



QUALITY AND STAFF ORIENTATION MANUAL Document ID# QS-Proc-1

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SCOPE

- This document complies with the **ISO 15189 Clause 4.2.4**.
- It applies to all areas of Pathology Services at the RHH.
- It must be read in association with the documents listed in the **Quality Systems section of QPulse.**
- Departments within Pathology Services may have **Departmental Quality Manuals** which contain additional material and those **must be read in association with this document.**
- In addition the Royal Hobart Hospital has Policy and Procedure Manuals which are now only available online on the RHH Intranet.

http://intra.dhhs.tas.gov.au/dhhs-online/page.php?id=16956



INTRODUCTION

The purpose of this document is to provide all staff with an outline of the Department's overall

- objectives
- functions
- management
- organisation
- policies





• procedures

and define how these are aligned with the specifications given in ISO 15189 : *Medical Laboratories – Particular Requirements for Quality and Competence.*

DESCRIPTION OF RHH PATHOLOGY SERVICES (Clause 4.1)

The Department is located in the Royal Hobart Hospital on Level 1, D Block. The Specimen Collection Service that operates under the name of Pathology South is located on the 2nd Floor of the Wellington Centre, Argyle Street. Royal Hobart Hospital Pathology Services is composed of the following discipline specific / functional units :

Anatomical Pathology

This includes Routine Histology, Immunohistology, Cytology, Electron Microscopy, and the Mortuary.

This Department is the major public sector specialist referral centre for Anatomical Pathology in Tasmania and provides

- a surgical biopsy service
- an autopsy service
- gynaecological and non-gynaecological cytology services, including fine needle aspirate cytology
- a statewide renal biopsy service
- a State Reference Service for specialist techniques such as electron microscopy and immunohistochemistry.

The Department also has a considerable involvement with undergraduate teaching in anatomical pathology and has trained the majority of specialist anatomical pathologists practising in Tasmania.

Core Laboratory

This includes Clinical Biochemistry, Coagulation, Haematology, Transfusion Medicine. It is also the location of the Central Specimen Receipt and Processing Unit, (CPU).

This laboratory provides the critical care and automated services to the RHH, the Hobart Private Hospital, Clinics and General Practitioners. These services include the routine investigations associated with

- Full Blood Examination
- Haematomorphology
- Routine Coagulation tests
- Coagulation Factor assays
- Hypercoagulability testing
- Platelet Function studies

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- Routine Biochemistry electrolytes, liver function tests, amylase, calcium and magnesium
- Lipids
- Cardiac Markers
- Therapeutic Drug Monitoring
- Drugs of Abuse Screening tests
- Arterial Blood Gases and Electrolytes
- Near Patient Testing Instrumentation support
- Routine Blood Transfusion Services including Antenatal Screening
- Provision of blood and blood products
- Red Cell Antibody Identification

The laboratory features modern instrumentation and is highly computerised with on-line data acquisition and electronic reporting. The services are offered 24 hours a day, 365 days a year.

Routine Tests are completed with as short as possible turn around times within the laboratory to meet their aim of providing Clinical Staff with the rapid and reliable information that they require for their patients' management.

The laboratory also coordinates the maintenance, general support and user training for the Near Patient Testing equipment in the RHH Departments of Emergency Medicine, Adult Intensive Care, Neonatal Intensive Care and the Cardiothoracic Operating Theatre.

Cytogenetics

Cytogenetics is the study of chromosome structure, function and pathology. Cytogenetic studies are used for diagnostic purposes in three main areas of medicine :

- Congenital Disorders Indications include dysmorphic infants, growth retardation, late onset of puberty or infertility
- Leukaemia diagnosis and prognosis
- Other Cancers

The Cytogenetics Laboratory performs constitutional cytogenetics on peripheral blood from patients suspected of having a congenital chromosome abnormality. Such patients may include dysmorphic infants, young children with growth retardation, adolescents with late onset of puberty or adult couples experiencing infertility.

Cytogenetic studies are also performed on cells from bone marrow where leukaemia is suspected and on cells from solid tumours. In cancer, particularly in leukaemia and lymphomas, the cytogenetic findings may be diagnostic or provide prognostic information important for the clinical management of the patient.





Molecular Medicine

The molecular basis of most human disease is being revealed by scientific and technical advances in the fields of molecular biology, genetics and recombinant DNA technology. Modern molecular diagnostics in this laboratory is directed towards three areas :

- Infectious Diseases
- Markers of neoplastic diseases
- Diagnosis of Inherited Disorders and the detection of carrier status.

Molecular Pathology Testing is playing an increasingly important role in routine patient management; from initial diagnosis through to monitoring response to specific therapies.

This laboratory has active externally funded research programmes and the staff are dedicated to the development, evaluation and use of technologies that will increase the speed, sensitivity and specificity of DNA testing in the future.

Endocrinology

The Endocrinology Laboratory functions as a tertiary referral centre for the investigation of most endocrine disorders. The service includes :

- A comprehensive range of basic and specialised hormone assays that are indicated in the areas of Diabetes, Thyroid, Adrenal, Pituitary, Fertility, Growth and Parathyroid disorders.
- Tests carried out in the dynamic assessments of patients to investigate abnormalities in trophic to target hormone relationships.
- Biochemical and genetic screening of patients who have Multiple Endocrine Neoplasia Type 1, (MEN1).
- The Department has strong research commitments in the areas of Thyroid Autoimmunity and metabolism, Diabetes management, MEN1 and other inherited endocrine malignancies, Parathyroid and Calcium metabolism. Both the Laboratory and the RHH Endocrinology Department have significant external funding to support these programmes and have gained significant recognition both nationally and internationally for their research work.

The staff contribute significantly to the undergraduate and postgraduate teaching programmes of the RHH and the University of Tasmania.

Microbiology

This includes Viral Serology, Infectious Diseases and Sexual Health Services

The Microbiology Laboratory supports clinicians managing patients with infections by isolating, identifying and characterising micro-organisms causing disease.

A variety of methods are used including

- direct microscopy,
- culture,





- serology
- and molecular techniques.

The laboratory has particular expertise in diagnostic molecular biology and is the Statewide Reference Laboratory for HIV and Hepatitis C testing.

The laboratory works in close collaboration with Public Health and Infection Control Services when and where necessary.

Special Investigations

This includes the Specialised Haematology, Stem Cell Transplant Service, the Flow Cytometry Laboratory and the Specialised Chemistry Laboratory.

This is the major Tasmanian Referral Laboratory for haematology investigations requiring specific expertise and receives specimens from all public and private sector pathology services in Tasmania. The laboratory is divided into four functionally distinct areas.

The *Stem Cell Transplant Laboratory* provides all aspects of the Tasmanian Statewide Bone Marrow Transplant Service, as well as expert advice and resources to clinicians. This laboratory receives harvested bone marrow or peripheral blood, processes, tests and cryopreserves the stem cells and maintains the bone marrow cryogenic facilities.

The *Flow Cytometry Laboratory* provides a Statewide Cell Marker service performing the following investigations :

- Immunophenotyping of lymphoproliferative and myeloproliferative disorders to assist in diagnosis and classification.
- Measurement of lymphocyte subsets as part of the assessment of immune status in HIV/AIDS and other suspected immune deficiency states
- Quantitative CD34 assays to evaluate the transplantation of potential stem cell harvests.

The Special Haematology Laboratory performs specialist testing including :

- Haem pigment investigations
- Lysozyme assays
- Red Blood Cell haemolysis investigations
- Identification of Malarial Parasites
- ELISA based assays including Anticardiolipin, $\beta 2$ glycoprotein, Intrinsic Factor antibodies
- ENA

The *Specialised Chemistry Laboratory* performs a range of specialised, complex and largely non-automated tests for clients throughout Tasmania including organizations requiring occupational monitoring. Specialist testing includes





- Trace element analyses : Lead and cadmium, usually for occupational monitoring and copper, zinc and selenium, usually for nutritional studies and parenteral nutrition patients
- Urinary free catecholamines
- A large number of qualitative and quantitative protein assays by
 - Automated immunoassays
 - Electrophoresis
 - and isoelectric focussing
- Faecal occult blood
- Antinuclear antibodies
- urinary free catecholamine analyses using high performance liquid chromatography, (HPLC), for the diagnosis of phaeochromocytoma as well as neuroblastoma and similar diseases in children.

Phlebotomy Service

A team of specialist nurses who provide Phlebotomy Services throughout the RHH Wards and Departments. They provide regular phlebotomy ward rounds on weekdays and a limited service on weekend and public holiday mornings for essential samples only. They have special skills in blood collection appropriate for acute care patients.

Pathology South is our specimen collection centre for patients referred by private medical practitioners and the RHH Specialist Clinics. It is located in the Wellington Centre on Argyle Street. Further details on this service is provided in Document ID# CPATH-Proc-2 and via their website : www.pathologysouth.com.au

Information Technology Support Group

The provision of a modern diagnostic pathology service is heavily reliant upon Information Technology for the speedy analysis and reporting of results. RHH Pathology uses the Kestral PLS system within the laboratories to register, track and report all pathology results. In line with modern trends the system has been extended out to the Wards and Clinics via a web browser interface known as Kestral CIS and by directly feeding Pathology Results into the Digital Medical Record (DMR). In addition the PLS system provides patient billing facilities and management statistics.

The installation is now quite extensive and operates on the Hospital's SITE2 compliant computers. This infrastructure of hardware and software requires a dedicated team of support staff comprising a Senior Scientist from the Laboratory with special responsibilities for the ongoing development and upgrades to the Kestral PLS software and an Information Technology Support Technician with special responsibilities for the installation and maintenance of fileservers, desktop PCs and printers. These staff work in close association with PEC and POC, and interface extensively with Kestral, DHHS IT Services and hardware vendors in order to maintain a 24 hour a day, 7 days a week, 365 days a year service.





DIAGRAM OF ORGANISATIONAL STRUCTURE SHOWING INTERNAL AND EXTERNAL RELATIONSHIPS







ROLES OF RESPONSIBILITIES OF MANAGEMENT (Clause 4.1.5)

LINES OF MANAGEMENT DIAGRAM



TERMS OF REFERENCE AND MEMBERSHIP OF MANAGEMENT COMMITTEES

a) PATHOLOGY MANAGEMENT COMMITTEE

Membership : Director of Pathology Principal Scientist Business Manager

Terms of Reference :

- Undertake strategic planning for Pathology Services and Pathology South
- Develop policies and guidelines to ensure the efficient use of the physical, human and financial resources of Pathology Services and Pathology South
- Act as a conduit for input from Pathologists via the Pathologists Advisory Committee and other staff via the Pathology Operations Committee.
- Ensure processes and procedures are in place for the ongoing development of high quality, customer-focused services.





- Enhance management reporting systems to facilitate optimum operational and financial control.
- Ensure that operational and financial systems are regularly reviewed for adequacy and compliance.
- Ensure compliance with legislative and regulatory requirements.
- Facilitate integration (where appropriate) and liaison with external agencies.

b) PATHOLOGY ADVISORY COMMITTEE

Membership : Director of Pathology

Principal Scientist Director of Haematology Director of Anatomical Pathology Director of Endocrine Services Laboratory Director of Microbiology Director of Clinical Chemistry All Full Time and Sessional Pathologists Business Manager Quality Manager

Terms of Reference :

- Staffing
- Education and Training
- Operational Issues
- Pathology South
- Equipment issues
- Quality issues
- Finance
- Business arising from other committee meetings
- Risk and safety
- Research

c) PATHOLOGY OPERATIONS COMMITTEE

Membership :

Director of Pathology Principal Scientist Scientists in Charge :

- Anatomical Pathology
- o Core Laboratory
- Cytogenetics
- $\circ \quad \text{Molecular Medicine} \\$
- Endocrinology
- \circ Microbiology

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o Special Haematology

Business Manager Quality Manager Information Systems Technician Pathology South Business Development Officer Preanalytical Manager

Terms of Reference :

The role and function of the committee are to:

- Assist in the implementation of strategies and resolutions received from the Pathology Management Committee (PMC) and the Pathology Advisory Committee (PAC).
- Assist in the implementation of the Division of Pathology Services business model
- Assist and report on the recruitment of staff and coordinate the duties, responsibilities and leave of staff in the division
- Provide details of staff development and workplace requirements and assist in the implementation of staff professional review and development
- Assist in the resolution of problems associated with equipment, quality of reagents and related consumables and in the coordination of equipment maintenance, repair and service and on the acquisition of new equipment, reagents and consumables
- o Assist in the use of information management systems
- Provide advice and assist in resolution of problems associated with all of those components associated with the production of a patient diagnostic result and on operational enhancements of processes and procedures associated with service delivery, cost, quality, and value to our clients
- Assist in the resolution of any complaint received
- Assist in the implementation of research programs
- The Committee is an ongoing Committee and has Statutory Immunity from FOI requests.

For full details refer to Document QS-Pol-16 (old number 7605)

d) INFORMATION TECHNOLOGY SUPPORT

Membership :

A Senior Laboratory Scientist An Information Technology Technician





Terms of Reference :

To ensure the adequate resources for the operation of Pathology Laboratory Information System.

To maintain the computing resources of the Department

To provide user support with computer programs

To ensure the regular and secure backup of all Departmental Computer Files and Datafiles

To safeguard the Departmental Computer Systems from unauthorized use and unauthorized access

To ensure that the Pathology IT activities are compatible with the DHHS computer network.

QUALITY STATEMENT, POLICY and SCOPE OF ACCREDITATION (Clause 4.2.3)

QUALITY STATEMENT

The staff of the Department are committed to

- the provision of a professional pathology service that abides by all legislative requirements and by all standards as set by their professional societies.
- the provision of the highest standard of service and support commensurate with their human and physical resources.
- abiding by all their published Objectives of the Department.
- maintaining their familiarity with all documented policies and procedures relevant to the performance of their work and the provision of service to their clients.
- the standards and sentiment of Total Quality Improvement as embodied in ISO 15189 and all relevant interpretative documents of that Standard as published by NPAAC, NATA and the TGA.

OBJECTIVES

- To provide a comprehensive Pathology Service to the Wards and Departments of the Royal Hobart Hospital and the wider community
- To deliver Pathology Results that have been subjected to strict Quality Control Procedures prior to their release.





- To deliver Pathology Results with the shortest possible Turnaround Times.
- To provide advice and consultation about interpretation of results and diagnostic procedures.
- To provide educational and general advice on pathological matters to the medical practitioners and people of Tasmania.
- To provide teaching and educational support to the hospitals and to the University of Tasmania Faculty of Health Sciences.
- To continuously upgrade our staff's professional and technical skills via support for continuing education and for attendance at meetings of relevant professional societies.
- To promote, collaborate with and conduct research and development in all areas of diagnostic pathology.
- To collaborate with the other units of the Department of Health and Human Services, the University of Tasmania and the Menzies Institute for Medical Research in areas of mutual responsibility and interest.
- To continuously review our activities and procedures to ensure that they remain consistent with the contemporary best practices expected of diagnostic pathology laboratories.
- To continuously upgrade our instrumentation and information technology infrastructure to keep the laboratories in line with the best possible practices

SCOPE OF SERVICES :

This laboratory was last accredited by NATA Medical Testing Accreditation following their inspection in March 2009 and is next due for their inspection in March 2012.

NATA Accreditation No: 3036 Medicare Accreditation No: 38273

Facilities: Category GX (General) Last Modified: 20th June 2012

This facility complies with the requirements of AS 4633:2004 (ISO 15189:2003)

Detailed Scope

10.10 Microbiology

10.11 Bacteriology

.01 Preparation of films for microscopic examination
.02 Inoculation of cultures
.03 Microscopic examination of clinical specimens
.04 Identification of organisms including antibiotic susceptibility testing

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.06 Detection of bacterial antigens by non-cultural non-molecular techniques .99 Miscellaneous tests Clostridium difficile toxin

10.12 Parasitology.01 Preparation and examination of films.02 Definitive identification of parasites

10.13 Virology
Cytogenetics and Molecular Medicine (incl virol)
.05 Detection of viral antigens by non-cultural non-molecular techniques

10.14 Mycology
.01 Microscopic examination of clinical specimens
.02 Culture of specimens
.03 Limited identification of fungi

10.15 Mycobacteriology.01 Microscopic examination of clinical specimens.02 Culture for isolation of mycobacteria

10.16 Serology of infection

.02 General serological testing

.03 Specialised or uncommon serological testing procedures

10.17 Detection and characterisation of microbial DNA/RNA Cytogenetics and Molecular Medicine (incl virol)
.01 Detection and characterisation of bacterial DNA/RNA
.03 Detection and characterisation of viral DNA/RNA

10.19 Miscellaneous

.01 Semen analysis (Screening Test) Post vasectomy specimens only

10.20 Immunohaematology

.01 Blood grouping including ABO, Rh(D)

.03 Blood group antibody screen

.04 Identification of blood group antibodies

.05 Determination of compatibility of donor units using appropriate techniques including the investigation of

transfusion reactions

.06 Red cell phenotyping

.07 Antibody elution

.10 Storage and distribution of blood and blood components

10.30 Haematology

Special Haematology (incl Flow & Stem Cell) .08 Blood film examinations involving special staining procedures .09 Examination for malarial parasites Thick and thin film examination, ICT kit.





- .25 Progenitor cell transplantation procedures Products received from:

 Oncology Outpatient Unit, Royal Hobart Hospital
 W P Holman Clinic, Launceston General Hospital

 .35 Tests to investigate haemolysis

 .36 Screening tests for G6PD deficiency
 .41 General haemostasis related tests
- .41 General naemostasis rela
- .70 Immunophenotyping

Cytogenetics and Molecular Medicine (incl virol) .80 Molecular genetic studies

Core Laboratory

- .01 Blood counts
- .02 Visual examination of blood films
- .03 Erythrocyte sedimentation rate
- .05 Automated differential leucocyte counts
- .06 Automated reticulocyte counts
- .20 Bone marrow examination
- .31 Tests for foetal Hb
- .41 General haemostasis related tests
- .45 Tests of platelet function
- .57 Screening test for infectious mononucleosis
- .58 Vitamin B₁₂ and folate (serum and red cell) Including intrinsic factor antibodies
- .59 Cryoglobulins
- .61 β_2 -microglobulin

10.40 Immunology

Special Haematology (incl Flow & Stem Cell) .12 Detection of autoantibodies in body fluids and biopsy material

Special Chemistry

.02 Qualitative investigation of immunoglobulins G, A, M and D in body fluids including paraprotein typing, CSF

oligoclonal bands and Bence Jones Proteins

.12 Detection of autoantibodies in body fluids and biopsy material

Endocrinology Laboratory .12 Detection of autoantibodies in body fluids and biopsy material

Core Laboratory .01 Quantitative investigation of immunoglobulins G, A, M and D in body fluids .10 Rheumatoid factor - quantitative assays

10.50 Anatomical pathology
10.51 Histopathology
.01 Histopathology of biopsy material
.02 Immediate frozen section diagnosis
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- .03 Immunohistochemical investigation
- 10.52 Cytopathology
 - .01 Gynaecological (cervical) .02 Non-gynaecological
 - .03 Fine needle aspiration of biopsy specimens
- 10.54 Examination by electron microscopy
- 10.60 Chemical pathology

10.61 General chemistry

Special Chemistry

.03 Proteins, qualitative and semiquantitative analysis; including by electrophoresis and immunoelectrophoresis

.09 Trace elements

- .30 Sweat electrolytes
- .56 Biogenic amines
- .60 Glycohaemoglobins

.62 pH of urine and fluids by electrode

- .63 Breath tests
- .74 Reducing substances and/or other sugars in urine and faeces including laxative screen .77 Calculi
- .78 Intermediary metabolites
- Endocrinology Laboratory .02 Proteins, quantitative analysis .20 Hormones .47 Vitamin assays Vitamin D .78 Intermediary metabolites Homocystine .99 Miscellaneous tests Chromogranin A

Core Laboratory

.01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies

.02 Proteins, quantitative analysis

- .04 Point-of-care testing for blood gases, glucose and other profiles Analysers located in the Intensive Care Unit, Neonatal Intensive Care Unit, Operating Theatres and Emergency Department of the Royal Hobart Hospital
- .06 Blood pH and gas tensions
- .07 Other analytes performed on a blood gas analyser
- .10 Drugs for therapeutic monitoring
- .14 Alcohol for non-legal purposes
- .15 Drugs for toxicological purposes

.20 Hormones

Quantitative β-hCG .40 Iron studies

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.50 Protein peptide tumour markers .61 Point-of-care testing for HbA1c Two analysers located with the Diabetes Educators in the Telstra Building and another in the Paediatric Diabetic Clinic.

10.70 Genetic Testing

10.71 Cytogenetics
.01 Blood
.02 Bone marrow
.20 Other tissues - malignant
Cytogenetics and Molecular Medicine (incl virol)
.25 Detection of defined, unbalanced chromosomal abnormalities by FISH

10.75 Molecular genetics
Endocrinology Laboratory
.99 Miscellaneous tests
Genetic testing for Multiple Endocrine Neoplasia Type 1

STAFF EDUCATION AND TRAINING (Clause 5.1)

Staff can access their Position Description and Statement of Duties via online access to the DHHS Human Resources site :

Generic SODs are located on ftp://intra.dhhs.tas.gov.au/pub/agency_sod/THO%20Sth/Clinical%20Support/

Older SODs are located on

ftp://intra.dhhs.tas.gov.au/pub/agency_sod/UNDER%20PREVIOUS%20STRUCTURE/Southern %20Tasmania%20Area%20Health%20Service/Royal%20Hobart%20Hospital/

You may be asked for your DHHS username and password before the page will open for you, and you will need to know your Position Number.

The Department is committed to providing and supporting all relevant educational and training activities. Whenever new complex items of equipment are purchased then the Department will ensure that relevant staff receive appropriate training. If it is warranted then certain staff will be given advanced training, usually by the supplier of the equipment, and they will then be expected to be part of a 'train the trainer' scheme for other staff in their area.

Staff are expected to share the responsibility with their supervisor for ensuring that their training and continuing education records are kept up to date. Supervisors must ensure that records on external training and education are kept up to date in the online database.





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RHH PATHOLOGY STAFF LEAVE DATABASE Including Conference and External Education Leave	×
ADD A NEW ENTRY	
DISPLAY BY DEPARTMENT : - No Selection -	
CLICK HERE to search for Entries for a SURNAME	

There are strict RHH guidelines for financial support of staff attending Conferences and Continuing Educational Activities that require payment of your registration fees, travel and accomodation costs. You should consult the DHHS Travel Policy online at

http://intra.dhhs.tas.gov.au/dhhs-online/page.php?id=279.

You should first discuss your intentions with your Scientist in Charge and obtain the necessary forms from our Business Support Officer. You application will be reviewed by our Business Manager, before it is sent to the RHH CEO for final approval. The following notes are for your further information :

- All applications must be on approved forms and will have to be countersigned by the Director of the Pathology Department and the CEO of the RHH.
- Applications for overseas travel will have to be countersigned by the Minister for Health.
- In view of the above two points you are well advised to follow the advice given by our Business Support Officer and Business Manager who have had considerable experience in meeting the expectations of these important counter signatories.
- Under current rules staff should not book and pay for flights themselves, with a view to seeking retrospective reimbursement. The Business Support Officer will book all flights through our Corporate Account with the Travel Studio, in consultation with you. Again there are acceptable and unacceptable ways of traveling in advance of the meeting or delaying departure after a meeting and you should follow the advice given.
- To ensure your attendance at the conference of your choice please initiate applications well in advance of your travel dates. Allow a minimum of 6 weeks for overseas travel applications to get through "the system".

FUNDING SOURCES AVAILABLE TO STAFF

• Pathology South profit allocation to your Department





Requests for accessing these funds should be directed to your Scientist in Charge.

• Discipline-based Unit Trust Funds

Requests for accessing these funds should be directed in the first instance to your Scientist in Charge, who will then discuss your application with the Staff Specialist(s) in charge of those funds.

• Pathology Department's Staff Development & Equipment Allocation

Requests for accessing these funds should be directed in the first instance to your Scientist in Charge who will then forward your application for consideration by PMC.

• Continuing Professional Fund

Staff Specialists wishing to access this source of funds, under the Salaried Medical Practitioner's Award, should contact the Business Manager.

There is an annual internal programme of regular meetings coordinated by the Quality Manager and presented by staff drawn from each area of pathology. The timetable for the year is available as a link from the Quality Systems Intranet webpage :





Date	Time	Title	Venue
FEBRUARY			
4 th	14:00 - 14:45	In service for specimen collectors : Biochemistry	Core Lab
19^{th}	11:30 - 12:30	Pathology Seminar : Anatomical Pathology	Room GO2 Ground Floor Clinical School
$22^{nd} - 24^{th}$		RCPA Pathology Update	Melbourne Convention Centre
MARCH			
4 th	14:00 - 14:45	In service for specimen collectors : Endocrinology	Endocrinology Lab
$16^{th} - 17^{th}$		THING (Tasmanian Haematology Immunology and Neoplasia Group)	Stanley
19^{th}	11:30 - 12:30	Pathology Seminar : Quality Management	Room GO4 Ground Floor Clinical School
APRIL			
8 th	14:00 - 14:45	In service for specimen collectors : Haematology	Core Lab
16^{th}	11:30 - 12:30	Pathology Seminar : Molecular Medicine	Room GO4 Ground Floor Clinical School
MAY			
6 th	14:00 - 14:45	In service for specimen collectors : Coagulation	Core Lab
14^{th}	11:30 - 12:30	Pathology Seminar : Transfusion	Room GO2 Ground Floor Clinical School
JUNE			
3 rd	14:00 - 14:45	In service for specimen collectors : Molecular Medicine and Serology	Molecular Medicine Lab.
18^{th}	11:30-12:30	Pathology Seminar : Microbiology	Room GO4 Ground Floor Clinical School
JULY			
1^{st}		In service for specimen collectors : Flow Lab and Special Investigations	Flow Lab
$7^{\rm th} - 10^{\rm th}$		Aust. Society for Microbiology Annual Scientific Meeting	Adelaide Convention Centre
16^{th}	11:30 - 12:30	Pathology Seminar : Biochemistry (Core Lab)	Room GO2 Ground Floor Clinical School
AUGUST			
$4^{\rm th} - 7^{\rm th}$		2013 HGSA Annual Scientific Meeting	Millennium Hotel in Queenstown, New Zealand
5 th		In service for specimen collectors : Microbiology	
20 th	11:30 - 12:30	Pathology Seminar : Cytogenetics	Room GO2 Ground Floor Clinical School
SEPTEMBER			
$16^{\rm th} - 19^{\rm th}$		AACB 51 st Annual Scientific Conference	Gold Coast Convention and Exhibition Centre
17^{th}	11:30 - 12:30	Pathology Seminar : Haematology & Coagulation (Core Lab)	Room GO2 Ground Floor Clinical School
OCTOBER			
15 th	11:30 - 12:30	Pathology Seminar : Endocrinology	Room GO2 Ground Floor Clinical School
20 th – 23 rd		HSANZ, ANZSBT & ASTH Joint Scientific Meeting	Gold Coast Convention & Exhibition Centre
NOVEMBER			
19th	11:30 - 12:30	Pathology Seminar : Special Investigations	Room GO2 Ground Floor Clinical School

EDUCATIONAL EVENTS CALENDAR : 2013





RHH PATHOLOGY SERVICES INTRANET QUALITY SYSTEMS WEB PAGES				
Most of our Quality Systems Activities are now recorded in the Q-Pulse Program. There should be a quick link to that program on your Desktop or on your 'Start' menu.				
If not please contact Graham Banks, Pathology IT Support.				
Useful External Quality System Links				
NATA Homepage NPAAC Homepage				
Westgard's QC Website Standards Australia Website				
<u>CLSI = Clinical Laboratory Standards Institute</u>				
Click here to return to go to 'Old' Pathology Document Control Pages				
QUALITY SYSTEMS ONLINE DATABASES				
- Haemoglobin A1c Analyzer Comparisons				
Blood Gas Machine Daily Comparisons				
Glucometer vs Architect Comparisons				
Fridges and Freezers Inventory System				
Pipette Calibrations Menu THEDMOMETED CALIBRATION CHECKING				
IIMERS CALIDRATION CHECKING Conference External Education and Taxining Attendance Natabase				
Conference, External Education and Training Attendance Database Internal Staff Meatings, Internal Staff Education and Inspiring Attendance Database				
Pathology Continuing Education Seminars				
Last updated : 8/2/2011				

http://rhhlas26.health.local/pathology/nata/documentation/toms-code/default_genuser2011.asp

A register of attendance at these meetings is taken. All scientific and technical staff are required to attend a minimum of three sessions per year.

All the relevant professional societies have branches in Tasmania and staff are encouraged to be active participants in the professional and educational activities organized by these Branches.

It is recognized that given the complexity of much of our work it requires a specialist to design and document technical training programmes and then to assess competency. It is expected that the components of on site training will include

- Initial Staff Orientation on their appointment to the position in the Department.
- Reading and discussion of the relevant Policy and Procedure Manuals
- Demonstration of procedures to new staff
- Observation by the trainer of new staff performing those procedures
- Sign off of new staff as competent to perform those procedures within prescribed limits eg only when senior staff are available, can work unsupervised etc.





On site training will be repeated for staff who

- have been involved in the production of sub standard work
- have been absent from a work area for more than a prescribed period of time and are returning to perform that work again
- have not been familiarised with recent technical modifications to the procedure(s)

Wherever possible Scientist in Charge will nominate specific trainers for the activities in their areas and periodically review the competency of those staff as trainers.

Reference :

Work based assessment: ABC of learning and teaching in medicine: John J Norcini : BMJ 2003;326;753-755

"In 1990 psychologist George Miller proposed a framework for assessing clinical competence. At the lowest level of the pyramid is knowledge (knows), followed by competence (knows how), performance (shows how), and action (does). In this framework, Miller distinguished between "action" and the lower levels. "Action" focuses on what occurs in practice rather than what happens in an artificial testing situation."



Training records will be developed in all areas and at each stage of the training the record will show that both the trainee and trainer have signed off and dated each stage or logical block as defined by the Scientist in Charge or Pathologist in their Training Policy and Procedures.

QUALITY ASSURANCE (Clause 4.2)

The overall coordination and management of the quality systems in this Department are the responsibility of the Quality Manager under the supervision of the Director of Pathology and the Principal Scientist. The departmental Directors and Scientists in Charge are the line managers with the responsibility for ensuring that these systems are practiced in their areas of responsibility.





The position of Quality Manager will normally be held by a person with a senior laboratory scientist background.

Quality Manager's Responsibilities :

Establish and maintain procedures to control all documents that form part of the quality system.

Establish and maintain procedures for the review of requests, tenders and contracts.

Ensure that work which is subcontracted by the laboratory is referred to a competent subcontractor who complies with ISO 15189 standards.

Ensure policies and procedures are in place for the selection and purchase of services and supplies which affect the quality of test results. Ensure procedures exist for the purchase, reception and storage of reagents and consumables.

Develop and implement mechanisms to obtain feedback from clients and monitor the laboratory's performance.

Establish and maintain policies and procedures for the resolution of complaints and non-conforming testing. Ensure that records are maintained of all complaints, their resolution and corrective action taken.

Identify opportunities for improvement of the technical and quality systems.

Ensure that all technical and quality records are retained according to acceptable policies and procedures. Acceptable policies and procedures are ones that comply with the stated requirements of NPAAC and NATA.

Establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records, including reports from internal audits and management reviews.

Gather and distribute relevant information and directives from NATA and other accreditation bodies and relevant hospital committees and ensure that they are distributed to the relevant areas of the Department.

Organise an ongoing programme of education and training as needed for the staff of the laboratory about general quality matters.

Oversee the internal audit process, including the training of internal auditors as necessary, and the ongoing scheduling, performance, reporting and follow-up of audits.

Organise and report on Management Review of the system.

The Quality Manager is assisted by a Quality Technician. The Quality Technician's duties are :





Perform calibrations and performance checks for pipettes, timers, thermometers, temperature loggers and glucometers in the Pathology Department.

Collect and collate data from all temperature monitors and temperature loggers in the Pathology Department.

Collate calibration and performance check certificates provided by external providers of services for pathology equipment.

Perform regular maintenance of all Pathology-maintained point of care instruments (POCT) held outside the Pathology Department and maintain adequate supplies of consumables for these instruments.

Enter all data collected during the above activities into the appropriate databases.

Report any detected departures from specifications to the responsible Scientist in Charge and to the Quality Manager.

DOCUMENT CONTROL. (Clause 4.3)

All documentation that relates directly to Medical Testing or our Quality Systems must be registered within the Document Control System. The purpose of a Document Control System is to ensure that we retain all documentation relevant to medical testing in an orderly and easily retrievable form both for the purposes of keeping staff advised of the documentation required in their work and also to enable us to retrieve documentation relevant to auditing all possible factors in an adverse event.

The objective of the Document Control System is to ensure that only approved documentation is used at the bench for Medical Testing Purposes. The system is designed to be as user friendly as possible so that by making a quick online search staff can be reassured that the documentation they are referring to at the time is in date and is relevant to the task they are performing.

Documentation throughout Pathology is classified as being

- o A Policy
- A Procedure
- $\circ \quad A \text{ Record Form}$
- A Reference
- A Technical Report

DEFINITIONS:

- Document text or pictorial items that are used in either paper or electronic form
- Procedure this is synonymous with Method

• Record (Form) - a template for hand entering or electronic entering of information by clients and/or staff eg Pathology Request Forms, Worksheets, Temperature Charts, Excel spreadsheets.

• Registers of Essential Information - Lists of information that staff are required to refer to as part of a procedure. Examples could include, Names and Address Lists, Test Codes, SNOMED codes, lists of Accepted Abbreviations, lists of Synonyms, website addresses, Normal Ranges, Panic Values, Delta Limits etc.





DOCUMENTATION THAT IS INCLUDED IN THE DOCUMENT CONTROL SYSTEM

Internal Documentation

- Policies
- Procedures
- Records (Forms)
- Technical Reports
- Minutes or Minute Books of Meetings
- Technical and Operational Memoranda

• Letters and/or Memoranda issued to clients that relate directly to the provision of Pathology Services.

External Documentation

• Instruction Manuals supplied with equipment

• Manuals and Electronic Media supplied with computers and computerised instrumentation

- Package Inserts supplied with Test Kits : See Note 1.
- Package Inserts supplied with Quality Control materials : See Note 1.

• Calibration / Specification Certificates for Balances, Thermometers, Centrifuges, Fume Cupboards, Biological Safety Cabinets, Timers, Standard Weights, spectrophotometric standards, radiometric standards, reference standards, calibration materials.

- Textbooks specifically referred to in Medical Testing Policies or Procedures and which must be referred to in order to perform the testing.
- Journals specifically referred to in Medical Testing Policies or Procedures and which must be referred to in order to perform the testing.
- Relevant ISO and AS Standards
- All relevant NATA documentation : See Note 2
- All relevant NPAAC documentation : See Note 2
- All relevant TGA documentation : See Note 2
- All posters, flow charts and wall charts that have information directly referred to a Laboratory Policy or Procedure

NOTE 1 : Laboratories should retain a complete set of package inserts so that it is possible to follow the audit trail of all critical materials used in testing. Every worklist should indicate the unique identity - (ie. Version Number, Lot Number, Pathology Document Control ID Number)- of the relevant package insert.

NOTE 2 : These organisations all have websites from which the most up to date documentation must be sourced as required. The relevant URLs are :

NATA : (To get full access to all their documentation you need to register as a Member : RHH Pathology staff qualify as Members – see the Quality Manager if you encounter problems)

http://www.nata.asn.au/publications

NPAAC :

http://www.health.gov.au/internet/main/publishing.nsf/Content/healthnpaac-publication.htm

Authorised by : Dr Marsden, Dr Vervaart & Dr Tom Hartley Issued February 2012





TGA : <u>http://www.tga.gov.au/industry/devices.htm</u>

All Pathology Policies, Procedures and Records documentation must have a Title or Header that shows :

• The identity of the area to which the documentation applies ie. **RHH Pathology Services : Name of Area involved**

All Pathology Policies, Procedures and Records documentation must have a footer that shows :

- The unique **Document ID Number** as issued by the QPulse Document Control System program.
- The name of the person(s) Authorising the document
- The Date Effective
- The **Page Number** if greater than One.
- The Total Number of Pages

A template for our documentation is available as Doc ID# QS-Form-1

All documentation must be reviewed by the author on a regular basis. The QPulse Document Control Program will automatically email authors on the anniversary of each document.

Externally produced documentation can often be obtained as PDF files. These can be processed by the staff responsible using the 'Typewriter' tool in the public domain program Foxit Reader, so that a Pathology Document Control Number becomes an integral part of that document before it is distributed electronically.

All Controlled Documentation should only be printed out on the special paper with the red stripe along the right hand edge. This paper is locatable from within Word from the available printers list viz. *RHH 1D Document Control Printer (Colour) HP LJ CP2025*

Scientists in Charge are responsible for ensuring that out of date hard copy documentation is physically removed from the work areas.

The use of 'sticky notes' and other handwritten instructions is not permitted. There is an electronic sticky notes system available on the Pathology Intranet. This records dates, times and authorship of short term communications about Medical Testing related matters. It is searchable by Test, Instrument and Lab. Requests for changes to controlled documents must be lodged via the QPulse Change Request module.

Q-PULSE QUALITY MANAGEMENT SYSTEM SOFTWARE

LEVEL 4 USERS GUIDE

Users of Q-Pulse with Level 4 will have access to the following functions:

1. Launch Pad:

- Logging in;
- Changing Password.





2. Document Module:

- Acknowledging Receipt of a New/Updated Document;
- Searching for and Viewing Documents;
- Adding a Change Request on a Document
- 3. **CA/PA Module** (<u>Corrective Action Preventative Action</u>) where we will lodge our Incident Reports
 - Read CA/PA's that involve your Department
 - Lodge new CA/PA's either by filling in the QPulse data entry screen, or the via the Wizard. (If you do not wish to use either and would prefer to use a handwritten form then you should call up QS-Form-3 (for Incidents) or QS-Form-6 (for Corrective Actions), print a copy out, fill it in and then forward it to the Quality Manager who will enter the details into QPulse on your behalf.)

HOW TO ACCESS Q-PULSE AND CHANGE YOUR PASSWORD

1. From the desktop double click on the Q-Pulse 5 icon.



2. The screen below should appear:

Welcome to Q-Pulse		×
Gael	Please Log on press F1 for help.	
Q I Pulse ®	User Name : Password :]
Q-Puise is a registered trademark of Gael Ltd. Copyright © 2007 Gael Ltd.		
Build 5.20.14.333	Log On)

- 3. Enter your user name this will be the same as your computer login user name.
- 4. The first time a staff member logs into Q-Pulse the default password will be nata. Click on the Log On button. Once logged in the Reset Password screen will appear.



- 5. You must change this to something you will remember. The new password will be case sensitive.
- 6. The Q-Pulse program will continue to login. The Launch Pad screen will appear.



7. To change your password in future click on the down arrow next to the second icon at the top of the launch pad (head icon) (arrowed).







8. Click on 'Change Password' then fill in the information required. Click OK.



- 9. To log out of Q-Pulse click on the **equation** icon at the top right hand corner of the launch pad.
- 10. If you are unable to log in or have forgotten your password contact the Pathology Quality Manager Tom Hartley or the Pathology I.T. Manager Graham Banks.

ACKNOWLEDGING RECEIPT OF A NEW/UPDATED DOCUMENT

Users of Q-Pulse will be notified via email when relevant documents are updated or added to the Q-Pulse quality management system.

The email will be sent to the users Microsoft Outlook account; details of the document will appear in the email as in the example below:

🖂 New d	ocument	create	d - Mess	age (H	TML)		
Eile Ed	it <u>V</u> iew	Insert	F <u>o</u> rmat	<u>T</u> ools	<u>A</u> ctions	Help	
Reply	🛛 🦂 Reply	/ to All	🙈 For <u>w</u> a	′d 🖪	B 🔻	' 🖄 🎦 🗙 🔺 🕶 👻 A‡ @ 🥊	
From:	OPulse@c	lhhs.tas.	oov.au				
To:	Banks, Gr.	aham R:	Hartley, Tr	000			
Cc:	barno, ar	anamity	naraoy, n				
Subject:	New docu	ment cre	ated				
Attachme	ents: 💽 Loo	cate Reci	ord.apulse	(295 B)			
				· · ·			_
Detail	s: The fol	lowing a	active doo	cument	has bee	en created:	
Tune						QuelManagement\Breedure	
Type						Qualiviariagement/Procedure	
Numl	ber					DOC1	
Title						Test2	
Revis	ion					1	
Statu	s					Active	
Autho	or					Hartley, Tom	
Owne	er					Banks, Graham	

When an email like this is received the user must read the document and acknowledge that they have read and understood the new or updated document. This is performed by following the procedure below:

1. Click on the "Locate Record in Q-Pulse icon".





New document created - Message (HTML)	
Eile Edit View Insert Format Tools Actions	Help
🙈 Reply 🙈 Reply to All 🙈 For <u>w</u> ard 🛃 🗈 🔻	' 🖄 🎦 🗙 🔺 🗸 🛷 - A [‡] @ 💂
From: OPulse@dhhs.tas.gov.au	
To: Banks, Graham R; Hartley, Tom	
Cc:	
Subject: New document created	
Attachments: 💽 Locate Record.qpulse (295 B)	
Details: The following active decument has be	
Details. The following active document has be	en created.
Туре	QualManagement\Procedure
Number	DOC1
Title	Test2
Revision	1
Status	Active
Author	Hartley, Tom
Owner	Banks, Graham

- 2. Log into Q-pulse.
- 3. The Document details record will open. The document can be viewed by clicking on one of three icons:
 - a. Click on the 'View Document' icon located at the top of the screen;



b. Click on the link located in the Filename field;

	Revision 1	
		*
Filename	Fire Safety - overview 2008 Questionnaire 100108	
Keywords		

c. A the top of the screen click on File, View Document;





a 1	PCyt-l	Rec-2	(1) - Do	cumer
Eile	<u>E</u> dit	<u>V</u> iew	<u>A</u> ctions	<u>W</u> indo
ŧ.	<u>N</u> ew		•	
	<u>V</u> iew D	ocumen	t	
	<u>S</u> ave	Ct	trl+S	

4. Review the document.

NOTE: For documents that have been updated, if it is not clear what changes have been made consult with the document owner.

- 5. Once the document has been reviewed and understood the document can be closed.
- 6. To acknowledge that the document has been read open the Distribution tab by clicking on

the located next to the symbol on the right hand side of the screen.

7. Locate and highlight your name in the distribution list.

Distribution		
Number 🔥	Name	Dept/Organisation C
=	Coles, Helena	Pathology\Anatomical Pathology
<u>_</u>	Account1, Test	Pathology\Information Technology
=	Townsend, Alistair	Pathology\Anatomical Pathology

8. Click on the Acknowledge document receipt icon.

Name	Dept/Organisation	Comment	Distribution Date	Acknowledged Date		
Coles, Helena	Pathology\Anatomi		19/08/2009 3:33 PM			*
Account1, Test	Pathology\Informat		19/08/2009 5:24 PM		- 2	
Townsend, Alistair	Pathology\Anatomi		5/08/2009 4:31 PM	5/08/2009 4:31 PM	3	Sx
						Acknowledge
						Acknowledge the receipt of this document for the select

9. The date and time the document was acknowledged will be recorded automatically.

Number	A Name	Dept/Organisation	Comment	Distribution Date	Acknowledged Date
=1	Coles, Helena	Pathology (Anatomi		19/08/2009 3:33 PM	19/08/2009 5:30 PM
=	Account1, Test	Pathology\Informat		19/08/2009 5:24 PM	

10. Click on the Save icon at the top of the screen.







11. Close down the Document Details screen and Exit out of Q-Pulse.

SEARCH FOR AND VIEWING DOCUMENTS

- 1. Login into Q-Pulse using appropriate credentials.
- 2. Click Documents on the Q-Pulse Launch Pad.

🝳 LaunchPad <cole th="" 🔀<="" 🔳="" 🗖=""></cole>				
ij - 🤱 -	🥑 -			
Gael				
Modules				
СА/РА	×			
Documents				

- 3. The Custom Filter screen will appear. Using the search engine on the left hand side of the screen (boxed in red) select from the following parameters:
 - a. Type a drop down menu will appear highlight and select the department the document originated from if known;
 - b. Owner a drop down menu will appear highlight and select the name of the document owner if known;
 - c. Keywords this is a free text field. Type in any of the words that are in the title of the document or any words that may relate to the document, e.g. "After hours", "Out of hours", "Spills", etc.
 Using any one of these parameters will be useful in searching for a document; searching using combinations of 2 or all 3 parameters will result in lists with fewer documents.





📱 Custom Filter - Documents List - Q-Pulse								
Ele Edit View Actions Window Help								
n - 🔁 🌆 🕹 🖉 🖪	legister: Active	• 📃 🔹 🖷 🗖		. 🕐 - 🗊	20 17			
My Actions	Document Number 🔷 🖊	Document Title	Revision	Active Date	^			
	APCyt-Rec-2	very testing	1	5/08/2009				
	CGen-RC-1	Analysis: Banding Quality (QAP)	4	3/08/2009				
	CGen-RC-3	Kestral Test Codes For FISH	2	11/06/2009				
	CGen-RC-4	Vysis FISH Certificate of Analysis	3	3/08/2009				
	CGen-RC-5	Temperature Chart	2	7/07/2009				
	CGen-RC-6	Test approval process	1	7/07/2009				
Search	CGen-RC-7	CYTOGENETICS TUBE FOR BONE MARROW	4	9/07/2009				
Туре	CGen-RC-8	ANALYSIS BY MICROSCOPY	2	3/08/2009				
Any 🗸	CGen-RC-9	ANALYSIS BY MICROSCOPY	3	3/08/2009				
Owner	CGen-RC-10	ANALYSIS	1	9/07/2009				
Any 🗸	CGen-RC-11	C-Banding	2	3/08/2009				
Keywords *	CGen-RC-12	Silver Staining NOR	3	3/08/2009				
Reywords	CGen-RC-13	Temperature Chart	1	28/07/2009				
	CGen-RC-14	Temperature Record	1	29/07/2009				
Advanced Search	CGen-RC-15	Temperature Record	3	3/08/2009				
	CGen-RC-16	Solid Staining	2	3/08/2009				
My Searches 🚷	CGen-RC-17	Selecting the best cell culture method	1	3/07/2009				
🖃 Default	CGen-RC-18	twest	1	14/08/2009				
➢ Documents Awaiting A	CGen-RC-20	Change request doc 1	1	19/08/2009				
P Documents Held	CGen-RC-21	change request doc 2	1	19/08/2009				
Contract Workflow Stopped	CGen-RC-22	change request doc 3	1	19/08/2009				
My Draft Documents	DOC1	Test2	4	5/08/2009				
	ICTC-Pol-1	How to Restart CIS	3	3/08/2009				
My Folders 🛛 🕙	ICTC-Pol-2	Testing Draft	1	23/06/2009				
Related Documents	ICTC-Pol-3		1	23/06/2009				
	ICTC-Pol-5	Test - 20090803A	1	3/08/2009	~			
Document(s) Found: 31								

- 4. Ensure that the Register field at the top of the screen is set to Active.
- 5. Click on the Search button.
- 6. A list of all the relevant documents stored in Q-Pulse will be presented in the Customer Filter screen.NOTE: Pressing the 'Search' button without filling in any of the details will produce a list

of all documents on the system.

- 7. To view the document click on the document title (underlined and highlighted in blue).
- 8. Documents stored in the Q-Pulse quality management system are Read Only.
- 9. If searching for the document could be improved by the addition of certain keywords contact the document owner with suggestions.

ADDING A CHANGE REQUEST

Adding a change request to a document is a way of logging improvement ideas, correction of errors or ensuring updates are made to that document. The document owner will be notified of the change request raised against the document; if the document owner chooses to reject the change request they must record reasons for the rejection.

- 1. While the Custom Filter screen is displayed highlight the document that you wish to raise a change request for.
- 2. Click on the Add Change Request Icon at the top right hand side of the screen.





🖥 Custom Filter - Documents List - Q-Pulse								
Ele Edit View Actions Window Help								
🐂 - 📇 📰 🌭 🕼 Register: Active 🔹 🔹 🔹 📲 📲 🖬 - 🗊 📳 🌉 🕲 - 🐲 🚣								
My Actions	Document Number	Document Title	Revision	Active Date				
ing / salorie	APCyt-Rec-2	very testing	1 Add Change Reques	st				
	CGen-RC-1	Analysis: Banding Quality (QAP)	4 Add a change request	to the selected documents				
	CGen-RC-3	Kestral Test Codes For FISH	2	11/06/2009				
	CGen-RC-4	Vysis FISH Certificate of Analysis	3	3/08/2009				
	CGen-RC-5	Temperature Chart	2	7/07/2009				
Canada	CGen-RC-6	Test approval process	1	7/07/2009				
Search	CGen-RC-7	CYTOGENETICS TUBE FOR BONE MARROW SPECIMENS	4	9/07/2009				
Туре	CGen-RC-8	ANALYSIS BY MICROSCOPY	2	3/08/2009				
Any	CGen-RC-9	ANALYSIS BY MICROSCOPY	3	3/08/2009				
Owner	CGen-RC-10	ANALYSIS	1	9/07/2009				
Any 🗸	CGen-RC-11	C-Banding	2	3/08/2009				
Keywords -	CGen-RC-12	Silver Staining NOR	3	3/08/2009				
Keynenee	CGen-RC-13	Temperature Chart	1	28/07/2009				
	CGen-RC-14	Temperature Record	1	29/07/2009				
Advanced Search	CGen-RC-15	Temperature Record	3	3/08/2009				
	CGen-RC-16	Solid Staining	2	3/08/2009				
My Searches	CGen-RC-17	Selecting the best cell culture method	1	3/07/2009				
🖃 Default 📃 🔺	CGen-RC-18	twest	1	14/08/2009				
📂 Documents Awaiting A	CGen-RC-20	Change request doc 1	1	19/08/2009				
P Documents Held	CGen-RC-21	change request doc 2	1	19/08/2009				
Draft Workflow Stopped	CGen-RC-22	change request doc 3	1	19/08/2009				
My Draft Documents	DOC1	Test2	4	5/08/2009				
	ICTC-Pol-1	How to Restart CIS	3	3/08/2009				
My Folders	ICTC-Pol-2	Testing Draft	1	23/06/2009				
Related Documents	ICTC-Pol-3		1	23/06/2009				
	ICTC-Pol-5	Test - 20090803A	1	3/08/2009 🗸				

3. The Add Change Request box will appear.

📓 Add Change Rec	juest - CGen-RC	-1, Analysis:	Banding	Quality (QAP) (? 🗙
Details					
					<u>_</u>
Supportinginformat	ion				
Confirm raise inform	ation				
Raised by	Account1, Test				
Raised Date	20/08/2009				
Severity	Normal		~		
,	L				
				ОК	Cancel

- 4. Supply information about the change request in the details field.
- 5. If there is any supporting information to be added to the change request this can be done by clicking on the supporting information field and selecting the appropriate file. Ensure that the 'Embed in Q-Pulse' option is selected to attach the file.
- 6. If required choose the severity of the change request from the drop down menu. If the change request does not require immediate attention the severity level should be kept at 'Normal'.




7. Click on the OK button.

The document owner will receive an email informing them that a change request has been received on this document. It will also appear on their 'My Actions' folder. If the change request is not dealt with the change request will appear on the next draft review.

HOW TO RAISE A NON-CONFORMANCE IN QPULSE

1. Login to QPulse and click on CA/PA and then *New then New Non-conformance.

IntanView	OM MAN	IAI	
叉 LaunchPad <account, test=""></account,>	(
	i) -	- 🛞 ד	
Gael			
Modules			
		*	
New		New No	n-conformance
Recently Viewed		From Wi	izard 🕨
🙀 Folders		From Te	mplate 🕨 🕨
	P		
Documents		\$	
Recently Viewed			
🙀 Folders			
	$\overline{\rho}$		
	IQ-F	Pulse.	

- 2. Complete Source from the drop down list.
- 3. Complete Owner as the Scientist in Charge of your area.
- 4. Complete two to four lines of details be brief.
- 5. Decide if the Incident is being raised by your Department (Internal) or raised on behalf of a Customer, e.g. a doctor or clinic has phoned and pointed out a mistake we have made.
- 6. If internal, select your name off the drop down list.



7. If raised on behalf of a Customer, search for the customer and select them off the list. You can then select a contact from the list of contacts for that customer.

(If the customer or customer contact that you want are not on these lists then let Tom Hartley or Graham Banks know and they will add them onto the list. You can continue filling in the form WITHOUT these details in the meantime).

Raised By	🔘 Internal	📀 Customer	Against 💿 Department	🚫 Supplier	Severity
Contact			Search for Customer		? 🔀
Process		~	Keyword		
Fault Category Product		~			<u> Search</u>
Service			Description Family Planning Tasmania		
Correcti	veAction		Specialist		
Propertie	p				
- Toponi	~~				
				ОК	Cancel





Raised By	🚫 Internal	📀 Customer	Against 🤇	 Departme 	nt
	Family Planning	Tasmania (••		
Contact			*		
Process	Roberts, Clare		Family Planning Tash	nania	
Fault Category					
Product Service					
Correctiv	×			.:	

- 8. Decide if the Incident is being raised against another Department in Pathology or against a Supplier.
- 9. If raised against another Department, pick the Department off the drop down list.

Against	💿 Department 🛛 🔿 Suppli	er	Seve
		~	Кеужс
	- Anatomical Pathology		~
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10. If raised against a Supplier then pick the Supplier and the appropriate contact off the drop down lists.

(If the Supplier or Supplier Contact that you want are not on these lists then let Tom Hartley or Graham Banks know and they will add them onto the lists. You can continue filling in the form WITHOUT these details in the meantime).





Against	🚫 Department	💿 Supplier	Severi
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- 11. Select the Severity Code off the drop down list. Be aware that SAC Codes '1' and '2' are actioned with high priority.
- 12. Complete the Process, Fault Category and Product Service from the drop down lists. These are not compulsory and may be altered by the Scientist in Charge or Quality Manager later on.
- 13. Fields 'Document', 'Resolution', 'Closed by', 'Standard', 'Root Cause', 'Closed Date', 'Target Date' should not be completed by you.
- 14. Open up the Corrective Action tab and only put your suggestions in the 'Details' box.
- 15. Do not complete anything in the Follow Up tab.
- 16. Click on the 'Floppy disk' icon to save your CA/PA record. When you do this the 'Number' on the very top row will be completed by QPulse. Write this number onto your handwritten copy of the Incident Form.
- 17. Put a copy of your handwritten Incident Form into the Quality Manager mail box. This will be scanned for you and attached to the Properties tab of the QPulse CA/PA form. This way the full details of the original incident and larger documents associated with follow up and correction will be lodged here.
- 18. You can log back into QPulse to view the progress of your Incident Report at any time.





LIFE CYCLE OF A CA/PA





RECORDS, MAINTENANCE AND ARCHIVING (Clause 4.13)

Request Forms : We use only request forms that have been approved by the Health Insurance Commission, Canberra. We use this as our method of document control for these forms. All Request Forms are scanned at time of Data Entry by the CPU staff and this image is viewable by pressing ALT and S keys simultaneously whilst in the Patient Details screen of Kestral PLS. This means that we have electronic records of all Request Forms received since this procedure was commenced in March 2006.

Original Request Forms have to be stored for 3 years. Those that are not stored on site are stored with the company Recall.

Results and Reports : All results are stored within Kestral PLS. These records go back to 1994. Reprints of these results as patient reports can be produced at anytime. Since November 2007 all reports on RHH Patients have been sent electronically via HL7 messages into the RHH Digital Medical Record system.

Results and Reports from Referral Laboratories : The relevant information from these reports have been transcribed into the Kestral PLS system and hence are just as retrievable as our internally generated reports. In 2013 we commenced scanning these reports into the Kestral PLS Request Form scanners system to make them 'electronically' searchable.

Instrument Printouts : These are usually stapled to the associated worklist and retained for three years.

Examination Procedures : Documentation of Procedures are retained indefinitely as electronic records within the Document Control system. Users of the Document Control system have the option of including 'obsolete document' within their search criteria and in this way can retrieve any document that has been document controlled but since withdrawn from use.

Laboratory Workbooks and Worksheets : These are retained for three years.

Calibration Functions and Factors : These are usually only applicable to computerized automated equipment and are stored in the instrument and on backup electronic media (if applicable). Factors associated with manual instrumental procedures, such as HPLC where there are retention times specific to the instrument setup, calibration factors etc are usually recorded on the worksheet. However if these factors are likely to be sufficiently persistent then the values are recorded within the versions of the procedures. Factors which are reagent batch specific (eg in INR testing) are similarly recorded on worksheets or within procedures.

Quality Control Records : Wherever possible Internal Quality Control Records have been computerized either within Kestral PLS or within the instrumentation. External Quality Control Records are still predominantly paper report based. These paper reports are filed in the relevant areas of the laboratories and are retained for three years. More recently we have been submitting a large proportion of our internal QC data into commercial system such as Bio Rad's Unity Realtime system and Radiometer's WDC programme.

Electronic Records : All Medical Testing related data held on computerized systems will be backed up to remote systems or removable media. The procedure for each particular item will vary according to the manufacturer's instructions and/or the procedure put in place by Pathology





IT Support staff. These data will be retained for up to three years; the criteria for earlier deletion will vary but normally will be related to the fact that the patient's data have been passed to the patient's database in Kestral PLS which is also the repository of the relevant Quality Control data obtained at the same time of testing of that patient's sample(s).

Complaints and Action Taken : The centralized computerized Incident Reporting system is the repository of all such records. The Incident Reporting system is also the repository of the Corrective Action records.

Records of Internal Audits : All audit reports are lodged within the Document Control system. The Audit Report is also the repository of the record of corrective actions taken.

Records of External Audits : The NATA Assessment Reports have all been filed since 1999 in individual folders. These folders include the paper records of the pre assessment questionnaires, the assessment reports and the responses to the assessment findings.

External Quality Assurance Records : The RCPA EQAP records are kept for a minimum of three years. They are located in the laboratory areas responsible for the actual data returns.

Quality Improvement Records : The RHH QI Unit provide forms for this purpose and they take on the responsibility for collection and follow up as part of the RHH ACHS Accreditation activities. A copy of the Form is in Appendix 2.

Instrument Maintenance Records and Calibration Records : These are held in the relevant laboratory areas in close proximity to the relevant instrumentation.

Maintenance records are held for the duration of the lifetime of the instrument.

In the case of highly automated instruments calibration records are kept electronically within the instrument and on backup media.

In the case of less sophisticated analyzers calibration records are kept as defined within the relevant procedure manuals, usually as a calibration worksheet.

Lot Documentation, Certificates of Supplies and Package Inserts : The original documents that come with calibrators, QCs and reagents which contain specific data as to assigned values, handling, preparation or storage are kept within the relevant laboratory areas. In the majority of cases these documents are scanned in whole or in part and these scanned images stored within the Document Control system as Word or Adobe PDF files; for example see FISH-Ref-13 and CHEM-Proc-46

Incident Records and Action Taken : Incidents are managed via the CA/PA module in QPulse.

Staff Training and Competency Records : Refer back to Section 6 for background information on this topic. Bench level training records are kept in the laboratories and retained until the person concerned resigns (but if there is a prospect that the staff member may return in the foreseeable future then the records are retained eg staff member goes on maternity leave, secondment to another Department etc.). The Departments are being encouraged to migrate some aspects of their Training Records system into Qpulse.





ACCOMMODATION AND ENVIRONMENT (Clause 5.2)

We are expected to provide adequate space and facilities for the

- Handling of Specimens
- Handling of Hazardous Substances
- Laboratory Testing
- Instruments and Equipment
- Reagent storage
- Specimen Storage
- Records Storage

This requires that all staff follow tidy work practices and good housekeeping.

Staff who work in 'common work areas' such as the Core Laboratory or use 'common instrumentation' such as the balances, fume cupboards etc. are under a particular obligation to conform with safe and tidy work practices. Bench space, results sheets and instruments must be left in a tidy and operational condition before you leave the area either having completed your analyses there or having come to the end of your shift there.

Staff should advise their Supervisor if they find that their work area has been left in an unacceptable condition by another staff member.

When new methods and procedures are introduced this will affect how bench space and instrumentation are used in the future. Staff are expected to be flexible, contribute to the redesign of their facilities and adapt to the changed requirements.

If you regard that any work area is being compromised on any of the above criteria then your must discuss this with your Supervisor.

The laboratories are all centrally air conditioned. If the ventilation appears to be inadequate inform your supervisor who should then follow the matter up with RHH Facilities Management. Some areas have additional air conditioning, eg Core Lab where there is a an extra thermal or other load. These can be adjusted by staff in those areas by using the unit(s) infra red controls.

Lighting must be adequate for your work and defective light globes, fluorescent tubes etc must be reported to your supervisor who should then call in RHH Facilities Management to replace the defective item(s).

Colour Coded Emergency Power Outlets are provided throughout the laboratories and you should ensure that all 'mission critical' instruments and computers are connected to these outlets. The Emergency Power generators are tested once a month by RHH Facilities Management and you should report any power fluctuations during these tests to your supervisor.





INSTRUMENTS, REAGENTS AND CONSUMABLES MANAGEMENT (Clause 5.3).

Analytical work on reportable pathology specimens, ie Medical Testing, must only be carried out using equipment owned or leased and maintained by this Laboratory. Specimens may be processed on equipment outside of this Laboratory provide it is formally included of our Laboratory's Quality Systems or is maintained at a level equal to or better than our Quality Systems.

• Staff must only use laboratory equipment that is appropriate to the tests being performed, well maintained and in good working order. Defective equipment must be reported to your Scientist in Charge immediately who should withdraw it from service until it is repaired. Defective equipment must be clearly labeled as defective and if possible disabled from use eg remove power cord, remove all sample trays, remove keyboard etc.

Redundant or backup equipment that has not been checked recently to be in good working order should be removed from the routine work area and/or clearly labeled as "*Not To Be Used for Medical Testing.*"

Staff are expected to check critical operating characteristics of all equipment that they are required to use and to do this at the specified intervals mentioned in the procedure manuals and as appropriate to the equipment and its workload.

• Staff are expected to complete the relevant Equipment Records in the QPulse Assets Module.

The Assets Module of QPulse currently has records on Centrifuges, Incubators, Laminar Flow Hoods / Biological Safety Cabinets, Microscopes, Thermocyclers and Weighing Balances. This list will be extended over the coming months as Scientists in Charge add more of their items to this list.

- Regular service checks, preventive maintenance and calibration checks must be made on all equipment and appropriate records kept.
- Repairs to equipment must be documented as part of the service record.
- Cleaning and decontamination of equipment and instruments must be performed on a regular basis and occasional spillages must be cleaned up immediately.
- Water baths and heating blocks must be checked regularly for growth of microorganisms and an appropriate decontamination program implemented on both a preventive and corrective basis.
- Where electrical power fluctuations are liable to occur and adversely affect equipment performance, voltage stabilisers must be fitted.

Blood Bank refrigerators must be provided with continuous temperature monitoring and include an appropriate alarm system to alert staff if the temperature exceeds pre-set limits. These refrigerators must be commissioned and maintained according to Australian Standard AS 3864.2 Medical Refrigeration Equipment for the storage of Blood and Blood Products (QS-Ref-21

All temperature sensitive supplies used in Medical Testing will be checked on receipt with regard to the temperature they were transported at and then stored under the conditions specified by the manufacturer.





Only supplies that are in date will be used in Medical Testing procedures.

Only supplies that are received intact will be used in Medical Testing.

Supplies used for Medical Testing will be purchased with the longest 'Lot Runs' and 'Use By Dates' possible.

Supplies which deviate from these requirements will be the subject of Incident Reports.

There will not normally be periodic review of supplier performance but instead supplier performance will be monitored continuously on a 'by exception model' ie. If there are no Incident Reports that cite a particular supplier then that supplier is classified as compliant with our requirements.

VALIDATION OF EXAMINATION PROCEDURES (Clause 5.5.2)

All medical testing procedures have to be validated before use and revalidated after any substantial change in the procedure. In our Department the usual situation is that we change from an 'old' kit to a 'new' kit or an 'old' instrument to a 'new' instrument. In these scenarios we must determine that if there are differences in the analytical and diagnostic performance associated with the change. A recent background article on the relevant issues and statistical data handling appeared in the Clinical Biochemist Review, August 2008 and a complete copy is on the document control system as Doc ID# QS-Ref-19. Staff should also refer to NATA Technical Note 17 - *Guidelines for the Validation and Verification of Quantitative and Qualitative Test Methods* - available on their website.

Currently our method evaluations for quantitative tests will follow as a minimum the Procedure described in

 INSTRUCTIONS FOR BLAND AND ALTMAN PLOTS USING EXCEL Document ID# QS-Proc-36

along with any additional practical investigations and statistics as suggested in Doc ID# QS-Ref-19

The raw and processed results will be recorded in a 'New Record' document with a unique Document ID number

A good example can be viewed in Document ID# QS-Rep-5

'EVALUATION OF THE EXISTING CELLDYNE CD4000 VERSUS THE NEW CELLDYNE CD3200 IN THE CORE LABORATORY'

 In addition the Uncertainty of Measurement Budget will be completed as per Document ID# QS-Proc-37 : UNCERTAINTY OF MEASUREMENT BUDGETS POLICY AND PROCEDURE

and the associated Excel Template, Document ID# QS-Form-8 : UNCERTAINTY OF





MEASUREMENT BUDGET TEMPLATE

Method evaluations will be performed whenever there is about to be a significant change in the testing procedure eg.

- Changeover from one Diagnostic Kit to another
- Changeover from one analytical instrument to another
- Changeover from one published method to another
- Changeover from one sample type to another

The evaluation will also include the effects upon Diagnostic Reference Intervals for the test(s). Pathologists are required to formally evaluate the clinical significance of any patient results observed in the comparison studies that fall into the zones with red dots in on the graph shown below :



Evaluation of non quantitative tests will be evaluated by appropriate Non-Parametric Statistical Tests; usually a Chi Squared Test and a rank test such as the Mann Whitney U Test, sensitivity and specificity calculations and expert evaluation by a pathologist of the clinical performance of the old test versus the new test. Areas performing microscopy based testing will use peer review as their method of method validation.

BIOLOGICAL REFERENCE INTERVALS (Reference Intervals) (Clause 5.5.5)

All laboratories producing numeric results must also provide the user with an appropriate biological reference interval or clinical decision limit against which the reported result can be interpreted. It is our policy to follow the CLSI guidelines described in 'Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory C28-A3, Third Edition, 2008. This is available from the document control system as QS-Ref-1. In the interest of brevity only the Summary points have been reproduced here.





The basic principles that follow are uniformly important and must underlie any reference value study:

(1) The selection of reference individuals must be thoughtful, with advance consideration given to exclusion and partitioning criteria. The reference population must be appropriate and useful to the process of determining disease or abnormalities in the patient population. The evaluation of the health status of the reference individuals must be documented and described as part of the reference value study or reference intervals defined. The better the reference individuals are defined and described, the greater the value of the reference interval studies.

a) The working group again rejected the concept of a "gold standard" reference population of absolutely healthy young adults as a prerequisite for the determination of a health-associated reference interval.

b) As a general rule, the use of hospital or clinic patients as a source for reference individuals was also rejected. Patient data should only be used for deriving a reference interval when "nonpatient' reference individuals cannot be obtained, and only with careful selection and attention to exclusion and partitioning criteria.

(2) All of the preanalytical and analytical processes related to the measurement of reference values must be thoughtfully considered and controlled where appropriate. It is essential that these factors be treated in the same manner for the reference individuals as for the patient population tested.

(3) Once the data are collected, a frequency histogram should be prepared and examined visually in order to facilitate analysis. A process for detecting and discarding outlier values is recommended. In addition to the Dixon-Reed rule (See QS-Ref-1, pages 18 and 31) recommended in the previous edition of C28, an alternative rule, based on Tukey (See QS-Ref-1, pages 18 and 19) was added to this document.

(4) The nonparametric method of estimation of the reference interval is again strongly recommended as the preferred method for analysis because of its simplicity and reliability. More importantly, this method requires no specific assumption about the mathematical form of the probability distribution of reference values.

For the nonparametric method, a minimum sample of 120 reference values is recommended for each reference population or subclass. This is the smallest number of samples that allows the determination of a 90% CI around the reference limits (eg, the 2.5th and 97.5th percentiles). Greater confidence or improved precision in an estimated 95% reference interval can be accomplished using a larger sample of reference individuals.

(5) Recognizing the difficulty for individual laboratories to obtain sufficient numbers of reference individuals, the working group has introduced the concepts of multicenter trials and robust statistical methods.

a) Well-organized multicenter trials should allow for pooling of data from multiple sites. By ensuring comparability in analytical methods as well as adhering to strict selection criteria, the only remaining reasons precluding pooling of data might relate to population differences such as race and region.





b) Even in the absence of multicenter trials, individual laboratories may be able to establish reference intervals with smaller numbers of reference individuals by employing modern statistical methods. Examples of one of those techniques are provided.

(6) The working group has placed new emphasis on the concept of confidence limits of reference intervals. With too few points, confidence limits can be so wide as to make the reference intervals virtually meaningless. As noted, even though one can theoretically establish 95% reference intervals with the nonparametric method using just 39 values, one actually needs 120 values to obtain 90% confidence limits for such intervals. For any method of data analysis, the use of more points translates into tighter, and more useful, confidence limits.

(7) A rigorous and systematic approach is recommended for determining when separate reference intervals for subclasses are necessary.

(8) In those cases where a laboratory implementing a new analytical method wants to adapt a reference interval determined previously on its own patient population, the process of transference can be used. Several specific caveats are described. In addition, the working group strongly encourages laboratories to verify the new reference interval with a small group of reference individuals.

(9) The working group recognizes that establishing reference intervals is beyond the capability of most individual laboratories. However, the working group believes that verifying reference intervals established elsewhere (eg, manufacturers' product inserts) is feasible for most individual laboratories.

One can, with as few as 20 samples from reference individuals, use a relatively simple test to verify the applicability of a reference interval to one's own population. The performance characteristics of this test and several other tests are described.

(10) In increasing numbers of cases (eg, cholesterol, glycatedhemoglobin), establishing and verifying traditional reference intervals as described in this document is not appropriate. For such analytes, where national (or international) consensus on decision limits exists, it is critical that manufacturers and laboratories ensure their methods provide accurate results on patient samples.

SAFETY (Clause 5.1.4 (m), 5.1.19, 5.2.2, 5.2.10)

All Staff must familiarise themselves with the *Safety Manual*; *Document ID# QS-Proc-4* viewable and printable from the Pathology Intranet. Hardcopies have been issued to all Scientists in Charge for display in their areas. If you have any difficulties in obtaining access to a Safety Manual then contact the Principal Scientist who will issue you with a copy.

All staff should complete the Staff Laboratory Safety Induction Form in the Appendix of the Safety Manual.

All specimens must be regarded as potentially infectious and handled accordingly. Gloves, aprons, face shields, masks and laboratory glasses are available for all staff. If you require particular non stock sizes or types eg. hypoallergenic gloves then you should contact your supervisor to arrange for these to be supplied. There are adequate fume hoods, laminar flow hoods





and 'designated containment areas' around the laboratories for you to handle all specimen types and chemical hazards.

It is essential that when leaving a laboratory area you remove your laboratory apron and gloves and wash your hands. It is not acceptable practice for staff to be seen walking into office and other non laboratory areas while still wearing laboratory aprons and/or gloves

The laboratories have adequate hand wash basins and you must wash your hands after all bench work involving specimens or chemicals and before leaving a laboratory area. You should be careful not to contaminate telephone keypads or handsets and computer mice and keyboards by carelessly moving from your bench work to handling the 'phone or PC whilst still wearing gloves or before you have washed your hands. Some areas have designated 'dirty' telephones; these should always be used with gloves on. Some PC keyboards have keyboard protectors on - these should be regarded as potentially contaminated / infectious. You must familiarise yourself with the contamination containment practices within your work area.

There are Spill Clean Up kits for the containment and clean up of chemical and biological material spills. You must familiarise yourself with their location in your area and how to use them.

Your outdoor clothing, personal bags, shopping etc. should be stored away from possible contact with lab coats or specimens so as to minimise the risk of contamination being carried outside of the laboratory areas. Staff lockers are available in various areas of the laboratories and in Room D1-65 adjacent to the Pathology Administration area.

Consumption of food or drink in laboratory areas is strictly forbidden. These activities must be restricted to the Common Room adjacent to the Core Laboratory, the Conference Room D1-05 and staff offices.

Personal food items that require refrigeration must be placed in the 'Food Only' designated refrigerators.

ENVIRONMENTAL ASPECTS (Clause 5.4.6)

All specimens should be transported as soon as possible to the laboratory Specimen Reception Area. The RHH Wards all have access to Vacuum Tube Stations which makes it easy to send the majority of their specimens. Bulky specimens have to hand delivered.

The online database of Pathology Tests and Specimen Requirements located on the RHH Intranet provides details on specimen transport and storage requirements.

Specimens that we refer to other laboratories have to be specially packed in accordance with the referring laboratories requirements and statutory authorities such as IATA. This activity is coordinated on a Pathology Department wide basis. You should not dispatch specimens yourself without first discussing it with your Scientist in Charge.

All staff are responsible for checking that specimens have been handled correctly before they proceed to analyze them. Incorrectly handled specimens will probably give erroneous results and they should not be processed. Some specimens such as biopsies cannot usually be repeated so any mishandling is a 'disaster'. Some 'disasters' can be fully or partially compensated for but this decision must be given to your supervisor or Scientist in Charge to make. Results obtained from specimens that may have been mishandled prior to analysis must be clearly annotated as having





been obtained under non-ideal conditions and that the results may therefore be of inferior quality and/or accuracy.

All staff are expected to record notes on specimen conditions that may affect results eg blood staining of CSF; haemolysis, lipaemia or icterus in serum samples etc.

Specimens collected for referral to other laboratories must be collected and transported under the conditions specified by the Referral Laboratory. Any errors or deviations from their procedures must be documented on the Pathology Request Form we send to them with the specimens so that they are fully informed of the circumstances.

LIST OF EXAMINATION PROCEDURES (Clause 5.1.4)

Consult the online Specimen Requirements Database :

http://rhhlas26.health.local/path_tests/dhhs_default.asp

REQUEST PROTOCOLS, PRIMARY SAMPLE, COLLECTION AND HANDLING OF LABORATORY SAMPLES (Clause 5.4)

We are obliged to give to our requesting doctors and their patients adequate information and equipment to enable them to understand

- what patient preparation is required
- what equipment is required

for appropriate specimen collection.

Because this information changes on a regular basis the Department has opted to distribute this information via the RHH Intranet. You should familiarise yourself with this facility so that you can guide people making telephone enquiries to this resource.

 Login to the new THO South Website <u>http://www.dhhs.tas.gov.au/intranet/stho</u> and go down to the 'Shortcuts' and click on Pathology Test Search





Shortcuts Select shortcut ▼ -New Employee Orientation PageUp (recruitment management system) PAS (DHHS) Pathology Results (CIS) Pathology Test Search Policies, Protocols, Guidelines (THO South) Research (THO South) **RHH Clinical Intranet** Right Job Right Person! Smartfleet (vehicle booking system) SoDS (Statements of Duties) from Monday 14 January More news...

Alternatively staff can access the same database via Pathology Results (CIS) ... login using your Kestral User Name and Password

🧭 CIS Login		🔄 🛉 🔹 📄 🖛 👻 Page 🗸 Safety 👻 Tools 👻 🕡 🔻
	Royal Hobart Hospi	tal
	- Pathology Results	s -
	You need to log in	
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	PASSWORD	
	Help	42
	The System Administrator may be contacted via 6222 8410.	R AR
	Royal Hobart Hospital users may also use their personal network log-in (as supplied by I.T. Services) to access pathology results for RHH patients via the DMR system on	
SOUTH	DISCLAIMER: The information on these pages is	
OWNED BY TASMANIANS	confidential, and is intended for authorised Pathology results lookup system (CIS) users only.	
	If you are not authorised by the Royal Hobart Hospital to view patient information, please notify the Pathology I.T. coordinator immediately via 6222 8410, and return any printed pages to Royal Hobart Hospital Pathology Services	





Then click on Pathology Test Information Search

Royal Hobart Hospital Clinical Integration	🛉 🕶 🔊 🗸
RHH Pathology Results	Enter Patient:
CIS LINKS BOOKMARKS HISTORY	/ User: Tom Hartley HELP LOGOUT
Welcome to the RHH Pathology Resu	ts System
*** Users can now search by Statewide TH	CI patient number directly from the 'Enter Patient' field ***
Royal Hobart Hospital medical staff are remin on the Digital Medical Record (DMR) system	nded that pathology result sign-off must be carried out at http://dmr.dhhs.tas.gov.au
Pathology Patient Search Pathology Test Information Search General Pathology Information Clinical Guidelines	<

Pathology tests
This database contains the details of tests available through Royal Hobart Hospital Pathology Services. To search, type the name of the test, eg. "fbc" or "full blood count". For best results, please make your search as specific as possible.
Search term Find
<u>New or Updated tests from the last 30 days</u> <u>Pathology Specimen Tubes Quick Reference Guide</u>

✤ Type in the Name or Acronym of the Test you wish to search for.





Digoxin			
Synonyms	: Lanoxin, Digoxin Levels	, Dig Levels	Print
Result availability	Daily, as required		
Test performed at	RHH Biochemistry (Tel: 6222 87	775)	
Comments	Collect sample immediately pric be reliable during treatment with achieved after digibind is cleare patients with normal renal funct	or to next dose or, alternatively, 6 - 8 hours post d h digibind as the drug interferes with the assay. F ed through the kidneys. The half life of digibind is tion.	ose.Digoxin assays will not Reliable results will only be some 15 - 20 hours in
	Click for appropriate sampling t	imes and intervals.	
Sample type	Venous Blood		
	Vol. required	Tube type	Preview
Tube details	2 mL	SST 4mL (Red top with gel)	
Billing Advice	This test is rebatable through M MBS Item No: 66800 Fee: \$18.45 Benefit: 75% = NOTE: * Approximate cost • Medicare coning rules may a • A Patient Episode Initiation (f General Advice: • Patients are asked to bring th	ledicare = \$13.84* Benefit: 85% = \$15.68* pply PEI) fee may be charged. peir Medicare card for bulk-billing	
	 Public Inpatients and Emerge 	ency Department admissions will not receive an i	nvoice
More Information	RCPA Pathology Test Informati	on	

A version of this database suitable for viewing on web enabled mobile phones can be accessed at

www.centrepath.dhhs.tas.gov.au/testinfo







In addition we have the RHH PATHOLOGY SERVICES USER MANUAL see QS-Proc-5.

VALIDATION OF RESULTS (Clause 5.7)

Staff responsible for validating patient results will take into consideration :

- The adequacy of the Internal Quality Controls run at the same time as the patient specimen.
- \circ The appropriateness of the specimen submitted for examination.
- The degree of agreement between the patient result and the Clinical Notes provided on the Request Form
- The comparison between this result and the same patient's previous results delta checks

On the basis of their assessment they will do one or more of the following

- Release the result for reporting Authorise
- Interim the result for review by a second person
- o Withold the result and place it on the Pathologist Verify List in Kestral PLS
- Institute repeat testing to confirm the result before releasing any information about the result
- Notify appropriate laboratory staff, Pathologists and Clinical Staff / Requestor according to triggers specified in the procedure for that examination.

Normal results and some abnormal results obtained from our highly automated online instrumentation are autoauthorised within the Kestral system without operator intervention. Staff who are operating these instruments are expected to be familiar with the autoauthorisation rules that are being applied.

QUALITY CONTROL (Clauses 4.9 and 5.6)

Test results from patient samples shall not be released if the analytical system is demonstrably not working within acceptable Quality Control Limits. This decision will be made during Normal Working Hours by the Senior Scientist or Pathologist responsible for the area. Out of Normal Working Hours this decision can be made by the Scientist performing the testing with or without consultation with the On Call Senior Scientist or Pathologist for the area provided this is in accordance with the local Departmental Policy under these circumstances.

Troubleshooting :

In general terms failures in Internal QC will reflect failures in the post patient sampling components of the test; ie failures in one or more of the following areas :

- a) The equipment or analytical methodology,
- b) The analytical skills of the operator or adherence to the analytical protocols specified for the test
- c) The integrity of the calibration material
- d) The integrity of the Internal QC material itself





It may be necessary to visit each of these areas in detail to solve a problem in the event of the internal QC appearing out of control.

Commoner areas to check in the event of Internal QC failure are

- e) Is the QC Material still in date?
- f) Has there been a batch change?
- g) Has there been recent equipment maintenance/repairs/engineering?
- h) Has there been a change of calibration material eg new calibrator lot numbers, new batch numbers or new sources?
- i) Does the QC Material appear homogeneous ie. Was it reconstituted properly and stored properly after reconstitution ?
- j) Are the appropriate method specific QC Values on the package insert being used ?

If one of these is the cause then the error should be corrected and the Internal QC Material re-run before proceeding to analyze any patient samples.

If none of these are the source of the Internal QC failure then consider :

- k) Use of different batches or lot numbers of the Internal QC Material.
- 1) Use of an equivalent Internal QC Material from a different manufacturer.
- m) Use of an equivalent Internal QC Material sourced from another laboratory.

In cases of equipment failure, decisions will need to be made about repairs in house with or without the assistance of engineering staff either on site or off site.

Where the analytical system has been checked as much as possible, the system has appropriate calibration and the QC materials are good, then the problem must be referred to a Senior Scientist, Scientist in Charge or Pathologist.

The Senior Scientist, Scientist in Charge or Pathologist for the particular area may waive the QC rejection using their judgement after considering factors such as:

- n) Is the rejected QC at a similar concentration to the test samples?
- o) The clinical impact of releasing the test results.
- p) The possibility of matrix effects in the QC material creating different responses in the analytical system to test samples, etc.

REVIEW OF INTERNAL QC

Initial review of internal QC is the responsibility of the analyst performing the testing and at the time of testing.

All numeric QC Data will be recorded on either paper or electronic forms of the Levy-Jennings Plot.

All areas involved in quantitative testing will document monthly Means, SDs and Coefficients of Variation on all of those assays.





All areas involved in quantitative testing will document monthly assessments of fixed or relative bias in the monthly Internal QC Data. Where batch frequencies are low this will be extended to a more relevant frequency eg once every 10 - 15 batches.

All areas involved in quantitative testing will periodically compare their Internal QC Statistics with their External QC Statistics and with the statistics reported by External Quality Assurance Programmes for the same methodologies as their own. Periodically means at least at the end of each External QAP Cycle of testing.

In the event of an Internal QC failure then the analyst will attempt to ascertain any causes in the first instance, but failing to find solutions to the problem then he or she will alert the Senior Scientist for the area and then work with the Senior Scientist to try and effect a solution.

Monthly review of Internal QC is the responsibility of the Senior Scientist for the particular area of the lab.

Once testing has been halted because of Quality Control failures then it can only recommence when the Senior Scientist, Scientist in Charge or Pathologist has issued a clear directive to this effect.

Unity Real Time QC: In 2009 we began be rolling out BioRad's Unity Real Time QC package to most areas involved with quantitative QC. You should check with your Section Supervisor as to the current situation in your area.



Refer also to CHEM-Proc-79 for further details on the Unity Real Time QC system and its use.

LABORATORY INFORMATION SYSTEM. (Annex B.)

Pathology Services uses Kestral PLS as its Pathology Laboratory Information system. This system then feeds results data into the web based Clinical Information System and the Digital Medical Record system. From the hardware point of view the system is maintained by our IT Support Technician. From the functionality point of view this is maintained under contractural arrangements with Kestral Pty Ltd. Staff who have issues with functionality should direct these to the Pathology IT Coordinator.





Access to the DHHS Network is administered by DHHS IT Services who can be contacted on 1300655564. They should be contacted in relation to problems with the programs included in the Microsoft Office suite.

Access to Kestral PLS is administered by the Pathology IT Coordinator who may consult with your Scientist in Charge or Departmental Director to determine the finer details of the level of access you require to perform your work. Access to the Pathology Intranet site is administered by the Pathology IT Support Technician.

Up to date documentation on Kestral PLS is retained on the Kestral PLS website which can be accessed at any time :

<u>http://kms.kestral.com.au/products/pls/help/index001.htm#11</u>

You will need to be a registered user to access this online information; IT Support can assist you with this if necessary.

The key functionalities of Kestral PLS documented there (in alphabetical order) include :

Aliquotting Anatomical Pathology Blood Bank Central Specimen Reception Daybook Faxing Hot Keys : Reproduced here KMail : Reproduced here Quality Control Result Entry – Word Processing Types of Notifications Report Group Scripts Worklists - Entry Turnaround Time Utility

Hot Keys - PLS Purpose

Throughout PLS there are a number of "shortcuts" available to the user to speed up the navigation to more frequently used tables or menu options. These are available in the form of **"HOT" Keys.**

Hot Keys

<Alt 1> - Table 1 <Alt 1>
<Alt 2> - Table 2 <Alt 2>
<Alt 2> - Comments Table
<Alt 4> - Table 4 <Alt 4>
<Alt 5> - Urno/Request# Table
<Alt 6> - Notifications





X

	<alt 7=""> - Sample Sequences</alt>	
	<alt 8=""> - Print Definitions <alt 8=""></alt></alt>	
	<Alt 9> - Test Information Table	
	<Alt B> - Edit Samples for Bactec	
	<alt d=""> - View Scanned Images - Refresh</alt>	
	<alt e=""> - EMail Facilities</alt>	
	<alt f=""></alt>	
	<u><alt q=""> - Quick Test Entry</alt></u>	
	<u>Alt S> - View Scanned Images Prompt</u>	
	<u>-<alt v=""> - View Doctor Table</alt></u>	
	<u>_<alt w=""> - Histology Worklists</alt></u>	
	<u>_<ctrl @=""> - Quick Entry Menu List</ctrl></u>	
	<u>-<ctrl b=""></ctrl></u>	
	< <u>Ctrl D> - View Scanned Images Refresh</u>	
	<u>-<ctrl l=""> - Logout</ctrl></u>	
	<u><ctrl p=""> - Change Password</ctrl></u>	
	<u>-<ctrl q=""> - Produce Quote</ctrl></u>	
	<u>-<ctrl r=""> - View Continuous Reports</ctrl></u>	
11-1 I	<u>_<ctrl s=""> - View Scanned Images</ctrl></u>	
Hot keys may be	e activated from any part of the application.	
LOOKUP/additions	s/modifications are permitted in the accessed table, then by pressing	
the ESC key, the	e user is returned to wherever they were when they selected the not	
Following is a list	t of the 'HOT' KEYS displayed when using the <alt 0=""></alt> hot key	
PI S32	tor the nor kers displayed when using the CAR o hot key.	
-	15:59:06 27 Dec 2000	MANAGER
Data	PLS Hot Keys	
	Hot Key Description	
Pa	t (Alt-0) PLS Hot Key Table	
Pa	t (Alt-1) Doc/Units/Hosp/Ward	
Ue Au	er (Alt-2) Dpt/Itms/Grp/Tst/RDL t (Alt-3) Comments	
Si	(a) (Alt-4) User Accounts	
Cu	(Alt-5) URNO/Request Number	
Da	y (Alt-7) Sample Sequence Numbers	
QU	I (Alt-8) Printer Definitions	
	N (Alt-B) Blood Cultures	
No	t (Alt-D) Uiew Scanned Images Prompt - Refresh	
31	$-\langle Alt-F \rangle$ Faxing	
	<alt-p> Printer Redirection</alt-p>	
	<enter>Select</enter>	





PLS32		16:00:19	27 Dec 2000	MANAGER
Data Pat Out Pat Ver Aut Sim Cum Ser Day QUI Hos URN Not Spe	Hot Key (Alt-Q) (Alt-S) (Alt-W) (Ctrl-Q) (Ctrl-B) (Ctrl-D) (Ctrl-L) (Ctrl-P) (Ctrl-R) (Ctrl-S)	PLS Hot Keys Description Quick Entry View Scanned Images Prompt Histology Worklists Quick Entry Menu List Blood Bank Information View Scanned Images - Refresh Logout Change Password View Continuous Reports View Scanned Images		
		<enter>Select</enter>		

Each of the above Hot Keys are described below listing the options each 'HOT' key will provide access to.

To choose the desired option within the menu option or table, press the corresponding letter.

<Alt 1> - Table 1 <Alt 1> .Return to Hot Keys Menu

Doctor Table Unit Table Surgery Table Surgery Packages Table Institution Table Hospital/Ward Tables Service Team Table Fax Table Collection Centres HIC Doctor Table HIC Speciality Reference

<Alt 2> - Table 2 <Alt 2> .Return to Hot Keys Menu

Department Table Cost Centres Item Table Group Item Table Single Test Table Combination Test Table Report Group Table (RDLs) Aliquots Table Sample RDLs Sample Ranges Test Information Ward Report Table

<Alt 3> - Comments Table .<u>Return to Hot Keys Menu</u>





This option takes the user straight to the comments table, listing each comment and its code, category and date added. Select from the options at the bottom of the screen as usual.

<INS>Add <Cr>Modify <F2>Find <F3>Report <F4>List

<Alt 4> - Table 4 <Alt 4> <u>Return to Hot Keys Menu</u>

Authority Department Table Authority Group Table Authority User Table EMail Groups

<Alt 5> - Urno/Request# Table Return to Hot Keys Menu

This Hot Key is in use at Royal Hobart Hospital. It links to a table where Urno may be associated to an episode number. Follow the <u>Urno/Request</u> link for more information.

<Alt 6> - Notifications <u>Return to Hot Keys Menu</u>
This hot key takes the user to the Notifications Menu.
<Alt 7> - Sample Sequences <u>Return to Hot Keys Menu</u>
Shortcut to printing labels for Anatomical Pathology/Cytology

<Alt 8> - Print Definitions <Alt 8> .Return to Hot Keys Menu

Print Definition Functions
Normal Print Definitions
Extended Report Definition
Additional Report Definitions
Request Letter Print Definitions
Print Properties

<Alt 9> - Test Information Table .Return to Hot Keys Menu

Shortcut to Test Information Table in Preparation Menu under Charges, RDL-Reports & Tests. This table is accessed also via the **Alt 2** hot key.

<Alt B> - Edit Samples for Bactec <u>Return to Hot Keys Menu</u>
Shortcut to Bactec Interface. For more information follow the link to <u>Sample</u> and Bottle Recording (Alt B).

<Alt D> - View Scanned Images - Refresh <u>Return to Hot Keys Menu</u> For sites with scanning of request functionality set up, this hot key allows the user to refresh the view of scanned images. See also Alt S - View Scanned Images Prompt and **Ctrl S -** View Scanned Images hot keys.

<Alt E> - EMail Facilities Return to Hot Keys Menu

This hot key takes the user to the PLS EMail screen to quickly write and send a new Email.

<Alt F> <u>Return to Hot Keys Menu</u>





Shortcut to activate the Manual Faxing option.

<Alt P> - Report Redirection Options <u>Return to Hot Keys Menu</u>

Shortcut to the Printer Report Redirection facility. Enables the user to temporarily redirect the printing of reports from the current workstation to a print queue other than the default print queue.

<Alt Q> - Quick Test Entry .Return to Hot Keys Menu

For sites where the Quick Test Entry functionality has been specified. Follow the link <u>Quick Test Entry</u> for more information.

<Alt S> - View Scanned Images Prompt Return to Hot Keys Menu

For sites with scanning of request functionality set up, this hot key allows the user to view a scanned image. See also **Alt D** - View Scanned Images - Refresh and **Ctrl S** - View Scanned Images hot keys.

<Alt V> - View Doctor Table <u>Return to Hot Keys Menu</u>

This hot key allows for a user to view the doctor table without the ability to edit any of the enteries and add a new entry. To activate this hot key, the user must also have the authority Access - View Doc Table enabled. It would also advisable to deactivate the authority, Setup - Doctors.

<Alt W> - Histology Worklists Return to Hot Keys Menu

This hot key takes the user to the Histology worklists available for a specified sample letter.

<Ctrl @> - Quick Entry Menu List Return to Hot Keys Menu

This hot key takes the user to Q Menu. Only available for some sites. Q Menus are generally run from Services.

<Ctrl B> Return to Hot Keys Menu

Shortcut key to Blood Bank Information Table where specified for site.

<Ctrl D> - View Scanned Images Refresh .Return to Hot Keys Menu

For sites with scanning of request functionality set up, this hot key allows the user to refresh the view of scanned images. See also **Alt S** - View Scanned Images Prompt and **Ctrl S** - View Scanned Images hot keys.

<Ctrl L> - Logout Return to Hot Keys Menu

Logs the user out back to Login Screen. Shortcut to the Utilities Menu Option - "Log Off".

<Ctrl P> - Change Password <u>Return to Hot Keys Menu</u>

From anywhere in the application, the **Ctrl P** hot key allows the user to change their password. As a security measure, before any modification is permitted, the user is prompted to enter their old password. If the user forgets their password, they should contact their key user to have a new password issued.

<Ctrl Q> - Produce Quote Return to Hot Keys Menu

From anywhere within the application, the Ctrl Q key combination allows the user to produce a quote for the test codes and bill category entered.

<Ctrl R> - View Continuous Reports Return to Hot Keys Menu

Authorised by : Dr Marsden, Dr Vervaart & Dr Tom Hartley Issued February 2012





For sites where Continuous Reporting is set up, **Ctrl R** displays Page Number, Series Number of the specified report.

<Ctrl S> - View Scanned Images Return to Hot Keys Menu

For sites with scanning of request functionality set up, this hot key allows the user to view scanned images. See also **Alt S** - View Scanned Images Prompt and **Ctrl D** - View Scanned Images Refresh hot keys.

Further 'Hot' Keys

<<u>Alt A></u>
<u><Alt C></u>
<u><Alt C></u>
<u><Alt T></u>
<u><Alt U></u>
<u><Ctrl A></u>
<u><Ctrl Arrow Left/Right></u>
<u><Ctrl End></u>
<u><Ctrl W></u>
<u><Esc></u>
<u><F4></u>
<u><Tab></u>

There are a number of keys available that act like **Hot Keys**. Unlike the Hot Keys described above, the following keys vary in where they may be activated from. Some may be activated anywhere in the application, others require the user to be in specific fields.

<Alt A> <u>Return to Further Hot Keys Menu</u>

With the cursor positioned on a test field, the individual test will be marked as an "Add-on" and will appear in magenta. In browsers the test will be flagged with a "&" to indicate it is an add-on test. ("Add-on" tests are tests which are request, usually verbally, after the specimen has been received in the laboratory). For more information on using this hot key, please refer to the document <u>Flagging Test Codes - PLS</u>.

<Alt C> .<u>Return to Further Hot Keys Menu</u>

If a specific field within an RDL (Report Script) is set up to take comment codes from the Comment Table (follow this <u>LINK</u> to see how this is done) and the user is in a report in edit mode with the cursor resting in that field, then by pressing the **Alt C** hot key the user is displayed the list of codes in the specified category for the specified comment letter.

<Alt H> .<u>Return to Further Hot Keys Menu</u>

Host Lookup facility. For sites with a PMI interface, the user has the facility to access data stored in the PMI Host database by hitting the **Alt H** hot key. This is typically done while in the Patient Episode screen or in Bag Tracking. The user may search by **Name**, [*]URNO, or [.]Episode Nbr Lookup :

<Alt T> <u>Return to Further Hot Keys Menu</u>

With the cursor positioned on a test field, the individual test will be marked as "to be telephoned" and will appear in green. In browsers the test will be flagged with a "^" to indicate it is to be phoned. For more information on using this hot key, please refer to the document <u>Flagging Test Codes - PLS</u>.





In request entry, **Alt T** will display the Telephone browser and allows details to be viewed or entered for telephoned results.

<Alt U> .Return to Further Hot Keys Menu

For larger sites making comprehensive use of the notifications system, it has become necessary to implement a method of not only marking an entire request urgent (using the U Special Condition), but also to allow central specimen reception to flag only some test(s) on a request as urgent. For example, on a request containing multiple tests such as full blood count, coagulation screen and liver function tests only the coagulation may be required urgently. Hence it is now possible to flag just the coagulation as urgent.

From the List of Patient Request screen, **Alt U** is used to remove an episode from archive and back into the main file. The user must have privileges View Archive and Maintain Archive.

In PLS, a user is able to nominate that only specific tests are urgent. In the case of fully automated laboratories, then PLS will only generate URGENT notifications for those departments/tests, that is, an URGENT notification would only be generated for the coagulation sample, but not for the FBE or the biochemistry samples.

To mark an individual test URGENT, use the new <Alt><U> facility. Place the cursor on the relevant test code, and press <Alt><U>. You will see that PLS will change that test code to be displayed in RED on the request entry screen. Any number of individual tests may be marked as urgent.

When viewing results for requests that have individual tests marked as urgent, that PLS will display the list of test codes with an asterisk (*) in front of any urgent tests (as they are not shown in RED).

Note that <Alt><U> has a toggle action. That is, pressing <Alt><U> repeatedly will add and remove the urgent status assigned to the test in question.

For more information on using this hot key, please refer to the document <u>Flagging Test Codes - PLS</u>.

<Ctrl A> <u>Return to Further Hot Keys Menu</u>

This shortcut opens a sub screen that displays information that relates to the current session of PLS or RMS and the workstation it is run on. To learn more about the information that this screen provides, follow the link $_<$ Ctrl A> - A world of information at your fingertips.

<Ctrl Arrow Left/Right> .Return to Further Hot Keys Menu

Alter the date forward or backward a day at a time when used in any date field within the application.

<Ctrl End> <u>Return to Further Hot Keys Menu</u> Will return user to the main data entry.

<Ctrl F12> <u>Return to Further Hot Keys Menu</u>





End session without saving. This is a hot key that may be used from anywhere within the application. It is a shortcut to the Utilities Menu Option - "Exit".

<Ctrl W> <u>Return to Further Hot Keys Menu</u>

Where multi-worksite functionality is activated, it is possible to allow users to change their worksite using the **Ctrl W** hot key. The user must have the <u>Worksite</u> privilege to allow this. By pressing **Ctrl W** the list of worksites will appear. If the user does not choose a worksite then it will not be changed.

<Esc> _Return to Further Hot Keys Menu

To quit without saving and return to the previous screen.

<F4> <u>Return to Further Hot Keys Menu</u>

Lookup of tables from specific fields within the application. Any field that has a table associated will give the user access to the table via the **F4** key. In the Episode Entry screen, at the Referring Doctor field for example, one may gain access to the entire Doctor Table by pressing the **F4** lookup key. If the user types a few letters of the Doctor's surname as a prefixed search, **F4** will display all entries that start with the typed letters.

Further to this, in a Date or Time field, **F4** will insert the current date or time.

The **F4** key is the only way to gain access to the Isolate and Sensitivity Module (ISM). Access to the ISM is achieved by pressing the **F4** key from the Sample Number field (Internal Number 253) within a report in edit mode.

<Tab> <u>Return to Further Hot Keys Menu</u>

Move to the next mandatory field in the episode registration screen.

KMail - Overview Purpose

The purpose of this overview is to outline the use Kmail within PLS and RMS.

Overview

Kmail provides the facility for internal Kestral email (Kmail) to be sent to users of PLS or RMS. Only certain users will have the ability to send, but everyone will be able to receive and view mail.

How to Send and Receive KMail (internal Kestral Email) <u>Purpose</u>

It is now possible for internal email to be sent to users of PLS or RMS. Only certain users will have the ability to send, but everyone will be able to receive and view mail. The





EMail facilities can be accessed using the Alt-E hot key.

EMail Options

The options available within the EMail browser are to Send, Reply to, Read, and Delete EMail. EMail can only be sent by users who have the "Send EMail" flag set to Y in the <u>Authority Group Table(PLS)</u> and "Can Send Email" in <u>Privileges (RMS)</u> You are able to send EMail to individuals or groups, where the latter needs to be set up via the <u>EMail Group Table</u>. To access the EMail facility use Alt-E.

If you don't have any EMail in your browser, you will be presented with a box as seen below with the option to either:

<W>rite Mail

This option is described later in "Sending EMail". You must have the authority to send mail to have this option (via the <u>Authority Group Table(PLS)</u>) and <u>Privileges (RMS)</u>).

<Esc>ape No Mail To View

You have not received any mail. You do not have the authority to send mail.

PLS32							
	PLS E	Mail	-12:16:03	11	Jan	2001	MANAGER
	<w>rite</w>	Mail					





K PLS32					
	PLS	EMail	12:19:13	11 Jan 20	01 ZZZZZZZ
	<esc>ape No</esc>	Mail To) View		

However, if you have EMail that you have either sent or received in your browser, then the first screen you will be presented with is the Main EMail Screen which is described next.

Main EMail Screen

This is the screen that displays all the information regarding your own personal EMail. From here you are able to perform all functions associated with EMail.

_					11:	51:56	11 Jan	2001	MANAGER
Irgent	Sent	Who	Date & Tim	PLS EF	lail Subject				
		Z2222222	11/01/2001	11:51	Patient	Detai	ls		
J	7	Manager	11/01/2001	11:50	Patient	Detai A Tes	ls t		
		Enter>Read	Mail <w>r</w>	ite Mai	il ⟨R>ep	1y <d< td=""><td>el≻ete</td><td>Mail</td><td></td></d<>	el≻ete	Mail	
	<	Enter>Read	Mail <w>r</w>	•ite Mai	il ⟨R≽ep	ly <d< td=""><td>el≻ete</td><td>Mail</td><td></td></d<>	el≻ete	Mail	
	<	Enter>Read	Mail (W)r	ite Mai	il ⟨R>ep	1y <d< td=""><td>el>ete</td><td>Mail</td><td></td></d<>	el>ete	Mail	
	« Field	CEnter>Read	Mail ≺W>r	•ite Mai	il ⟨R>ep	ly <d< td=""><td><mark>el></mark>ete</td><td>Mail</td><td></td></d<>	<mark>el></mark> ete	Mail	
	Field	Enter>Read	Mail ⟨W>r	•ite Mai	il ⟨R>ep	ly <d< td=""><td><mark>el>ete</mark></td><td>Mail</td><td></td></d<>	<mark>el>ete</mark>	Mail	
 	Field	CEnter>Read	Mail (W)r	indicat	il ⟨R>ep	ly ⟨D	<mark>el>ete</mark>	Mail	
	Fiel Jrgent	CEnter>Read	∎ Mail ⟨₩>r e displayed	ite Mai indicati	il <r>ep</r> ing that t	ly <d his is a</d 	<mark>el>ete</mark> an urgel	Mail nt EMa	il.
	Field Jrgent / Sen	Enter>Read ds A tick will b	∎ Mail <w>r</w>	•ite Mai indicati	il ⟨R>ep	ly <d his is a</d 	<mark>el≻ete</mark> an urge	Mail nt EMa	il.

Issued February 2012





<u>Who</u>

Depending on whether or not the EMail is received or sent by you this field will display your code if you sent the EMail, or the senders code if you are receiving the EMail. Also notice that EMails sent by you are coloured white and those received by you are coloured yellow.

Date and Time

Displays the date and time the EMail was sent.

<u>Subject</u>

Displays the subject of the EMail.

Browser Options

<Enter> Read Mail

Allows you to enter into a screen where the entire contents of the EMail are viewable.

<W>rite Mail

Allows you to write/send a new EMail.

<R>eply

Allows you to reply to a specific EMail.

ete Mail

Allows you to delete mail from your list.

Sending EMail

You are able to send EMail by selecting $\langle W \rangle$ rite Email. You will be presented with the screen below.

PLS32					_ [] >
		PLC	11:56:44	11 Jan 2001	MANAGER
rgent Sent	Who	Date & Time	Subject		
	Zzzzzzz	11/01/2001 11:5	1 Patient Deta:	ils	
To Subject Urgent Include	: : File :	-::		:	
ESC = Abando	n input, F	9 = Accept input			
Fie	lds				
Fie <u>то</u>	lds				





or RMS user code, by entering an <u>EMail Group code</u> or by selecting F4 to view all.

Subject

This field allows you to specify the subject of your EMail - up to 20 characters.

<u>Urgent</u>

You are able to specify if the EMail is urgent or not by using either $\rm Y$ - Yes or N- No.

Include File

This field allows you to attach a file to your EMail. Here you specify the path to access that file.

For example: H:\WORKPLS\EXEC\UPGRADE\CUSTOMER.LST The Word Processing field where you type the contents of your EMail is the last section to complete and can be accessed by pressing <F10>. Once you are happy with the contents of your EMail - select <F9> to Accept/Send, or if you no longer want to send the EMail press <Esc> and all input is abandoned. After selecting either of these options you are presented with the Main EMail screen as described earlier.

Replying to EMail

EMail can be replied to by any user by pressing the <R>eply key when positioning the highlight bar on a received email in the browser. As you can see below some details are automatically filled in for you. Users who do not have the authority to "Send EMail" are not allowed to change the recipient.

K PLS	632					_ 🗆 🗵
			זס	12:47:54	11 Jan 2001	ZZZZZZZ
Urge	nt Sent	Who	Date & Time	Subject		
		Manager	11/01/2001 12	:47 Hello		
	To Subject Urgent Include	:Manager :Hello :N: File :	:: :		=	:
ESC	; = Abando	on input, F	9 = Accept inp	ut		
pls00	<u>200.htm</u>					
Rea	ading	EMail				
		A . (1			TT (1	





EMail can be viewed by any user of PLS and RMS by pressing the <Enter>Read EMail key if they have received any mail.

Compile - PLS					_ 8 ×
		PLS EMail	15:02:51	07 Jan 1998	MANAGER
Jrgent Sent Who	Date	Subject			
To : Manager Subject : Hello Worl Date : 07/01/1998	đ				
<u>M</u> y very first email.					
	<f9>Bac</f9>	k To Main Mer	u		

A background task may also be set up to alert users to any Email which has come in. Refer to <u>Check For New Email</u> for further information.

Deleting EMail

Deleting EMail will remove it permanently from the browser.

REPORTING OF RESULTS (Clause 5.8)

Reporting of results is all handled in the first instance by Kestral PLS. This system then feeds results data into the web based Clinical Information System (CIS) and the Digital Medical Record system. Hard copy reports related to Medical Testing are only issued on colour coded stationery with a watermark showing the approved RCPA NATA Logo and Accreditation wording. Reports that are not related to Medical Testing are issued on plain stationery.

Kestral PLS also has the functionality to fax reports.

For details on how to access Pathology Results on the CIS system staff should consult Document QS-Proc-52.

Within the RHH the Digital Medical Record (DMR) and the Clinical Information Portal (CLIP) are the two access points to online results :





The DMR Results System

Username: Password: Login
Password:
Login

Logout thartley	Advanced Search
-Enter UR-	Patient Search Episode Search
Advanced Search	Patient details
Patient List	
Search 🔺	Domain : 🔤 All -
	Family Name :
Advanced	Given Name(s) :
Ward List Clinic List	DOB (dd/mm/yyyy) : / / /
Unit List	Sex : - All -
Doctor List	Treating doctor (inpatients)
My Details 🔹 🔻	Family Name:
Support 🔹	Given Name(s):
	Clear Search





Logout	LC	<mark>/en</mark> HCI\ Sev: E. DOB: 13J	Feb. 1949		Patient Summary	
	List : Patient : Cove	er 10	60-1343	Cover	Add to My Patient List	
-Enter UR- Advanced Search Patient List	Date of Death	28 21 Bo	ad	Emergency	Filter / Search	
Search Advanced Ward List Clinic List	Post Code Medicare No. Home Phone	Be t SC RT 70 60 62		Outpatient Community	Select action	7 episodes Patient Bookmarks
Unit List Doctor List	Mobile Phone ATSI Status	nıl Neither Aboriginal Torres Strait Islano origin	nor ler	Diagnostic	Section	Number of documents
My Details 🔹 🔻	Religion	Anglican		C/pondence	Cover	0
Support 🔹	Language	English		Admission	Outpatient	33
					Community	13
				Archive	Diagnostic (Pathology)	(189)
	Description		Date		(Radiology)	(16)
					(Documents)	(24)
					Correspondence	61
					Admission	327
					Archive	0
					Total	774

Logout	LO					Cumulativ	ve Test Su	mmary			
maney	List : Patient : Diagnostic		-Feb-1	949	Cover						
-Enter UR-	Add Add	ction 🔻			Cover	RHH - Full Blo	od Exam				
Advanced Search	Filter : ALL				Emergency						
	Test Type	Date	Time			<u>Graph</u>				P	rint
Search 🔺	RHH - Blood Gases/Elecs. RHH - Blood Gases/Elecs.	30-Jan-13 30-Jan-13	12:12 09:58		Outpatient	Test Type	30-Jan-13(04:00)	29-Jan-13(03:50)	28-Jan-13(04:00)	27-Jan-13(04:00)	Units
Advanced	RHH - Blood Gases/Elecs. RHH - Blood Gases/Elecs.	30-Jan-13 30-Jan-13	06:54 04:13		Community	Film Made					
Clinic List	RHH - Biochemistry (Routine)	30-Jan-13 30-Jan-13	04:00			□ wcc	9.6	7.1	6.9	5.1	/nL
Unit List	RHH - Full Blood Exam	30-Jan-13	04:00	J	Diagnostic	П нь	134	130	127	118	g/L
Doctor List	RHH - Blood Gases/Elecs. RHH - Blood Gases/Elecs.	30-Jan-13 29-Jan-13	22:54			C RCC	4.38	4.24	4.12	3.84	/pL
My Details 🔹 🔻	RHH - Blood Gases/Elecs. RHH - Blood Bank	29-Jan-13 29-Jan-13	18:35 18:30		C/pondence	Hct	0.41	0.38	0.38	0.35	
Support 🔻	RHH - Blood Gases/Elecs.	29-Jan-13	16:19		Admission	П мсv	92	91	92	92	fL
oupport	RHH - Blood Gases/Elecs.	29-Jan-13	11:59		Admission	П мсн	31	31	31	31	pg
	RHH - Blood Gases/Elecs. RHH - Chest X-Ray	29-Jan-13 29-Jan-13	10:03 07:13		Archive	П мснс	331	339	336	333	g/L
	RHH - Blood Gases/Elecs. RHH - Blood Gases/Elecs	29-Jan-13 29-Jan-13	06:05 04:01			E RDW	12.6	12.4	12.2	12.1	%
	RHH - Biochemistry (Routine)	29-Jan-13	03:50			Platelets	277	258	223	220	/nL
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		lto	me 1.20	(of 229)			10.2	10.3	10.7	10.5	%
				(01 220)		Neutrophils	4.7	3.1	2.9	2.0	/nL
		4 5 of1	2			Immature Gran	<0.1	<0.1	<0.1	<0.1	/nL
						Lymphocytes	3.1	2.7	3.1	2.3	/nL
						Monocytes	1.3(H)	0.9(H)	0.6	0.6	/nL
						Eosinophils	0.48(H)	0.29	0.29	0.20	/nL
						Basophils	0.03	0.03	0.03	0.03	/nL

The CLIP Results System

When logged into Internet Explorer as a valid DHHS user of the intranet type 'clip' into the address bar :




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Clinical Information Porta Patient Lists > Unit >	CARDIOTHORACIC >	CLEN	29101		Wednesday
Demographics I Alerts Pathology	Pathology > Last 7 Days	-Jan-:	1946 (67y) Female	53998	
Last 8 Hours	Observation Request	Status	Ordered By	Date Collected	Full Details
Last 7 Days	Biochemistry (Routine)	Final	New Doctor Code Reqd	13:50 Tuesday, 29 January 2013	View Detail
	Full Blood Exam	Final	New Doctor Code Reqd	13:50 Tuesday, 29 January 2013	View Detail
▷ ALL	Full Blood Exam	Final	Dr Xiaoping Jiang	11:30 Friday, 25 January 2013	View Detail
Radiology	Biochemistry (Routine)	Final	Dr Xiaoping Jiang	11:30 Friday, 25 January 2013	View Detail
Pharmacy	Blood Cultures	Final	Dr Geetha Kottakad- Gopalakrish	06:26 Friday, 25 January 2013*	View Detail
Remarks	Microbiology Urine	Final	Dr Golsa Adabi	07:46 Thursday, 24 January 2013*	View Detail
Audit	Microbiology Swab	Final	Dr Golsa Adabi	19:30 Wednesday, 23 January 2013	View Detail
	Microbiology Swab	Final	Dr Golsa Adabi	19:00 Wednesday, 23 January 2013	View Detail
	Blood Bank	Final	Dr Madeleine Beaumont	11:25 Wednesday, 23 January 2013	View Detail
	Coagulation Profile	Final	Dr Madeleine Beaumont	10:55 Wednesday, 23 January 2013*	View Detail
	Full Blood Exam	Final	Dr Madeleine Beaumont	10:55 Wednesday, 23 January 2013*	View Detail
	Biochemistry (Routine)	Final	Dr Madeleine Beaumont	10:55 Wednesday, 23 January 2013*	View Detail
	* A star denotes that the collect	ion time has been estir	mated (due to the omission of a wr	ritten time on the sample).	

Telephoned Results Policy

- Pathology results are only to be given to the Requesting Doctor or to medical staff involved in the care of the patient.
- In the RHH Ward and Clinic environment pathology results can be given to Senior Nursing Staff and Senior Clerical Staff.
- You should always make sure that telephone enquirers identify themselves to you first. If in doubt take the patient details and the caller details and then arrange to call them back. You can then check with your Supervisor that they are entitled to be given the results in question and that they are calling from a phone number in a known RHH, Specialist Clinic or GP location.
- Unauthorised, incomplete, interim or results awaiting verification by a pathologist may be communicated verbally to a Requesting Doctor or medical staff involved in the care of the patient by qualified scientists and experienced technical staff if circumstances warrant. The staff member MUST make it clear that the result being given is a <u>preliminary or provisional report only</u>. Where applicable the laboratory should have documentation detailing the circumstances when release of such results is warranted.
- Transcription errors are not uncommon when results are given over the telephone. If you are giving out numeric results such as biochemistry or haematology then you should ask the caller to repeat each result as you read it out or ask the caller to read back all the results before they hang up.
- Staff are required to use the ALT T function in Kestral PLS to record the date, time and ID of the person to whom telephoned results have been issued.

Telephoned Results Procedure Checklist

✓ Identify yourself to the caller





- \checkmark Identify the caller
- ✓ Ask for the Name and UR number of the patient
- \checkmark Ask for the Dates and Times of the specimens
- \checkmark Read back the results
- ✓ Ask the caller to read back all numeric results
- ✓ Record the ID of the caller using the ALT T Function in Kestral or by recording more extensive detail in the silent field of the relevant Kestral report.

Patients are not normally given their results over the telephone. You should acquaint yourself with 'Policy and Procedure for the Release of Pathology Results to Patients', Document ID# QS-Proc-51.

REMEDIAL ACTIONS AND HANDLING OF COMPLAINTS (Clause 4.8)

All complaints that are considered to be of sufficient importance are to be lodged into the Incident Reporting System (refer back to relevant section in this document) The full policy and procedure for Incident Reporting is covered in Document ID# QS-Pol-8. The Incident Reporting System, now referred to as the CA/PA module in QPulse, is also the repository of all Corrective Actions taken as a result of an incident. A copy of the Incident Report Form is available online as Document ID# QS-Form-3 and also in Appendix 4. A copy of the Corrective Action Request and Report Form is available online as Document ID# QS-Form-6 and also in Appendix 3.

COMMUNICATIONS AND OTHER INTERACTIONS WITH PATIENTS, HEALTH PROFESSIONALS, REFERRAL LABORATORIES AND SUPPLIERS (Clauses 4.4, 4.5, 4.6, and 4.7)

All staff are expected to conduct their communications in a professional and ethical manner regardless of the medium being used, - phone, email, memorandum, letter etc.

Any communication directly related to Medical Testing and which has the potential to affect testing operations, testing equipment, testing controls, testing results or testing interpretations must be formally recorded and retained as per the guidelines in 'Records, Maintenance and Archiving' of this document.

The internal telephone system is maintained by Tasinet and has a number of user features. In addition staff who have a dedicated phone extension can have voice mail activated on their phone.

This Feature	Code	Will Let You	How?
Automatic Callback	RECALL *88	Call back a busy extension When your line and the called line are free, automatic Callback rings you and the call is automatically connected when you lift the receiver	To Activate: On hearing a busy tone, press the recall button, hear Special dial Tone. Dial *88 , hear confirmation Tone. Hang Up. To Answer: You hear an automatic





			Callback Tone. Pick up the receiver.
Call Forward All calls	*70	Forward all incoming calls to another extension. Some extensions may be able to call forward to a mobile phone.	To Activate: listen for dial tone. Dial *70 and hear special dial tone. Dial the number to which calls are to be forwarded. Wait for confirmation tone. To Cancel: Listen for dial tone. Dial #70 . Wait for Confirmation Tone. Hang up.
Call Forward if no answer	*80	Divert calls to another extension if not answered in the prescribed time	To Activate: Dial *80 and the extension number to which calls are to be forwarded To Cancel: Dial #80
Call Forward if busy	*90	Calls will divert if the extension is busy	To Activate: *90 and the extension number to which calls are to be forwarded. To Cancel: #90
Call Hold	RECALL *74	Place a call on hold	To Activate: Press the recall button, hear Special Dial Tone. dial *74. Wait for confirmation Tone. Hang up. Call is now on hold. Your phone will ring every 60 seconds as a reminder that you have a held call. To Retrieve Held Call: Pick up the receiver or press the switch hooks if receiver not hung up.
Consultation Hold	RECALL	Talk privately with a third party before returning to held call, transferring the call, or establishing a Three-way Conference	To Activate: Press the recall button. Original call is now on hold. You hear Special dial Tone. Dial the third party. Consult with third party. Press the recall button twice.
Call Park	RECALL *75	Park a call against the extension on which the call is answered or placed and retrieve the parked call from any other extension in the TASINET system	To Activate: Press the recall button to place the call on hold. dial *75. Wait for Confirmation Tone. Hang up. The call is now parked against the number of that extension. To Retrieve: Dial #75 . followed by the extension number against which the call is parked.
Call Pick-Up	*77	Answer incoming calls to other extensions within your defined Call Pick-up Group	To Activate: Pick up receiver, Dial *77
Call Transfer	RECALL Dial Hang up	Transfer Calls to another number.	To Transfer: Press the recall button. Caller is now on hold. Hear dial tone dial the number to which the call is being transferred. Announce call. To Return to Original Caller: If the called extension is busy or there is no answer press recall twice to return to original party.
Redial	##	Enables you to redial the last number called	To Activate: Pick up receiver, Dial # #
3 Way Conference	RECALL Dial RECALL	Establishing a telephone conference call between you and two other parties	To Activate: Call the first party. explain you will be adding another party. Press the recall button, dial the other party. Explain you are establishing a conference call. press the recall button to connect all parties.





The RHH Hospital switchboard can provide Voice Paging when required; dial 9 to speak to the operator.

Most RHH clinical, senior RHH clinical support staff and some Pathology staff carry NEC Pagers. These can be used to alert those staff to call you back on a nearby telephone extension. To do this dial 50 and follow the voice prompts. In response to the request 'Enter message...' type in the 4 digit extension number you wish to be called back on followed by two asterisks - **.

Mobile phones are used by some staff, however, there is a risk that these can interfere with the electronics of computers and instrument electronics. You should check with your supervisor before using a personal mobile phone in your laboratory area.

Some laboratory areas issue Departmentally owned mobile phones to on call staff.

Official Pathology business calls to mobile phones should be kept to a minimum because of the extra costs associated with these. A recent directive recommends that if possible you should use SMS messaging to mobile phones :

To use the GDS SMS messaging service:

- Go to DHHS Online : http://intra.dhhs.tas.gov.au/dhhs-online/dhhsonline.php
- Click on the GDS item at top right of the Home Page
- Enter Family Name e.g Carey
- Click on Family Name Displayed
- Scroll to bottom of page
- Click on Mobile Number (Hyperlinked and will open field for short specific SMS Message)

To Change Details (eg to have your mobile number listed):

- Click on GDS Change Form
- Click on Submit

Should you require further information please contact RHH Communications on telephone Ext 7999





TELEPHONE DIRECTORY GENERAL ENQUIRIES : Ext 8416

Senior Management

Director of Pathology Dr Katherine Marsden 6222 8410

Principal Scientist Dr Peter Vervaart 6222 8240

Business Manager Mr Mike Jones 6222 8948

Fax : 6222-8996

Pathologists

Anatomical Pathology Dr David Challis (Director) 6222-8770 Dr Peter Jessup 6222-8770 Dr Vince Murdolo 6222-8770 Dr Eileen Long 6222-8770 Dr Shaun Donovan 6222-8770 Dr John McArdle 6222-8770

Clinical Chemistry Dr Udayan Ray (Director) 6222-8234

Endocrinology Dr John Burgess (Director) 6222-8732 Dr Tim Greenaway 6222-8732

Haematology Dr Katherine Marsden (Director) 6222-8337 Dr Liz Tegg 6222-8410 Dr Anna Johnston 6222-6637

Microbiology Dr Alistair McGregor 6222-8022 Pager 2414 Dr Louise Cooley 6222-8255 Dr Tara Anderson 6222-7449 (Infection Control) Dr Alison Ratcliffe 6222-8255

Sexual Health Service Dr Louise Owen (Statewide Director) 6233-3557

Senior Staff

Anatomical Pathology Mr Alistair Townsend (Sci. in Charge) 6222-8771 Deanne Lamb (Cytology) 6222-8235 Nino Mele (Mortuary) 6222-8333

Core Laboratory Mr Rob White (Sci. in Charge) 6222-8199 Ms Terri Kidd (Haematology) 6222-8776





Mr Michael Robinson (Coagulation) 6222-8776 Mr Michael Smillie (Biochemistry) 6222-8775 Ms Gina Aitken (Transfusion) 6222-8411

Central Specimen Reception Brett Clem (Preanalytical Manager) 6222-8775 Ms Kathy Barry : 6222-8657 Fax : 6234-7463

Pathology South (Located in the Wellington Centre) Reception Desk 6214-3058 or 6222-7121 Jane Stevenson (Business Development Officer) 6166-0152 Fax : 6222-7097

Cytogenetics Ms Karen Dun (Sci. in Charge) 6222-8297

Endocrinology Dr V (Paramesh) Parameswaran (Sci. in Charge) 6222-7991 Pager 3640

Infection Control Mrs Rachel Thomson (Clinical Nurse Consultant) 6222-7882

IT Support—(Pathology Results Lookup System only) Mr Andrew Hudspeth 6222-8396 Mr Graham Banks (IT Technician) 6222-8941

Microbiology Mr David Jones (Sci. in Charge) 6222-8909 Viral Serology 6222-8777

Molecular Medicine Dr Jan Williamson (Sci. in Charge) 6222-8912

Phlebotomy Service Mrs Claire Beattie 6222-7955

Purchasing Officer : Philip Bakes : 6222-8347 Fax : 6222-8047

Quality Systems Dr Tom Hartley (Quality Manager) 6222-8780

Specialised Investigations Mr Andrew Hudspeth (Sci. in Charge) 6222-8396 Dr Scott Ragg (Flow Cytometry and Stem Cell Transplantation) 6222-8431 Pager 5812 Ms Janet Bartle (Special Chemistry) 6222-8742





INTERNAL AUDITS (Clause 4.14)

Internal audits are conducted on a regular basis with the objective of covering all clauses of the ISO 15189 standard within a twelve month period. Emphasis, however, is usually given to the Technical Clauses of the standard as deficiencies in those areas will directly affect the quality of Medical Testing results.

The policy for internal auditing is covered in Document ID# QS-Pol-7, the procedure in Document ID# QS-Proc-9, and the schedule of audits in Document ID# QS-Form26.

The list of qualified auditors in covered in Document ID# QS-Ref-17.

There are currently two principal audit questionnaires in use, Document ID# QS-Proc-66 is a questionnaire directed at the Management of Laboratory Activities. Document ID# QS-Proc-50 is a technical clauses questionnaire designed for use with staff while they are performing a procedure.

There is a Staff Training audit questionnaire in Document ID# QS-Proc-69.

ETHICS. (ANNEX C.)

PROFESSIONAL INTEGRITY AND IMPARTIALITY : It is important that in your dealings with both clients of and suppliers to RHH Pathology you say or do nothing that could compromise the Laboratory's impartiality and independence.

This is particularly important for those staff involved with the choice of suppliers of laboratory goods and services. Major items of equipment have to be purchased via a formal tendering process and there are strict State Government Guidelines for the conduct of evaluations, tendering, short listing etc.

All staff must be careful that their actions could be construed as an acceptance of an inducement or that their comments are a 'Departmental' endorsement or censure of a particular product or service. It is not unusual for colleagues at other Laboratories who are considering a new purchase contacting you because you use the equipment they are considering. Verbal and written replies to such enquiries should be very carefully worded so that they are not misconstrued either by the enquirer or by the supplier of the goods or services in question. If in doubt you should refer the enquiry to a more senior member of staff.

Although we are a public laboratory we do compete in the private arena via Pathology South. Consequently you should not discuss or reveal aspects of our operations that give us various competitive advantages over other providers of pathology services.

LABORATORY CONFIDENTIALITY : Virtually all laboratory tasks are privileged and confidential. In addition to this a large amount of privileged information is available to staff in laboratory reports, requests and records. It is mandatory for every staff member to observe the utmost discretion with regard to their duties. On no account are patients' affairs of any kind to be discussed, or any laboratory records or reports improperly or without authority disclosed to any unauthorised person whether within the Department or outside.

Staff must familarise themselves with the Department's full Confidentiality Policy and procedures – see QS-Pol-4.





PUBLICATION OF PATIENT DATA IN PROFESSIONAL JOURNALS, LECTURES AND ELECTRONIC MEDIA : Professional publications and educational material prepared by you for publication or display at forums such as Grand Rounds, Conferences, Workshops etc. must be rendered as anonymous as possible. You should remove anything that identifies the patient(s) from photographs, data tables, pathology reports, slides etc that you intend to use outside of the RHH Pathology Dept. Electronic transmission of information on patients, eg as email attachments, to colleagues outside the RHH Department should be rendered anonymous before transmission. Encryption of such electronic information should also be considered; the Pathology IT Group should be consulted on your options in this area. Faxes of patient information must only be sent to fax machines that are known to be in secure professional environments.

Before a computer leaves the Department for disposal or relocation elsewhere outside of the RHH Pathology Dept. you must delete all confidential patient related information. The Pathology IT Group should be consulted on your options in this area.

If you remove electronic media, eg floppy disks or CDs, with confidential patient information on it to do further work on it using eg. your home computer then you must not store that information in an unencrypted form on that computer's hard drive. Ideally the data components should remain on the portable electronic media at all times and returned to the RHH Department or destroyed. If in doubt then the Pathology IT Group should be consulted on other options in this area.

If you are approached by an external agency for patient related information, eg an insurance company, a solicitor, the police etc. then you must decline to assist and refer them to your Supervisor, your Director, the Principal Scientist or the Director of Pathology.

RESPECT FOR HUMAN SAMPLES AND REMAINS : Staff are reminded that all Pathology Specimens, particularly those sent for Histopathological examination, are 'body parts' and should be treated with respect. Staff involved with the handling of post mortem and 'products of conception' specimens are under particular obligation to handle these items ethically. You should consult with your Supervisor in those areas as to the correct procedures.

GENETIC MATERIAL AND INFORMATION : All samples that are examined for genetic information must be processed as confidentially as is practical. Electronic and Hardcopy Records of genetic information must be stored in secure locations. Genetic information must only be released to persons entitled to view it.

AUTOPSY INFORMATION: A national code of Ethical Autopsy Practice was released in 2002 and staff are requested to follow these guidelines. Staff of RHH Pathology carry out work on both clinical and coroner's cases. Those involved must observe the highest levels of confidentiality practical.

AIDS / HIV INFORMATION : Staff involved with this testing and information must observe the highest levels of confidentiality practical. There is National and State Legislation that applies to AIDS testing. Electronic access to these results has been strictly restricted within Kestral PLS, DMR and CIS.

A copy of the Tasmanian *HIV/AIDS Preventive Measures Act 1993 (No. 25 of 1993)* and associated Guidelines can be viewed on the internet at

http://www.thelaw.tas.gov.au/index.w3p





You should type in HIV in the quick search box and that will take you to the document. It is anticipated that during 2009 this Act will be repealed or modified to bring it into line with the more relaxed legislation operating in the mainland States of Australia.

STAFF ORIENTATION AND ORIENTATION CHECKLIST (Refer to ADMIN-Proc-02 for latest version)

When the new employee begins their manager will need to ensure the following information is conveyed:

Pathology Tour:

- \Box Introduction to all relevant staff.
 - a. Pathology Administration;
 - b. Central Processing;
 - c. Stores;
 - d. Pathologist and Scientists in Charge of departments;
 - e. Staff working with the new staff member.
- □ Location of Staff Tea Room and cafeteria.
- □ Locations of Staff Toilets and Change Rooms.
- \Box Location of Mail Boxes.
- □ Arrangements for sending and receiving Faxes.
- \Box Locations of Meeting Rooms.
- \Box Location of resources for continuing education
- □ Orientation of relevant areas of the hospital outside Pathology.

I.T. Systems:

- □ Familiarisation with DHHS Intranet site.
- □ Familiarisation with Pathology Intranet site.
- \Box Familiarisation with the Kestral LIS.
- □ Familiarisation with the Q-Pulse Management System.

DHHS / Pathology Policies and Procedures:

- □ Organisational Structure.
- □ Pathology Quality System.
- \Box NATA Standard and accreditation.





- \Box Specimen workflow.
- □ Logging Incidents / EIMS.
- \Box Human Resources, who to contact in situations.
- □ Continuing Education Expectation of staff / Staff Entitlements.
- □ Policies concerning working hours, meal allowances, sickness whilst on duty, what to do in the event of sick leave, applying for annual leave, T.O.I.L. and other internal arrangements.
- \Box Outline the probation procedure.
- □ Discuss Performance Review and Development.

Safety:

- □ Location of EXITS, Emergency Evacuation Routes and assembly points.
- □ Location of Fire Extinguishers and Fire Blankets.
- □ Location of Emergency Power cut outs.
- \Box Location of Duress Alarms.
- □ Location of protective clothing and procedure for replacement (if applicable).
- □ Location of Hot and Cold Room Duress Alarms and Escape technique (if applicable).
- $\hfill\square$ Organise appropriate eye protection equipment (if applicable).
- □ Location of First Aid Kits, Emergency Showers and Eye Wash Station.
- □ Location of Spill Cleanup Kits.
- □ Introduced to the local Safety Representative and Fire Warden.
- □ Location of printed MSDS and shown how to access online.
- \Box What to do in case of Accident at work.
- □ Attend staff health clinic and reminded of recommended immunisations for work area.
- □ Read Pathology Laboratory Safety Manual.

NOTE: In addition to the Pathology Safety Manual some laboratories have developed their own Safety Manual. The new staff member must also read their departments safety manual if available.





APPENDIX 1 : ISO 15189 Contents Page

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APPENDIX 2 : RHH QI Activity Form

ROYAL HOBART HOSPITAL QUALITY IMPROVEMENT ACTIVITY REGISTRATION – Part A



			S Contraction of the second of
🗆 Unit / Department	\Box Division	Cross I	Divisional Organisation Wide
Date: / /2008	Expected (Completion Date:	/ /2008
UNIT / DEPARTMENT		DIVI	SION
QUALITY IMPROVEMENT ACTIVITY TITLE			
EXECUTIVE SPONSOR RESPONSIBLE PERSON			ITACT IBER
		TE	
	<u>EQUIP4 CRI</u>	TERION NUMBER	EQUIP4 CRITERION NUMBER
QUALITY I	MRPOVEMEN	T ACTIVITY INITI	ATED IN RESPONSE TO:
SAC RATING	Comments:		
ACT	ION TAKEN T	O ACHIEVE PREI	DICTED OUTCOME
1. AIM OF THIS QUALITY IMPROV	EMENT		
Define the Activity in clear, concise st	atement.		
2. DESIRED OUTCOME			
 The purpose or desired out 	come of the		
 The reasons why it is neces 	ssary to change		
3. METHOD (gathering the information	ation)		
 Criteria Audit Documentation Audit Patient Questionnaire Patient Focus Group Staff Questionnaire 		Pamphlet – Patier Interview – In-pati Staff Consultation Staff Education / N Consumer Involve	ht / Staff ent / Staff / Phone h Workshop ement
 4. PLAN OF ACTION Break down activity in key t tasks will form the major go "milestones' that will need t order for the activity to be c What, Who, When How are you going to ensurabout this activity? How will you know if this activity is a s 	asks. The key als or o be achieved in ompleted. re staff know success? Is this		

Authorised by : Dr Marsden, Dr Vervaart & Dr Tom Hartley Issued February 2012





activity designed to prevent i	incidents etc?		
6. EVALUATION When will this QIA	be evaluated?		
TIMEFRAME 3 6 9	□ 12 months		
THIS QUA	LITY IMPROVEMENT ACTIV	VITY MUST BE ON YOUR DEP	/ UNIT MEETING AGENDA
DATE REGISTERED AS Q. QIA FILE NUMBER	I.A.	ACHS EQuIP NUMBER	
	DATE		DATE
RECEIVED BY	DATE	EXEC / HOD	DATE
Safety & Quality Unit			
Please complete this any assistance please Patient Safety & Qual	registration form and e contact 6222 7804. I ity Unit do not keep e	return to the <u>Quality In</u> Please ensure you save lectronic copies.	nprovement Officer. If you require the completed document as the

Administration Only





APPENDIX 3 Corrective Action Form : OS-Form-6 RHH PATHOLOGY CORRECTIVE ACTION REQUEST AND REPORT FORM

Brief title of the problem requiring corrective action.

Date Issued:

Issued by: _____ Issued to: _____

Full description of the problem requiring corrective action.

Define and verify the root cause of the problem.

Describe any interim corrective action taken.





Describe the permanent corrective action taken.

Describe the follow-up taken to verify the corrective action has been a success.

Names of participants in this corrective action activity.

Signed off by participants on: _____

Signed off by Senior Management on: _____





APPENDIX 4 : INCIDENT REP	ORT FORM : QS-Form-3	
RHH PATHOLO INCIDENT RE	GY SERVICES PORT FORM	
This form and its attachments will be accounted and	QPulse No.	
This form and its allachments will be scanned and		
Date of Incident: Time:		
Reported by:		
Location of Incident:		
Sample Numbers and/or UR Numbers Involved:		
Do you need this Customer	Or	
Customer Contact	added into QPulse?	
Do you need this Supplier		
or Supplier Contact	added into QPulse?	
Objective account of what happened and what has	been done to correct it so far.	
Give the names of staff who you think need to follo	ow this Incident up.	

Who knows about this Incident?

Attach copies of request forms, invoices, letters etc. that are relevant to this Incident. Make a photocopy of this completed form for your records and put the originals into the Quality Manager's mail box