

23 March 2020

Amy S Van Wey Lovatt
Via FYI.org.nz

Email: fyi-request-12431-bcd3a421@requests.fyi.org.nz

Dear Ms Van Wey Lovatt

Official Information Act (1982) Request

I write in response to your Official Information Act request, received by us on 11 March 2020. You requested the following information.

Request 1:

- I am writing to request a copy of the CMDHB best practice protocol for the archiving, storage, or biobanking of human tissue for diagnostic purposes, whether they are formalin fixed, paraffin embedded or pathology slides, and the standards, legislation or scientific evidence which provides the basis for the CMDHB protocol.

Request 2:

- Is the CMDHB best practice protocol for the archiving, storage, or biobanking of human tissue for diagnostic purposes, whether they are formalin fixed, paraffin embedded or pathology slides, is a standard which is universally adopted by all NZ DHB's and medical laboratories, or does each DHB or medical laboratory determine their own best practice?

Request 3:

- Please explain the potential hazards of leaving formalin fixed, paraffin embedded or pathology slides in an unsecure, non-temperature regulated environment (say a on an employee's desk outside of the laboratory) for 2 months.

Request 4:

- Please provide me with the name of the independent agency or agencies which provides oversight for medical laboratories in NZ.

Thank you for your assistance in this matter.

Please note, this request is for my information and is not a reflection upon the practices at CMDHB, but to ascertain if there is a universal standard within NZ. I will be making this same request to every DHB in NZ.

As context, Counties Manukau Health (CM Health) provides health and support services to people living in the Counties Manukau region (approx. 569,400 people). Our services are delivered via hospital, outpatient/ ambulatory and community-based models of care. We provide regional and supra-regional specialist services (for orthopaedics, plastics, burns and spinal services). There are also several

specialist services provided for our community via other metro Auckland DHBs, including tertiary surgical/ medical services, some mental health and addiction services.

Our responses to each of your questions are below.

Request 1:

- I am writing to request a copy of the CMDHB best practice protocol for the archiving, storage, or biobanking of human tissue for diagnostic purposes, whether they are formalin fixed, paraffin embedded or pathology slides, and the standards, legislation or scientific evidence which provides the basis for the CMDHB protocol.

Retention of specimens/ blocks/ slides after diagnostic testing by CM Health Histology Laboratory is in accordance with the National Pathology Accreditation Advisory Council (NPAAC) Seventh Edition 2018 (**attached**). That publication defines the minimum retention times, and is used in Laboratories throughout New Zealand and Australia.

CM Health Laboratory: documented retention requirements:

Department	Reference/Requirement	Actual Retention times	
		ON SITE	⁷ OFF SITE
HISTOLOGY & NGC	NPAAC Guidelines 2018		
⁶ Reports/Records	Copy of original or ability to reprint 10 years ⁶	² Electronic - Indefinite from April 1993	
Slides - Routine - FNA Cytology - Frozen section	10 years ⁶	2 years Current year	1974 to 2 year ago 1997 to last year
NGC & FNA Slides & Cell blocks	10 years ⁶		
Blocks - all	10 years ⁶	20 years (1 year on site)	back to 1956
Containers with residual tissue	1 month from reporting	1 month post reporting	None
Unblocked wet tissue from specimens removed at surgery	1 month from reporting		
Containers with no residual tissue	1 month from date report issued	1 month post reporting	None
External QC - slides		10 years	
Request forms	GDA DA262 - 2.6/18 months	Current year	1996 to last year

6 Histology

Where the report or specimen pertains to a paediatric patient retention should be 10 year, or 7 year from age of majority (18 year), whichever is the greater.

The CM Health Laboratory onsite storage is secure and within the Laboratory facilities. Off-site storage is at a secure facility.

Request 2:

- **Is the CMDHB best practice protocol for the archiving, storage, or biobanking of human tissue for diagnostic purposes, whether they are formalin fixed, paraffin embedded or pathology slides, is a standard which is universally adopted by all NZ DHB's and medical laboratories, or does each DHB or medical laboratory determine their own best practice?**

The NPAAC requirements for the retention of diagnostic material noted above are used throughout New Zealand and Australia.

Request 3:

- **Please explain the potential hazards of leaving formalin fixed, paraffin embedded or pathology slides in an unsecure, non-temperature regulated environment (say a on an employee's desk outside of the laboratory) for 2 months.**

At the CM Health Laboratory, no employee in Histopathology has a work-desk outside of the secure purpose-built Laboratory facility. Paraffin blocks and slides are stable, and do not pose a hazard.

Request 4:

- **Please provide me with the name of the independent agency or agencies which provides oversight for medical laboratories in NZ.**

International Accreditation New Zealand (IANZ) assesses all NZ Medical Laboratories against the International Standard: *Medical laboratories – Requirements for quality and competence*, ISO 15189:2012.

I trust this information satisfactorily answers your query. If you are not satisfied with this response you are entitled to seek a review of the response by the Ombudsman under section 28(3) of the Official Information Act.

Please note that this response or an edited version of this may be published on the Counties Manukau DHB website.

Yours sincerely,



Fepulea'i Margie Apa
Chief Executive Officer
Counties Manukau Health