3 of this Agreement.

17 Claiming restrictions

A number of tests listed in the NCSP Test Purchase List are subject to claiming restrictions specified in Schedule G2 of this Agreement because of gender restrictions or because of their relationship with other tests also listed (for example, because they form part of a group test). Where you submit a claim that breaches any of the claiming restrictions in Schedule G2 of this Agreement, no payment will be made for the tests concerned.

18 Payments for additional NCSP Tests

Where additional tests are performed by you in terms of clause 6 in Schedule C1 of this Agreement, no payment will be made for any such test if the claim for that test does not also include the New Zealand Medical Council number of the Pathologist who authorised the performance of that additional test.

19 No payment where failure to comply with Quality Standards

For the avoidance of doubt, no payment will be made for any NCSP Test carried out during such period of time as we reasonably consider that your ability to perform that test, has been compromised by your failure to comply with the policy, quality and service standards and other requirements set out in clause 2.1 of Section F of this Agreement.

20 Overpayment

If you fail to provide all or part of the Services for which we have paid you under this Agreement or if, for any other reason, we have overpaid you for having delivered the Services, we may determine, whether in accordance with the findings of any Audit under Section I or otherwise, the reasonable amount that you must repay to us. We will notify you in writing of our determination and may accompany such notice with notice of our intention to invoke our right of set-off under clause 23 of Section G of this Agreement in relation to the next payment we are due to make to you, and any future payments as necessary.

21 Default Interest on late payment

21.1 Ability to charge Default Interest

Where either of us does not pay any amount due to the other under this Agreement within 5 Business Days of the date that payment is due, but not otherwise, the owed party may charge the defaulting party interest from the date payment was due until the amount due and any interest is paid (**Default Interest**).

21.2 Rate of Default Interest

The Default Interest rate will be 2% per annum above the index lending rate charged by ANZ Banking Group (New Zealand) Limited for the period involved and shall be calculated on a daily basis.

21.3 Notice of intention to charge

In order for the due party to claim, and the defaulting party to be liable to pay, Default Interest, the due party must give written notice to the defaulting party of its intention to claim Default Interest within 30 days after the due payment date.

22 Withholding of payment

Without derogating from any other rights we have under this Agreement, we may withhold payment on a claim, after giving you 30 days' prior written notice, where:

- (a) you have failed to provide all or part of the Services;
- (b) you have not complied with any material information and reporting requirements under Section H of this Agreement;
- (c) after Audit, Monitoring or Evaluation conducted pursuant to Section I of this Agreement, you are found to be in material breach of this Agreement;
- (d) your Staff have not allowed us access for Audit, Monitoring or Evaluation under Section I of this Agreement,

until such time as compliance occurs or the relevant breach is remedied. We will discuss with you the reasons for your non-compliance.

23 Set-off

23.1 Power of set-off

Where you owe us any amount under this Agreement, including:

- (a) in the case of overpayment in terms of clause 20 of Section G above;
- (b) where you are obliged to indemnify us under clause 3.1 of Section M of this Agreement;
- (c) where we have made a payment that has subsequently been found, following an Audit, not to be properly payable under this Agreement;
- (d) where you are found to be in material breach of the terms and conditions of this Agreement following Audit, the costs of that Audit, in accordance with clause 2.9 (c) of Section I of this Agreement,

we may set that amount off against any amount that we owe to you at any time, after we have given you written notice of our intention to do so.

23.2 Set-off deemed to be payment

Where we exercise the power of set-off conferred by clause 23.1 of Section G above you will be deemed to have made payment to us to the extent of the set-off.

24 Payment agents

We may, at our discretion and at any stage during the term of this Agreement, employ an agent to receive claims and make payments on our behalf (the **Payment Agent**). Where we choose to employ such an agent we will give you at least 20 Business Days' prior written notice. We will ensure that any Payment Agent has the information necessary to carry out its functions, including information on any changes to the prices for NCSP Tests that both of us may agree on from time to time.

Section H. Reporting, monitoring and risk management

1 Provision of cervical screening information

1.1 Cervical screening information

- (a) You must continue to maintain and provide timely cervical cytology, HrHPV testing and histology test results and information to the National Cervical Screening Programme Register, in accordance with the requirements of the Health (National Cervical Screening Programme) Amendment Act 2004 and the NCSP Operational Policy and Quality Standards, and to the Cancer Registry in accordance with the requirements of the Cancer Registry Act 1993.
- (b) You will use HL7 messaging according to the specifications in the NSU HL7 Implementation Guide for the exchange of result information between your laboratory and the NCSP-Register, in accordance with Schedule C1.

1.2 Other cervical screening information

You must provide quarterly, six monthly and annual reporting in accordance with Schedule C1 of this Agreement

1.3 Changes to format

After we have consulted with you and given you reasonable notice of the nature of any changes to the content or form of any information and reports, we may vary the required content of the information and reports and the form in which the information and reports must be submitted.

1.4 Change to address

We may change the address for the submission of information and reports on 10 Business Days written notice.

1.5 Late information

Without limiting our rights under this Agreement in respect of any delay in providing information under clauses 1.1, 1.2, or 1.3 of Section H above:

- (a) where you anticipate potential delays in providing the cervical screening information required under clause 1.1 of Section H above, you must notify us immediately. You must explain in the notice the reason for the anticipated delay and notify us of the date on which you will provide the relevant information. The amended due date must be mutually acceptable and agreed by both of us in writing.
- (b) where you anticipate potential delays in providing the cervical screening information required under clause 1.2 and 1.3 of Section H above, by their due dates, you must notify us of this at least 10 Business Days before the date on which the relevant information is due, except where the potential delay is anticipated within that 10 Business Day period, in which case you must notify us immediately. You must explain in the notice the reason why you may be unable to meet the due date and notify us of the date on which you will submit the relevant information.

1.6 Ad-hoc report requirement

Subject to our rights and your obligations relating to access to, and the provision of, information under Section I of this Agreement, we may require additional information from you from time to time in relation to the Services. Where we do, we will notify you of our reasonable information requirements, the reasons for those requirements and the intended usage of the information gathered. You must provide us with reasonable assistance to obtain the required information. We will both agree to a mutually acceptable time frame for delivery of this additional information. Where you reasonably satisfy us that the costs of meeting the ad-hoc reporting requirements under this clause 1.6 are material and you clearly identify those costs, we will meet those costs provided that no such costs will be met by us unless agreed by us in writing prior to the costs being incurred by you.

1.7 Cost of reporting

The costs to you associated with the provision of information specified under this Section H shall be borne by you and are deemed to have been included in the prices for the Services as detailed in the pricing table set out in Schedule G1 of this Agreement.

2 Report to a Minister

From time to time we may request, and you must provide within a reasonable time, such information as is necessary to enable us to report appropriately to any Minister of the Crown where such Minister has required us to report on the use of public funds under this Agreement or for any reason contemplated by the New Zealand Public Health and Disability Act 2000.

3 Risk management

3.1 Where either of us becomes aware of any risks, issues or Sentinel Events that will, or are likely to, materially reduce or affect the ability of either of us to meet our obligations, (including without limitation financial risk, subcontract risk, professional risk, clinical risk, compliance risk and restructuring risk) we will promptly notify the other of those risks or issues and must discuss with each other options for avoiding or remedying the risks or issues identified. The fact that discussions are undertaken does not affect either party's rights under any other clause of this Agreement.

3.2 You are to notify us immediately of any issues concerning the Services that might have high media or public interest.

4 Civil Defence

4.1 You must maintain:

- (a) an up to date civil defence plan that details how you intend to manage continued delivery of Services in the event of a major incident; and
- (b) an appropriate level of preparedness and reactive capacity in the event of any civil defence emergency in order to ensure continued delivery of such Services in the event of a major incident.

4.2 You must work proactively to enable intersectoral co-operation and co-ordination of all services in the event of a civil defence emergency.

- 4.3** You must meet the relevant requirements outlined in the version current on the commencement date of this Agreement of part six (health) of the National Civil Defence Plan current on the commencement of this Agreement, as varied from time to time.

5 Records

5.1 Records of Eligible People

You will maintain a record of all Eligible People to whom you provide the Services, and all substantial personal interviews with Eligible People which impact on their health or disability, for the following minimum periods from the date on which a payment was claimed for the test:

- (a) 14 years for records relating to cytology tests and HrHPV tests;
- (b) 20 years for records relating to histology tests,

or for such longer period as may otherwise be required by law, by the Royal College of Pathologists of Australasia or by any other appropriate body.

5.2 Records in respect of Laboratory test results

You will maintain Records in respect of the laboratory test results of Eligible People referred to you for testing for the following minimum periods from the date on which a payment was claimed for the test:

- (a) 14 years for Records relating to cytology tests and HrHPV tests;
- (b) 20 years for Records relating to histology tests,

or for such longer period as may otherwise be required by law, by the Royal College of Pathologists of Australasia or by any other appropriate body.

5.3 Content of Laboratory referrer test request forms

Your referrer test request forms will include:

- (a) provision for an Eligible Person's name and NHI, address, date of birth, ethnicity and gender data.
- (b) provision for the Referring Practitioner's Referring Practitioner Identifier, name, PAN/PIN number data, name of health facility, provision for smear site and technique, clinical history and comment. This will be completed by the Referring Practitioner.
- (c) a declaration by the Referring Practitioner of the eligibility of the Eligible Person and the services being referred, and provision for the declaration to be signed by the Referring Practitioner in accordance with clause 3.2 of Schedule C1 of this Agreement.

5.4 Consultation on referrer test request forms

You will consult with the NSU, your Referring Practitioners and their professional bodies or organisations, over the layout of your referrer test request forms and the tests that are included on it.

5.5 Retaining referrer test request forms

You will keep a copy of each request form, or a complete electronic image of each request form, referred to you by a Referring Practitioner requesting a NCSP Test for which a payment is claimed, and a copy of each report that you make on a NCSP Test, for a minimum of 18 years from the date on which a payment was claimed for the test: or for such longer period as may otherwise be required by law or by any other appropriate body.

6 Other information

- 6.1** You will have a co-ordinated process for collecting, collating, analysing and reporting information relevant to the Services, and otherwise required under this Agreement.
- 6.2** You are to provide information annually on request regarding the cost of salaries, operational costs and costs and overheads attributed to the delivery of these Services, in accordance with a template provided by the NSU and developed in consultation with you.

7 Audited annual financial statements

You are to supply us on request with the latest copy of your audited annual financial statements.,

Section I. Audit, Monitoring and Evaluation

General Provisions

1 Audit, Monitoring and Evaluation

1.1 Purpose of Audit, Monitoring and Evaluation

- (a) The goal of the NCSP is to reduce the incidence of, and mortality from, cervical cancer among New Zealand women. To achieve this goal all services within the screening programme need to be of the highest quality. To ensure that service provision meets these expectations a range of Audit, Monitoring and Evaluation activities are required. Ongoing Audit, Monitoring and Evaluation is an integral part of an organised screening programme. The performance of the NCSP and of the providers to the NCSP will be Audited, Monitored and Evaluated on an ongoing basis by us and/or our agents.
- (b) All providers are expected to fully co-operate with the processes of Audit, Monitoring and Evaluation and to promptly attend to any necessary improvements identified during these processes.
- (c) We intend the Audit, Monitoring and Evaluation processes in this Section I will help ensure that public money is effectively applied in the health sector so as to provide optimum health benefits to Eligible Persons and to maximise the quality of services provided by the NCSP. The rights and obligations set out in this Section I are conferred for the purpose of enabling us to inspect, Monitor, Audit, investigate and Evaluate:
 - (i) whether you are delivering the Services;
 - (ii) whether you are complying with the Quality Standards set out in Section F of this Agreement;
 - (iii) whether you have been claiming for payment appropriately according to the procedure set out in Section G of this Agreement;
 - (iv) whether you are complying with all of your other obligations under this Agreement;
 - (v) ways of improving the quality of Services provided by you; and
 - (vi) the overall effectiveness of the NCSP.

1.2 Audits, Monitoring and Evaluation after Agreement Terminated

Audit, Monitoring and Evaluation activities by us may continue to be conducted under this Section I after the Agreement has terminated, but only to the extent that it is relevant to the

period during which the Agreement was in force. You must assist us with those Audit, Monitoring and Evaluation activities as if this Agreement remained in force.

1.3 Provision of Information Documentation

To assist us to Audit, Monitor and Evaluate your information and reporting processes, you must provide us with the following information, within 10 Business Days of our request:

- (a) name and contact details of the Staff or other persons responsible for collecting and managing all information and reports regarding the Services and the nature of their responsibilities;
- (b) the nature of all policies and systems that you have developed or established to meet the information and reporting requirements of this Agreement, and the NCSP Operational Policy and Quality Standards;
- (c) data definitions available to help your Staff with data responsibilities; and
- (d) any other matters relating to your information and reporting processes that we consider necessary to assist us to Audit, Monitor and Evaluate your information and reporting processes.

Audit

2 Audit provisions

2.1 Frequency of and reasons for Audits

Without limiting clause 1.1 of Section I above we both agree that we may conduct an Audit for the following reasons:

- (a) as part of a routine Audit round, which we envisage may occur annually or biennially;
- (b) in relation to a particular national, regional or Service specific issue;
- (c) where we believe on reasonable grounds that you may not be performing Services as required by this Agreement or are not otherwise meeting your obligations under this Agreement; and
- (d) at any time in relation to data management and systems matters, provided that the frequency of any such Audits shall not be vexatious.

2.2 Appointment of Auditors

We shall appoint suitably qualified and competent members of our staff or third parties as an Auditor or Auditors to carry out on our behalf any Audit under this Agreement.

2.3 Disclosure to us

- (a) We shall ensure that any Auditor shall be bound by an obligation of confidentiality such that any information obtained by an Auditor during the course of an Audit shall be used only for the purposes of the Audit itself, subject to Clause 2.10 of Section I of this Agreement.
- (b) Notwithstanding Clause 2.3(a), any Auditor shall have the power to raise and disclose to us any issues discovered in the course of an Audit that the Auditor considers are material to the performance of the Services under this Agreement.

2.4 Notice of Audit

We will give you 10 Business Days prior written notice of our intention to carry out an Audit, except where we have reasonable grounds to believe that:

- (a) there has been a material breach of the Agreement; or
- (b) a delay of 10 Business Days would unreasonably prejudice the integrity of the Audit; or
- (c) a delay of 10 Business Days would unreasonably prejudice the interests or safety of any Eligible Person; or
- (d) an audit is required as a matter of public safety,

in which case a reduced notice period may be given which is reasonable in the circumstances (and may include less than 24 hours notice in some circumstances). This notice will include the identity of the person or persons we intend to appoint as Auditors, their qualifications, and the reasons for the Audit.

2.5 Objection to Auditor

(a) Grounds for objection

If you consider on reasonable grounds that any person that we intend to appoint as an Auditor is not suitably qualified and competent or has a material conflict of interest (provided that appointment by us does not in itself give rise to a conflict of interest), you may object to the appointment but must do so promptly after advice to you of the identity of the Auditor.

(b) Agreeing on an Auditor

Except where a reduced notice period has been necessary as provided for in clause 2.4 of Section I above, if you have objected to the appointment of an Auditor we will discuss with you the intended Auditor with a view to agreeing that the intended Auditor is suitable or agreeing on a replacement. We shall both co-operate to ensure that these discussions are completed as expeditiously as possible. Where no agreement can be reached before the

Audit is due to commence, we may appoint either the Auditor identified in the notice referred to in clause 2.4 of Section I above or a replacement Auditor determined by us.

2.6 Access for Audits

You must co-operate with us to allow our Auditor or Auditors access to:

- (a) your Site;
- (b) your Records and any other information, in whatever form, that relates to this Agreement;
- (c) any slides or other samples relating to the Services provided by you;
- (d) Service Users; and
- (e) employees, contractors, subcontractors, agents or other personnel used by you to provide the Services,

for the purposes of, and during the course of, conducting an Audit, and must ensure that we and our authorised agents have equivalent access in relation to any Services provided through any contractor, sub-contractor, agent or other personnel.

2.7 Access

Subject to clause 2.8 of Section I below, in conducting any Audit our Auditors may:

- (a) access Confidential Information about you and/or any Service User ;
- (b) observe the provision of the Services;
- (c) interview Service Users, their families or their associates, or any employees, contractors, sub-contractors, and other personnel used by you to provide the Services; and
- (d) make copies of any part of the Records or information for the purposes of the Audit, except to the extent restrained by law.

2.8 Privacy obligations

The conduct of any Audit shall be in accordance with the Health Act 1956, the Privacy Act 1993, the Health Information Privacy Code 1994, and any other relevant law, as applicable.

2.9 Audit Process

- (a) Any aspect of an Audit that involves access to your Site or personnel may be carried out at any time during business hours or at any other time by arrangement with you.
- (b) We shall ensure that the conduct of any Audit does not unreasonably disrupt your ability to provide, and the provision of, the Services.
- (c) We shall bear our own costs of the conduct of an Audit by us under this Section I, except where you are found to be in material breach of the terms and conditions of this

Agreement following Audit, in which case we may recover the costs of Audit reasonably incurred as a debt due and owing by you and/or exercise our rights of set-off pursuant to clause 23 of Section G of this Agreement. You may not charge us, and we are not obliged to pay, for the time your employees, contractors, sub-contactors, or agents spend co-operating with an Audit or any other costs you may incur in relation to an Audit or any matters arising from an Audit.

2.10 Results of Audit

- (a) We will report to you the results of any Audit conducted under this Section I.
- (b) Without derogating from any other rights we have under this Agreement, where the Audit has disclosed any material failure or any other failure to comply with the terms of this Agreement we will discuss together the nature of the failure or concern with a view to establishing what action should be taken. This will not preclude us from taking immediate action pursuant to any right or remedy available to us in terms of this Agreement or otherwise, without discussion with you, if we consider a serious health and safety risk exists or if there appears to have been fraudulent activity by you.
- (c) We may disclose the results of any Audit to any agent of ours engaged by us in Audit, Monitoring and/or Evaluation activities and to our professional advisors in addition to any disclosure permitted or required pursuant to the law.

2.11 Audit Framework

An audit framework and associated audit documentation will be developed by us. This audit framework and audit documentation will be indicative of the process and procedure likely to be followed on audit, provided that in the event of any conflict between the audit framework and audit documentation and this Agreement the terms and conditions of this Agreement shall prevail.

Monitoring and Evaluation

3 Monitoring and Evaluating Information

3.1 Obligations to provide information for Monitoring and Evaluation

Pursuant to clause 112N of the Health (National Cervical Screening Programme) Amendment Act 2004, section 5 of the Cancer Registry Act 1993 (or any other relevant legislation), the NCSP Operational Policy and Quality Standards, and this Agreement (including in particular Section H of this Agreement), you must provide certain information to the National Cervical Screening Programme Register, the Cancer Registry, and to us or our agents.

3.2 Monitoring and Evaluation Process

We, and our agents, may Monitor and/or Evaluate:

- (a) your compliance with your obligations to provide the information referred to in clause 3.1 of Section I above;
- (b) your performance against the National Indicators; and
- (c) any other aspect of the information provided by you that we determine appropriate from time to time to address performance of your obligations under this Agreement, or the performance of the NCSP.

3.3 Monitoring Reports

- (a) We and/or our agents may issue reports addressing those matters that have been Monitored and/or Evaluated (Monitoring reports).
- (b) You will be provided with a copy of any Monitoring report relating to Services provided by you. You will have a period of 10 Business Days to provide in writing any comments you may have about any matter contained in that Monitoring report. If you provide any such written comments we will consider those comments and determine whether or not to amend the Monitoring report before the report is made available publicly.
- (c) Monitoring reports may be made publicly available.
- (d) As a result of matters raised in any such Monitoring report we may determine that we will conduct an Audit, or a further Audit, if we consider it appropriate, or exercise any of our rights under this Agreement or otherwise.
- (e) You shall comply with any recommendations reasonably made in any such Monitoring report in regard to Services provided by you.

Section J. Dispute resolution

1 Application of this Section

This Section J is intended to apply to the resolution of disputes arising under this Agreement, provided that it is not intended to be used to compel agreement between us on any matter which this Agreement contemplates is to be resolved by agreement between us. This Section J shall apply subject to paragraph 1(b) below to any relevant dispute arising under this Agreement, other than a dispute relating to:

- (a) whether or not any person is an Eligible Person, which is a matter to be determined by the Minister of Health; and
- (b) where the dispute relates to the matters covered by clauses 4.6 or 7 of Section K of this Agreement, the process specified in those clauses, as applicable will apply.

2 Dispute resolution process

2.1 Resolution by agreement

If a dispute arises under this Agreement we will both act in good faith and use our best endeavours to resolve the dispute by agreement.

2.2 Mediation and arbitration

If the dispute is not settled by agreement within 30 days then, unless we both agree otherwise in writing:

- (a) each party must give the other full written particulars of the dispute within 7 days; and
- (b) the dispute will be referred to mediation (but not arbitration, unless agreed otherwise) and dealt with in accordance with the Health Sector Mediation and Arbitration Rules 1993.

2.3 No litigation

We both agree that neither of us will initiate proceedings in any court or other tribunal:

- (a) where this agreement contemplates that the matter be resolved by agreement between us both; or
- (b) where this agreement does not contemplate that the matter be resolved by agreement between us both, while the dispute resolution process referred to in clause 2.2 of Section J above is under way, unless such proceeding is necessary to preserve that party's rights.

2.4 Obligations continue

We both acknowledge that we both continue to be bound to comply with all of our obligations and exercise our rights under this Agreement while the dispute is being resolved, including withholding payments from you under clause 22 of Section G of this Agreement or exercising

our rights of set-off under clause 23 of Section G of this Agreement to the extent that they are the subject of a dispute.

2.5 Reimbursement of disputed sum

Where the dispute relates to payment(s) already made by us and this dispute is resolved in our favour under this Section J, you will immediately reimburse the disputed portion of such payment(s) to us.

Section K. Variation and renewal of Agreement

1 Nothing precludes termination

Nothing in this Section K precludes either of us from terminating this Agreement in accordance with the provisions of Section N of this Agreement.

Variation

2 Grounds for variation

2.1 Grounds for variation

This Agreement may be varied in one of the following ways only:

(a) **Mutual agreement**

by mutual agreement;

(b) **Reviews**

as a consequence of a review, in accordance with the procedure set out in clause 3 of Section K below;

(c) **Crown Direction**

in order to give effect to any Crown Direction to us or to you, as applicable, in accordance with the procedure set out in clause 4 of Section K below;

(d) **Crown Funding Agreement**

in order to give effect to our or your obligations, as applicable, under the Crown Funding Agreement, in accordance with the procedure set out in clause 4 of Section K below;

(e) **Law change**

in order to give effect to any law change, in accordance with the procedure set out in clause 4 of Section K below;

(f) **Policy change**

in order to give effect to any change in policy, in accordance with the procedure set out in clause 4 of Section k below;

(g) **Insufficient appropriation**

as a consequence of any shortfall in funding due to Insufficient Appropriation under the Public Finance Act 1989 as a result of a Hung Parliament, in accordance with the procedure set out in clause 4 of Section K below;

(h) **Variations to Quality Standards**

in order to give effect to any variation in the Quality Standards.

2.2 Nature of variations

A variation described in clause 2.1(a) or (b) of Section K above will be termed a "**Voluntary Variation**". A variation described in clause 2.1(c), (d), (e), (f) and (g) of Section K above shall be termed a "**Compulsory Variation**". The variation described in clause 2.1(h) of Section K above is imposed and is to be effected in accordance with the procedure in clause 7 of Section K of this Agreement.

3 Variation after review

3.1 Consideration of Agreement

This Agreement shall be reviewed in accordance with this clause 3. A review is intended to provide a forum for consideration of proposed amendments to the terms of particular Sections of or Schedules to this Agreement.

3.2 Review at 12-monthly intervals

Any Section of or Schedule to this Agreement may be reviewed, if either of us initiates a review, approximately 12 months after the Commencement Date and at 12-monthly intervals thereafter, in accordance with the procedure set out in clause 3.4 of Section K below.

3.3 Review in exceptional circumstances

(a) **Notice**

Where either of us considers that exceptional circumstances exist that warrant a review of any Section of or Schedule to the Agreement outside the 12-monthly opportunity for review under clause 3.2 of Section K above, either of us may notify the other in writing of the nature of the issues it wishes to address and the reasons why it believes exceptional circumstances exist.

(b) **Acceptance**

Where the party receiving such notice reasonably accepts, after discussions with the initiating party and any other interested parties, that exceptional circumstances exist that warrant such a review, we both agree to conduct a review in accordance with the procedure set out in clause 3.4 of Section K below.

3.4 Procedure for reviews

(a) Variation proposals

The party initiating a review shall provide a written notice to the other party identifying the issues it wishes to address, proposing variations to any Section of or Schedule to the Agreement and giving reasons for seeking those variations. The recipient must respond in writing within 20 Business Days of receiving the notice, either accepting or declining the proposals or putting forward any alternative proposals.

(b) Negotiations

Each of us must negotiate in good faith and use our best endeavours to reach prompt agreement on any proposal promptly.

(c) Amendment

- (i) If we are both able to agree on any proposed variations to any Section of or Schedule to the Agreement, then we both agree to amend the Agreement accordingly in accordance with clause 6 of Section K below.
- (ii) If we are both unable to agree on any proposed variations to any Section of or Schedule to the Agreement within 1 month of the initiating party receiving the response referred to in clause 3.4(a) of Section K below, then the Agreement will continue without variation.

4 Procedure for Compulsory Variations

4.1 Notice

Where it is likely that a Compulsory Variation will be required, we will give you reasonable notice to that effect where we are able to do so. This notice will include the details of any such variation, our proposed draft of the variation of the Agreement and the date that the variation is to come into effect.

4.2 Form of proposed variation

We agree that our proposed draft of the variation referred to in clause 4.1 of Section K above will be written to give effect to the relevant event specified in clause 2.1(c), (d), (e), (f) or (g) of Section K above, in a way that endeavours to minimise the adverse impact on you, financial or otherwise.

4.3 Agreeing the variation

We will specify a period of time, which is reasonable in the circumstances, within which you are to reply to the proposed draft of the variation notified to you under clause 4.2 of Section K above. After that period has expired, or at such earlier time as may be convenient to us both, we both will seek to agree on the terms of the variation of the Agreement.

4.4 Commencement of variation

(a) **Where full agreement**

Where we both agree on the terms of the variation of the Agreement, the variation will commence as soon as the relevant event specified in clause 2.1(c), (d), (e), (f) or (g) of Section K above comes into effect, or at any earlier time agreed between us, provided that any variation to give effect to a Crown Direction can only be effected by the party to whom the Crown Direction has been issued.

(b) **Where partial or no agreement**

Where we cannot both agree on the terms of the variation before the relevant event specified in clause 2.1(c), (d), (e), (f) or (g) of Section K above comes into effect, the Agreement will be deemed to be varied on the terms set out in our proposed draft of the variation referred to in clause 4.2 of Section K above, subject to any changes to specific parts that we may have agreed between us, as soon as that relevant event specified in clause 2.1(c), (d), (e), (f) or (g) of Section K above comes into effect.

4.5 Where provision of Services no longer viable

Where this Agreement has been varied in accordance with this clause 4 of Section K and where it is no longer viable, financially or otherwise, for you to continue providing the Services that have been affected by that variation, you may:

(a) **Seek amendment**

in conjunction with us, explore the possibility of amending the Crown Direction or Crown Funding Agreement provision in order to mitigate its effect;

(b) **Terminate**

terminate the obligation to provide the relevant Services, provided that you give us at least 3 months prior written notice of your intention to do so, except that where it is not viable, financially or otherwise, for you to continue providing the relevant Services for the duration of that notice period, you may give such shorter period of notice as is reasonable in the circumstances and agreed with us.

4.6 Referral of dispute to mediation

without in any way derogating from the application of 4.1 to 4.5 of Section K above, where any dispute arises between us both in relation to the impact on you of (but not the circumstances giving rise to or reasons for a Compulsory Variation), the matter may be referred to mediation in accordance with clause 2.2 of Section J of this Agreement.

5 Group negotiation

Notwithstanding any other clause in this Section K, where either of us initiate a variation proposal which in our reasonable opinion may have application to other Providers in addition to you, you agree that we may negotiate any matter related to the proposed variation with a representative or representatives of those Providers affected, instead of you, to the extent we consider reasonably practicable to avoid undesirable duplication given limited funding resources.

6 Variation must be in writing

No variation of this Agreement will be effective unless it is in writing and:

(a) **Agreed variations**

in the case of a Voluntary Variation or a mutually agreed Compulsory Variation under clause 4.4(a) of Section K above, is signed by us both; or

(b) **Imposed variations**

in the case of a Compulsory Variation necessarily imposed by us under clause 4.4(b) of Section K above, or a variation imposed by us under clause 7 of Section K below, signed by us and notified to you.

7 Update, clarification, replacement provision or amendment relating to NCSP laboratory services documents

In addition to the Voluntary and Compulsory Variations referred to above, we may from time to time:

- (a) update;
- (b) issue a clarification relating to a particular provision in;
- (c) notify you of a replacement provision in; or
- (d) otherwise amend,

NCSP laboratory service documents including the NCSP OPQS, Guidelines for Cervical Screening in New Zealand, the NCSP Monitoring Technical Specification for Laboratories and the Laboratory Reporting Template. We will consult with you prior to updating, clarifying, replacing a provision in or amending any of the above documents where we consider that our actions would have a material impact on you. Without in any way derogating from our rights under this clause 7 of Section K, where any dispute arises between us in relation to the impact on you of (but not the circumstances giving rise to or reasons for) our updating, clarifying, replacing a provision in or amending any of the above documents, the matter may be referred to mediation in accordance with clause 2.2 of Section J of this Agreement. Any referral to mediation is not to delay the update, clarification, replacement, provision or amendment coming into effect at such time as we reasonably consider necessary.

Renewal

8 No guarantee regarding future contract

Nothing in this Agreement, or in our conduct, confers on you any right or shall be construed as providing any guarantee that:

- (a) we will enter into any future contract with you following the expiry of this Agreement; or
- (b) the terms of any future contract we may enter with you will be similar to the terms of this Agreement.

9 Renewal and renegotiation

9.1 No obligation to negotiate

We may both discuss whether or not we will enter into a future contract, and the terms of any future contract, at any time before this Agreement terminates but neither of us is obliged to participate in any such discussion.

9.2 No agreement

Where we cannot reach an agreement in relation to any negotiation initiated under clause 9.1 of Section K above, this Agreement, or the relevant part of it, will terminate on the Set Termination Date.

10 Allowing expiry of Agreement

10.1 Notification of expiry

Where either of us intend to allow this Agreement to expire on the Set Termination Date, the relevant party must notify the other of this intention in writing at least 6 months before the Set Termination Date.

10.2 Failure to give proper notice

Where we fail to give at least 6 months notice as required under clause 10.1 of Section K above you may, notwithstanding that the Set Termination Date may have passed, at your option, continue to provide, and we will continue to fund, the Services on the terms set out in this Agreement until you have been given 6 months notice and that notice period has expired.

Section L. Terms governing your dealings with third parties

1 Dealings with third parties

1.1 Rights not exclusive

This Agreement gives you the right to provide the Services to us but does not give you any right to provide those Services to the exclusion of other Providers. We have the right to contract with other Providers, including those in your area of expertise or in your vicinity, for the provision of the Services. Equally, but subject to clause 1.2 of Section L below, you have the right to provide the Services to people where this is not funded by us.

1.2 Rights not to impinge

You must not enter into any contract, arrangement or understanding with any other person that would prejudice your ability to meet your obligations under this Agreement.

2 Sub-contracting

2.1 Generally no sub-contracting

Subject to clause 2.2 of Section L below, you must not sub-contract any of the Services covered by this Agreement, except under special circumstances agreed with the NSU and a variation is effected under clause 2.1(a) of Section K of this Agreement

2.2 Specimen collection sub-contracting

You may sub-contract the incidental service of collection and delivery of Specimens for cervical screening laboratory diagnostic purposes, provided that:

- (a) any sub-contractor engaged by you must have the qualifications and accreditations, experience and competency to enable it to perform all of the obligations sub-contracted to it;
- (b) any sub-contract you enter into must require the sub-contracted Services to be performed to the Quality Standards required under this Agreement and must enable us to exercise all our rights under this Agreement, and require the sub-contractor to perform all your obligations under this Agreement in respect of the sub-contracted Services, to the same extent as we may exercise those rights or you must perform those obligations under this Agreement;
- (c) you must notify us of any sub-contractor engaged by you and provide a copy of this subcontract, if requested by us;

- (d) where you sub-contract Services under this clause you will remain liable in all respects for the subcontractor's performance of, and compliance with, your obligations under this Agreement.

3 Responsibility and liability for others

Each of us respectively is responsible and liable in all respects for the acts and omissions of our respective employees, sub-contractors, contractors, agents or other personnel in performing or complying (or failing to perform or comply) with our respective obligations under this Agreement.

4 Transfer of rights and obligations

4.1 No transfer without consent

Subject to clause 4.3 of Section L below, you may not assign or transfer any or all of your rights or obligations under this Agreement without our prior written consent, which we will not unreasonably withhold. The term “**transfer**” in this clause 4 is deemed to include any sale, transfer or other disposal of any majority interest in the ownership or control of you or your business, including as a result of a corporate merger or acquisition.

4.2 Information required

In order that we can make an informed decision about whether to consent to a transfer of any or all of your obligations under this Agreement, you must provide us with details of the proposed transferee's financial solvency, qualifications, experience, competence and ability to perform those obligations, and any further details that we may reasonably request.

4.3 Exception for assignment to obtain finance

You may assign your right to receive payment from us under this Agreement where:

- (a) the assignee provides or will provide finance to you; and
- (b) the assignment is for the sole purpose of ensuring the continuation or obtaining of such finance.

4.4 Conditions of transfer of Agreement

We reserve the right to require reasonable conditions to be met before we give consent to a transfer or assignment. In particular, we may require that the proposed transferee or assignee enter into an agreement with us on terms and conditions similar to those set out in this Agreement, to the extent applicable to the proposed transfer.

4.5 Successors, assignees and transferees bound

This Agreement is to be binding on and exists for the benefit of us both respectively and our respective successors and permitted assignees or transferees, provided that we reserve the right to terminate this Agreement if there is any successor to you where we have reasonable

concerns regarding that successor's ability to comply with your obligations and the Quality Standards in this Agreement. Each such successor, assignee or transferee is to have the same respective rights and obligations as if it were named in this Agreement as a party.

5 Confidentiality and publicity

5.1 Confidentiality

(a) Prohibition on disclosure

Except as provided under this Agreement, neither of us will disclose any Confidential Information to any person. Either of us may publish this Agreement, except for any information within it that is expressly agreed in writing between us as being confidential, in any media, including publication on the Internet.

(b) Permission for disclosure

Either of us may only disclose Confidential Information:

- (i) to those involved in the provision of the Services or a Service User's clinical or care management, where necessary;
- (ii) to our respective professional advisors;
- (iii) where disclosure is permitted under this Agreement, including under the Audit provisions of Section I of this Agreement;
- (iv) which is required to be disclosed under any Crown Directions or Crown Funding Agreement;
- (v) which is already in the public domain without being in breach of this clause 5;
- (vi) in so far as it is required to be disclosed by law, including where we consider it necessary to disclose Confidential Information under the Official Information Act 1982 or otherwise under our public law obligations; or where disclosure of Confidential Information is ordered by a court and
- (vii) where the other party has consented in writing to such disclosure.

(c) Legal requirements

Each of us will ensure that Confidential Information is kept in accordance with any legal requirements. In particular, but without limiting the foregoing, any disclosure of information by either of us identifying any natural person must comply with the Health Act 1956, the Privacy Act 1993 and the Health Information Privacy Code 1994, as applicable.

(d) Audit

Each of us will ensure that Confidential Information is subject to user authorisation procedures and regular Audits.

5.2 Public statements

Where either of us intends making a public statement criticising the other, either directly or indirectly, that party must first notify the other of such an intention and discuss with the other the matters of concern in good faith. Nothing in this clause 5.2 prevents either of us discussing any matters of concern with our own employees, subcontractors, contractors, agents or other personnel or with our own advisors.

5.3 Use of name, logo or fact of relationship

Neither of us may use the other's logo, name or the fact that there is a business relationship between us either in any advertising or for any other promotional purpose without the prior written consent of the other.

6 Material Interest

6.1 Notifying material interest

You must notify us in writing immediately if:

- (a) you become an owner of, or have any material interest in, any other Provider's business or the business of any of your sub-contractors; or
- (b) you become aware that any of your employees is, or has become, an owner of, or have any other material interest in, any other Provider's business or the business of any of your sub-contractors; or
- (c) you become aware of anything else which might give rise to a conflict between your responsibilities under this Agreement and any other responsibilities or business or professional interests you have.

6.2 Definition of material interest

For the purposes of clause 6.1 of Section L above a "material interest" is expected to be a financial interest which would generally arise through beneficial ownership and, for that

reason, carry the ability to influence decision-making by the other Provider or sub-contractor in relation to the provision of health or disability services.

Section M. Other miscellaneous terms governing our relationship

1 Independent contractor

We both agree that you are engaged to provide the Services as an independent contractor to us, and not as an employee or agent. Consequently, under no circumstances will we be liable to pay, or be called upon by you to pay, any sums due to employees under law (such as holiday pay or sick pay) and you have no authority to act on our behalf.

2 Insurance

2.1 Insurance cover required

You must have insurance to an appropriate and reasonable extent, to cover your business and its assets against risks associated with the performance of and compliance with your obligations under this Agreement. You must maintain such insurance throughout the duration of this Agreement and for as long afterwards as is prudent to provide for circumstances that may arise in relation to this Agreement after the Termination Date.

2.2 Information

We may request, and you must promptly provide to us any information concerning the insurance maintained pursuant to clause 2.1 of Section M above.

3 Indemnity

3.1 Indemnity

You will indemnify us and keep us indemnified against all claims, losses, damages, penalties and reasonable costs and expenses (including all legal or other costs or expenses associated with the enforcement of this Agreement) but excluding any indirect or consequential loss, made or incurred by us that have been caused, either directly or indirectly, by your failure to comply with any provision of this Agreement, or the failure of anyone for whom you are responsible pursuant to this Agreement.

3.2 Contribution

Where we have contributed in some material way to the circumstances giving rise to the loss under clause 3.1 of Section M above, the level of indemnity due to us will be reduced to the extent of such contribution.

3.3 Other

Notwithstanding anything else in this Agreement, this clause 3 of Section M shall not apply where compensation for failure to comply with the relevant provision has been provided for elsewhere in this Agreement.

3.4 Effective after termination

This clause 3 of Section M will remain in full force and effect after the termination of this Agreement.

4. Information and Intellectual Property

4.1 Purpose and definitions

The purpose of this clause 4 is to give us all the rights we need to use and own the results of the Services, without the need for further consent. This clause shall survive the termination of this Agreement. In this clause:

Author's Rights means those rights given to an author in Part IV of the Copyright Act 1994 (including rights to identification and restrictions on certain uses of the work);

Information means all the outputs and deliverables produced in connection with the Services, including without limitation, all reports, papers, IT systems, databases, data, information, software, electronic documents, and recordings (including data held on individual Eligible Persons);

Intellectual Property (IP) Rights means copyrights, design rights, patents, trade or service marks (whether or not registered and including applications for registration) and all rights or forms of protection of a similar nature.

4.2 Your IP

We acknowledge that the Intellectual Property Rights that you own prior to you providing the Services remain your property. You grant us a non-exclusive, transferable, irrevocable licence to use your Intellectual Property Rights but only to the extent that is necessary for us to use and own the results of the services.

4.3 Your Ngā Mea Tikanga Me Ngā Taonga Māori

Nothing in this Agreement gives us ownership of your ngā mea tikanga me ngā taonga Māori.

4.4 Our IP

You acknowledge that the Intellectual Property Rights we own remain our property. We grant you a non-exclusive licence to use these Intellectual Property Rights, for the purpose of you performing your obligations under this Agreement.

4.5 Use not to infringe

You warrant that:

- (a) the creation and use of the Information, the assignment and licence of any rights to us under this Agreement and your performance of the Services will not infringe the rights of any person; and
- (b) you have, or will obtain, all necessary licences and consents required to perform the Services and your obligations under this Agreement (before you start to perform them), including the irrevocable waiver by all relevant persons of their Author's Rights in the Information in relation to its use by either of us.

4.6 Assistance in defending infringement claim

If any claim is made against us that our use of the Information infringes the Intellectual Property Rights of anyone, you will, at your cost, provide us with all reasonable assistance to defend the claim.

5. Transfer of Information to new NCSP service provider

- 5.1 We want to ensure that all Information that you use to provide the Services, (including information held on electronic, paper, tape and film media but excluding information such as staff personnel records) can be transferred to another provider so that the new Provider can continue providing the same Services without any loss of Information or Service function.
- 5.2 Within 90 days of receiving written notice from us, you must provide us, or to an organisation nominated by us, all Information that you use to provide the Services including but not limited to:
 - (a) Records you hold;
 - (b) data related to women's screening episodes and treatment at gynaecological colposcopy services;
 - (c) scheduling, administration and accounting information;
 - (d) schedules relating to services, Staff, equipment and other mechanisms used to deliver the Services; and
 - (e) all operating system and application system configuration settings and data.

- 5.3 You must provide all Information in a format and on the medium specified by us.
- 5.4 We may require you to provide multiple versions of the Information to ensure that the transfer is successful.
- 5.5 You must make your staff available to assist the extract, transfer, interpretation and successful import of the Information onto an information system specified by us.
- 5.6 We will reimburse you for reasonable staff costs incurred to extract, transfer, interpret and import the Information into an information system specified by us.
- 5.7 The Information required to provide the Services is our sole property. We authorise you to use the Information required to provide the Services for the purposes of providing the Services only. The Information used to provide the Services must not be used for any other purpose other than to provide the Services.
- 5.8 When this Agreement ends (for whatever reason) you will assist us to transfer the Information within your possession or control to us or to a Provider nominated by us in a manner that preserves the Information and its integrity or if it is agreed between us that it is more appropriate, you will store the Information and maintain its integrity on our behalf and will provide us, our nominees, agents and service providers with full and unlimited access to the Information when requested by us. You must ensure that the Information transferred or stored is of sufficient quality, clarity and completeness to enable us to understand it and use it for our purposes. If this Agreement is lawfully ended due to a breach by a party, then the party in breach will pay the costs of complying with this transfer clause, otherwise these costs will be shared equally.
- 5.9 This clause 5 of Section M survives termination of this Agreement.

6. Warranty

6.1 Warranty

Each of us warrants to the other that:

(a) **Information correct**

to the best of our knowledge and belief all material information provided to the other is correct and not misleading in any material respect;

(b) **No impairment**

there is nothing impairing or preventing either of us from carrying out our respective obligations under this Agreement;

(c) **Authorisation**

we have obtained all authorisations and have done all things necessary in order to enter into this Agreement and to perform its obligations under this Agreement; and

(d) **Expertise**

you have the expertise, experience, resources, capacity and ability to perform and discharge its obligations under this Agreement in accordance with its terms.

6.2 Warranties continuing

Each of the warranties in clause 6.1 of Section M above are deemed to be repeated continuously throughout the term of this Agreement and will remain in full force and effect after termination of this Agreement with respect to events occurring during the term of this Agreement.

6.3 Change of circumstances

If any of the warranties in clause 6.1 of Section M above are not true or become no longer true, each of us will, as applicable, inform the other of the change as soon as is practicable.

7. Compliance

7.1 Compliance with law

We both will comply with all statutory, regulatory and other legal requirements in so far as they are applicable to the performance of our respective obligations under this Agreement, including the Health Act 1956, the Health (National Cervical Screening Programme) Amendment Act 2004, the Cancer Registry Act 1993, the Privacy Act 1993 and the Health Information Privacy Code 1994 and the New Zealand Public Health and Disability Act 2000.

7.2 Compliance with request for information

Both of us will comply, within a reasonable timeframe, with any request for information that either of us is entitled to make pursuant to any legislation.

8. Waiver

8.1 Waiver

Either of us, as applicable, may by notice in writing to the other party waive a specific right conferred under this Agreement.

8.2 Failure to exercise right no waiver

Delay or failure to exercise a right does not constitute a waiver of that right.

9. Entire agreement

This Agreement constitutes the entire agreement and understanding between us, and supersedes and replaces all prior agreements and understandings between us in relation to the provision of the Services and NCSP Tests.

10 Enforceability

10.1 Severability

If any provision of this Agreement is found or held to be illegal, invalid or unenforceable, such determination shall not affect the remainder of the Agreement, which will remain in force.

10.2 Modification

If any provision of this Agreement is found or held to be illegal, invalid or unenforceable, we will each, if possible, take the steps necessary to make reasonable modifications to any such provisions to ensure that they are legal, valid or enforceable and, otherwise, such provisions are deemed to be modified to the extent necessary to ensure that they are legal, valid or enforceable.

11 Contracts (Privity) Act 1982

No person who is not a party to this Agreement may enforce any of the provisions of this Agreement. Nothing in this Agreement shall confer any benefit on Eligible Persons or on any other third party for the purposes of the Contracts (Privity) Act 1982 or otherwise.

12 Counterparts

12.1 Number of counterparts

This Agreement may be executed in any number of counterparts each of which is to be deemed an original, but all of which together are to constitute a single instrument. A party may enter into this Agreement by executing any counterpart.

12.2 Facsimile exchange

This Agreement may be executed on the basis of an exchange of facsimile copies and execution of this Agreement by such means is to be a valid and sufficient execution.

13 Governing law and jurisdiction

This Agreement is governed by the law of New Zealand. We both submit to the non-exclusive jurisdiction of the Courts of New Zealand.

14 Notices

14.1 Form of notice

Each notice, invoice or other communication that is required to be in writing under this Agreement is to show the Agreement Number and be made by facsimile, email, personal delivery or post at the facsimile number or address, and marked for the attention of the person or office holder (if any), designated for the relevant purpose by the addressee from time to time by notice to the other party. The initial details are set out on the cover of this Agreement.

14.2 Change of contact details

Any change to a party's contact details must be notified to the other party at least 20 Business Days before the change comes into effect.

14.3 When notice effective

No communication is to be effective until it is received by the addressee. A communication is deemed to be so received (where the addresser is not aware of any failure in the communication) in the case of:

(a) **Facsimile**

facsimile, on the Business Day on which it is sent or, if sent after 5pm in the place of receipt or on a non-Business Day, on the next Business Day;

(b) **Email**

email, on the Business Day on which it is sent or, if sent after 5pm in the place of receipt or on a non-Business Day, on the next Business Day;

(c) **Personal delivery**

personal delivery, when it is delivered;

(d) **Post**

post, on the third Business Day after posting by fastpost or airmail.

Section N. Failure to perform and termination of Agreement

Failure to perform

1 Actions available where failure to perform

Where either of us has failed to perform our respective obligations under this Agreement, the other party may act in accordance with this Section N. Except where express provision has been made in this Section, this Section does not limit the legal rights either of us may have against the other.

2 Where you have failed to perform

If you fail to perform any material obligation under this Agreement we may do one or more (or none) of the following:

- (a) seek specific performance of the Agreement;
- (b) withhold payment from you in accordance with clause 22 of Section G of this Agreement;
- (c) seek Default Interest from you in accordance with clause 21 of Section G of this Agreement;
- (d) make alternative arrangements for the provision of the Services in accordance with clause 4 of Section N below;
- (e) suspend or terminate this Agreement in accordance with clause 5 of Section N below;
- (f) seek damages,

except where the failure to perform is due to an Uncontrollable Event, which must be dealt with under clause 6 of Section N below.

3 Where we have failed to perform

If we fail to meet any material obligation under this Agreement, and we fail to remedy the failure within 20 Business Days of receiving from you written notice of the failure, you may, in addition to any other rights you may have under this Agreement or otherwise, do one or more (or none) of the following:

- (a) seek specific performance of the Agreement;
- (b) seek Default Interest from us in accordance with clause 21 of Section G of this Agreement;
- (c) seek damages from us;
- (d) terminate the Agreement on 30 days' written notice;
- (e) terminate the part of the Agreement that relates to the Services in respect of which our failure applies,

except where the failure to perform is due to an Uncontrollable Event, which must be dealt with under clause 6 of Section N below.

4 Alternative arrangements on failure to perform

4.1 Alternative arrangements on non-performance

Where you fail to perform any material obligation under this Agreement, or are in our reasonable opinion likely to do so, we may suspend your right to perform and claim payment from us for the performance of the relevant Services and we may make such alternative arrangements as are reasonably necessary for the supply of those Services during the period of your non-performance at your expense and risk provided that you will not be required to bear the risk of non performance of the relevant Services by another Provider in these circumstances.

4.2 Notice of suspension

Where we intend to act pursuant to clause 4.1 of Section N above, we will give you:

- (a) 30 days' written notice, during which you will have the opportunity to respond in relation to the suspension; or
- (b) such shorter notice as we consider reasonable in the interests of the health and safety of Service Users, in which case we will give you a reasonable opportunity to respond where this is possible.

After the conclusion of the period allowed for your response (if any), we may determine to withdraw the original notice by further notice to you or to let the original notice stand.

4.3 Payment for our costs

On our demand, you must pay or reimburse us for all reasonable costs we incur acting under clause 4.1 of Section N above. Where you fail to pay we may withhold under clause 22 of Section G of this Agreement, or set off under clause 23 of Section G of this Agreement against any amount that we owe you at any time, a portion of the payment for Services which is due to you equal to the amount of the costs incurred under this clause and will give you prior written notice of our intention to do so.

4.4 Reinstatement

Where we are satisfied on reasonable grounds that you are willing and able to perform the material obligations referred to in clause 4.1 of Section N above, we will give you written notice that you must resume performance.

4.5 Uncontrollable events

This clause does not apply where your failure to perform is caused by an Uncontrollable Event, which must be dealt with under clause 6 of Section N of this Agreement.

5 Suspension or termination for material failure to perform

5.1 Notice of failure

If we have reasonable grounds to believe that you have not met any material obligation under this Agreement, we may give you written notice:

- (a) setting out the details of the obligation we believe you have not met; and
- (b) where the failure can be remedied, giving you 30 days to meet the obligation and to demonstrate to our reasonable satisfaction that you have met the obligation; or
- (c) where the failure cannot be remedied, terminating this Agreement on the expiry of a period of 30 days, or such shorter period as we consider reasonable in the interests of the health and safety of Service Users.

5.2 Suspension

Notwithstanding anything else in this Agreement, where we have issued to you a notice under clause 5.1 of Section N above and where we have reasonable grounds to believe that the health or safety of any Service User is at risk, we may suspend your right and your obligation to provide the relevant Services for us while we investigate the issue.

5.3 Termination on 7 days notice

If after the 30 day period allowed under clause 5.1 of Section N above you have not demonstrated to our reasonable satisfaction that you have met the obligation, we may terminate this Agreement on 7 days' written notice, or such shorter period as we consider reasonable in the interests of the health and safety of Service Users.

5.4 Dispute

If you receive a notice under clause 5.1 of Section N above but you disagree that the obligation we believe you have not met is a material obligation, then you may refer the matter to mediation (but not arbitration) in accordance with Section J of this Agreement. Notwithstanding anything in Section J of this Agreement, where mediation is pursued under this clause 5.4 of Section N:

- (a) it must be completed within the 30 day period provided under clause 5.1 of Section N above;
- (b) where it is agreed that the relevant obligation is a material obligation you will have a further 30 days beyond the original 30 day period during which to meet the obligation;
- (c) where it is agreed that the relevant obligation is not a material obligation, the notice given under clause 5.1 of Section N above will have no further effect.

5.5 Immediate termination

If after the further 30 day period allowed under clause 5.4(b) of Section N above you have not demonstrated to our reasonable satisfaction that you have met the obligation, we may terminate this Agreement immediately on written notice.

5.6 Mediation

Where mediation under clause 5.4 of Section N above:

- (a) is not completed within the 30 day period, then mediation may continue, if we both agree, on such terms and conditions and for such further period as we both agree, provided that failing such agreement, clause 5.3 of Section N above applies as if the material responsibility had not been met within the original 30 day period under clause 5.1 of Section N above; or
- (b) is completed within the 30 day period but without agreement being reached, then you will have a further 30 days beyond the original 30 day period to meet the material responsibility.

5.7 Uncontrollable Events

This clause does not apply where your failure to perform is caused by an Uncontrollable Event, which must be dealt with under clause 6 of Section N below.

6 Uncontrollable Events

6.1 No default

If either of us is prevented from or delayed in performing our respective obligations under this Agreement by an Uncontrollable Event, the party directly affected by that Uncontrollable Event will not be in breach of the Agreement.

6.2 Notice of inability to perform

The party whose performance is directly affected by an Uncontrollable Event must promptly give written notice to the other specifying:

- (a) the nature of the circumstances giving rise to the Uncontrollable Event;

- (b) the extent of that party's inability to perform; and
- (c) the likely duration of that non-performance.

6.3 Duty to mitigate

The party whose performance is directly affected by an Uncontrollable Event must take all reasonable steps to avoid or reduce the impact of the Uncontrollable Event on the due performance of the Agreement. This clause 6 of Section N does not require a party to settle any strike, lock-out or other industrial disturbance.

6.4 Duty to resume performance

The party whose performance is directly affected by an Uncontrollable Event must resume due performance of its obligations under this Agreement as soon as is reasonably possible after the Uncontrollable Event ends or its impact is sufficiently reduced to allow due performance.

6.5 Alternative arrangements

Notwithstanding anything else in this Agreement, if you are unable to provide the Services because of an Uncontrollable Event, we reserve the right to and may make alternative arrangements for the supply of the Services during the period of your non-performance (and for such reasonable time afterwards as may be necessary to secure an alternative provider or providers at the time the alternative arrangement are entered into) as we see fit.

6.6 Variation of Services

If either of us is unable to perform an obligation under this Agreement for 30 days or more because of an Uncontrollable Event, both of us must seek to agree to what extent, if any, the affected Services can be varied and or continued by you.

6.7 Termination

If we cannot agree under clause 6.6 of Section N above within 5 Business Days of the end of the 30 day period, either of us may terminate the relevant Services upon at least 30 days' prior written notice.

Termination

7 Termination

Either of us may terminate this Agreement in accordance with our respective rights and obligations under this Section N.

8 Mutual agreement to terminate

We may both mutually agree to terminate this Agreement or any part of it. No agreement to terminate shall be effective unless it is in writing and signed by us both.

9 Our right to terminate

Notwithstanding that we both may be engaged in a process of dispute resolution, variation or renegotiation of this Agreement we may terminate this Agreement;

(a) **Material failure**

where you have failed to meet any material obligation under this Agreement, in accordance with clause 5 of Section N above;

(b) **Inability to perform**

where we have good reason to believe that you are unable, or will soon become unable, to carry out all of your obligations under this Agreement, immediately on written notice, subject to us Consulting with you first about the possibility of termination;

(c) **Disposal of business**

where you have disposed of, or have entered into any arrangement that will result in the disposal of, a substantial part of your business, property or assets that are required in order for you to be able to carry out your obligations under this Agreement, or the same are lawfully seized or appropriated, without our prior written consent, immediately on written notice;

(d) **Business failure**

where you are insolvent, you are unable to pay your indebtedness as it falls due, you stop payment to creditors generally, you have entered into any composition or other arrangement with creditors, or a receiver has been appointed over you assets or you are put into liquidation, or you are adjudged bankrupt, as the case may be, immediately on written notice;

(e) Illegality

where you commit any fraudulent or unlawful action that we consider on reasonable grounds will seriously affect your ability to perform your obligations under this Agreement, immediately on written notice;

(f) Uncontrollable Event

where an Uncontrollable Event occurs, in accordance with clause 6 of Section N above;

(g) Breach of warranties

where you breach any of the warranties in clause 6 of Section M of this Agreement, in accordance with clause 5 of Section N above;

(h) Breach of quality standards

where you fail to comply with the policy, quality and service standards and other requirements set out in clause 2.1 of Section F of this Agreement, in accordance with clause 5 of Section N above;

(i) Suspension or cancellation of accreditation or registration

where your IANZ accreditation or registration is suspended or cancelled, or you are denied IANZ accreditation, in accordance with clause 5 of Section N above, provided that where any of these events occur in respect of a particular NCSP Test(s), we may, at our option, cease to fund such tests under this Agreement rather than terminate the entire Agreement;

(j) Failure to provide records

where you fail to allow us or our Auditor access under clause 2.6 of Section I of this Agreement for the purposes of, and during the course of, conducting an Audit under Section I of this Agreement, in accordance with clause 5 of Section N above;

(k) Succession

where there is any successor to you in terms of clause 4.5 of Section L of this Agreement, immediately on written notice.

The matters described in paragraphs (g), (h), (i) and (j) above are deemed to be breaches of material obligations for the purposes of clause 5 of Section N above and, accordingly, clauses 5.4, 5.5 and 5.6 of Section N above do not apply to any such breaches.

10 Your rights to terminate

You may terminate this Agreement, or any part of the Agreement that relates to the Services in respect of which our failure applies:

(a) **Material failure**

in relation to material failure in accordance with clause 3 of Section N above;

(b) **Compulsory Variation**

in relation to a Compulsory Variation in accordance with clause 4.5 (b) of Section K of this Agreement;

(c) **Termination on notice**

where you give us 6 months' written notice. Your right to terminate on notice under this paragraph (c) will apply notwithstanding any other provision in this Agreement, including where we may both be engaged in a process of dispute resolution, variation or renegotiation of this Agreement;

(d) **Uncontrollable Event**

where an Uncontrollable Event occurs, in accordance with clause 6 of Section N above.

11 Alternatives to termination of Agreement

In the event that we become entitled to terminate this Agreement, as an alternative to terminating the Agreement, we may withdraw from the coverage of this Agreement and terminate the Service or Services relevant to the reason for termination, and cease payment for any such Services from the date of such withdrawal. In the event that we do so, you will continue to provide all other Services in accordance with this Agreement and, subject to our rights under clauses 22 and 23 of Section G of this Agreement or otherwise, we will continue to pay for those other Services.

12 Consequences of termination

Any termination of this Agreement pursuant to this Section N will not prejudice:

- (a) any other rights or remedies that either of us may have against the other arising out of any breach of this Agreement that occurred before termination; or
- (b) the operation of any clauses of this Agreement that are expressed or implied to have effect after termination.

Section O. Special terms

1 Nature of This Section

1.1 Special Terms Specific to You

This Section O contains special terms that are departures from, or additions to, the standard provisions in Sections A to N of this Agreement. These special terms are terms specific to you, your Provider type or the type of Services you provide.

1.2 Special Terms Prevail

The provisions in this Section shall apply notwithstanding anything in the remainder of this Agreement. Where there is a conflict between these special terms and any other terms in this Agreement, these special terms take precedence and apply over any other terms.

Schedule B1. Summary and history of this Agreement

Schedule B1 anticipates inserting a summary that tracks the history of this Agreement. This summary could indicate a list of variations to this Agreement, including the dates when the variations were executed.

Schedule C1. Service Specifications

1 Responsibilities of you and your supervising Pathologist(s)

- 1.1** You will be responsible, at all times, in respect of NCSP Tests and Services provided by you under this Agreement for:
- (a) the Services described in clause 2 of Section C of this Agreement
 - (b) the Health Education services specified in clause 4.5 of Section F of this Agreement;
 - (c) compliance with the requirements relating to incentives to Referring Practitioners, as specified in clause 6 of Schedule C1 below;
 - (d) the training and development of your staff, including Pathologists, performing the NCSP Tests, including demonstrated internal quality assurance specifically aimed at reducing false negative reporting for NCSP Tests;
 - (e) regular participation in multidisciplinary meetings with colposcopy services you provide the Services, in accordance with NCSP standards and which includes documentation of process and outcomes;
 - (f) the maintenance of strong and effective networks with Referring Practitioners, and provision of training and support for smear takers and specialists, including regular update sessions and advice on collection, storage and transport of Specimens to laboratories;
 - (g) the provision of advice to the Regional Service of the NCSP;
 - (h) participation in national NCSP network forums;
 - (i) provision of laboratory placements for Bachelor of Medical Laboratory Science graduates completing the Vocational Registration Programme in Cervical Cytology, subject to a suitable position vacancy;
 - (j) provision of placements for fourth year undergraduate Bachelor of Medical Laboratory Science students who are undertaking gynaecological cytology.
 - (k) provision of placements for Registrars undertaking gynaecological cytology and histology training;
 - (l) provision for Continuous Professional Development for the workforce in accordance with NCSP OPQS and Health Practitioners Competence Assurance Act 2003, and including the maintenance of competence, knowledge and awareness of best practice with respect to HrHPV testing as part of cervical screening;
 - (m) provision of support for the National Gynaecological Cytology Training School (or its equivalent) through the use of your laboratory facilities for education and training purposes; and
 - (n) support and advice to the NCSP regarding audit, research, evaluation and development.

- 1.2** You must ensure a supervising Pathologist or supervising Pathologists is/are responsible at all times in respect of Services provided by you under this Agreement for:
- (a) the IANZ accreditation and registration requirements in clause 2 of Section F of this Agreement;
 - (b) the NCSP Operational Policy and Quality Standards requirements in clause 2 of Section F of this Agreement;
 - (c) the professional and ethical standards in clause 4.4 of Section F of this Agreement;
 - (d) the provision of advice to, and for, Referring Practitioners and the reporting of the results of NCSP Tests to them; and
 - (e) the provision of HrHPV testing in accordance with the Guidelines for Cervical Screening in New Zealand available on www.nsu.govt.nz. HrHPV testing must be undertaken using a test which has been approved by an international approval body (for example FDA or CE marking), validated by the laboratory and be part of the IANZ accreditation accredited by International Accreditation New Zealand (IANZ);
 - (f) mechanisms for control of screening requests that are inconsistent with the Guidelines for Cervical Screening in New Zealand, particularly under 20 year olds;
 - (g) gynaecological cytology will be performed using liquid based cytology at no cost to Eligible Persons; and
 - (h) only one liquid based cytology product must be used per fixed laboratory site.
- 1.3** Multiple supervising Pathologists are individually responsible under this clause 1 of Schedule C1 of this Agreement.
- 1.4** Your supervising Pathologist(s) as identified to us in accordance with clause 7.1(a) of this Schedule C1 is/ are recognised by us as responsible under clause 1 of Schedule C1 of this Agreement.
- 1.5** Any changes in your supervising Pathologist(s) must 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, who meets the requirements in the IANZ Quality Service Standards for Medical Testing Laboratories and the NCSP OPQS. 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.

2 Reporting of results

- 2.1** You must comply with the reporting requirements specified within the NCSP Operational Policy and Quality Standards and this Agreement.
- 2.2** You must obtain approval from the NSU in writing of any significant changes in your method of reporting of results prior to any such changes taking effect.

- 2.3** You must use all reasonable endeavours to ensure you have systems in place from the Commencement Date to enable you to provide information on NCSP Test results to any Referring Practitioner in an electronic form that is compatible with the reasonable needs of the Referring Practitioner and you shall provide that information in such form where requested to do so by the Referring Practitioner.
- 2.4** You will use HL7 messaging according to the specifications in the NSU HL7 Implementation Guide for the exchange of result information between your laboratory and the NCSP-Register.

In particular this must include:

- (a) the participant's address which is contained with the PID (Patient Identification) within the sequence PID-11;
- (b) the participant's ethnicity, as provided by the Referring Practitioner, which is contained with the PID within sequence PID-10;
- (c) the health facility ID or Placer Facility ID which is contained within the OBR within sequence OBR-46; and
- (d) the health worker ID or Placer Facility ID which is contained within the OBR within sequence OBR-46.

Any results rejected by the NCSP Register must be reviewed and amended where appropriate and resubmitted to the NCSP Register.

- 2.5** When you report a cervical cytology result for a woman under 20 years you will advise the Referring Practitioner that the woman should not be having a routine (ie there are no specific clinical indications mentioned on the laboratory request form) screening cervical smear test until 20 years of age as per the Guidelines for Cervical Screening in New Zealand.
- 2.6** When you receive a request for a HrHPV test from a smear taker in primary care that is not in accordance with the Guidelines for Cervical Screening in New Zealand, you will advise the Referring Practitioner that the test will not be funded by the NCSP.

3 Eligible People and Services

- 3.1** Under this Agreement you will provide the Services at no charge to an Eligible Person referred to your Laboratory by Referring Practitioners for the tests listed in the NCSP Test Purchase List as being appropriate for that practitioner. It is the responsibility of the Referring Practitioner 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 Services. It is the responsibility of your Laboratory to determine whether HrHPV testing is required, where the result is ASC-US or LSIL and in accordance with the definition of HrHPV reflex testing as referred to in the Guidelines for Cervical Screening in New Zealand. There is an expectation by your Laboratory that the Referring Practitioner has explained to the Eligible Person the potential HrHPV reflex test that may be performed and that consent has been obtained.
- 3.2** A declaration, as agreed to by both of us, of the eligibility both of the Eligible Person being referred by the Referring Practitioner and of the service being requested by the Referring

Practitioner is to be included in your laboratory request forms in accordance with Section H clause 5.3(c). This declaration is to be signed by the Referring Practitioner. Both of us agree to work with Referring Practitioners to encourage them to sign this declaration.

- 3.3** The failure by the Referring Practitioner to complete a declaration regarding a patient's eligibility in accordance with clause 4.2 if Schedule C1 above does not, in itself, mean that the patient is ineligible.

4 Eligibility of Referring Practitioners

- 4.1** You must provide the Services under this Agreement at the authorisation and subsequent written request of:
- (a) any registered medical practitioner other than a Pathologist employed by you or who has an ownership interest in you. However, such a Pathologist will be eligible where he or she is also engaged in medical practice other than as a Pathologist and is acting in his or her capacity as a medical practitioner other than as a Pathologist, and is of the opinion after personal examination of a patient that it is necessary or advisable in the interests of the patient that the cervical screening laboratory diagnostic service be performed;
 - (b) a non-registered health worker who at a minimum complies with the standard 401 and training and continuing education requirements set out in Section 4 of the NCSP Operational Policy and Quality Standards;
 - (c) a registered midwife with a current annual practicing certificate, registered by the Midwifery Council of New Zealand under the Health Practitioners Competency Assurance Act 2003;
 - (d) a nurse assistant, enrolled nurse, registered nurse or nurse practitioner with a current annual practising certificate, registered by the Nursing Council of New Zealand under the Health Practitioners Competency Assurance Act 2003; and
 - (e) other persons who have appropriate registration or equivalent approval by their relevant professional body (as applicable), and who at a minimum comply with standard 401 and the training and continuing education requirements set out in Section 4 of the NCSP Operational Policy and Quality Standards.

5 Incentives to Referring Practitioners

- 5.1** You must not provide any Referring Practitioner or any person connected with a Referring Practitioner either directly or indirectly with any incentive or inducement.
- 5.2** An incentive or inducement includes, without limitation:
- (a) the provision of goods or services (excluding goods and services provided under this Agreement) to a Referring Practitioner or a person connected to a Referring Practitioner where those goods or services are capable of being expressed in monetary terms and are provided without any corresponding obligation on the Referring Practitioner or connected person to pay a reasonable price for the goods or services;

- (b) the payment of any money to, or on behalf of, a Referring Practitioner, or any person connected with a Referring Practitioner,

provided that the following is not an incentive or inducement:

- (c) the provision of the following items to Referring Practitioners free of charge, in quantities reflecting regular patterns of usage:
 - (i) LBC vials;
 - (ii) cervical brushes and brooms and spatulas;
 - (iii) slides, fixatives and slide carriers;
 - (iv) biohazard/plastic bags, rubber bands;
 - (v) request forms, telephone request forms, laboratory handbook, antibiotic handbook and other laboratory information documents;
 - (vi) other similar, small consumables;
- (d) training in or quality assurance of Specimen collection techniques;
- (e) the provision of computer software where the software is specific to the ordering of NCSP Tests or the receiving of NCSP Test results; and
- (f) payment to the provider of electronic mail services for costs of electronic transmission of NCSP Test results.

5.3 For the avoidance of doubt, the provision of the following or the making of a payment relating to the following is an incentive or inducement:

- (a) fax equipment, including fax machines;
- (b) computer equipment;
- (c) computer programmes and network services, except as allowed under clauses 5.2(e) and (f) of Schedule C1 above;
- (d) medical equipment, excluding the items listed in clause 5.2(c) of Schedule C1 above;
- (e) office equipment, excluding the items listed in clause 5.2(c) of Schedule C1 above;
- (f) motor vehicle and accessories;
- (g) conference fees;
- (h) travel expenses;

- (i) gifts, other than minor tokens of goodwill, not exceeding \$50 per annum per practitioner/provider, in value;
- (j) collection facilities, other than those provided under clauses 5.4(a) or (b) of Schedule C1 below; and
- (k) collection and/or transportation of samples, other than a payment under clause 5.6 of Schedule C1 below.

5.4 Collection facilities are not an incentive or inducement if:

- (a) the facilities are not shared with a Referring Practitioner; or
- (b) the facilities are shared with a Referring Practitioner but are:
 - (i) provided for clearly demonstrable reasons of economy or service effectiveness;
 - (ii) all transactions between you and the Referring Practitioner(s) are conducted at arm's length; and
 - (iii) a reasonable payment for all services provided within the facility (such as cleaning) is made to or by the Referring Practitioner(s) at current market rate.

5.5 For the purpose of this clause 6, "collection facilities" and "facilities" means physical rooms or buildings used for the collection of laboratory samples or Specimens.

5.6 A payment to a Referring Practitioner for the collection and/or transportation of samples is not an incentive or inducement if:

- (a) the payment is for the actual costs of providing the collection and/or transportation of samples; and
- (b) where such costs are identifiable, the payment is an amount equal to those costs; or
- (c) where such costs are not identifiable, the payment is an amount that reflects a fair and reasonable reimbursement of the Referring Practitioner's costs, having regard to the Referring Practitioner's use of labour, premises and consumables and to any other payments made by us or patients for the collection and/or transportation of samples,

provided that the payment for collection and/or transportation:

- (d) is on a 'per patient' and not a 'per sample' basis;
- (e) is only for actions, in relation to the collection of samples, which you would ordinarily carry out if the Referring Practitioner or his or her staff did not do so;
- (f) is not for actions which the Referring Practitioner or his or her staff would ordinarily carry out, and which could be covered by a separate payment for those services, such as the completion of a referral form;

- (g) is only to cover services reasonably provided by the Referring Practitioner or his or her staff to the extent that such services are not already funded by us;
- (h) does not result in the Referring Practitioner in any other way profiting from providing the collection and/or transportation.

For the avoidance of doubt, our ability to audit you and any Records or other information under this Agreement includes audit for the purpose of verifying your compliance with your obligations under this clause.

5.7 If you provide any Referring Practitioner or any person connected with a Referring Practitioner either directly or indirectly with any incentive or inducement or encourage a Referring Practitioner to use laboratory services inappropriately, you will forfeit any right to receive any fee, benefit or payment in respect of the relevant Referring Practitioner(s) and you agree to indemnify us in accordance with clause 3.1 of Section M of this Agreement. We will provide you with a reasonable opportunity to comment on any allegation that you have provided an incentive or inducement before the forfeiting of any fee, benefit or payment under this clause. This does not derogate in any way from clause 9 of Section N of this Agreement.

5.8 If you are providing any incentive or inducement to a Referring Practitioner or a person connected with a Referring Practitioner at the Commencement Date no payment will be forfeited if the incentive or inducement has been removed or has ceased to be an incentive or inducement by reason of payment or otherwise equivalent to the incentive or inducement (any such payment being by the Referring Practitioner or connected person, as applicable, to you) within 3 months from the Commencement Date.

6 Pathologist generated tests

Where a Pathologist believes that, for the purposes of an accurate diagnosis for an individual Eligible Person, a NCSP Test which has not been ordered by the Referring Practitioner is also required, the Pathologist may undertake a NCSP Test for that Eligible Person.

7 Reporting to the NSU

7.1 You must provide the following information in a narrative form on an annual basis (i.e. for the 12 month period ending 30 June), within four weeks of the end of each year:

- (a) name of the supervising Pathologist/s;
- (b) name of the cytopathologist responsible for the cytopathology service and their cytology experience;
- (c) name of the senior registered cytoscientist and their cytology experience;
- (d) name of the primary and secondary screening staff, in a format specified by the National Screening Unit;

- (e) name of the virologist/microbiologist responsible for HrHPV testing and their experience;
- (f) description of the status of the Laboratory's IANZ assessment and identification of any changes in its accreditation status; and
- (g) description of the gynaecological cytology and gynaecological histology ongoing education and work evaluation processes you have in place for enhancing competency and supervision.

7.2 You must report to the National Screening Unit:¹

- (a) in accordance with the NCSP Monitoring Technical Specification for Laboratories and the NCSP OPQS according to the NCSP Laboratory Reporting Template, at the frequencies indicated; and
- (b) any additional monitoring information required by the NSU, in accordance with clause 1.6 and 1.7 of Section H of this Agreement

¹ The information will be used by the National Screening Unit and the NCSP monitoring group to assist in monitoring your performance and the performance of the NCSP.

Schedule F1. IANZ Quality and Service standards for Medical Testing Laboratories

The version of the International Accreditation New Zealand (IANZ) ISO/IEC 15189:2007 Medical Laboratories - Particular Requirements for Quality and Competence in force as at the date of this Agreement and which may be varied from time to time, is made available to you by IANZ by way of a separate document and is incorporated by reference pursuant to this Agreement.

Schedule F2. NCSP Operational Policy and Quality Standards

The version of the NCSP Operational Policy and Quality Standards that is in force is available on www.nsu.govt.nz and is incorporated by reference pursuant to this Agreement.

Schedule G1. NCSP Test Purchase List

1 Definitions

The 8 columns in the NCSP Test Purchase List in clause 5 are defined as follows.

- (a) **Test Code** means the identification code listed in column 1 for each individual NCSP Test.
- (b) **Test Description** means each individual NCSP Test listed in column 2.
- (c) **Price per test (GST excl.)** means the prices (GST exclusive) which we will pay you to carry out one completed testing procedure for the specified NCSP Test. The price per test (GST exclusive) is listed in column 3.
- (d) **Maximum Number** means the maximum number of a specified NCSP Test, which we will pay you to carry out for any individual patient on any individual sample. The maximum number of tests is listed in column 4.
- (e) **CST** means a cervical smear taker, as defined in clause 4.1 of Schedule C1 of this Agreement, who is listed as a Referring Practitioner type (where appropriate for each individual NCSP Test) in column 5.
- (f) **MP** means any registered medical practitioner, as defined in clause 4.1 of Schedule C1 of this Agreement, who is listed as a Referring Practitioner type (where appropriate for each individual NCSP Test) in column 6.
- (g) **Midwife** means a registered midwife, as defined in clause 4.1 of Schedule C1 of this Agreement, who is listed as a Referring Practitioner type (where appropriate for each individual NCSP Tests) in column 7.
- (h) **Nurse** means a registered nurse, as defined in clause 4.1 of Schedule C1 of this Agreement, who is listed as a Referring Practitioner type (where appropriate for each individual NCSP Test) in column 8.

2 Provision of NCSP Tests

- 2.1** You will carry out NCSP Tests upon receipt of a referral request from a Referring Practitioner.
- 2.2** If a health professional who is not a Referring Practitioner refers a sample to you for laboratory analysis, we will not pay you for carrying out that test.

3 Diagnostic Purpose

We will pay you only for NCSP Tests which you carry out on referral from Referring Practitioners where the test:

- (a) is required for cervical screening diagnostic or monitoring purposes and relates to the identification and treatment of medical conditions for individual Eligible People;
- (b) is part of the recognised NCSP screening programme.

4 Amending NCSP Test Purchase List

We may at any time amend the NCSP Test Purchase List (excluding prices), whether for purposes of national consistency or otherwise, by adding new NCSP Tests to, or removing existing NCSP Tests from, that list, provided that we carry out such Consultation as we consider appropriate for a period of not less than 21 days. Following such Consultation in terms of this clause 4, we will notify you not less than 30 days before any amendment of the NCSP Test Purchase List taking effect.

5 NCSP Test Purchase List

| Test Code | Test Description | Price per test (GST excl) | Maximum Number | Referring Practitioner Type | | | |
|-----------|--|---------------------------|----------------|-----------------------------|----|---------|-------|
| | | | | CST | MP | Midwife | Nurse |
| N | NCSP - Cytology and Morbid Histology | | | | | | |
| N01# | Cytological examination of cervical smears (per accession) | \$27.54 | 1 | Y | Y | Y | Y |
| N02* | NCSP Histology (per accession) | \$73.67 | 1 | | Y | | |
| N03* | Immunohistochemistry, first stain | \$62.51 | 1 | | Y | | |
| N04* | Immunohistochemistry, subsequent stains (up to a maximum of 5 in total) | \$31.26 | 4 | | Y | | |
| N05* | Immunocytochemistry, first stain | \$62.51 | 1 | | Y | | |
| N06* | Immunocytochemistry, subsequent stains (up to a maximum of 5 in total) | \$31.26 | 4 | | Y | | |

| Test Code | Test Description | Price per test (GST excl) | Maximum Number | Referring Practitioner Type | | | |
|-----------|---|---------------------------|----------------|-----------------------------|----|---------|-------|
| | | | | CST | MP | Midwife | Nurse |
| N07* | NCSP Histology – frozen section during surgery, extra | \$129.42 | 1 | | Y | | |
| N08 | HrHPV testing for the presence or absence of a pool of HrHPV oncogenic genotypes (collectively, not individually) using an accredited test. | \$42.48 | 1 | Y | Y | Y | Y |
| N09# | Cytological examination of cervical smears (per accession) using liquid based cytology. | \$29.74 | 1 | Y | Y | Y | Y |

* NCSP Tests falling within the NCSP test codes of N02 to N07 codes will be generated for procedures, where appropriate, by using the 1986 or 1993 SNOMED Topography code T81000 (vagina), T82000 (vagina) or T83200 (cervix, including endocervix and exocervix).

Only one Test Code can be claimed if a single patient has both a conventional cytology test as well as a liquid based cytology test on the same accession.

| |
|---|
| Schedule G2. Claiming restrictions on NCSP Tests |
|---|

| Test Code | Test Description | Gender limited to | Minimum age for test | Pre-requisite test | Test Exclusions |
|-------------|---|-------------------|----------------------|--------------------|-----------------|
| | | | | | Tests excluded |
| N01# | Cytological examination of cervical smears (per accession) | Female | | | N09 |
| N02* | NCSP Histology (per accession) | Female | | | |
| N03* | Immunohistochemistry, first stain | Female | | N02 | |
| N04* | Immunohistochemistry, subsequent stains (up to a maximum of 5 in total) | Female | | N02 | |
| N05* | Immunocytochemistry, first stain | Female | | N09 | |
| N06* | Immunocytochemistry, subsequent stains (up to a maximum of 5 in total) | Female | | N09 | |
| N07* | NCSP Histology - frozen section during surgery, extra | Female | | N02 | |
| N08 | HrHPV testing for the presence or absence of a pool of HrHPV oncogenic genotypes (collectively, not individually) using an accredited test. | Female | | N09 | |
| N09# | Cytological examination of cervical smears (per accession) using liquid based cytology. | Female | | | N01 |

* Histology specimens, which contain a cervical or vaginal component (as defined in the National Cervical Screening Programme Operational Policy and Quality Standards), including histology specimens associated with cervical component of total hysterectomies.

Only one Test Code can be claimed if a single patient has both a conventional cytology test as well as a liquid based cytology test on the same accession

Schedule G3. Laboratory system requirements

1 Claims for Services Provided.

A claim consists of the following:

- (a) a Claim Summary Form (in the format detailed below), containing aggregate claim data as well as certification as to the validity of the claim in accordance with clause 7.3 of Section G of this Agreement; and
- (b) an electronic file containing individual records of claim data (in the format detailed below).

2 Claim Summary Form

Laboratory Diagnostic Services Claim Summary



Claimant's Claim Reference Number

Agreement Reference Number

Payee Number

Claimant's/Laboratory Name

Date(s) of Service
(inclusive)

To

Summary

| | |
|-------------------------------|-------------------------|
| Number of Patients | <input type="text"/> |
| Number of Tests | <input type="text"/> |
| Total (Excluding GST) | \$ <input type="text"/> |
| GST | \$ <input type="text"/> |
| Total Claimed (GST Inclusive) | \$ <input type="text"/> |

| Health Benefits Use Only | | |
|--------------------------|----------|------|
| Total Fees | | |
| PATS | | |
| TESTS | | |
| Certified | Initials | Date |

Certification - Authorised Officer

I certify that this claim for fees for laboratory services under the agreement specified above between ourselves and the Ministry of Health is a valid and accurate claim made under the terms and conditions of the agreement.

| | | | |
|-----------|-----|------|---------------------|
| Signature | / / | Date | Name (please print) |
|-----------|-----|------|---------------------|

Certification - Supervising Pathologist

I certify that the tests covered by this claim were completed to the service specifications detailed in the contract with the Ministry of Health and that my responsibilities as specified in the contract have been fulfilled with regard to the tests for which fees are claimed.

| | | | |
|-----------|-----|------|---------------------|
| Signature | / / | Date | Name (please print) |
|-----------|-----|------|---------------------|

3 Electronic Claim Data File

Input Disk Format

- (a) Claim data is received on standard 3.5 inch double density or high density diskettes formatted under MS DOS 3.20 or higher.
- (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 95 bytes long. Numeric fields are not 'packed' nor any other non-ASCII format.

Input Record Format

| Field Name | Data Type | Length in Bytes | Start Position | Mandatory Data |
|-----------------------------------|--------------|-----------------|----------------|----------------|
| Claim 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 |
| Claimed Fee | Numeric | 9 | 31 | 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 |
| Referring Practitioner Identifier | Alphanumeric | 8 | 59 | Yes |
| PAN/PIN Number | Numeric | 6 | 67 | * 2 |
| Practitioner – Pathologist | Alphanumeric | 8 | 73 | * 3 |
| Agreement Reference Number | Numeric | 8 | 81 | Yes |
| Payee Number | Numeric | 6 | 89 | Yes |

*1 Mandatory for specified tests otherwise mandatory if supplied by referrer

*2 Mandatory if supplied by referrer

*3 Mandatory if pathologist performing additional test(s)

- (d) A claim will comprise of one record for each schedule item requested on a referral form. Repeats of the same schedule item 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.
- (e) All schedule items on a referral MUST be completed before a claim is made, and all submitted in the one claim.
- (f) All fees claimed are to be GST exclusive.

Referring Practitioners

- (a) Sector Services will hold a list of Referring Practitioners. These referrers will be identified by the 'Referring Practitioner' field. A list of Referring Practitioners will be maintained by Sector Services.
- (b) Sector Services will advise Laboratories of existing Referring Practitioners and also of new referrers. Any NCSP Tests claimed under a Referring Practitioner number, which has not been formally notified by an appropriate professional body to Sector Services, will be rejected by Sector Services.
- (c) Locums are to use their own MCNZ number when ordering NCSP Tests. Further to this, any practitioner who is part of a budget-holding or other type of agreement that has an allocated PAN or PIN number must ensure that this number is shown and the Laboratory must capture this along with other referral details.
- (d) If additional NCSP Tests are deemed necessary by the Laboratory's Pathologist and have not originally been ordered by the Referring Practitioner, the new tests are to be claimed with the Pathologist's MCNZ number inserted in the Practitioner - Pathologist field.

4 Detailed Description and Format of Fields

(a) Claim Identification

A unique code that identifies a particular claim.

Format is XXYY9999 where XX is Laboratory identifier, YY is financial year, 9999 is a sequential number to identify a claim within a financial year.

(b) Referral Identification

A unique identification code for each referral.

Format is XXnnnnnnnn where XX is the Laboratory identification (as in Claim id) and nnnnnnnn is the unique number assigned to the referral, filled with leading zeros.

(c) Test Code

The unique 3 alphanumeric characters identifying a clinical test as defined in the NCSP Test Purchase List.

Only one record may exist for a particular test in a referral.

(d) Date of Service

The date the referred Specimen was initially submitted to the Laboratory. There can only be one date of service for a referral.

(e) Must be a valid date.

Format is DDMCCYY 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.

(f) Number of Tests

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

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

(g) Claimed Fee

The cost claimed by the Laboratory for carrying out the scheduled items and is equal to the approved cost of the item times the Unit of service number. This amount is GST exclusive.

Format is 9999999.99 with no period or dollar sign, and leading and trailing zeros inserted i.e. \$29.50 will be entered as 02950, \$1.00 will be 00100.

(h) Date of Birth

The Eligible Person's date of birth.

(i) Must be a valid date.

Format is DDMCCYY 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.

(j) Gender

The gender of the Eligible Person clinically tested.

F = Female, M= Male, U = Unknown

(k) NHI Number

The National Health Index identifier for the Eligible Person being clinically tested.

Format is 7 alphanumeric characters (ABC1234), left justified with spaces inserted if NHI is not available.

(l) CSC Card

The community services card (CSC) as assigned by NZ Income Support Services for the Eligible Person 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 Referring Practitioner, but the field must be included in each claim record.

(m) HUHC Card

The high use health card number (HUHC) is assigned by Sector Services for the Eligible Person being clinically tested. Format is 1 alpha character, (Y = yes Eligible Person has HUHC, N = no Eligible Person does not have HUHC). The data required for this field is currently non-mandatory unless supplied by a Referring Practitioner, but the field must be included in each claim record.

(n) Referring Practitioner Identifier

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 I.E.

M Medical Council of NZ

N Nursing Council of NZ

L Lay Cervical Smear Taker (as defined by the National Cervical Screening Programme)

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

Format is 8 alphanumeric characters (M12345), left justified, with trailing spaces inserted.

(o) PAN/PIN Number

The Practice Identifier Number allocated by the Ministry of Health to Independent Practitioner Association (IPA) or other referring group to indicate budget holding practices.

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

(p) Practitioner - Pathologist

The MCNZ code associated with the Laboratory's Pathologist when performing additional NCSP Tests on behalf of the referring provider. This code to be inserted in association with the referring provider's details when additional NCSP Tests are ordered by the Pathologist.

Format is 8 alphanumeric characters and spaces inserted if not applicable. This is exactly the same format as the Referring Practitioner ID.

(q) Agreement Reference Number

A unique number allocated by us relating to a particular Agreement with you for the provision of Services.

Format is 8 numeric characters where a hyphen differentiates the Agreement Reference Number from the Agreement version e.g. 999999-99, left justified, with trailing spaces inserted.

(r) Payee Number

A unique number allocated by Sector Services to identify the location of payment.

Format is 6 numeric characters and must be included in each claim record, left justified, with trailing spaces inserted.

Schedule G4. Business Rules for the Laboratory System

For the purpose of these business rules the following definitions apply:

- (a) Referring Practitioner may be, (in accordance with clause 5.1 of Schedule C1 of this Agreement), a cervical smear taker, a registered medical practitioner, a registered midwife, a registered nurse or other practitioner type (who at a minimum complies with standard 401 and the training and continuing education requirements set out in Chapter 4 of the NCSP Operational Policy and Quality Standards).
- (b) Referral Identification (ID) is a unique code for each referral.
- (c) Claim Identification (ID) is a unique code generated by a Laboratory to identify a particular claim submitted to Sector Services.
- (d) A Referral is a request for NCSP Tests from a Referring Practitioner submitted to a Laboratory.
- (e) PIN/PAN is allocated by us to IPAs or other referrer groups to indicate budget holding practices.

1. General Rules

- 1.1 Any records with invalid data formats or an invalid claim identifier will be rejected.
- 1.2 All scheduled tests on a referral must be completed before the claim is made, and all submitted in the one claim.
- 1.3 If the total number of Eligible Persons, total number of tests or the total amount claimed varies by 5% or greater compared with the claim summary then the whole claim is rejected.
- 1.4 To assist in claims tracking, Laboratories must allocate to each claim a unique sequential number. If a claim number in the sequence is not used or submitted to Sector Services, Sector Services should be notified. If a claim number is not in sequential order and no notification has been given to Sector Services, the claim will be rejected.
- 1.5 Before a claim sequence used by the Laboratory is changed, Sector Services must be notified of the last claim in the old sequence and of the first number of the new sequence. (For example: When the last claim produced on 30 June 1995 is numbered 95324 and the first claim for July 1996 is 96001).
- 1.6 Referral numbers used by Laboratories to identify each referral must be unique. These numbers are not to be recycled either within a year, or from year to year within any consecutive three year period.
- 1.7 Claims for NCSP Tests must be first submitted within 3 months following the date of service otherwise the claim is automatically rejected unless a submission in terms of clause 1.8 of Schedule G4 below is made to Sector Services with the claim.

- 1.8 Where a Laboratory can establish satisfactory grounds that a problem occurred within its claiming systems which delayed the making of a claim, Sector Services will receive a claim submitted separately more than 3 months after the date of service for the tests being claimed for. Sector Services will refer the submission and process such a claim on the written authority of the National Screening Unit (NSU).
- 1.9 Rejected claims or referrals must be resubmitted separately within a month following advice of rejection by Sector Services. Rejected claims must be submitted with the same claim number, rejected referrals must be submitted with the same referral number but in a different claim.
- 1.10 No claims will be accepted under any circumstances for tests submitted for the first time more than twelve months following date of service.
- 1.11 At present some fields submitted within a claim are non-mandatory or are only mandatory where relevant test restrictions apply. Where a referrer includes these non-mandatory fields of their own volition on the laboratory request form, the Laboratory must record these fields and include these data as part of their claim for that referral.
- 1.12 The NSU will determine which tests may be ordered by each referring provider group.

2. End of Month Procedures

- 2.1 Laboratories are required to 'cut-off' cleanly and send in a claim at the end of a month that covers dates of services provided up to and including the last day of the month. As a minimum requirement, each Laboratory must make at least a monthly claim that meets these end of month 'cut-off' requirements.
- 2.2 The last claim for the month must be received by Sector Services no later than midday on the third working day of the new month. Sector Services will record this last claim with the date of receipt and General Ledger date being the last day of the month. This will ensure a claim received in the new month but produced and billed in the prior month is posted to the month of production. This assists in reconciliation both for accrual purposes and for reconciliation of Sector Services Laboratory System data to Sector Services Accounts Payable data.

3. Claim Validations

- (a) All tests will be validated using the NCSP Test code rules, including pricing, that were current at the date of service.
 - (b) If prices for NCSP Tests are altered in the NCSP Test Purchase List, Laboratories should claim as normal and Sector Services will make price adjustments and pay accordingly. Full advice of alterations will be supplied by Sector Services. Rule 1.4 above shall be suspended in these circumstances only with regard to variance of prices paid per test and only for a maximum of 3 months following any price changes.
- 3.2 Tests will be rejected if any one of the following validation tests fail:
- (a) All mandatory fields must contain data. Zeros count as data in mandatory fields. Data which is non-mandatory in a field (e.g. HUHC and CSC data) should be represented by spaces.

- (b) The test exist in the NCSP Test Purchase List.
 - (c) Where date of birth (DOB) is mandatory for a test, the age of the Eligible Person (in years and calculated from the date of birth of the Eligible Person) must be in the allowable range for that test.
 - (d) The gender of the Eligible Person is not equal to the excluded gender of that test.
 - (e) The number of times the test was claimed within the referral is less than or equal to the maximum allowed for that test.
 - (f) The required prerequisite test(s) exist(s) within this referral and has/have not itself/themselves been rejected.
 - (g) The excluded tests are not present on this referral.
 - (h) The NCSP Test is allowed to be ordered by that referrer.
 - (i) The Referring Practitioner Identifier is valid and exists on the Sector Services table of referrers.
 - (j) The Referring Practitioner is a valid referrer.
 - (k) A NCSP Test code may only be claimed once in each claim line for each Eligible Person referral (except in the case of a pathologist ordered tests - see below). Where there is more than one test claimed under a single NCSP Test code, the number of tests claimed is recorded in the field called "number of tests".
 - (l) Where new or additional NCSP Tests are initiated by the pathologist, these are to be identified as a separate record within the claim. All items within the record remain the same as if the referring practitioner had initiated the test and in addition, the field "Practitioner - Pathologist" must contain the pathologist's MCNZ number.
 - (m) The referral number, date of service, test code and Practitioner - Pathologist combination does not exist for NCSP Tests previously claimed by the same Laboratory.
 - (n) The Referrer must be an individual and not a group or organisation, unless there is a departure approved in writing by NSU.
 - (o) If the PIN/PAN is supplied, this must exist within the approved list of PIN/PANs as notified by the Ministry of Health to Sector Services.
 - (p) The Agreement Reference Number is valid and active.
 - (q) The Payee Number is valid and active.
- 3.3 Note that the fee claimed for the NCSP Test should be equal to the number of times the test was taken multiplied by the allowable cost of the test. If not, Sector Services will adjust the claim payable for this test to reflect the calculated figure.
- 3.4 All NCSP Tests within a referral are rejected if any one test is rejected in that referral.