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## **Concept of Operations**

### **e-Pathology Request-Test-Report Cycle**

Version 2.0 — 9 November 2010

Final

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0.5	NEHTA Architecture team	Subject Matter Review	To verify that the content of the document is architecturally and operationally consistent with NEHTA's strategy.
0.6	NEHTA Head of Solutions Development	Fit for Purpose Review	To verify that the document is appropriate and of the standard required for its review by selected stakeholders.
0.7	Owen Smalley, Department of Health ACT; and Co-chair, Diagnostic Services Reference Group (DSRG)	Subject Matter Review	To verify that the document proposes clinical/business processes and conceptual architecture which are appropriate for the e-Pathology Request-Test-Report cycle.
0.8	Members of the Diagnostic Services Reference Group*	Subject Matter Review	To verify that the document proposes clinical/business processes and conceptual architecture which are appropriate for the e-Pathology Request-Test-Report cycle.
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0.9	Members of the e-Pathology ConOps Tiger Team^	Subject Matter Review	To verify that the document proposes clinical/business processes and conceptual architecture which are appropriate for the e-Pathology Request-Test-Report cycle.
	NEHTA Policy and Privacy	Privacy Review	To verify that privacy laws and policy are appropriately integrated into the design of e-health solutions.
0.9.1	NEHTA Head of Solutions Development	Fit for Purpose Review	To verify that feedback from the review of version 0.9 has been appropriately incorporated within the document.
0.9.2	Members of the Diagnostic Services Reference Group*	Endorse	To verify that the document is fit for its purpose based on the appropriate clinical and non-clinical input having been obtained during

Version	Name	Role	Purpose
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1.1	NEHTA Head of Solutions Development	Fit for Purpose Review	To verify that feedback from the review of version 1.0 has been appropriately incorporated within the document and the document is of the standard required for its purpose.

\* Refer to Appendix A.1 for further details

^ refer to Appendix 0 for further details.

## Document Authorisation

This document has obtained the following approvals and endorsements:

Version	Name	Authorisation	Date
2.0	Paul Williams Head of Solutions Development	Approved	9 November 2010
2.0	Diagnostic Services Reference Group*	Endorsed	9 November 2010

\* Refer to Appendix A.1 for further details

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# Preface

## Document Purpose

The purpose of this document is to describe the high-level clinical/business processes and conceptual architecture which NEHTA has developed for the pathology Request-Test-Report cycle, in the context of the e-Pathology Future State which has been articulated by pathology stakeholders. The document identifies the ongoing benefits for participants within the Australian health sector which would be provided by widespread adoption of clinically-validated specifications for the e-Pathology Request-Test-Report cycle, and describes its workings, its possible implementation and its key policy and privacy considerations.

## Intended Audience

This document should be read and understood by:

- Consumers, clinicians, administrative and IT staff involved with the pathology Request-Test-Report cycle;
- Organisations which provide pathology services;
- Vendors of software involved in the pathology Request-Test-Report cycle;
- The Department of Health and Ageing (DoHA);
- Jurisdictional departments of health;
- Medicare Australia;
- NEHTA Clinical Leaders;
- NEHTA Diagnostic Services Reference Group; and
- NEHTA Architecture and Technology Reference Group.

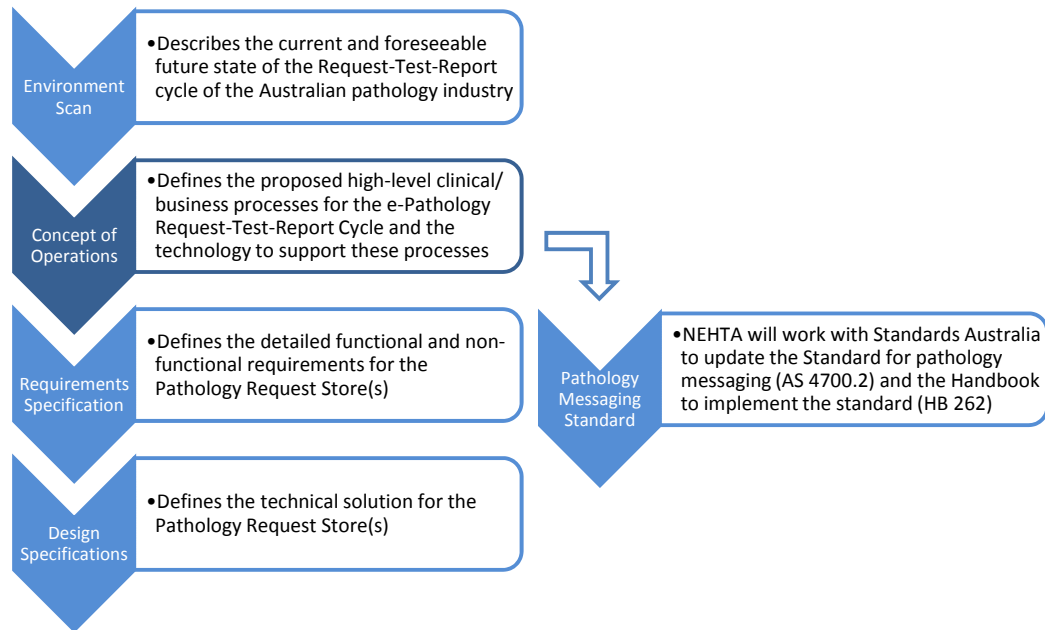
## Approach

This document was developed collaboratively with a sub-group of members of the Diagnostic Services Reference Group\*, and was refined during the course of nine quality reviews before being published in draft form for public comment. The document was further refined in response to the 12 submissions received during the external review period and has been published as 'Final' with regard to NEHTA's current work on the e-Pathology Request-Test-Report cycle.

\* refer to Appendix A.1 for further details.

## Document Context

This document is the second in what will be a set of documents which will be delivered by NEHTA for the e-Pathology Request-Test-Report cycle.



This document will be an input to the revision of the pathology messaging Standard (AS 4700.2) and the Handbook (HB 262) for implementation of the Standard by Standards Australia.

\* refer to Appendix A.1 for further details.

## Definitions, Acronyms and Abbreviations

For lists of definitions, acronyms and abbreviations, see the Definitions section at the end of the document, on page 24.

## References and Related Documents

For lists of referenced documents, see the References section at the end of the document, on page 26.

# 1 e-Pathology Overview

## 1.1 Background

NEHTA's e-Pathology Program is responsible for working with stakeholders to develop and implement clinically-endorsed specifications and supporting material required to enable the secure exchange of reliable and meaningful pathology Requests and Result Reports between healthcare professionals. This section describes:

- The core capabilities of the e-Pathology Future State, as defined by pathology stakeholders;
- The key drivers for e-Pathology; and
- The rationale for NEHTA's focus on the pathology Request-Test-Report cycle.

## 1.2 Potential

The majority of decisions affecting diagnosis or treatment involve a pathology investigation, with 17.4 per cent of all patient encounters with a GP resulting in a Request for at least one pathology test [AIHW2008d]. Approximately 40 per cent of pathology testing in the Australian primary care setting is used for diagnostic purposes, 40 per cent for monitoring and 20 per cent for preventative purposes [NCOP2008].

Australia is recognised internationally for the quality of its pathology services [NPAA2007] and our laboratories are among the most efficient in the world [MLA2007]. Considerable progress in e-health has already been made by Australian pathology providers. However, a conformance, compliance and accreditation framework for pathology messaging does not exist and, as a consequence, there is evidence that "as the quality of the laboratory testing continues to improve, the relative risk of patient harm or adverse outcome is now far greater in the processes leading to delivery of the pathology specimen to the laboratory, or in the process by which the pathology result is communicated to the treating clinician" [NPAA2007].

The Department of Health and Ageing's Quality Use of Pathology Program (QUPP) aims to achieve improvements in health and economic outcomes from the use of pathology in health care, through the pursuit of better practice amongst requesters/referrers and providers of pathology services and knowledgeable and engaged consumers. The e-Pathology Future State supports these aims by improving the availability of meaningful pathology test information and Result Reports.

## 1.3 Capabilities of the e-Pathology Future State

NEHTA has identified six capabilities required for comprehensive e-Pathology, described below.

*The first three of these capabilities will be the focus of NEHTA's specifications for the e-Pathology Request-Test-Report cycle.*

*The fifth and sixth of these capabilities are not within the current scope of NEHTA's e-Pathology program, nonetheless it is considered important that these capabilities are taken into account.*

### 1. Electronic Exchange of pathology Requests and Result Reports

The generation of pathology Requests and Result Reports according to the consistent implementation of a common standard (e.g. HL7) that incorporates terminology (e.g. SNOMED CT-AU; LOINC) and Healthcare Identifiers, and which are exchanged reliably and securely between healthcare providers.

*Note that the notification of pathology Results to clinical registries by healthcare providers is not included in NEHTA's work for the e-Pathology Request-Test-Report cycle. However, care will be taken to ensure that existing arrangements and capabilities for these notifications will not be negatively impacted as a consequence of this work.*

### 2. Support for the informed patient choice of pathology provider

Provides for patient choice consistent with government policy and professional practice (e.g. RCPA Policy 1/1994: Request Form Impropriety in Australia [refer RCPA2010]) and enables the requester to identify the pathology provider which was ultimately chosen by the patient.

### 3. Auto-reconciliation of electronic Requests with electronic Result Reports in clinical systems

Supports efficient matching of an electronic Result Report with the corresponding electronic Request against the correct patient record.

### 4. Access to prior test Results

Provides the basic infrastructure and standards to support an Electronic Health Record-type facility that will allow clinicians with the relevant authority to access the Results of prior pathology testing for a patient, irrespective of the provider of those tests.

NEHTA recognises that access to the Results of a patient's prior healthcare pathology testing is extremely complex to deliver, with requirements for filtering of Results likely to vary according to pathology discipline and clinical setting.

*Note that access to prior test Results is not included in NEHTA's work for the e-Pathology Request-Test-Report cycle. However, it is likely that the Personally Controlled Electronic Health Record (PCEHR) will have some requirement to access pathology Results from one or more Report Repositories, in which case NEHTA will work with stakeholders in order to understand their requirements.*

### 5. Decision Support for pathology Requests

Facilitates the appropriate choice of tests by clinicians in order to confirm or differentiate a diagnosis and to treat or monitor disease.

*Note that Decision Support is not within the current scope of NEHTA's program of work.*

## 6. Secondary use of pathology Request and Result data

Supports the collection, delivery, storage and analysis of more complete and detailed pathology Request and Result data than is currently possible. This may allow business rules for Clinical Decision Support Systems to be derived and refined according to evidence-based best practices. Policy and privacy considerations will be required to determine appropriate secondary uses.

*Note that secondary use of pathology Request and Result data is not within the current scope of NEHTA's program of work.*

It should be noted that these capabilities reflect various stages in the evolution of e-Pathology and are not to be interpreted as a roadmap for national implementation across healthcare communities. The realisation of these capabilities is likely to vary between communities according to their priorities and capacity to implement changes to existing policies and practices.

## 1.4 Benefits

An e-health enabled pathology sector, over and above the electronic transmission of Requests and Results Reports, has the potential to achieve many benefits:

- Improvements in health information;
- Continuity of care for a mobile population;
- Reduced reliance on the consumer's recollection of their past pathology testing and Results;
- Improved ability to create graphical representations of important 'longitudinal' pathology data; and
- Improved support for permissible secondary uses of data.

Expected benefits that flow from the above improvements include:

- **For requesters of pathology tests:**
  - Increased knowledge of, and access to, prior pathology Result Reports;
  - Improved clinical safety due to:
    - The use of Healthcare Identifiers to ensure that a Result Report is automatically matched with the correct patient record in clinical systems; and
    - Standardised structure and content of Result Reports, as a consequence of the consistent implementation of the Australian Standard for pathology messaging (AS 4700.2) by all requesters and pathology providers.
 

*Note that pathology providers will still have the ability to differentiate and value-add to Reports in a manner which is consistent with the standard.*
  - Reduced time spent on the reconciliation of pathology Result Reports with Requests and identifying outstanding Requests needing to be followed up.
- **For pathology providers:**
  - Improved quality of Request data due to the presence of mandatory data fields in an electronic Request form which must be validated before it can be issued by the requester; and
  - Improved efficiencies and fewer errors in not having to manually enter the details of a Request into provider systems.

## 1.5 Priorities and rationale

Pathology providers have well established processes and systems for the electronic storage and communication of pathology information. However, there is often considerable variability in the way the pathology messaging Standard (AS 4700.2) has been implemented and the terminology code sets being used - not just between providers, but between the various laboratories operated by a single provider. While there is considerable advantage to be gained by the entire healthcare system by the consistent implementation of the pathology messaging Standard (AS 4700.2), terminology code sets, and messaging protocols, the associated costs are considerable. Pathology providers have demonstrated a keen interest in furthering the secure exchange of reliable and meaningful pathology information between healthcare providers, however the conformance, compliance and accreditation framework required to deliver this on a national scale is not yet in place.

With Australian pathology laboratories already amongst the most efficient in the world, it's not the pathology providers who have sole responsibility for enabling some of the key opportunities for better patient outcomes as a result of e-Pathology. For example, the automated reconciliation of Requests with the relevant Result Reports would enable timely and efficient follow-up and closure of the pathology Request-Test-Report cycle. However, significant commitment by clinicians and support by Government are required for electronic Requesting to become a standard business practice by General Practitioners, Physicians and other requesters - in both public and private facilities - across Australia.

## 2 Proposed Operating Model of the e-Pathology Request-Test-Report Cycle

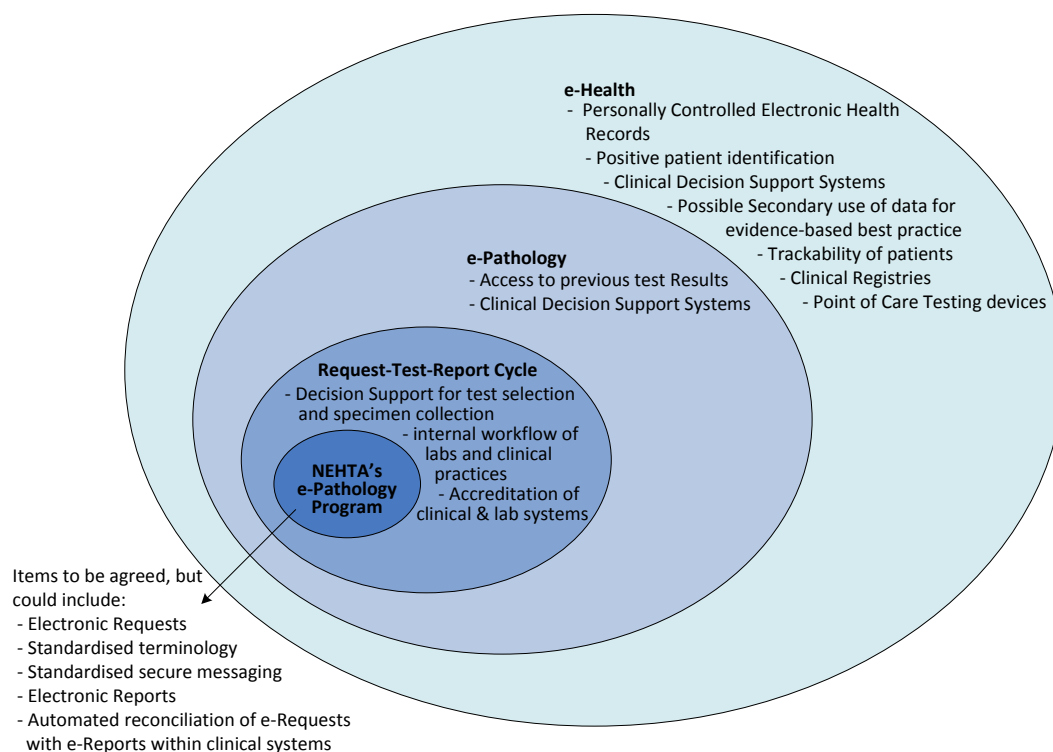
### 2.1 Introduction

This section describes the high-level clinical/business processes of the e-Pathology Request-Test-Report cycle and the conceptual architecture which supports these processes.

### 2.2 Context

In order to understand the context of NEHTA's e-Diagnostics Program, stakeholders need to consider potential capabilities of the Request-Test-Report cycle as a subset of capabilities of the e-Pathology Future State which, in turn, are a subset of capabilities of the e-Health Future State.

It is the responsibility of requesters, consumers providers and other industry stakeholders to define and redefine the capabilities of the e-Pathology Future State. Working with stakeholders, NEHTA has identified the following capabilities which are likely to impact, or be impacted by, NEHTA solutions for the Request-Test-Report cycle.



**Figure 1: NEHTA's e-Diagnostics program in context**

The various e-Pathology capabilities described in section 1.3 will be delivered to healthcare providers through the various clinical and laboratory information systems, supported by strong clinical governance. The cooperation of the vendors of these systems in supporting NEHTA-specified services for the Request-Test-Report cycle is, therefore, vital to the success of e-Pathology.

## 2.3 The e-Pathology Request-Test-Report cycle

### 2.3.1 Introduction

The pathology Request-Test-Report cycle refers to:

- The initiation of a request (most commonly by a General Practitioner or Physician);
- The performance of the requested pathology services by a pathologist and/or pathology provider; and
- The reporting of the test results and/or professional opinion(s) back to the requester.

A single Request-Test-Report cycle for a patient may involve a number of medical and non-medical health professionals, health institutions and commercial organisations [RCPA2007].

### 2.3.2 Phased implementation

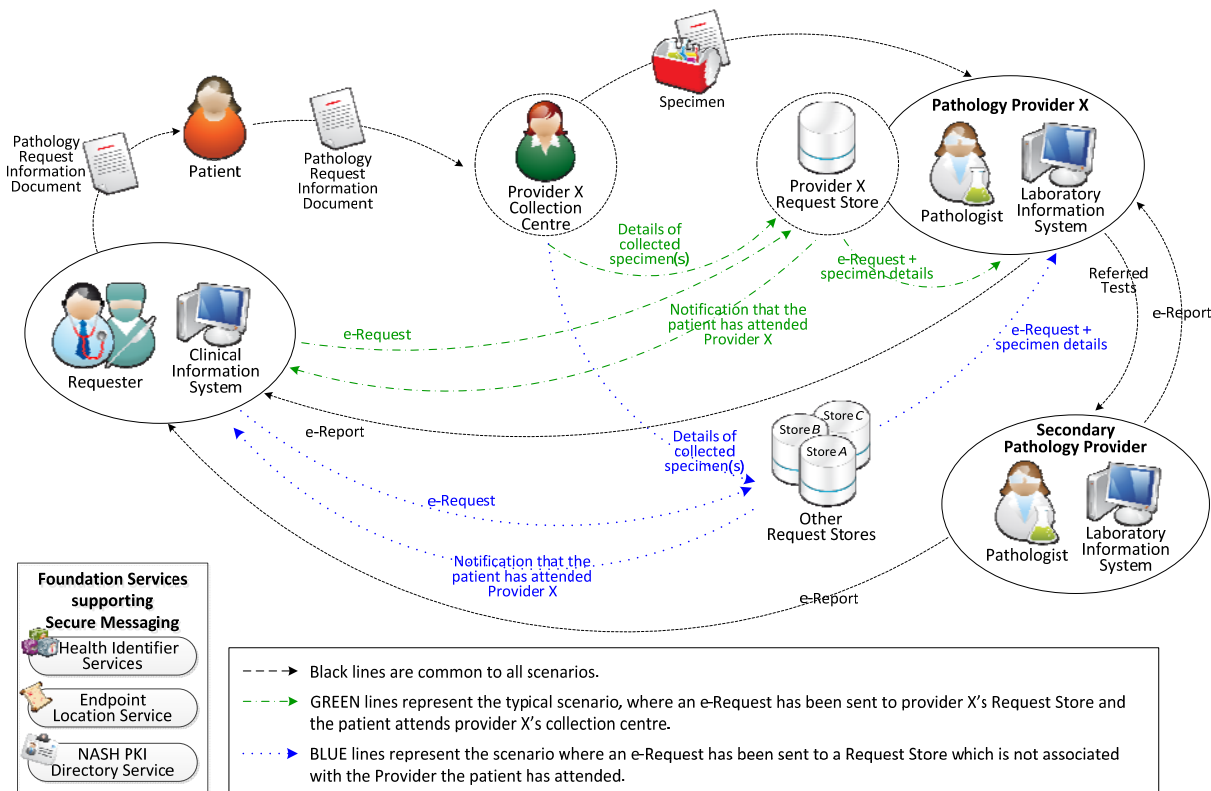
The e-Pathology Request-Test-Report cycle will be implemented incrementally in terms of both functionality and adoption within and between various healthcare communities. The Roadmap for NEHTA-specified services (e.g. Pathology Request Stores) will be developed as and when implementation partners are identified.

An initial step will see NEHTA work with Standards Australia to update the pathology messaging Standard (AS 4700.2), and the Handbook (HB 262) to implement the Standard, to include guidance on the use of Healthcare Identifiers, terminology, conformance details and defined testing points moving towards accreditation definition. The revised Standard (AS 4700.2) and Handbook (HB 262) will be published by Standards Australia in Draft form for public comment prior to being finalised.

Note that all releases will harmoniously support parallel use of existing paper-based requesting and reporting processes where the new electronic cycle is not adopted or unable to be implemented.

### 2.3.3 Conceptual Architecture

The focus of NEHTA-specified Request-Test-Report cycle services is the exchange of electronic pathology Requests between the requester and the patient's chosen provider, via a Request Store, and the automatic reconciliation of the corresponding electronic Result Report(s) within the requester's clinical system.



**Figure 2: Conceptual Architecture of the Request-Test-Report cycle.**

The components of the e-Pathology Request-Test-Report cycle conceptual architecture (refer Figure 2) are as follows:

- **Clinical Information Systems**

These systems interact with Pathology Request Stores to create electronic pathology Requests and receive notification of the patient's chosen provider for a Request. Depending on the setting in which the pathology specimen(s) relating to a Request are collected (e.g. specimens which are collected by the requester), these systems may also send details of collected specimens to a Pathology Request Store. Clinical Information Systems will also receive pathology Result Reports and reconcile them with the relevant Request and/or patient record.

- **Pathology Request Stores**

A number of Pathology Request Stores are likely to be established which, by complying with NEHTA specifications, will be jointly interoperable. The Pathology Request Stores will behave and appear to the user as if they are a centralised service, irrespective of the design.

Pathology Request stores will be required to support electronic requesting for reasons including:

- To maintain patient privacy in instances where an electronic request has been generated by a requester however the patient has elected not to proceed with the pathology test(s); and
- Future support for patient choice of pathology provider (consistent with government policy and professional practice)

An individual Pathology Request Store might be operated by a single pathology provider, a group of pathology providers, or a group of requesters, and bring the following capabilities to the Request-Test-Report cycle:

- Notification to the requester of the provider that has been chosen by the patient; and
- Management of the security of the records that it stores by requiring a healthcare provider accessing a Request to have the appropriate “document access key” (DAK) for that Request:
  - Each document access key provides access to a single pathology Request, including any details of collected specimen(s) associated with that Request;
  - A document access key is simply a secret string of random text characters, plus the identity of the repository that contains the electronic pathology Request document;
  - Document access keys are protected against forgery by the use of strong cryptographic techniques; and
  - NEHTA will specify a standard barcode format for the document access key [refer ISO2007], and the barcode (plus text string) will be printed on the Pathology Request Information Document.

- **Laboratory Information Systems**

These systems interact with the Pathology Request Stores to retrieve electronic Pathology Requests. Depending on the setting in which the pathology specimen(s) relating to a Request are collected, these systems may also send details of collected specimens to the Pathology Request Store. Note that the design and function of these systems is outside of the scope of NEHTA's work on the e-Pathology Request-Test-Report cycle, however the Result Reports generated will be required to conform to the Australian Standard for pathology messaging (AS 4700.2).

### Foundation services supporting secure messaging

#### – Health Identifier (HI) Service

Systems that implement e-Pathology Request-Test-Report Cycle services will use the HI service to identify:

- The patient to whom an individual message within the Request-Test-Report cycle relates (i.e. the patient's HI);
- The healthcare provider(s) (i.e. individual clinician) who is associated (i.e. as the sender or recipient) with an electronic pathology Request or Result Report (i.e. the HPI-I);
- The healthcare provider (i.e. individual pathologist) who is responsible for reporting the Result(s) of the corresponding pathology test(s) (i.e. the HPI-I);
- The healthcare organisations to and from which a message is being sent (i.e. the HPI-O); and
- The healthcare organisation (i.e. the HPI-O) associated with a healthcare provider (i.e. individual clinician, the HPI-I) who is nominated in a Request as a 'copy to' recipient for the corresponding Result Report.

#### – Endpoint Location Service (ELS)

Systems that implement e-Pathology Request-Test-Report Cycle services will use the ELS to find the communication endpoint address(es) for the organisation(s) to which an electronic message is being sent.

#### – NASH PKI Directory Service

Systems that implement e-Pathology Request-Test-Report Cycle services will use the NASH PKI Directory Service to get healthcare organisation-specific public key certificates and certificate revocation lists so that communicating systems can authenticate them.

### 2.3.4 Clinical/Business Processes

The high-level clinical/business processes of the e-Pathology Request-Test-Report Cycle have been designed to support:

- **Informed Patient Choice of Provider**  
Provides for informed patient choice consistent with government policy and professional practice.
- **Continued use of hard-copy Requests and Result Reports**  
Circumstances which require a hard-copy Request or Result Report to be issued, including as a reminder to the patient, will continue well into the future. Consequently, these hard-copy Requests and/or Result Reports will be accommodated within the e-Pathology Request-Test-Report cycle.

Key features of the clinical/business process are as follows:

- Where a requester has a preference for the provider that performs the test(s) being requested, they have the ability to specify the name of their preferred provider in the electronic Request. Where a preferred provider has been specified, this will be noted on the printed pathology Request Information Document (e.g. "The requesting clinician has a preference that these pathology tests are performed by Provider X").  
The clinical/business process associated with Requests where a patient attends an alternate provider would need to be defined by stakeholders.

- A patient is deemed to have chosen the pathology provider for a Request at the point at which the specimen is collected. As a consequence of the patient having exercised their right to choose, the electronic Request is no longer available to other providers on presentation of the DAK.

Depending on the setting in which a specimen is collected, this will be realised in clinical and laboratory systems as follows:

- a) Where the Pathology Request Store is updated with specimen details for a particular Request via the Collector System, the collector will be required to specify in the e-Request the pathology provider organisation to which they will send the specimen;
- b) Where details of collected specimen(s) are hand-written on the Pathology Request Information Document by the specimen collector and transported to the laboratory with the specimen(s), it will be the responsibility of the laboratory staff to enter details of the specimen into their Laboratory Information System after the e-Request has been retrieved from the Pathology Request Stores;
- c) Where a specimen(s) is collected within the requester's clinical practice prior to the creation of the e-Request, details of the specimen(s), and the provider to which they will be sent, can be entered into the e-Request before it is sent to the Pathology Request Stores.

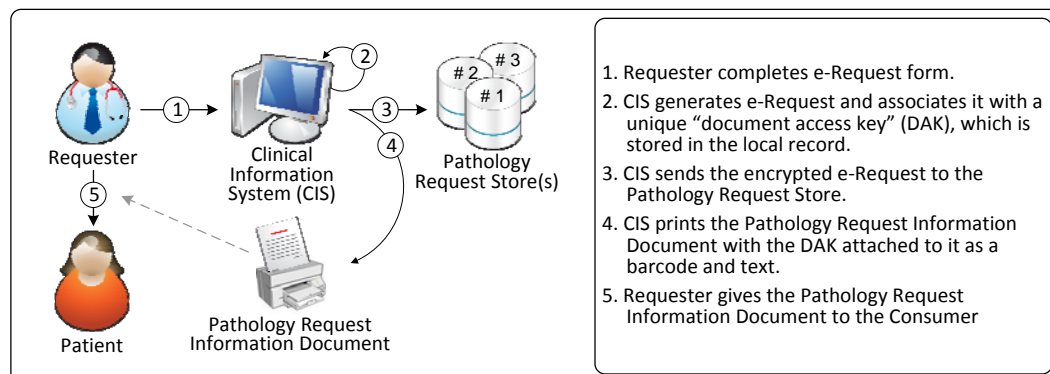
Note that a system-based message advising which provider organisation will process the Request is sent to the requester's Clinical Information System following any of these scenarios.

Finally, it is noted that changes to the following clinical/business processes are outside of the scope of NEHTA's program of work and are, therefore, not discussed within this document:

- Clinical/business processes prior to the point at which a decision that one or more pathology tests will be requested;
- The reason(s) why a particular provider is preferred by either the requester or the patient;
- The identification of a patient;
- The informed consent of a patient regarding pathology testing;
- The collection and labelling of a specimen;
- Billing for and payment of pathology testing;
- Identification of a specimen and transport to the laboratory for testing;
- Specimen testing and validation;
- The referral of one or more of the tests within a Request by the patient's chosen pathology provider to a secondary provider; and
- Clinical/business processes following the point at which a Result Report has been received and automatically reconciled within the requester's clinical system.

### 2.3.4.1 Create electronic Request

The process by which an electronic Request is created has been designed to be the same for all requesters who utilise a clinical information system to produce a Request, regardless of whether the Request will be transmitted electronically.



**Figure 3: Creating an electronic Request**

When creating an electronic Request, the requester will be prompted to enter only the data that is relevant to the test(s) which are being requested. For example, the gestational age is mandatory information to be included in a Request for a thyroid function test, but would not be required when requesting electrolytes.

The content of the Pathology Request Information Document has yet to be defined. However, initially, it is likely to include all of the information that is contained in the e-Request.

Note that the Pathology Request Information Document would not be given to the patient in all situations. Where the specimen has already been collected by the requester, the Pathology Request Information Document would be sent with the specimen directly to the laboratory. In hospital settings the Pathology Request Information Document is likely to be substituted for the paper-based Request form within the hospital's existing process(es) pre- and post-collection of a specimen.

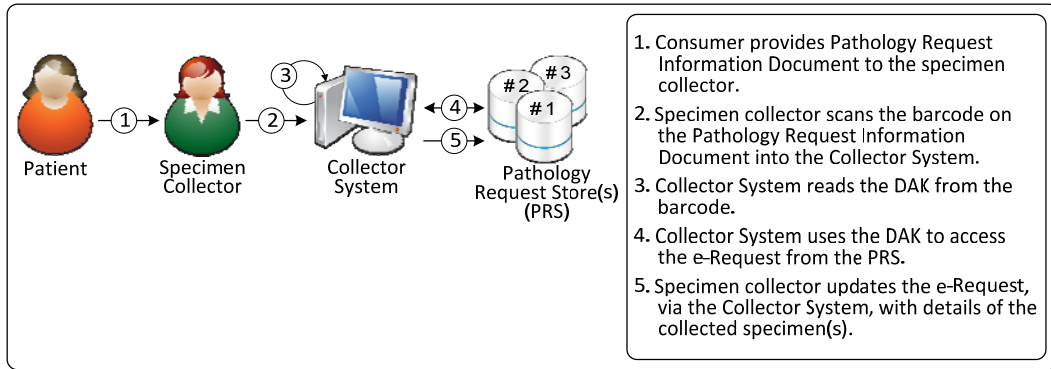
Also note that the DAK must be generated using NEHTA-specified processes in order to ensure that it is unique and cannot be forged.

### 2.3.4.2 Update electronic Request with details of collected specimen(s)

The clinical/business process to update a Request with details of the collected specimen(s) varies greatly according to the available technology of the clinical setting in which the specimen(s) was collected.

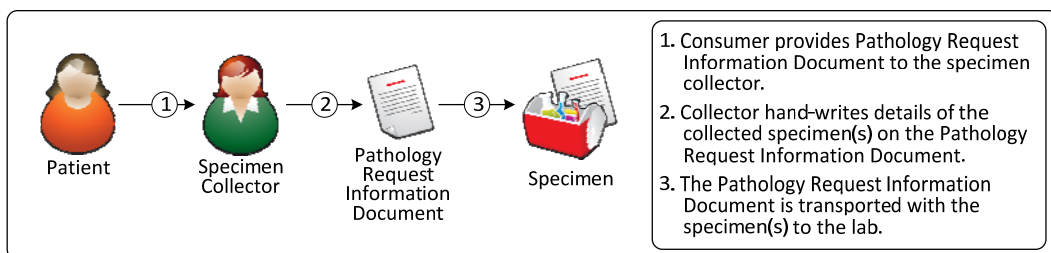
Where the Pathology Request Store is updated with specimen details for a particular Request via the Collector System (refer Figure 4) by a collector who is affiliated with a specific pathology provider, the details of that provider will automatically be associated with the Request. Where a collector is not affiliated with a single provider (for example, a nurse in the requester's practice), the collector will be required to specify in the e-Request the pathology provider organisation to which the specimen will be sent.

Note that once the provider has been associated with the e-Request the Pathology Request Stores sends a system-based message to the requester's Clinical Information System to notify the requester of the provider that has been chosen to process the Request. At this point the e-Request would no longer be accessible to an alternate provider, should they obtain the DAK (but would still be available to the chosen provider).



**Figure 4: Updating e-Request with specimen details via a Collector System**

Where a specimen collector does not have access to the Pathology Request Stores via the Collector System, details of collected specimens will be hand-written on the Pathology Request Information Document by the specimen collector and transported to the laboratory with the specimen.

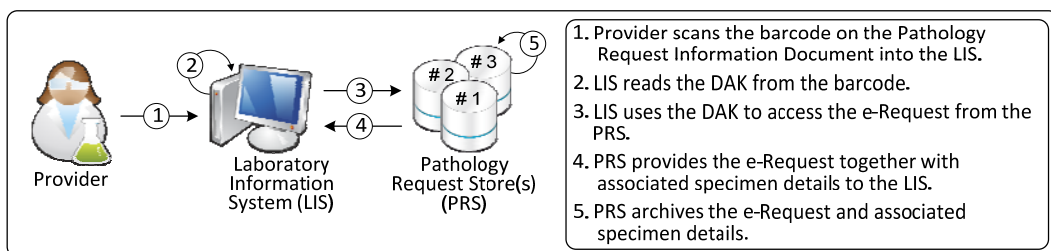


**Figure 5: Updating e-Request with specimen details at the lab**

Once Pathology Request Information Document (with hand-written notes) is received at the laboratory, staff would retrieve the Request (refer section 2.3.4.3) and then manually enter specimen details into their Laboratory Information System.

2.3.4.3 Retrieve electronic Request

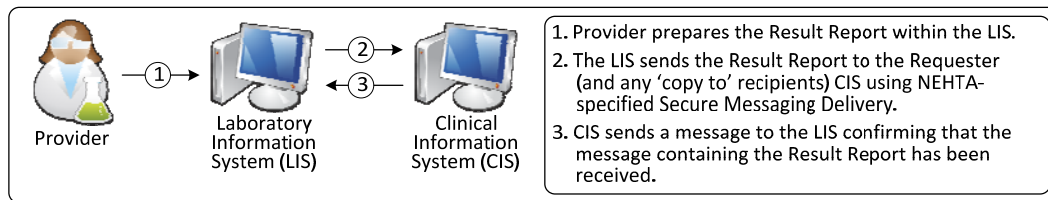
Irrespective of the setting in which a specimen was collected, it is expected that the Pathology Request Information Document, which contains the DAK, will be transported to the laboratory with the specimen so that the e-Request can be retrieved from the Pathology Request Store (refer Figure 6).



**Figure 6: Retrieving an electronic Request**

#### 2.3.4.4 Send electronic Result Report

Changes to the clinical/business processes for producing and sending an electronic Result Report are not expected to change, however the mechanisms by which the Result Reports are sent will change to incorporate NEHTA-specified Secure Message Delivery (refer Figure 7).



**Figure 7: Sending an electronic Result Report**

It should, however, be noted that some pathology providers have indicated a desire to change the model by which Results are communicated; rather than send a message containing the Result Report to the requester and any nominated 'copy to' recipients, the pathology provider would send a message which contains a link via which the Result Report can be accessed from the provider's Report Repository.

*Development of specifications for these Report Repositories is not part of NEHTA's current work for the e-Pathology Request-Test-Report cycle.*

However, it is likely that the Personally Controlled Electronic Health Record (PCEHR) will have some requirement to access pathology Results from one or more Report Repositories, in which case NEHTA will work with stakeholders in order to understand their requirements.

#### 2.3.4.5 Re-collection of Specimen(s)

No changes to existing processes have been identified.

#### 2.3.4.6 Add-on Tests

Stakeholders involved with the development of the e-pathology Request-Test-Report cycle Concept of Operations have indicated no interest in defining system capability to allow requesters to electronically add tests to a Request which a provider is currently processing or has recently completed. However, feedback received in response to the publication of this document in Draft form for public comment indicates that such capability is required, along with capability to amend or cancel a Request.

Accordingly, NEHTA will work with stakeholders in order to understand the detailed requirements for requesting add-on tests and amending or cancelling a Request.

## **3 Enabling the Operating Model**

### **3.1 Governance, Policy and Privacy**

NEHTA is working within existing (and where known proposed) government policy and regulation frameworks for the e-Pathology Request-Test-Report cycle of services. Where additional requirements are identified to ensure interoperability, privacy and patient safety are reliably and effectively maintained, NEHTA will work with governments and stakeholders to inform future policy and clinical governance models where required.

NEHTA recommends that healthcare providers (and other users of e-Pathology Request-Test-Report cycle services) continue to exercise diligence and obtain independent legal advice to ensure that their operations meet the requirements specific to their jurisdiction.

### **3.2 Security Controls**

The e-Pathology services within the Request-Test-Report cycle will implement a range of security controls to ensure that only appropriately authorised users are permitted to access the services. All access to the service from an external healthcare organisation will require the user to be authenticated with NASH PKI credentials and will be undertaken on appropriately secure/encrypted links. All access to the Pathology Request Stores will be recorded within an audit log.

# 4 Implementation

## 4.1 Adoption Model

The e-Pathology Request-Test-Report cycle will be implemented incrementally - different parts of the profession and healthcare communities will be able to proceed at different rates depending on their particular capabilities, priorities and constraints. The overall approach to implementation will see a mixture of:

- Initial deployments in which early adopters will collaborate with NEHTA to validate the e-Pathology solutions and designs;
- Vendor initiatives to achieve compliance with NEHTA specifications and designs;
- An evaluation framework to measure the success of the project and identify lessons learned that can provide insight for future activities; and
- Development of a robust conformance, compliance and accreditation framework which is supported by regulatory levers, as appropriate, to ensure reliable and trustworthy interoperability.

Note that e-Pathology Request-Test-Report cycle solutions services will be designed to ensure no loss of compatibility or interoperability with current or legacy components within the pathology Request-Test-Report cycle in the event of individual or localised early adoption work.

## 4.2 Change Management

In order to support the adoption of e-Pathology Request-Test-Report cycle solutions a mix of implementation support approaches will be provided by NEHTA. As lessons are learned from implementation in the field, it is expected that the mix will evolve to meet the changing environment. As suggested by the National E-Health Strategy, the initial approaches to supporting adoption of e-health (in general) and e-Pathology (in particular), may include:

- Utilisation of the existing Stakeholder Reference Forum and specialised working groups to ensure that a wide range of stakeholders are engaged and represented in the ongoing evolution of e-Pathology solutions;
- National awareness campaign to educate consumers, requesters, providers and vendors about e-Health and e-Pathology solutions;
- Financial Incentives Programs to encourage requesters and providers to adopt systems which are certified as supporting e-Pathology solutions;
- Linkages into the various accreditation programs to ensure that requesters and providers adopt certified systems; and
- Training for requesters, providers and their administrative support staff who need to use e-Pathology Request-Test-Report Cycle services.

# Definitions

## Glossary

This table lists specialised terminology in alphabetical order.

Term	Description
Add-on Test(s)	A test that is Requested to be performed on a previously collected specimen.
Consumer	Unless otherwise stated, within the context of this document a "consumer" represents the patient (i.e. the subject of a pathology Request or Report) and their carer, where applicable. Note that the terms "consumer" and "patient" (as described below) are interchangeable within this document.
DAK; Document Access Key	A Document Access Key comprises a document identifier, a repository identifier and a cryptographic key. This ensures that only people with the DAK can access the document.
HPI-I; Healthcare Provider Identifier - Individual	A unique identifier for an individual healthcare provider, for example an individual General Practitioner,
HPI-O; Healthcare Provider Identifier - Organisation	A unique identifier for an individual healthcare organisation, for example an individual General Practice.
IHI; Individual Healthcare identifier	A unique identifier for an individual patient.
Interoperable	Interoperability is the ability of two or more systems or components to exchange information and to use the information that has been exchanged.
NASH; National Authentication Service for Health	A system for verifying the authenticity of patients and professionals for the purpose of ensuring the privacy of a person's electronic health data, while enabling secure access to the data by the person's authorised health providers.
NEHTA Clinical Leaders	Clinical Leaders are a select group of practising clinicians with diverse clinical backgrounds. The Clinical Leaders team has been assigned to various areas of the NEHTA work program to provide an important sounding board for the development of the work in real world contexts and to advise on likely issues and appropriate mechanisms for engaging with clinical stakeholders.
PRS; Pathology Request Stores	The Pathology Request Store will, by design, behave and appear to the user as if it is a centralised service, irrespective of how it is designed. The actual solution may be centralised, federated or distributed (in a database management sense), or made up of separate repositories hosted by different organisations, with services to allow interoperability.
Patient	Unless otherwise stated, within the context of this document a "patient" represents both the patient (i.e. the subject of a

Term	Description
	pathology Request or Report) and their carer, where applicable. Note that the terms "patient" and "consumer" (as described above) are interchangeable within this document.
PKI; Public Key Infrastructure	Public Key Infrastructure (PKI) is a set of procedures and technology that provides security and confidentiality for electronic business.
Provider	Unless otherwise stated, within the context of this document the "provider" is the provider of pathology services, not the more generic meaning of "healthcare provider".

# References

This section lists documents and other artefacts that have been referenced within this document. Some of these artefacts may not be freely available in the public domain.

At the time of publication, the document versions indicated are valid. However, as all documents listed below are subject to revision, readers are encouraged to use the most recent versions of these documents.

[REF]	Document Name	Publisher	Link
[AIHW2008b]	Australia's Health 2008	The Australian Institute of Health and Welfare, Jun 2008.	<a href="http://www.aihw.gov.au/publications/aus/ah08/ah08.pdf">http://www.aihw.gov.au/publications/aus/ah08/ah08.pdf</a> Accessed 22 July 2010.
[AIHW2008d]	General Practice Activity in Australian 2007-08	The Australian Institute of Health and Welfare, Oct 2008.	<a href="http://www.aihw.gov.au/publications/gep/gpaia07-08/gpaia07-08.pdf">http://www.aihw.gov.au/publications/gep/gpaia07-08/gpaia07-08.pdf</a> Accessed 22 July 2010.
[AJM1998]	Bates, DI, Boyle, DL, Rittenberg, E, Kuperman, GJ, Ma'LufB, N, Menkin, V, Winkelman, JW, Tanasijevic, MJ, 'What Proportion of Common Diagnostic Tests Appear Redundant?', <i>The American Journal of Medicine</i> , vol. 104, Apr 1998, pp. 361-368.	Elsevier Inc, Apr 1998.	<a href="http://www.amjmed.com/article/S0002-9343%2898%2900063-1/abstract">http://www.amjmed.com/article/S0002-9343%2898%2900063-1/abstract</a> Accessed 20 July 2010.
[CHCF2003]	Moving Toward Electronic Health Information Exchange: Interim Report on the Santa Barbara County Data Exchange	California HealthCare Foundation, July 2003.	<a href="http://www.chcf.org/publications/2003/07/moving-toward-electronic-health-information-exchange-interim-report-on-the-santa-barbara-county-data-exchange">http://www.chcf.org/publications/2003/07/moving-toward-electronic-health-information-exchange-interim-report-on-the-santa-barbara-county-data-exchange</a> Accessed 20 July 2010.
[ISO2007]	ISO/IEC 15417:2007 - Information technology -- Automatic identification and data capture techniques -- Code 128 bar code symbology specification	ISO (International Organization for Standardization), May 2007.	<a href="http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=43896">http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=43896</a> Accessed 19 July 2010.
[KPMG2007]	Cost benefit Analysis of Shared Electronic Health Records, Draft Report.	KPMG, Sep 2007.	
[MEDI2007]	2006-2007 Annual Report, Statistical Tables	Medicare Australia. Oct 2007.	<a href="http://www.medicareaustralia.gov.au/about/governance/reports/06-07/stats">http://www.medicareaustralia.gov.au/about/governance/reports/06-07/stats</a> Accessed 22 July 2010.
[MLA2007]	Report from the National Workshop on Safety and Quality in Pathology Held in Canberra 28 November 2007	Michael Legg & Associates. Nov 2007.	<a href="http://www.health.gov.au/inter-net/main/publishing.nsf/Content/6F5EED48F956E4D6CA25756D000E3487/\$File/Safety&amp;Qual%20ReptNov07.pdf">http://www.health.gov.au/inter-net/main/publishing.nsf/Content/6F5EED48F956E4D6CA25756D000E3487/\$File/Safety&amp;Qual%20ReptNov07.pdf</a> Accessed 22 July 2010.
[NCOP2008]	National Coalition of Public Pathology, Importance of Pathology.	National Coalition of Public Pathology. 2008.	<a href="http://www.ncopp.org.au/site/ImportanceofPathology_.php">http://www.ncopp.org.au/site/ImportanceofPathology_.php</a> Accessed 22 July 2010.

[REF]	Document Name	Publisher	Link
[NPAA2007]	National Pathology Accreditation Advisory Council (NPAAC) Strategic Plan. 2007-2009.	National Pathology Accreditation Advisory Council. Sep 2007.	
[RCPA2007]	Chain of Information Custody for the Pathology Request-Test-Report Cycle in Australia (Guidelines for Pathology Requesters and Pathology Providers)	Royal College of Pathologists of Australasia. Mar 2007.	<a href="http://www.health.gov.au/internet/main/publishing.nsf/Content/FDD654DOC46DC374CA2573A0000A9C1A/\$File/ChainInfoCustody.pdf">http://www.health.gov.au/internet/main/publishing.nsf/Content/FDD654DOC46DC374CA2573A0000A9C1A/\$File/ChainInfoCustody.pdf</a> Accessed 22 July 2010.
[RCPA2010]	Policy 1/1994: Request Form Impropriety in Australia.	Royal College of Pathologists of Australasia. 1994, revised Feb 2010.	<a href="http://rcpa.edu.au//static/File/Asset%20library/public%20documents/Policy%20Manual/Policies/Request_Form_Impropriety.pdf">http://rcpa.edu.au//static/File/Asset%20library/public%20documents/Policy%20Manual/Policies/Request_Form_Impropriety.pdf</a> Accessed 31 Jul 2010.

## Related Reading

The documents listed below may provide further information about the issues discussed in this document.

Document Name	Publisher	Link
e-Diagnostics Program Workshop Report v1.0	National E-Health Transition Authority. May 2009.	<a href="http://www.nehta.gov.au/e-communications-in-practice/epathology">http://www.nehta.gov.au/e-communications-in-practice/epathology</a> Accessed 22 Jul 2010.
Environment Scan - The Pathology Industry v1.0	National E-Health Transition Authority. Jun 2009.	<a href="http://www.nehta.gov.au/e-communications-in-practice/epathology">http://www.nehta.gov.au/e-communications-in-practice/epathology</a> Accessed 22 Jul 2010.

# Appendix A: Contributors

A number of individuals were involved with the development of the e-Pathology Request-Test-Report Cycle Concept of Operations. NEHTA thanks those individuals for their time and effort involved in developing and reviewing this document.

## A.1 Diagnostic Services Reference Group

The Diagnostic Services Reference Group (DSRG) was established to provide advice to the Stakeholder Reference Forum (SRF), NEHTA Board and CEO. Membership of the DSRG consists of those who are responsible for both implementing and using the deliverables of the e-Diagnostics Program and includes representation from jurisdictions, clinicians, consumers, industry and public and private healthcare organisations.

Current Members of the DSRG are as follows:

Member	Representing
Neville Board	Australian Commission on Safety and Quality in Health Care
Lawrie Bott	The Royal College of Pathologists of Australasia
Paul Carroll	Queensland Health
Phillip Dubois	Australian Diagnostic Imaging Association
Nick Ferris	The Royal Australian and New Zealand College of Radiologists
Peter Garcia-Webb	NEHTA Clinical Unit
Hugh Greville	The Royal Australasian College of Physicians; NEHTA Clinical Unit
Graham Grieve	Medical Software Industry Association
Michael Guerin	NEHTA Clinical Unit
Rob Hosking	NEHTA Clinical Unit
Scott Jansson	The National Coalition of Public Pathology
Katherine McGrath	Australian Association of Pathology Practices
Jennifer Muller	BreastScreen Australia
Geraldine Robertson	Consumer representative (Diagnostic Imaging)
Owen Smalley	National Health CIOs Forum
Luke Twyford	Department of Health and Ageing / Diagnostic Services Branch
Janney Wale	Consumer representative (Pathology)
Roger Wilson	The National Coalition of Public Pathology

## A.2 e-Pathology Request-Test-Report Cycle ConOps "Tiger Team"

A working group of stakeholders of the pathology industry was formed in July 2010 to discuss and agree the high-level clinical/business processes and the proposed conceptual architecture to support these processes. Members of the working group are as follows:

Member	Background
Jenny Bartlett	Clinical Leader, Medical Administration
Lawrie Bott	Pathologist, CEO of Diagnostic Services P/L
Peter Garcia-Webb	Clinical Leader, Pathology
Trina Gregory	Clinical Leader, GP
Hugh Greville	Clinical Leader, Specialist – Thoracic Medicine
Michael Guerin	Pathologist (retired)
Rob Hosking	Clinical Leader, GP
Scott Jansson	Operations Manager, Melbourne Health Shared Pathology Service
Leonie Katekar	Director of NEHTA's Clinical Unit
Katherine McGrath	CEO, Australian Association of Pathology Practices
Alan O'Keefe	IT Manager, Dorevitch Pathology
Janney Wale	Consumer representative

## A.3 Public Comment

The e-Pathology Request-Test-Report Cycle Concept of Operations was published on the NEHTA website as Draft - For Public Comment on 20 August 2010. Feedback to the Draft document was received from the following individuals and organisations:

- Australasian Association of Clinical Biochemists;
- Australian Association of Pathology Practices;
- Communicare Systems;
- Consumers Health Forum;
- General Practice Victoria;
- National Coalition of Public Pathology;
- National Cervical Screening Program SNOMED Working Group;
- Owen Smalley (Chief Information Officer, ACT Health);
- Queensland Health;
- Dr Rob Hosking (Clinical Leader, GP);
- Royal College of Pathologists of Australasia; and
- Smart Health Solutions.