QUEENSLAND CANCER REGISTER

PATHOLOGY LABORATORIES

INSTRUCTION MANUAL

AND

TECHNICAL SPECIFICATIONS

FOR NOTIFYING CANCER

December 2018

Queensland Cancer Register
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Version 2.0

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1. INTRODUCTION

1.1 Establishment of the Cancer Register

The Queensland Cancer Register (QCR) operates under the *Public Health Act 2005,* to receive information on cancer in Queensland. The Cancer Register is a population-based register and maintains a Register of all cases of cancer diagnosed in Queensland since the beginning of 1982. Cancer is a notifiable disease in all States and Territories and is the only major disease category from which an almost complete coverage of incidence data is available. It is also the only major cause of death in Australia that is continuing to increase. Through the National Cancer Statistics Clearing House – a collaborative enterprise of the Australian Association of Cancer Registries and the Australian Institute of Health and Welfare, Queensland data is used in the compilation of Australia-wide figures and can be compared with cancer statistics from other States.

1.2 Aims of the Register

The main aim of the Register is to collect data to describe the nature and extent of cancer in Queensland. This can be combined with related data to assist in the control and prevention of cancer. To this end, Queensland Cancer Register data is available for use:
- in research projects on the causes, treatment and prevention of cancer,
- in the planning and assessment of cancer treatment and prevention services,
- in monitoring survival times of cancer patients, and
- for the education of health professionals and members of the general public.

1.3 Notification and sources of data

Notification of cancer is a statutory requirement for all public and private hospitals, nursing homes and pathology services. Notifications are received for all persons with cancer separated from public and private hospitals and nursing homes. Queensland pathology laboratories provide electronic copies of pathology reports for cancer specimens. Data on all persons who die of cancer or cancer patients who die of other diseases are abstracted from the mortality files of the Registrar of Births, Deaths and Marriages and linked to hospital and pathology data.

1.4 The Act and Regulations

The *Public Health Act 2005,* Division 3 – Notifications about cancer 234 and 235 states the Director of the pathology laboratory must give a notification to the chief executive of Queensland Health if a pathological examination of a specimen of human origin indicates that the person from whom the specimen was taken is or was suffering from cancer.

Public Health Regulations 2005, Part 5 - Cancer Notifications outlines further details regarding Notification about cancer in the *Public Health Act 2005*.

The legislation may be viewed on the following website:
https://www.health.qld.gov.au/system-governance/legislation/health-portfolio

1.5 Confidentiality of data

Queensland Cancer Register is housed in a secure office only accessible by Cancer Alliance Queensland staff and approved visitors.

All unit record information collected by the Queensland Cancer Register is treated as strictly confidential in compliance with the Department of Health privacy policies. Information collected is used for statistical or research purposes only.

1.6 Enquiries

If you would like more information about the Queensland Cancer Register or you wish to obtain any publications you may contact the:

Senior Director
Cancer Alliance Queensland
Level 1, B2, 2 Burke St
Woolloongabba Q 4102

PH (07) 3176 4400
Email QCR@health.qld.gov.au

Further information about cancer may also be obtained from the following web sites:

www.cancerallianceQld.health.qld.gov.au   (Queensland Health site, QCR data)
www.aihw.gov.au/cancer/index.html   (AIHW site, national data)

2.   ELECTRONIC NOTIFICATION

Over 60% of cancer notifications are from pathology which is a major contributor to the validity of cancer incidence. The pathology report is, in the majority of cases, the initial identification of a cancer patient, making the pathology report a key data source.

Receiving pathology information electronically makes a significant impact on:

- improving the timeliness of cancer reporting

- the manual handling currently required to process the cancer data

- missing pathology cancer notifications

Cancer Alliance Queensland in collaboration with CSIRO have developed Medtex, a smart clinical natural language processing software which automatically scans HL7 pathology messages and analyses free-text reports for terms and concepts relevant to cancer.

Utilising Medtex has proven effective in the identification of reportable neoplasms and coding of specific cancer notification data items such as primary site, histological type, grade, laterality and basis of diagnosis. Medtex can also identify re-excision and lymph node excision specimens.

In addition, it assists with decision support for QCR coders processing the neoplasm pathology notifications.

The inclusion of electronic pathology into a fully integrated cancer system delivers benefits in the diagnosis and management of patients and in the monitoring, evaluating and research.

3.   BUSINESS RULES

3.1 What pathology laboratories should notify?

All pathology laboratories in Queensland are required to report validated neoplasm related specimens (pre-cancer diagnosis, at the time of cancer diagnosis and post cancer diagnosis) to the Queensland Cancer Register.

3.2 What cancers should be notified?

All cancers as defined in Part 2 Division 1, Section 229 of the *Public Health Act* 2005 are to be notified. The Act defines cancer as:

(a) a neoplasm of human tissue—
(i)   in which cell multiplication is uncontrolled and progressive; and

     (ii) that, if unchecked, may invade adjacent tissues or extend beyond its site of origin; and

     (iii) that has the propensity to recur, either locally or remotely in the body;

  (b) skin cancer and non-invasive carcinoma, other than skin cancer and non-invasive carcinoma of a type prescribed under a regulation.

Therefore, all invasive cancers are to be reported (excluding Basal Cell Carcinomas and Squamous Cell Carcinomas of the skin where the ICD-10-AM site code range is C44.0 to C44.9 and morphology is M805 to M811). Merkel cell tumours of the skin and Kaposi's Sarcoma are to be reported.

Please report any cancer with uncertain behaviour.

Please notify **all** in-situ conditions as well. The Register collects for example, in-situ cancers of the cervix (CIN III - cervical intra-epithelial neoplasm), vagina (VAIN III - vaginal intra-epithelial neoplasm), vulva (VIN III - vulval intra-epithelial neoplasm), prostate (PIN - prostatic intra-epithelial neoplasm) bladder, breast and in-situ melanomas.

Benign central nervous system and brain tumours are also of interest to the Register and must be reported.

Follow-up re-excisions, further surgical excision specimens or lymph node excisions **even if these do not contain any residual neoplasm** are also required to be notified.

Non-malignant conditions, such as CIN I or II, VAIN I or II, VIN I or II, solar keratosis or keratoacanthoma, are outside the scope of the collection.

4. PATHOLOGY LABORATORY REQUIREMENTS

Division 3, Section 234 of the *Public Health Act* 2005 states notifications about cancer to be given to chief executive:

 (1) If a pathological examination of a specimen of human origin indicates that the person from whom the specimen was taken is or was suffering from cancer, the Director of the pathology laboratory where the examination is undertaken-

  (a) must complete a notification for the person; and

  (b) must give the notification to the chief executive within 30 days after the pathological examination

4.1 Ensure all neoplasm specimen results are notified to the QCR within 30 days after the pathological examination is validated

All validated neoplasm related specimens listed below (pre-cancer diagnosis, at the time of cancer diagnosis and post cancer diagnosis) are required to be notified.

Sub-division (if performed)	Types of test

Anatomical Pathology (Histology)
    Diagnostic, Staging and follow ups
    Externally reviewed/referred specimens
	Biopsy: needle, core, excisional, incisional, endoscopic, sentinel lymph node, skin, laparoscopic, thoracoscopic, mediastinoscopic, bone marrow (aspirate and trephine)
	Excision: resection, frozen section, laparotomy, thoracotomy, re-excision, immunohistochemical staining
	Cytology: Fine needle aspiration, cerebrospinal fluid, scrapings, brushings, pap smears, urine, sputum, pleural fluid, ascitic fluid
	
	Follow-up re-excisions, further surgical excision specimens or lymph node excisions even if these do not contain any residual neoplasm
	
	Autopsy/Post Mortem findings of a neoplasm

Haematology	Bone marrow biopsy (aspirate and trephine), flow cytometry, peripheral blood, surface markers (LSM), lymphocyte markers, TCR rearrangement, Chromosome analysis, AML panels (PCR), immunophenotyping, blood film
Markers	Immunoassay: PSA, AFP, NSE, C3,C4, CEA Carcinoembryonic Ag (15.3, 19.9,125,72-4, tag 72), BHCG, HPV, Hep B, Hep C
Bloods	FBC, HCT,CASA, Creatinine, eGFR, ELFT, ESR, H.pylori, differential count, protein, EVP (EBV), thyroid, Albumin, ALP, AST, CA, Creatinine, ALT, AFP, hCG, TSH, CgA, IgM, IgA, IgD, IgG, B2-Microglobulin (urine and post diagnosis)
Chemistry	Paraprotein typing – serum (plasma cell neoplasms) T/B Lymphocyte, Protien electrophoresis – serum (plasma cell neoplasms), Glucagon – plasma (neuroendocrine tumours)

Genetics
    Cytogenetics (oncology)
    Molecular genetics for neoplasia
	PCR based analysis, molecular, BRCA, FISH/ISH, JAK2 mutation, BCR-ABL fusion gene, KRAS mutation, BRAF mutation, EGFR mutation

Respiratory function	Respiratory function

Please note additional tests or new tests not mentioned above may be required

4.2 Ensure neoplasm specimens notified to the QCR include required information within the approved form

Division 3, Section 234 of the *Public Health Act* 2005 states notifications about cancer to be given to chief executive:

(2) A notification for a person under subsection (1) must –
   (a) be given for each pathological examination; and
   (b) include the name of the doctor who referred the persons specimen for pathological examination; and
   (c) be in the approved form

The approved QCR form is standard HL7 messages ORU^R01 (Observation Results) versions 2.3.1 up to 2.4 via electronic transfer.

All OBX results **must** have Observation Identifier (OBX-3), typically it is a LOINC number e.g. 2951-2^Sodium^LN

4.3 Provide supplementary reports, updates and deletions in the approved form

If you have sent a result it will be reported through to the Register. The Filler Order Number (Laboratory test number) in the OBR Segment identifies each test, if a result is sent again with the same filler order number the old test results are replaced with the additional/updated results.

Each laboratory has its own method of notification for deletion of results. Once the Register receives notification of deletion the result is flagged as 'deleted'.

4.4 Provide further information to the QCR if requested

Division 3, Section 236 of the *Public Health Act* 2005 states further information may be required. After processing a cancer notification, the Register may identify a need for further information to be supplied electronically.

Cancer Alliance Queensland must undertake regular compliance monitoring of all cancer notification by Queensland pathology laboratories. Missing cancer notifications will be identified and a list of these results will be sent to each laboratory. A response to the request for further information is required **within 30 days**.

It is recommended that laboratories maintain a record of the completion and dispatch of the responses to the requests for further information.

4.5 Inform Cancer Alliance Queensland of any changes to your laboratory electronic cancer notification method

See enquiries and contact details 1.6.

5. TRANSFER AND STORAGE

As soon as the HL7 messages are received the HL7 listener, the messages are imported into a HL7 SQL server database that sits on a secure Queensland Health production server.
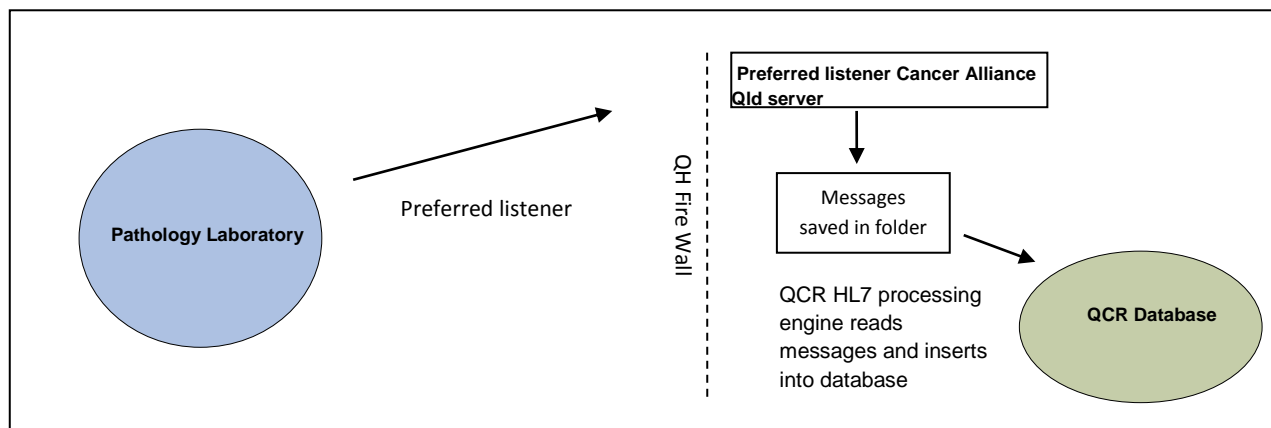
As soon as the HL7 messages are received the HL7 listener, the messages are imported into a HL7 SQL server database that sits on a secure Queensland Health production server. The QCR database servers are built on Microsoft technologies (Windows Server 2012 and SQL Server 2012) using the following security best practices:

- Strictly limit access to the physical server and hardware components by housing the server in a dedicated, locked, data centre with restricted access
- Configure server firewall to work with SQL Server
- Open only specific ports on the server firewall to enable access to SQL Server and restrict access to these ports
  QCR servers are configured behind the Queensland Health firewall
- Services configure with domain accounts
- Files for database instances are configured with restricted access to specific domain accounts and authorised users
- Databases are configured with restricted access to authorised users only. Access to server and database objects is provided to only those users needing access to each object
- Databases use integrated security and plain text passwords not sent over the network
- The latest security patches, service packs and updates are tested then applied to all QCR servers at least once per month, more if necessary
- QCR databases are backed up nightly with backups held within a secure backup environment only accessible by authorised users
- QCR applications, and access to databases, have also undergone a thorough penetration test to ensure there are no security risks or, risks are appropriately mitigated.

6. ARCHIVING

Once the requested messages are imported into the HL7 SQL server database filters can be applied. These filters remove specific results eg Blood results from the HL7 database into an archive database still located on the Queensland Health production server.

Currently the criteria for archiving results being used is results 3 months or older except histology, cytology and haematology. These results will be retained in the archive database indefinitely or until a time is specified by the pathology laboratories. These results are easily retrievable if they are ever needed in the future.

APPENDIX A – STORAGE OF APPROVED FORM HL7 FILE FORMATS

The HL7 files are stored in the SQL server database which consists of 2 tables:

1. Table dbo.HL7Data_Request-This table stores additional information about the patient and requesting doctor

Column names	Format	Description
ID	bigint	Table identifier
SendingFacility	varchar 180	Facility code identifying source sending results eg SNP,AUSLAB etc
HospitalCode	varchar 180	Facility code identifying the laboratory where the test was carried out (QCCAT/QH code)
OBRPlacerOrder	varchar 22	Unique ID that is provided by SNP when the test is requested. (Laboratory Number)
OBRFillerOrder	varchar 22	Same as OBRPlacerOrder
RequestingDoctorName	varchar 150	Name of doctor that requested the test
Archived	bit	True/False if the result has been achieved
Deleted	bit	True/False if the result has been deleted
URN	varchar 20	Hospital patient identifier. Ur Number
FirstName	varchar 100	First name of person result is carried out for (may include middle name(s))
LastName	varchar 100	Surname of person result is carried out for
DOB	datetime	Date of birth of person result is carried out for
Sex	varchar 1	Gender of person result is carried out for M or F
HomePhoneNumber	varchar 50	Home phone number of person result is carried out for
IndigenousStatus	varchar 50	Indigenous status of person result is carried out for (if recorded)
PatientAddressStreet	varchar 100	Street address of person result is carried out for
PatientAddressCity	varchar 50	Suburb/city of person result is carried out for
PatientAddressPostCode	varchar 50	Postcode of person result is carried out for
ProviderPatientID	varchar 50	Provider patient id
FillerField1	varchar 40	Custom laboratory number used by provider

2. Table dbo.HL7Data_Result- This table is the primary table used to store all pathology result information

Column names	Format	Description
ID	bigint	Table identifier
SendingFacility	varchar 180	Facility code identifying source sending results eg SNP,AUSLAB etc

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Partnership   qccat   qcr

HospitalCode	varchar 180	Facility code identifying the laboratory where the test was carried out (QCCAT/QH code)
OBXProducerID	varchar 10	Null
URN	varchar 20	Hospital patient identifier. Ur Number
PatientUR_Conversion	int	Null
FirstName	varchar 100	First name of person result is carried out for (may include middle name(s))
SearchFirstName	varchar 100	First name separated from middle name(s)
LastName	varchar 100	Surname of person result is carried out for
MiddleName	varchar 100	Middle name of person result is carried out for
DOB	datetime	Date of birth of person result is carried out for
SEX	varchar 1	Gender of person result is carried out for M or F
MSGID	varchar 30	HL7 connect message identifier
OBRPlacerOrder	varchar 22	Unique ID that is provided by SNP when the test is requested. (Laboratory number)
OBRFillerOrder	varchar 22	Same as OBRPlacerOrder
OBRUniServId	varchar 20	Orderable code. **Result panel** name details. Tes "Parent" eg FBC, UEG, ELFT
OBRUniServdesc	varchar 100	Orderable code text description eg Full Blood Count, Liver Function Tests
OBRObsDateTime	datetime	Time and date when result is carried out
OBRRelevantclinical	varchar 300	Clinical notes. Text field
OBRSpecRecievedDateTime	datetime	Date time specimen received by laboratory
OBRSpecSource	varchar 10	Specimen Type eg blood, histology
OBROrderingProvider	varchar 50	Laboratory internal identification code
OBRDiagServSectID	varchar 10	Test type Eg HM = haematology
OBRResultsStatus	varchar 10	Indicates if the panel of results are final or corrected. E.g. F or C
OBRTiming	datetime	Null
OBRParentPlacerID	varchar 22	Same as OBRPlacerOrder
OBRParentFillerID	varchar 22	Null
OBRID	int	Allocated identification number for panel of tests
OBXSeqenceNo	int	Sequence of results within the panel of same test
OBXValueType	varchar 3	Result value format whether it is a plain string, a formatted string or a number. eg NM = Number, TX = Text
OBXObsIdentifier	varchar 20	Identifier of the observation result, e.g. Alb, ALP, RBC

OBXObsIdDesc	varchar 100	OBXobsidentifier code text description, e.g. Albumin, Alkaline phosphatase, Red blood cell
OBXObsLOINCIdentifier	varchar 20	This is the LOINC code which identifies the test performed. For example Albumin has a universal LOINC number or text value that identifies it as Albumin.
OBXObsLOINCDesc	varchar 100	This is the LOINC code text description
OBXObsValue	varchar (max)	Result value. This is the most important information, for example this field contains the text for histology reports, Blood test values
OBXUnits	varchar 20	Units of measurement e.g. mmol/L, U/L
OBXReferenceRange	varchar 50	Normal result specific reference range for specific test e.g 33 – 47, < 34
OBXAbnormalflag	varchar 5	Indicates if the results are normal. N – Normal, L – Low, H – High
OBXObsResultStatus	varchar 1	Indicates if the specific result is final or corrected. E.g. F or C
OBXAccessCheck	varchar 1	Null
OBXObsDateTime	datetime	The date that the observation results were recorded
Processed	varchar 1	Null
Archived	bit	True/False if the result has been achieved
Deleted	bit	True/False if the result has been deleted
DateCreated	datetime	Date the result is loaded into the QCCAT database
DateLastModified	datetime	QCCAT internal use
ExternalReferenceId	varchar 20	QCCAT internal use

UR No: XXXX	Patient: xxxxxx	DOB: 01/01/1900	Sex: F
Lab No: 1234-5678	Doctor: xxxxx		
Source: Auslab	Histo Biopsy	Collection Date: 01/01/2014	

Histopathology Report
PLEASE SEE SUPPLEMENTARY REPORT BELOW 01/01/14 (Her2, ER/PR results and AE1/AE3)

HISTORY
Left mastectomy, suture 12 o'clock + sentinel lymph node Bx + 4 x sentinel LN. Left large breast mass Bx - IDC.

MACROSCOPIC
Five specimens received.

1. The specimen is labelled'', left mastectomy, suture 12 o'clock' and consists of a left simple mastectomy, weighing 1055 grams and measuring 235mm medial to lateral by 218mm superior to inferior by 54mm anterior to posterior. There is an overlying nipple bearing ellipse of skin measuring 170mm medial to lateral by 80mm superior to inferior. The nipple measures 11mm in diameter. A 4mm skin nodule is seen (likely seborrhoeic keratosis).

The specimen is differentially inked orange superior, green inferior, and black posterior. A suture is present at 12 o'clock/superiorly. The specimen is serially sliced from medial to lateral into thirteen slices with the nipple corresponding to slice 5. In slices 6 and 7 inferiorly at approximately 25mm and 5 to 6 o'clock from the nipple there is a rock hard well circumscribed lesion measuring 39mm superior to inferior by 26mm anterior to posterior by 32mm medial to lateral. The lesion is 3mm from the posterior margin and more than 10mm from all remaining margins. The surrounding breast parenchyma has a mixed adipose and glandular appearance with no other lesion identified.
Summary of blocks: 1A 4 TS nipple; 1B subareolar shaving; 1C skin lesion (? Seb K); 1D-E composite section slice 5 adjacent medially from tumour with posterior margin 1D; 1F-J sections slice 6; 1F-G tumour and posterior margin; 1H-I composite sections of tumour with inferior margin in1I; 1K-L tumour slice 7 with posterior margin 1L; 1M-N composite sections slice 8 adjacent laterally from tumour; 1O rep UIQ; 1P rep LIQ; 1Q rep LOQ; 1R rep UOQ; with RS taken 10mm from any margins. Please see annotated diagram.

2. The specimen is labelled '', left axilla sentinel lymph node' and consists of a piece of fibroadipose tissue measuring 30x20x10mm. One single blue coloured oblong lymph node is present measuring 13mm in maximal extent. Node serially sectioned, all embedded 2A to 2C.

3. The specimen is labelled '', left axilla sentinel lymph node 2' and consists of a piece of fibroadipose tissue measuring 20x10x6mm and contains a single oblong node measuring 10mm and a pale grey pallor. The specimen is serially sectioned and all embedded in 3A.

4. The specimen is labelled '', left axilla sentinel lymph node 3' and consists of a single node with surrounding adipose tissue measuring 15x10x6mm. The node is pale grey, oblong, and measures 10mm. The specimen is serially sectioned all embedded in 4A.

5. The specimen is labelled '', left axilla sentinel lymph node 4' and consists of a small ovoid pale grey lymph node, 7mm, and surrounding

adipose tissue measuring 12x6x5mm. The specimen is serially sectioned,
all in 5A. (Dr A Caudron/ph).

MICROSCOPIC
Specimen: Left mastectomy with sentinel lymph nodes
Site: 5 o'clock

Invasive carcinoma
Maximum size of invasive Cancer: 39mm
Type: Invasive ductal carcinoma, NST
Grade: 3
    Tubules: 3
Nuclei: 3
    Mitoses: 3 (>100 mitoses per 10hpf)

Peritumoural lympho-vascular invasion: Present

Multifocal: No
Multicentric: No

DCIS
Not seen

Lobular Neoplasia (ALH/LCIS):
Not seen

Skin: Seborrhoeic keratosis
Muscle: Normal
Nipple: Normal, no evidence of Paget disease
Treatment Effect: Not applicable
Calcifications: Not identified
Adjacent Breast Tissue: Nil

Margins:
Invasive carcinoma: Posterior 3mm, rest >10mm

Lymph nodes
Site: SLN
Total nodes: 4
Involved nodes: 0 on H&E

Additional comments: Nil.

Hormone status
Pending

FINAL SUMMARY
39 mm Grade 3 IDC, completely excised, 0/4 LN+, ER/PR pending

Pathologist: xx
Pathology Queensland
xx
Telephone: xx
Reported xx

T-04000 M-85003

SUPPLEMENTARY REPORT
HER2 status (block 1K):
Immunohistochemistry score (4B5): 1+ (Negative)

HER-2 Probe: Signal detection has been performed for HER2 gene that maps
to chromosome 17q21 using Ventana Inform detection system.

SISH result: Negative

Mean HER2 copy number per cell: 3 (Not amplified, polysomy)

Reference Range:
Single Probe HER2:
(No amplification: Diploid 1-2.5)
(No amplification: Polysomy >2.5-4)
(Equivocal: >4-6)
(Low Gene Amplification: >6-10)
(High Gene Amplification: >10)

Pathologist: xx
Pathology Queensland
xx
Reported xx

SUPPLEMENTARY REPORT
ER result: Positive
Percentage of nuclei stained: 95%
Predominant staining intensity: 3+

PR result: Positive
Percentage of nuclei stained: 90%
Predominant staining intensity: 2+

Immunohistochemistry for AE1/AE3 demonstrates isolated tumour cell
clusters in the subcapsular sinus of one lymph node (specimen 2). These
have a maximum diameter of 0.15mm, with fewer than 200 cells per lymph
node cross section.

Pathologist: Dr xxxxxxx
Pathology Queensland
xxxxx xx
Telephone: xxxxxxx
Reported 01 January 2014