



Llywodraeth Cymru  
Welsh Government

**INFORMATION STANDARDS  
ASSURANCE PROCESS**

**INFORMATION STANDARD  
PROPOSAL**

*Replacement Laboratory Information Management System Data*

*Friday, 11 May 2012*

**INFORMATION STANDARD FINAL PROPOSAL  
FOR NEW OR CHANGED (INCLUDING RETIRED) INFORMATION STANDARD****REVISION HISTORY**

Date of this revision:

Version no.	Revision date	Summary of Changes	Changes marked
0.1	11/05/12	First draft	No

**SUBMITTED BY:***Document completed by: Brent Varley**Role & organisation: National Pathology IT Programme Lead**Phone: 02920 502860**Email: brent.varley@wales.nhs.uk***FEEDBACK TO BE PROVIDED TO:***Name: Simarmmeet Singh**Email: Simarmmeet.singh@wales.nhs.uk***SUBMISSION PURPOSE**Proposal submitted for: **Formal Approval to support implementation approval.**

**Glossary of Abbreviations:**

BT	Blood transfusion
CAB	Change Advisory Board
CSG	Clinical Strategy Group
EMPI	Enterprise Master Patient Index
GP	General Practice
IGAP	Information Governance Assurance Process
IHC	Informing Healthcare
IHR	Integrated Health Record
IQ	Installation Qualification
ISC	InterSystems Corporation
IT	Information Technology
LHB	Local Health Board
LIMS	Laboratory Information Management Systems
MHOL	My Health Online
NADB	National Architectural Design Board
NAGIOS	Industry standard in enterprise-grade IT infrastructure monitoring
NPHS	National Public Health Service
NWIS	NHS Wales Informatics Service
OAT	Operational Acceptance testing
Op team	Operational team
PHW	Public Health Wales
QC	Quality Control
RFC	Request for Change
UAT	User Acceptance testing
WPH	Wales Pathology Handbook

## SECTION 1: BASIC INFORMATION STANDARD DESCRIPTORS

### 1. Information Standards Reference Number

### 2. Name of Information Standard

Replacement Laboratory Information Management System (LIMS) Data

### 3. Type of change

The LIMS replacement project will consolidate all current NHS Wales Pathology systems onto a single platform. The development of this solution has required a high level of standardisation of information processes and nomenclatures that will provide (as far as practicable) a more integrated service to support current and future IT strategies. This submission identifies the data items processes relating to the solution being delivered. It should be noted that the project approach is to utilise NWIS, National or Professional standards where possible.

### 4. Sponsor

Jane Fitzpatrick, Head of the Programme Management Unit/Programme Director, Diagnostic Services, as Chair of National Pathology Programme Board.

Andrew Griffiths, Programme Implementation Director, Chair of National Pathology IT Programme Board

### 5. Developer

LIMS Solution is being supplied by InterSystems Corporation (ISC). The system has been configured by a team of NHS Wales Pathology staff (with support from ISC) managed by the National Pathology IT Programme based in NWIS.

### 6. Implementation Date

First Go-live date in the week commencing 11/06/2012

LIMS Implementation is staggered over 10 months beginning June 2012. Detailed Plan embedded in Section 6- sub-section 19

## SECTION 2: BUSINESS JUSTIFICATION

### 7. Purpose

Extracted from the Full Business Case (2009):

The main strategic drivers for the LIMS Project are:

- Designed for Life which places an emphasis on service reconfiguration via clinical networks and performance management as key enablers for improving health and social care across Wales.
- The Diagnostic Services Strategy "Getting Results" (WHC (2004) 061) which identifies the dependency on an integrated information management and technology infrastructure to support the delivery of modern diagnostic services.
- The Future Delivery of Pathology Services in Wales (2008) which provides the vision for the future planning and delivery of services

The Case for Change can be made based on the following:

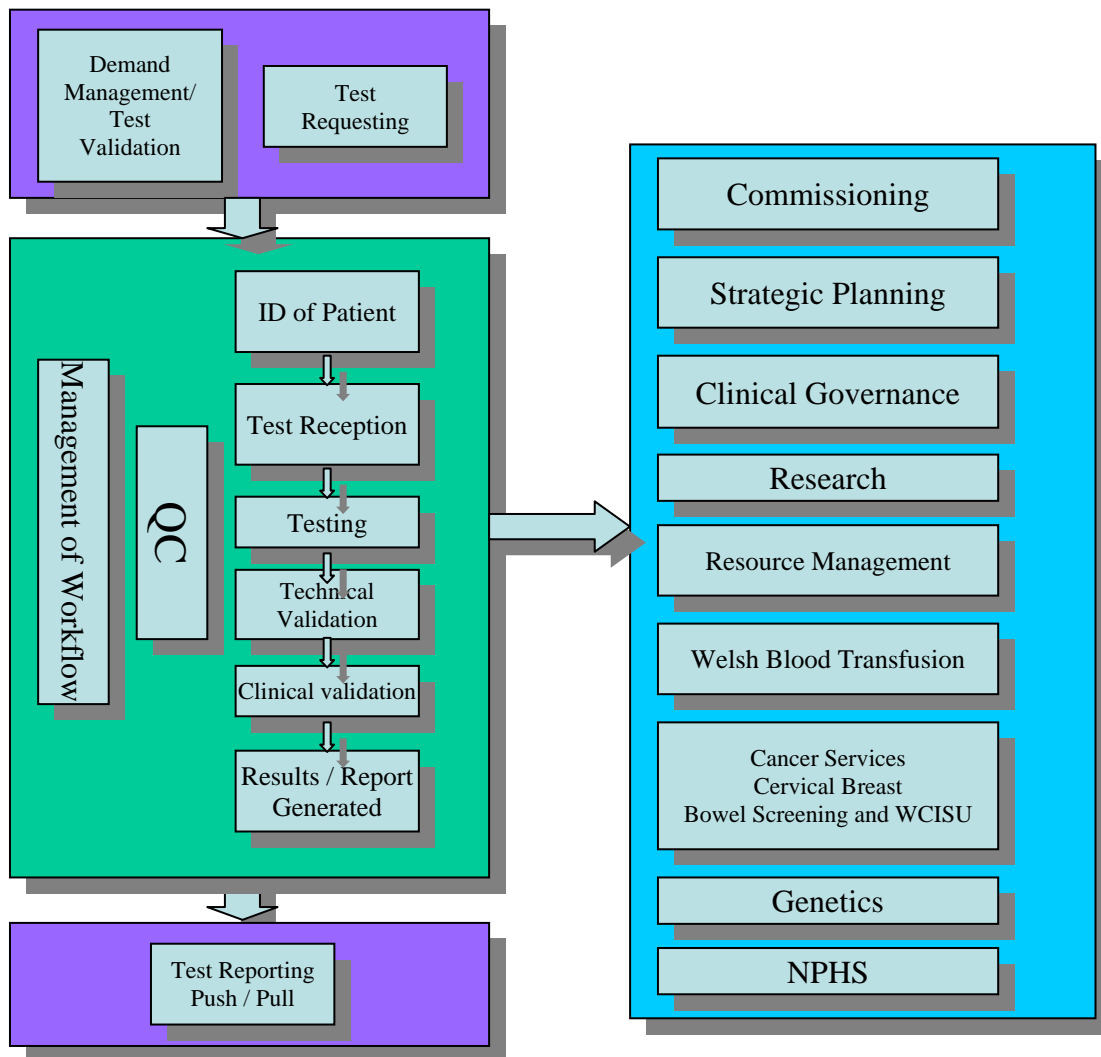
- There are currently 13 Laboratory Information Management Systems supporting 18 main NHS Pathology Laboratories across Wales. The majority of these systems were procured around 16 years ago and the full contractual term of those original agreements have expired. At present, all LIMS in Wales are supported on legacy contracts which were implemented in 2003/4 and carry an associated risk for medium term viability. The terms of the contracts state that from March 2006 suppliers can contractually give 2 years notice to withdraw support for the systems.
- The current configurations of Laboratory IM&T systems are not considered capable of delivering the goals for information set by Designed for Life and Informing Healthcare as they restrict the ability to facilitate fast and effective access to patient pathology results irrespective of where the tests were completed.
- The current systems do not support performance management of pathology services across Wales. Collection of information generally relies on labour intensive methods and processes.

A single solution based on standardised coding, nomenclature and tests sets would support an enhanced pathology service, providing a high degree of flexibility to the service via a system where tests can be carried out anywhere and results accessed outside current organisational boundaries meeting the new Health Board and modernisation requirements.

### 8. Scope

TrakCare LIMS solution is a single system computer solution that will be distributed across all NHS Pathology Laboratories in Wales and is provided by InterSystems Corporation (ISC). The product has been configured to an agreed standardised build and is initially being piloted at Hywel Dda Health Board and Screening Services (Cytology Screening)

A diagram outlining the full scope of the LIMS functionality is shown below (Diagram 1).



**Diagram 1: Scope of LIMS**

The replacement LIMS will cover the following laboratories:

Laboratory Site	NHS Local Health Board (From October 2009)
Ysbyty Gwynedd	North Wales Betsy Cadwaladr LHB
Llandudno Hospital	
Ysbyty Glan Clwyd	
Ysbyty Maelor	
Prince Charles	Cwm Taf LHB
Royal Glamorgan	

University Hospital of Wales	Cardiff and Vale University LHB
Llandough	
Royal Gwent	Aneurin Bevan LHB
Caerphilly	
Nevil Hall	
Prince Phillip	Hywel Dda LHB
West Wales	
Withybush	
Bronglais	
Princess of Wales	Abertawe, Bro Morgannwg University LHB
Neath Port Talbot	
Morrison	
Singleton	
Welsh Blood Service	Velindre NHS Trust

## 9. Funding

The Full Business Case for Replacement LIMS was approved in June 2010 by the Welsh Government.

## 10. Support

The project is a joint exercise between Pathology Service, NWIS and InterSystems Corporation (LIMS Supplier).

Delivery of the Laboratory Information Management System (LIMS) Project requires system configuration (Hardware and Software), testing, validation and implementation of TrakCare Lab across Pathology Service in Wales.

The product is supported as follows:

Organisation	LIMS Application Development	Configuration	Implementation	On-going LIMS Support
InterSystems	Yes	Support	Support	Yes
NWIS Technical	No	Support	Support	Limited
NWIS Infrastructure, Systems and Support	No	Limited	Support	Yes
NWIS Applications and System Support	No	Limited	Support	Yes
NWIS – LIMS Configuration Team	Contribute specifications	Yes	Support	Support
LIMS Change Advisory Board	Not directly	Approve changes	No	Yes – assess and approve any changes

**SECTION 3: HEALTH INFORMATION STRATEGIC AND OPERATIONAL FIT**

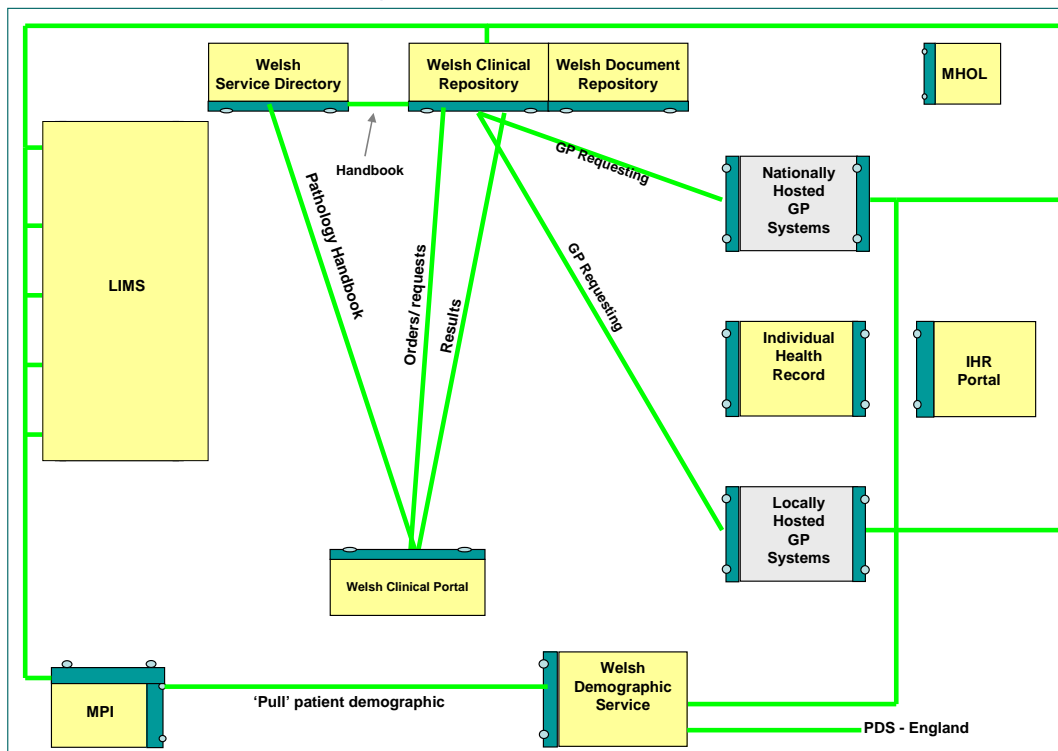
**11. Strategic National Fit**

The Informing Healthcare (IHC) strategy was published in 2003. The vision is being achieved by developing a common technical architecture<sup>1</sup> (see Diagram 2 below) to support the provision of integrated information to clinicians and patients at the point of consultation.

It is recognised that the effective delivery of pathology services will require a standardised approach to managing information. Connectivity to the existing multiple LIMS systems introduces a level of complexity that could be eliminated, with a single networked LIMS proving an efficient and ergonomic solution meeting national IT architecture and infrastructure objectives.

Diagram 2 - Technical Architecture

**Pathology roadmap – New LIMS**



**12. Known standards in use nationally and internationally**

The LIMS has been configured to use all available and applicable standards as identified in section 18.

<sup>1</sup>For Further Details see <http://www.wales.nhs.uk/sites3/docopen.cfm?orgid=770&ID=103220&6D16AC9B-1143-E756-5C4E8A3D389EB758>



## SECTION 4: THE PROPOSAL

### 13. Proposed Solution

The LIMS solution provided by InterSystems Corporation requires a high level of configuration to deliver a working system. This requires a large number of code tables to be populated with information by the project team. The collation of the information was gathered from a number of sources including national data dictionaries, national pathology catalogues, existing LIMS data and standardisation processes within the pathology service.

### 14. Testing / Pilot

LIMS test activities have followed the NWIS Test Framework. Relevant documents for the lifecycle of the LIMS Project:

- PR028 Test Strategy
- PR061 Test Plan
- PR068 Test Scripts
- PR086 Test Closure Report

Discipline Specific Risk Assessments for User Requirements identified in Schedule 4.1 ([ISFT Response InterSystems Schedule 4.1 incl 2.1 Technical Solution](#)) are being undertaken as part of Validation procedures being followed for the LIMS Project. The Risk assessment approach for blood transfusion will be validated by MHRA and therefore has not been included in this report. Testing activities (as detailed in the Table below) have been guided by the outcomes of the Risk Assessments undertaken as part of different work streams. LIMS Document Register details reference to all the Testing activity reports.

**Table:**

Testing activity	Scope
Common Functional Acceptance Testing (CFAT)	<p>The CFAT phase of testing covered the following Core Functional Requirements from Schedule 4.1</p> <p>Schedule_4.1_Section 5.1: Core Requirements            Schedule_4.1_Section 5.2: Patient Demographics            Schedule_4.1_Section 5.3: Request Registration            Schedule_4.1_Section 5.4: Results Entry            Schedule_4.1_Section 5.5: Referral Specification            Schedule_4.1_Section 5.7: Validation            Schedule_4.1_Section 5.8: Outputs            Schedule_4.1_Section 5.11: Specimen Tracking            Schedule_4.1_Section 5.12: Electronic Result Requesting and Reporting</p> <p>Also covered in this phase of testing is the E-MPI interface which is tested as part of the Core Requirements.</p>
National User Acceptance Testing (UAT)	<p>During this phase the following was included in the testing:</p> <p>Common functionality of the system from a user perspective            Access levels for specific security groups            Booking in patients            Booking in tests for patients            Checking results of tests            Authorising tests            Authorising results of tests (for higher access levels)            Viewing report documents (soft and hard copy)</p>

Health Board Testing (Local UAT)	Health Board Responsibility
Hardware Validation and Operational acceptance testing (OAT)	Scope of Hardware Installation Qualification (IQ): Establish the documentation status. Capture the versions of all system software, configurable network device firmware and verify consistency with approved specifications. Verify the system software configuration. Verify the hardware specification and configuration. Procedures are in place to maintain the validation status of the system once IQ has been started.
Application Validation and OAT	Scope of LIMS Production Environment Installation Qualification (IQ): Ensemble Database TrakCare Suite of Applications Print Server Instrument Interface Server NAGIOS Monitoring Server Citrix Server Haemonetics Primary Server Wales NHS LIMS Configuration

## 15. Information Governance

The NHS Wales Informatics Service (NWIS) Information Governance Assurance Process (IGAP) has identified a number of issues and the document titled '**Information Governance Approach- LIMS**' [Doc Ref: SEC.4.1.1], Appendix 1, outlines the recommended approach that will be taken to ensure that effective information governance processes are developed. This will ensure that patient information is safeguarded, thus preserving the confidentiality, integrity, availability and accuracy of information whilst maintaining the confidence of, and meeting the needs of, patients and clinicians.

Clinical Risk Assessment Report [Doc Ref: SEC.3.2.2], Appendix 2, prepared to comply with 'Step 3' of the NWIS Clinical Risk Management Process [NWIS Clinical Risk Management Process FINAL 2011 12 03] has been approved by NWIS Clinical Risk Manager on 04/05/2012. The purpose of report document is to provide a comprehensive list of all the risks identified with the LIMS Project for the planned pilots at Hywel Dda Health Board and Screening Services.

## 16. Commercial Considerations

Commercial issues with InterSystems are defined within the contractual documentation.

A contract to utilise the content of the National Laboratory Medicines Catalogues is being drafted (should be noted they intend to utilise some of the work we have done for LIMS within a revised version).

## 17. Fitness for Purpose

Information provided by NRDS or obtained from other 'national sources' is considered fit for purpose.

Internally defined Pathology information has been obtained through the Welsh Assembly defined Pathology 'Standing Specialist Advisory Groups' with support from agreed All Wales Pathology subject matter experts. All standardised information has been defined in standardisation portfolios and reviewed by a defined 'Clinical Strategy Group'. The governance structure relating to the project is detailed in Appendix 3.

The LIMS configuration will be described in an ongoing 'LIMS configuration document' that defines the settings allocated for key configuration items.

## SECTION 5: IMPACT ASSESSMENT

### 18. Impact Assessment

Specific data items are identified under the heading LIMS Data items, high level information streams are identified below:

Source	Data	Comment
NRDS	Current: SNOMED GP requester data, GP location data, Consultant data, NHS UK Pathology bounded code list, NHS Wales Source Codes Proposed: Nursing codes, Allie3d Health Professional codes and National Prescriber codes	Work ongoing to automate feeds from NRDS to LIMS to maintain and update information
Lower level source codes: Ward names etc	Agreed structured code	Developed with NRDS staff
EMPI	All Wales demographic feed	
Pathology Specific Data Items	Specific information relating to test names, reference names, clinical comment codes, reporting formats etc	Where applicable the National Medicine Laboratory Catalogue has been used for test names and reporting units. An agreement to use the NMLC with the NHS Wales LIMS is in process <sup>2</sup> .  Harmony- Pathology Harmony is an initiative working towards harmonisation of results reporting in UK pathology laboratories which was established in January 2007. Where applicable reporting against Harmony agreed standards are being implemented <sup>3</sup>  All other pathology data has been agreed nationally through the creation of standardisation groups. This has produced a number of standardisation portfolios which are maintained centrally.

#### Governance Model for the Project:

Governance arrangements adopted by the National Pathology IT Programme Implementation Board, in relation to the Laboratory Information Management System (LIMS) are outlined in the Document titled 'LIMS Implementation Board Governance Arrangements' [Document Ref.: PRC.7.7]- Appendix 3 in order

<sup>2</sup> <http://www.connectingforhealth.nhs.uk/systemsandservices/pathology/projects/nlmc>

<sup>3</sup> <http://www.pathologyharmony.co.uk/>

to ensure :-

- Control of the work
- Co-ordination between different pieces of work.
- Measurement of outcomes.
- Compliance with internal policy, regulation and standards.
- Accountability and transparency
- Connecting with the needs of users, the broader organisation, and other stakeholders and identifying pathways of advice / decision making

It is important to note that the National Pathology IT Programme Implementation Board is part of the overarching NWIS IT Programme Framework and therefore, the proposed governance approach seeks to enhance and not negate the importance of the existing NWIS IT Governance arrangements. Appendix 4 depicts the Governance arrangement during Implementation- when the Information Standard is being developed and Appendix 5 depicts the Governance Arrangement for Changes to LIMS (i.e. the maintenance of Information Standards)

LIMS Change Advisory Board has the following stated aims:

- to allow proposed Changes due consideration to ensure that their implementation is within the best interests of both the LIMS service and NHS Wales. The method of this consideration is described under CAB Activities below
- to ensure that Changes do not introduce new risks to the IT Service
- to ensure that nationally agreed NHS Wales policies and processes for Change Management are adhered to for the IT Service
- to ensure that the Change Management Procedure for the IT Service is robust, fit for purpose, and adequately balances the tension between development, production and maintenance of the IT Service
- to ensure that there is a process of appeal, discussion and escalation for Change requests that users believe are relevant but have been rejected by the Change Manager or declined by the CAB
- to ensure that there is a process for escalation of RFCs that the CAB is unable to approve without support from either the Service Management Board (SMB) or a higher authority (see Appendix 5 – National IT Change Management Governance)

As required by the Governance arrangements for the programme, LIMS Implementation has NADB Stage 2 approval to pilot at Hywel Dda Health Board and Screening Services. Clinical Risk assessment report was also approved for Lab usage (NADB stage 2).

Secondary feeds (to local or national interfaces and feeds to PHW) from LIMS are identified in Health Boards submissions (Secondary Systems paper) to NADB. Submissions of Betsi Cadwaladr UHB, Cwm Taf HB, Hywel Dda HB and matrix of secondary care system links to LIMS are embedded as Appendix 6. National secondary system feeds Screening Services and PHW are depicted as diagrams in Appendix 7 and 8 respectively.

The Governance arrangements shall be adhered to for maintenance of data in LIMS.

#### **LIMS Data items- detailed:**

The tables below identify all data items used in Replacement LIMS. It also noted the source of data i.e. the data is being sourced either externally (NRDS, National Pathology Catalogue, or other relevant sources) or the data items (mainly test items in LIMS) are being standardised by the National Standardisation groups in Wales (for each discipline), which is again being linked to representative bodies for Pathology in UK (like Pathology Harmony). Individual/group/team responsible for making changes to the data is identified along with process of ongoing review and any amendments to standard data, as applicable.

**Billing**

<b>Sub-table Name</b>	<b>Description</b>	<b>Source-Pathology Service or External</b>	<b>Who Actions changes or Maintains</b>	<b>Process for Ongoing Review</b>	<b>Description of Process used to amend the data to fit LIMS, if any</b>
Activity	Billing code tables or data will not be used	n/a	n/a	n/a	n/a
Bank Codes	Billing code tables or data will not be used	n/a	n/a	n/a	n/a
Banking Codes	Billing code tables or data will not be used	n/a	n/a	n/a	n/a
Batch Audit Codes	Billing code tables or data will not be used	n/a	n/a	n/a	n/a
Batch Credit Codes	Billing code tables or data will not be used	n/a	n/a	n/a	n/a
Batch Credit Types	Billing code tables or data will not be used	n/a	n/a	n/a	n/a
Billing Address	Billing code tables or data will not be used	n/a	n/a	n/a	n/a
Billing Location	Billing code tables or data will not be used	n/a	n/a	n/a	n/a
Complexity Levels	Billing code tables or data will not be used	n/a	n/a	n/a	n/a
Contracts	Billing code tables or data will not be used	n/a	n/a	n/a	n/a
Credit Cards	Billing code tables or data will not be used	n/a	n/a	n/a	n/a
Debtor Action Codes	Billing code tables or data will not be used	n/a	n/a	n/a	n/a
EDI Types	Billing code tables or data will not be used	n/a	n/a	n/a	n/a
GST	Billing code tables or data will not be used	n/a	n/a	n/a	n/a

Sub-table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
Initiation Codes	Billing code tables or data will not be used	n/a	n/a	n/a	n/a
Invoice Type	Billing code tables or data will not be used	n/a	n/a	n/a	n/a
Item Definition	Billing code tables or data will not be used	n/a	n/a	n/a	n/a
Item Schedule	Billing code tables or data will not be used	n/a	n/a	n/a	n/a
Journal Codes	Billing code tables or data will not be used	n/a	n/a	n/a	n/a
Paycodes	Billing code tables or data will not be used	n/a	n/a	n/a	n/a
Reminders	Billing code tables or data will not be used	n/a	n/a	n/a	n/a
Visit Action Codes	Billing code tables or data will not be used	n/a	n/a	n/a	n/a

**Blood Bank**

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
Blood Bank Comments		BT Standardisation	Config Lead	Pathology Service Review – subject to change control	Governance model
Blood Bank Registry	Used to configure the Test Sets and Test Items that will be used for the saving of information to the Antibody Register, Antigen Registry and Transfusion Reaction Registry that have been configured on this	BT Standardisation	Config Lead	Pathology Service Review – subject to change control	Governance model

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
	Code Table.				
Blood Bank Stock Level		BT Standardisation	Config Lead	Pathology Service Review – subject to change control	Governance model
Blood Groups	deals with the set up and configuration of all the Blood Groups that will be received and reported by Lab.	BT Standardisation	Config Lead	Pathology Service Review – subject to change control	Governance model
Blood Pack Actions		BT Standardisation	Config Lead	Pathology Service Review – subject to change control	Governance model
Blood Product	Used to configure the Blood Products that will be used across the Blood Bank Module.	BT Standardisation	Config Lead	Pathology Service Review – subject to change control	Governance model
Blood Product Groups		BT Standardisation	Config Lead	Pathology Service Review – subject to change control	Governance model
Blood Tags	Used to configure attributes that can be assigned to Blood Packs or Patients. For example: CMV negative, Irradiated Blood etc.	BT Standardisation	Config Lead	Pathology Service Review – subject to change control	Governance model
Country Collection Facility	Used for ISBT128 configuration for International Identification of Blood Product country of origin.	BT Standardisation	Config Lead	Pathology Service Review – subject to change control	Governance model
Emergency Issue		BT Standardisation	Config Lead	Pathology Service	Governance model

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
				Review – subject to change control	
Location of Blood Products	Used for the configuration of storage locations where the Blood Product Units can be located.	BT Standardisation	Config Lead	Pathology Service Review – subject to change control	Governance model
Mode of Transport		BT Standardisation	Config Lead	Pathology Service Review – subject to change control	Governance model
Phenotype	Used for the configuration of Phenotypes for Pack Units for patients.	BT Standardisation	Config Lead	Pathology Service Review – subject to change control	Governance model
Status Codes	Used for the configuration of Status codes that will be used when entering Blood Bank results and for Pack Transactions.	BT Standardisation	Config Lead	Pathology Service Review – subject to change control	Governance model
Suppliers of Blood Products	used for the configuration of the supplier of Blood Products to the laboratory	BT Standardisation	Config Lead	Pathology Service Review – subject to change control	Governance model
Transactions		BT Standardisation	Config Lead	Pathology Service Review – subject to change control	Governance model
Transfusion Events		BT Standardisation	Config Lead	Pathology Service Review – subject to change control	Governance model
Visible Inspection		BT Standardisation	Config Lead	Pathology Service Review – subject to change control	Governance model



Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
X-Match Messages		BT Standardisation	Config Lead	Pathology Service Review – subject to change control	Governance model

### Clinical Terminology

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
Snomed Codes		External Reference Data/via Health Reference Data team	Op Team	Only to used by Cellular Pathology	
Snomed Modifier		External Reference Data/via Health Reference Data team	Op Team	Only to used by Cellular Pathology	

### Day Book Laboratory

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
Failure Codes		Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Laboratory Codes	used to define the Daybook laboratories that will be using Daybook	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Laboratory Codes - Block Codes		Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
Laboratory Codes - Procedures		Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Laboratory Codes - Stain Codes		Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Laboratory Codes - Anatomical Sites		Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Laboratory Codes - Original Site Code		Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Laboratory Codes - Status		Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Laboratory Codes - Location		Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Laboratory Reports	Used to construct a wide range of laboratory reports. The reporting format can include Test Items, Test Sets, Snomed Codes, T-Codes. The reports generated in Snomed, T-Code and M-Code format are used to supply Statutory Bodies such as the Cancer Council. Reports generated by Test Items are distributed to	Standardisation Group/Clinical Strategy Group	Config Lead	Pathology Service Review – subject to change control	Governance model

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
	interested parties internally and occasionally, externally.				
Method of Collection	User can assign a P-code to each entry. When the method of collection is added against a Daybook number the P code is automatically added. It will form a group with any T-code entered in Patient Entry on the same Accession number line.	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Reports	Allow Users to define and configure reports that will use Line of Text for their searches. The report can only be generated for Word Test Sets or RTF's Test Sets such as CCR Reports.			Pathology Service Review – subject to change control	Governance model
Workbench Actions		Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Workbench Actions - Conditions		Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model

**Doctor Information**

<b>Sub table Name</b>	<b>Description</b>	<b>Source-Pathology Service or External</b>	<b>Who Actions changes or Maintains</b>	<b>Process for Ongoing Review</b>	<b>Description of Process used to amend the data to fit LIMS, if any</b>
Doctor Codes	Information configured in this Code Table ranges from demographic, billing, report formats etc.	NRDS/Clinical Strategy Group	Op Team	Amended as New National Codes are issued	Eventually automated or semi-automated using Upload sheets
Doctor Codes - Speciality		NRDS/Clinical Strategy Group	Op Team	Multiple Specialities require Service to define defaults	Data Input when new Doctor is Entered
Doctor Groups	Facilitates the grouping of Doctors, Regions, and Practices etc. which can be used for statistical reporting.	Clinical Strategy Group	Op Team	Applies to GPs only	Changes on update from NRDS
Doctor Groups - Doctors in Group		Clinical Strategy Group	Op Team	Applies to GPs only	Changes on update from NRDS
Marketing Codes	Used for the realisation and distribution of commissions paid by the laboratories to client.	n/a	n/a	n/a	n/a
Special Interest Codes	Used to extrapolate data for client Doctors who are engaged in special interest medicine. For example a Doctor may have a special interest in the Diabetes Association and therefore would be interested in test result data sugar levels, biochemistry profiles etc.	n/a	n/a	n/a	n/a
Speciality Codes	Used to define and configure Doctors Specialties.	External Reference Data	Op Team	National Lists	Amended if Changed

**General Laboratory**

<b>Sub table Name</b>	<b>Description</b>	<b>Source-Pathology Service or External</b>	<b>Who Actions changes or Maintains</b>	<b>Process for Ongoing Review</b>	<b>Description of Process used to amend the data to fit LIMS, if any</b>
Cancer Council		n/a	n/a		
Category (patient category list)		Clinical Strategy Group	Op Team	Historical Standard Categories	Amended as required
Centre Codes (collection centre list)	Used for sites that operate or partner collection centres. It can be used for gathering billing and statistical data.	n/a	n/a		
Client Codes	Used for the configuration of client codes that are used for the transmission of requests or results via EDI or Email. (Electronic Requesting)	Change Manager	Op Team	No need unless a new requirement	As required
Clinical Conditions	Used to configure Clinical Conditions that may require unique Reference Ranges applied to the condition.	Clinical Strategy Group	Op Team	Specific Codes for Calculations, etc. As agreed with CSG	
Clinical History Codes	Affects Registration Modules by offering short cut codes within Registration Modules.	Clinical Strategy Group	Op Team	Upload from PCH using a Leeds University Coding Convention	Update as agreed with CSG
Collection Lists	Defines how the Patient collection list is to be distributed. This can represent the Name of individual collectors, Collection sites or Departments.	n/a	n/a	n/a	n/a
Company Codes	Defines Company Code details. The details defined on this table are the core competency for the recognition of revenue and affects all Billing	n/a	n/a	n/a	n/a

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
	Modules.				
Company Codes – Providers		n/a	n/a	n/a	n/a
Competencies		n/a	n/a	n/a	n/a
Courier Codes	Directly affects the all Doctor Reports functionality. Its principal purpose is the printing of Doctors reports distributed by courier runs.		Op Team	As required subject to change control	Code uses Site code (7A1A1) plus Alpha Character
Courier Codes - Schedule			Op Team	As required subject to change control	As defined by individual sites
Department	used for the configuration of Departments in Trak	Clinical Strategy Group	Op Team	Only required if new department is identified	n/a
Department - Staff Notes		Clinical Strategy Group	Op Team	Use to be defined by individual departments	n/a
Department - Department Pathologist		Clinical Strategy Group	Op Team	All Cellular Pathologists need classifying as such using their user name + full name	n/a
Department - Languages	English, Microbiology, Mortuary	Clinical Strategy Group	Op Team	Any others to be defined by CSG	n/a
Ethnicity	Used to code Ethnic Groups.	Clinical Strategy Group	Op Team	Combination of National codes from EMPI and Pathology Specific derived codes	n/a

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
Fasting	Configure fasting status of specimens collected- to be used only for positive ID of fasting status	Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	n/a
Issuing Authority	From EMPI	External source/EMPI	Op Team	Match to EMPI; some pathology specific ones	n/a
Label Code Definitions	Define specimen label types.	Clinical Strategy Group	Op Team	Suffix definitions for Specimen types must match with WPH	n/a
Label Codes - Test Definition		Standardisation Group	Op Team	Suffix definitions for Specimen types must match with WPH	n/a
Letter Codes (standard letter list)	User will establish the conditions by which the letter types (e.g. PAP reminders Letters, etc.) will be generated.	Standardisation Group	Op Team		As defined by departments using the codes
MRN Prefix Definitions	Used to define MRN prefix for different sites.	n/a	Op Team	n/a	n/a
Numeric Codes (numeric coded results list)	These are special codes that can be entered in numeric test items when a numeric result cannot be entered, such as when the specimens is clotted, haemolysed etc.	Standardisation Group	Config Lead/Op Team	Codes that can be used instead of numeric characters. May need reviewing depending upon electronic communications	
Patient Entry Actions	Actions that relate to Patient Entry Module are configured in this code table. Rules at registration are configured	Standardisation Group/Clinical Strategy Group	Config Lead/Op Team		As defined by individual disciplines

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
Patient Entry Actions - Conditions		Standardisation Group/Clinical Strategy Group	Config Lead/Op Team		As defined by individual disciplines
Patient Location	Used to define the various locations used by patients throughout the Hospital.	NRDS	Op Team		n/a
Patient Type		Clinical Strategy Group	Op Team		Generally from National returns but some Pathology Specific values added
Patient Warnings	Where the users configure the warning message boxes that will appear in the Registration modules- values used to trigger patient specific actions	Clinical Strategy Group	Config Lead/Op Team	Pathology Service Review – subject to change control	n/a
Person (personnel)	Used for administration purposes as it lists all employee details. It is also used to identify collectors in Patient Entry Modules and for security access purpose in Account Modules.	n/a	n/a	n/a	n/a
Personnel Type	Defines the job description of individual employees and is linked to System Management User Code Table- Only required if specific action against type of staff	Clinical Strategy Group	Op Team		
Post Code	Lists the postcodes applicable to locations, patients or any fields that require a postcode. A flat file can be	External Reference Data- EMPI. No postcode software to be used	Op Team		Mostly populated from EMPI



Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
	imported with all suburbs and postcodes				
Print Format Definition (print format list)	The information supplied in this code table is generated in Doctor Information code table and directly affect the printing modules.	Clinical Strategy Group	Op Team	Unlikely to change unless specific requirement identified	
Priority Codes	Internal use mainly to manage workflows	External Reference Data/Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	
Referral Laboratories	Laboratories to which samples may be sent in order to confirm results or to perform specialised tests not carried out in Wales	Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	As identified by the Service- Code structure first 2 letters of town/city plus acronym of Lab
Referral Laboratories - Test Sets		Clinical Strategy Group	Config Lead	Pathology Service Review – subject to change control	As defined by Specific sites
Report Page Definition	used to stipulate the layout in the printed test set report	Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	As defined by disciplines
Species	Users can configure gender and animal species (Values used- Male, Female and unknown)	n/a	n/a	Pathology Service Review – subject to change control	
Specimen Collection Point Type	Defines the physical and geographical collection points for a laboratory. This code table and its impact on various LabTrak modules only	Clinical Strategy Group	Op Team	n/a	n/a

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
	applies to Australian sites as it is a requirement of the Health Insurance Commission of Australia (HIC)				
State	Enter the code and description for the geographical State (where applicable).	n/a	n/a	n/a	n/a
Title	Enter the various titles that are applicable to patient(s) with the appropriate gender- not defined in detail	Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	n/a

### Hospital

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
Trak MPI		Change Manager	Op Team		

### Machine Interface

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
Machine	Used to configure Machine Interfaces that will be used in the laboratory	Change Manager	Op Team	Site/ Instrument specific	Governance model
Machine Flags	Used to map the Instrument flags.	Standardisation Group	Config Lead	Site/ Instrument specific	Governance model

**Microbiology**

<b>Sub table Name</b>	<b>Description</b>	<b>Source-Pathology Service or External</b>	<b>Who Actions changes or Maintains</b>	<b>Process for Ongoing Review</b>	<b>Description of Process used to amend the data to fit LIMS, if any</b>
Antibiotics	used for the configuration of Antibiotics that will be used in Microbiology	Micro Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Antibiotics - Sensitivities		Micro Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Antibiotics - Language		Micro Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Antibiotics Coded Comments	used for the configuration of Comments that are associated with the antibiotics	Micro Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Outbreak	Used to assign an identifier to outbreaks/incidents as an when they occur.	Micro Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Panels	Used for the configuration of Antibiotic Panels that can be assigned to a pathogen or a pathogen group.	Micro Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Panels - Bill Items		Micro Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Panels - Antibiotics		Micro Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Pathogen Groups	Used for the grouping of pathogens.	Micro Standardisation Group	Config Lead	Pathology Service Review – subject to	Governance model

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
				change control	
Pathogen Groups - Antibiotic Panels		Micro Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Pathogen Groups - Pathogens in Group		Micro Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Pathogen Groups - Antibiotic Cross Reference		Micro Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Pathogen Groups - Rules		Micro Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Pathogen Groups - Auto Comment Criteria		Micro Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Pathogens	Used for the configuration of Pathogen in Microbiology.	Micro Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Pathogens - Antibiotics Cross Reference		Micro Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Pathogens - Rules Conditions and Results		Micro Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Pathogens - Auto Comment Criteria		Micro Standardisation Group	Config Lead	Pathology Service Review – subject to	Governance model

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
				change control	
Pathogens - Antibiotics Panel		Micro Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Sensitivities	Used for configuration of sensitivity for the antibiotic selected.	Micro Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model

#### Print Information

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
Print Destination		Site specific	Op Team	As required by the site	
Print Destination - Alternative Destinations		Site specific	Op Team	As required by the site	
Print Destination - Print Destination Stationery		Site specific	Op Team	As required by the site	
Printer Type		Site specific	Op Team	As required by the site	
Printer Type - Variables		Site specific	Op Team	As required by the site	
Report Group		Site specific	Op Team	As required by the site	
Stationery		Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	

**QC**

Sub table Name	Description	Source-Pathology Service or External	Who Actions or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
QC Comments		Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
QC Groups		Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
QC Groups Rules (sub table of QC Groups)		Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
QC Materials		Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
QC Rules		Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model

**Systems- Defined by Service. Only likely to be changed based on specific HB/Service requirements.**

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
Accreditation Numbers	Used to assign laboratory accreditation numbers (CPA/UKAS) to sites and to assign individual accreditation numbers to tests. Important for Food, Water and Environmental +/- microbiology	n/a	n/a	Pathology Service Review – subject to change control	Governance model

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
Altitude		n/a	n/a	n/a	n/a
Calendar	Each site can add the dates that are classified as public holidays etc, the dates entered here will indicate to the laboratory not to perform any assays on these dates.	n/a	n/a	n/a	n/a
Client Specific Routines	As defined by InterSystems to support specific requirements	Standardisation Group/Clinical Strategy Group	Op Team		
Client Specific Routines - Parameters	As defined by InterSystems to support specific requirements	Standardisation Group/Clinical Strategy Group	Op Team		
Client Specific Routines - Schedule	As defined by InterSystems to support specific requirements	Standardisation Group/Clinical Strategy Group	Op Team		
Cross Match Fields		BT Standardisation Group	BT Config Lead	Pathology Service Review – subject to change control	Governance model
Laboratory Configuration	Default fonts, passwords etc	Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	Governance model
Labtrak / Medtrak Configuration		Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	Governance model
Out of Hours		n/a	n/a		Governance model
Patient Inquiry Fields		Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	Governance model
Print Variables		Change Manager	Op Team	Pathology Service Review – subject to change	Governance model

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
				control	
Queries		Standardisation Group/Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	Governance model
Report Generic		Standardisation Group/Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	Governance model
Report Generic - Parameters		Standardisation Group/Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	Governance model
Report Generic - Schedule		Standardisation Group/Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	Governance model
Report Header		Standardisation Group/Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	Governance model
Report Header Non Standard		Standardisation Group/Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	Governance model
Report Routines	Used to transform generic reports in to customized reports.	Standardisation Group/Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	Governance model
Request Type		Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	Governance model
Standard Variables		Clinical Strategy Group	Op Team	Pathology Service Review – subject to	Governance model



Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
				change control	
System Languages	Languages that the laboratory may require.	Standardisation Group/Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	Governance model
System Wide Defaults	Used to define parameters such as fonts, password lengths and expiry etc.	Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	Governance model
User Sites	Used to configure User Sites/Locations.	NRDS	Op Team		
User Sites - Workbench		Standardisation Group/Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	Governance model
VB Executables	Used for the design format to be used in the Main Menu Screen.	Change Manager	Op Team		
VB Executables - Language		Change Manager	Op Team		
VB Executables - Options		Change Manager	Op Team		
VB Messages	Used for the configuration of text messages which are accessible throughout the Trak system.	Standardisation Group/Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	Governance model
Verification Queue	Create a hierarchy of authorisation levels. For example verification queues can be set up to send a test set to a queue if a certain condition is met (similar to sending a test set to pathologist	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
	attention), or define a default number of queues that that the test set must travel before the final authorisation is complete- Discipline/site specific				
Verification Queue - Users	Discipline/site specific	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model

### Systems Management

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
Code Table Control	Only used by TrakHealth implementation staff. TrakHealth implementation staff will assign the laboratory the ability to delete certain entries in LabTrak.	Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	Governance model
Fax Exclusion		Clinical Strategy Group	Op Team	n/a	n/a
System Management Groups	Defines the access allowed to Security Groups within the Trak system.	Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	Governance model
System Management Users	deals strictly with the configuration of Users in Trak	Clinical Strategy Group	Op Team	Pathology Service Review – subject to change control	Governance model
Work Area		Standardisation Group	Config Team	Pathology Service Review – subject to	As required by the site/department

				change control	
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### Test Sets

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
Anatomical Sites	Used to configure anatomical sites. These sites can be associated specific with Day Book Laboratories.	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Animal Breed	Used to configure Animal Species for Veterinary Laboratories.	n/a	n/a	n/a	
Collection Containers	User defines the types of collection containers to be used by the Lab.	Standardisation Group/Clinical Strategy Group	Config Lead	n/a	
Container Manufacturers	User defines the Container Manufacturers for the collection containers	n/a	n/a	n/a	
Differential Counter Setup	Define the differential counter set up for pathology test.	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Down Syndrome	used for the configuration of the risk factor assessment for Down Syndrome	n/a	n/a	Pathology Service Review – subject to change control	Governance model
Dynamic Function Test (DFT)	used for configuration of Dynamic Function Test.	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Dynamic Function Test (DFT) - Test Sets		Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
Dynamic Function Test (DFT) - Samples		Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Dynamic Function Test (DFT) - Layout		Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Final Line Diagnosis	Used for the coding of final diagnosis comments. Users can create their own coding system, and perform ODBC queries on these codes.	Standardisation Group/Clinical Strategy Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Histology Codes	used for the configuration of Histology codes and comments	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Histology Report Group	Used for the grouping of Histology Codes. The bookmarks for the grouping are configured in this Code Table	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Methods	Used to configure the types of methods used in Lab Testing	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
National Test Codes	Code Table the User defines the National Test Codes to be used by the Lab	External Reference Data-NRDS (Read code list)	Op Team		Changes on update from NRDS
Reasons	User defines the Reasons to be used by the Lab - Specimen rejections	Standardisation Group/Clinical Strategy Group	Config Lead	Pathology Service Review – subject to change control	Service Code table 1 Prefix= Most common 2 Prefix = 2 <sup>nd</sup> most common 3 Prefix = Wrong specimen BT= Blood transfusion

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
					D= Denied request H = Histo RJ = Cell Path
Sections	Define sections with a department, and set some report printing options	Standardisation Group	Config Lead	n/a	n/a
Sections - Language		Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Specimen Class	Not used	n/a	n/a		
Specimen Groups	Used to group related specimen types	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Specimen Groups - Items		Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Specimens	Used to configure the specimen types.	Standardisation Group/Clinical Strategy Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Specimens - Specimen Types Blocks		Standardisation Group/Clinical Strategy Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Specimens - Anatomical Site		Standardisation Group/Clinical Strategy Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Specimens - Languages		Standardisation Group/Clinical Strategy Group	Config Lead	Pathology Service Review – subject to change control	Governance model

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
Specimens - Methods of Collection		Standardisation Group/Clinical Strategy Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Storage Containers	Racks in fridge	LHB/Site Defined	Config Lead	Pathology Service Review – subject to change control	Discipline/department specific
Storage Containers - Test Sets		LHB/Site Defined	Config Lead	Pathology Service Review – subject to change control	Discipline/department specific
Storage Containers - Procedures		LHB/Site Defined	Config Lead	Pathology Service Review – subject to change control	Discipline/department specific
Storage Places		LHB/Site Defined	Config Lead	Pathology Service Review – subject to change control	Discipline/department specific
Superset	Used to create pathology test profiles. Supersets are defined by individual Laboratories and are made up of a number of predefined Test Sets	Standardisation Group/Clinical Strategy Group	Config Lead	Pathology Service Review – subject to change control	National supersets to aid data entry. Localised ones to be prefixed with last character of health Board code
Superset - Fees + Items		Standardisation Group/Clinical Strategy Group	Config Lead	n/a	
Superset - SuperSet Items	Defines content of superset	Standardisation Group/Clinical Strategy Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Superset - DFT		Standardisation Group/Clinical Strategy Group	Config Lead	Pathology Service Review – subject to change	Governance model

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
				control	
Test Item Definition	Used to define and create Test Items, which are the building blocks of Test Sets	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Discipline specific
Test Set Group With	Discipline specific groups of tests to be reported together	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Discipline specific
Test Sets	Discipline specific	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Test Sets - Report/Collecting Info	Discipline specific	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Test Sets - Common Actions	Discipline specific	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Test Sets - Auto Auth/Exclude	Discipline specific	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Test Sets - Auto Comments	Discipline specific	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Test Sets - Fees + Items	Discipline specific	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Test Sets - User Site Specific	Discipline specific			Pathology Service Review – subject to change	Governance model

Sub table Name	Description	Source-Pathology Service or External	Who Actions changes or Maintains	Process for Ongoing Review	Description of Process used to amend the data to fit LIMS, if any
				control	
Test Sets - Containers / Specimens	Discipline specific	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Test Sets - Specimens	Discipline specific	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Test Sets - TS Layout Exceptions	Discipline specific	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Test Sets - Language	Discipline specific	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Test Work Group	Discipline specific	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Test Work Group - Group Test Sets	Discipline specific	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Test Work Group - Reporting	Discipline specific	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model
Test Work Group - Group Test Items	Discipline specific	Standardisation Group	Config Lead	Pathology Service Review – subject to change control	Governance model



## SECTION 6: IMPLEMENTATION PLAN

### 19. Implementation plan



Correction Plan  
Time-Line v8-0.xlsx

### 20. Official Documentation

Embedded under appropriate sections or as Appendix

## SECTION 7: MAINTENANCE AND REVIEW

### 21. Maintenance Process

The data feed via NRDS will be maintained as daily electronic updates which will be automatically loaded. Any amendments to existing data sourced from NRDS will be logged via Service Point and updated by LIMS operational team.

The data sourced from Pathology Service will undergo Governance process as noted earlier- to include Standardisation groups, standing Specialist Advisory Groups (if required), Clinical Strategy Group and Change Advisory Board.

### 22. Planned review dates

As required by the Service

## **Appendix 1**

### Information Governance Approach- LIMS



SEC.4.1.1.PR.Information\_Governance\_Aj

## **Appendix 2**

### Clinical Risk Assessment Report



SEC 3 3 2 PR  
LIMS\_Clinical\_Risk\_As

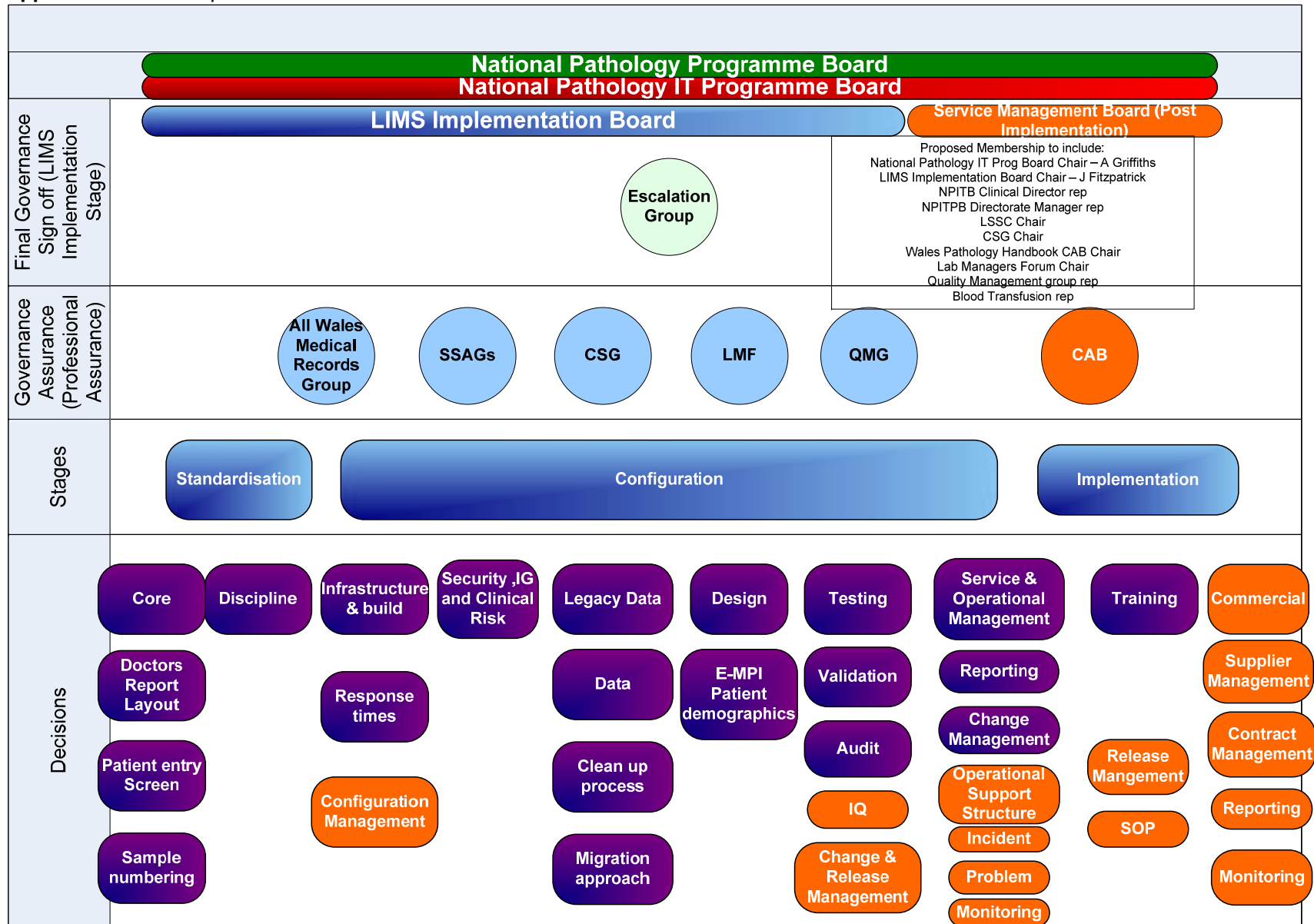
## **Appendix 3**

### LIMS Implementation Board Governance Arrangements

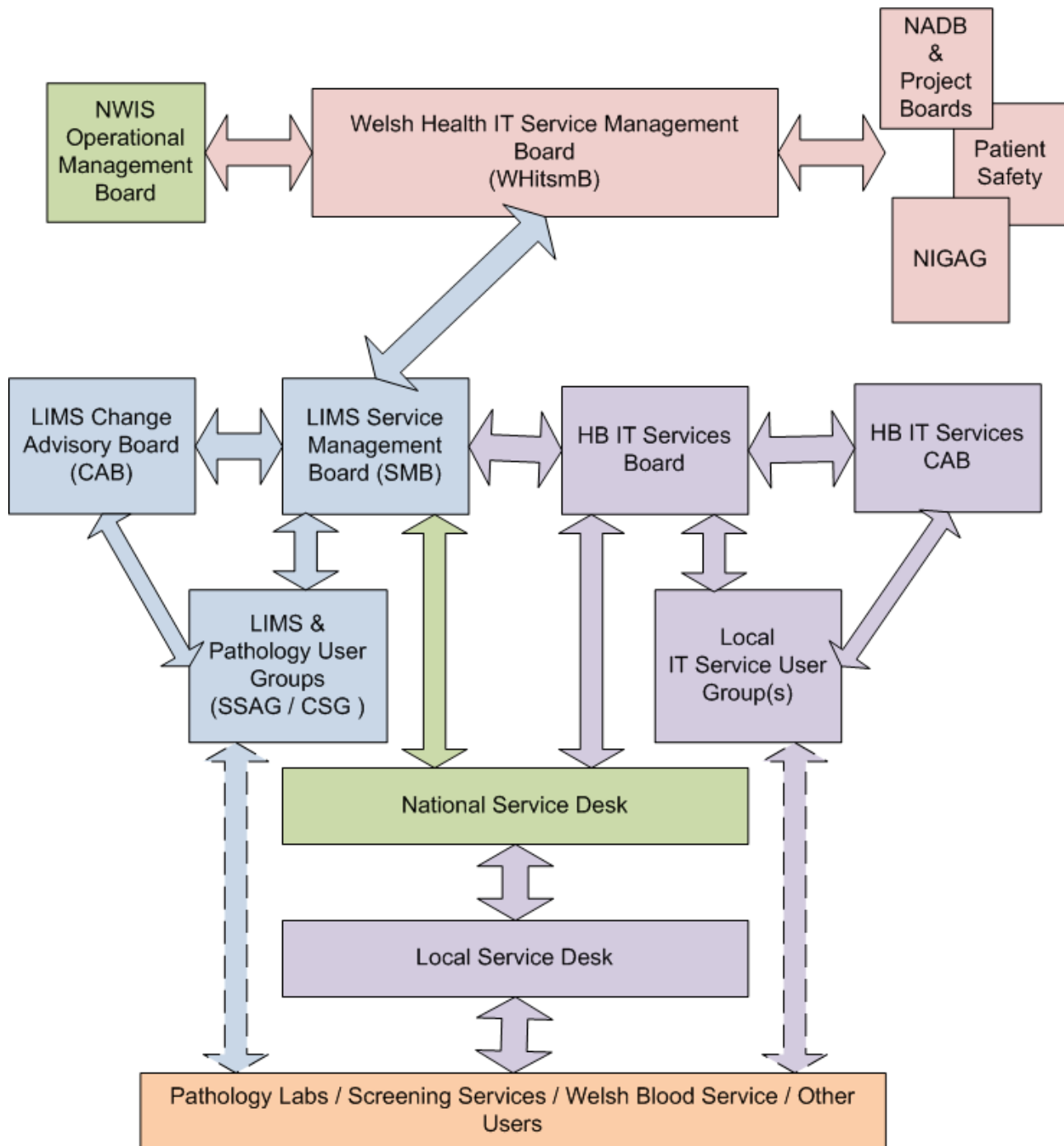


PRC.7.7.GE.LIMS\_Im  
plementation\_Board\_

**Appendix 4: LIMS Implementation Phase Governance Framework**



**Appendix 5: National IT Change Management – LIMS Change Governance**



## Appendix 6:

### Secondary systems submission to NADB by Betsi Cadwaladr UHB



NADB(Sept 2010) -  
BCU Secondary Syste

### Secondary systems submission to NADB by Cwm Taf HB



NADB -  
SecondarySystems\_C

### Secondary systems submission to NADB by Hywel Dda HB



NADB(2011)23 Apr -  
SecondarySystems\_F

### LIMS links with Secondary Care systems Matrix

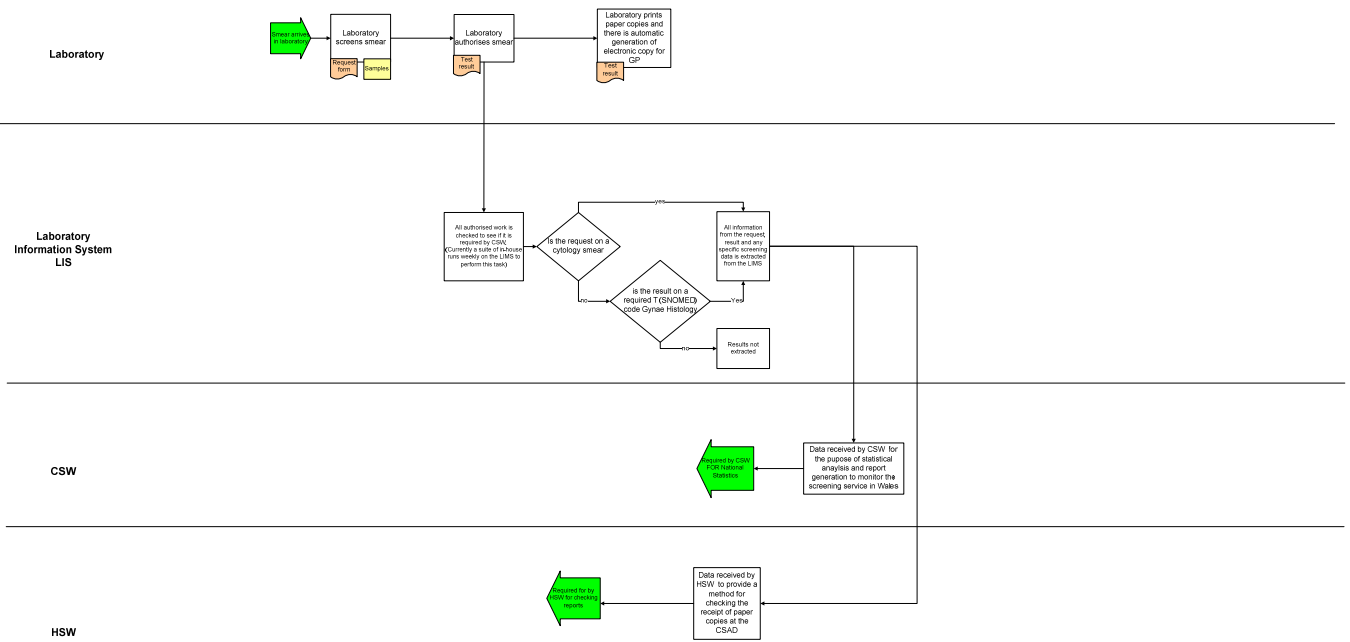


LIMS Links with  
Secondary Care Syst

Appendix 7:

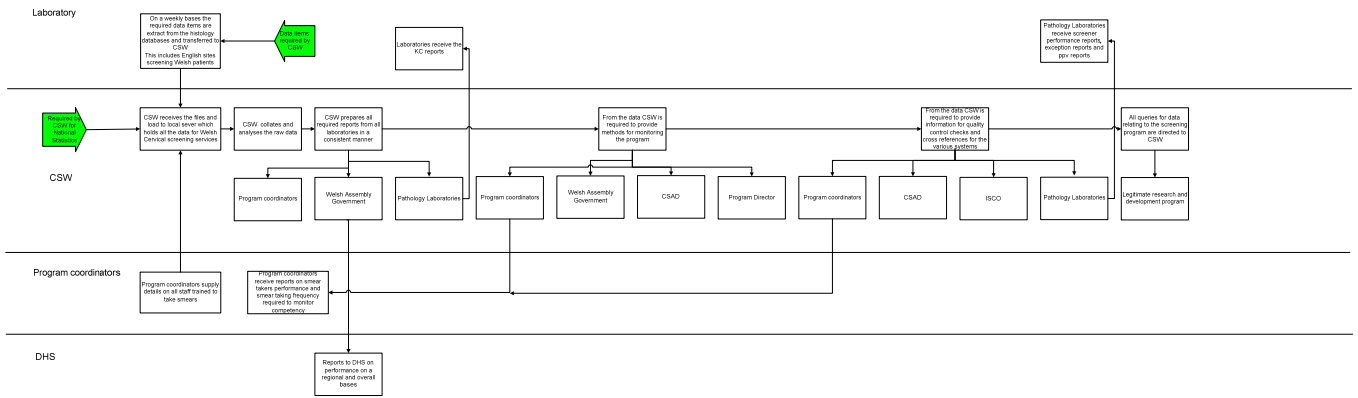
Data flow diagrams for Screening Services:

Electronic Data flow from Cytology Departments to Cervical Screening Wales – CSW and Health Solutions Wales - HSW



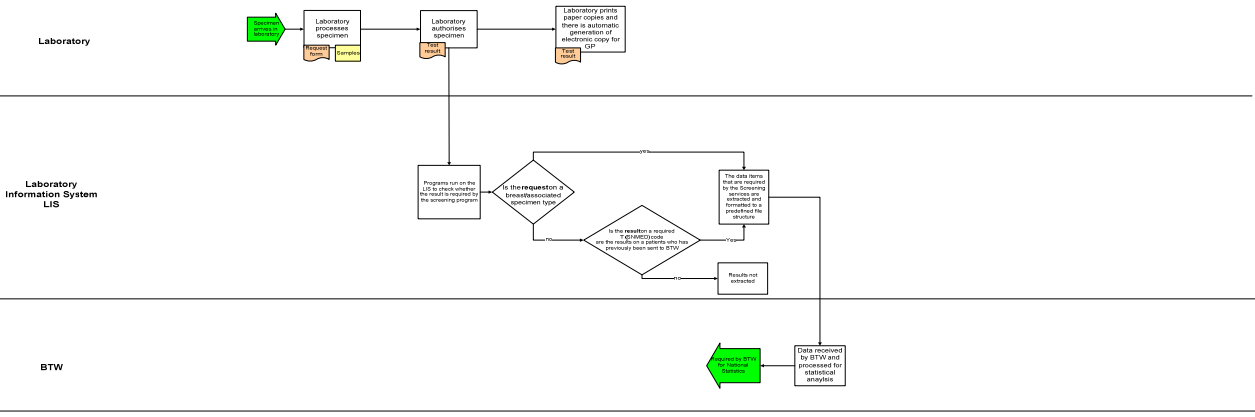
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Operation	Data flow to CSW		
Created by	Karen Winder	Date	28.06.10

Data processing and report generation in CSW



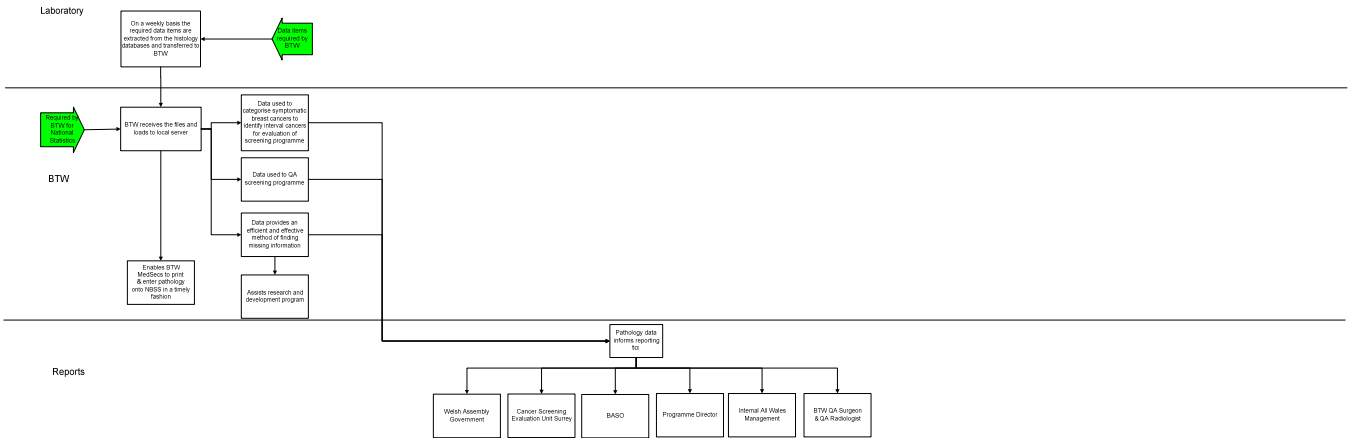
Title	Cervical Screening	Version	2
Operation	Data processing within CSW		
Created by	Karen Winder	Date	28.06.10

Weekly Electronic Data flow from Histology Departments to Breast Screening Wales' SQL Server



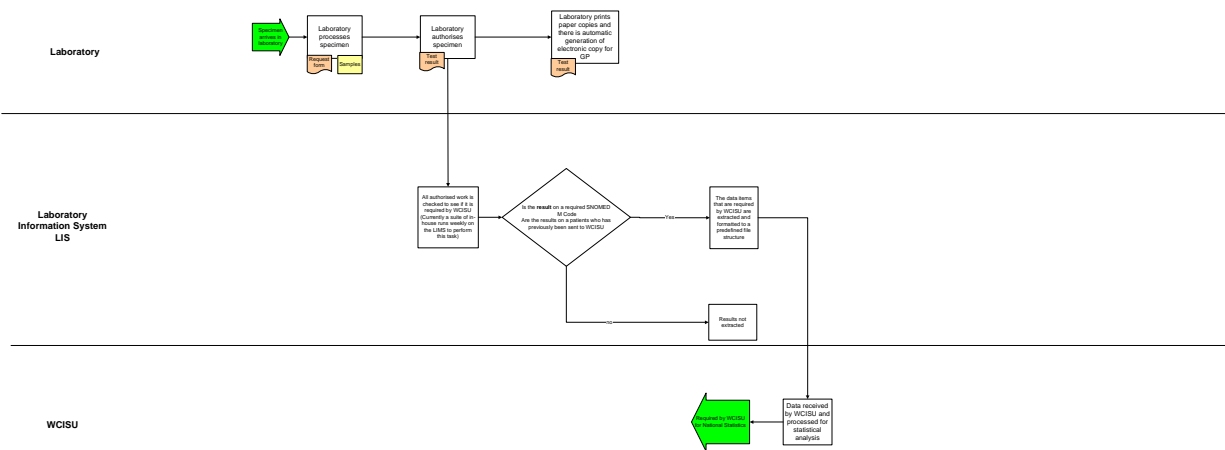
Title	Breast Screening	Version	2
Operation	Data flow to BTW		
Created by	Karen Winder	Date	28.06.10

Data processing and report generation in BTW



Title	BTW Screening	Version	2
Operation	Data processing within BTW		
Created by	Karen Winder	Date	28.06.10

Weekly Electronic Data flow from Histology Departments to WCISU SQL Server



Title	Breast Screening	Version	2
Operation	Data flow to BTW		
Created by	Karen Winder	Date	28.06.10



Appendix 8:

PHW Datastore Configuration

