

HAWKE'S BAY DHB LABORATORIES

Department: Quality

Date issued: 03/10/19

Folder: Quality Manual

TITLE: 4 Management requirement

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4.13 Control of records

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1.0 Introduction

Current regulations as stated within the District Health Board General Disposal Authority (DHB GDA) impose an obligation to retain health information (or health record) on an individual for a minimum period of 10 years from the date following the last day the provider provided services to that individual. This laboratory retains these health records electronically (and has done so since 1994) indefinitely.

In order for this laboratory to follow legal obligations to retain records, the following table shows retention times linked to the regulatory document(s) and our laboratory's actual retention times.

2.0 Types of records

The types of records the laboratory needs to retain for certain periods of time are (and not limited to);

- Request forms from requesting clinicians ordering specific tests on individuals
- Samples or specimens from individuals
- Reports of results on individuals to certain clinicians, clinics, locations, organisations
- Equipment/analyser selection, supplier, contracts, reagents/materials, maintenance, validation, quality control
- Worksheets from analysers, manual process
- Personnel records; job descriptions, qualifications, training, competency, meeting minutes
- Incident/accident records, quality improvement including corrective/preventive action
- Audits, reviews, amendments

3.0 Responsibilities

Documented procedures within each discipline shall describe how pertinent records within each area shall be retained. All retained records must meet the minimum requirements as stated in table below, in storage conditions appropriate to the type of record. All staff must comply, however HODs must ensure these are managed and maintained.

4.0 Retention times (minimum requirements)

Retention times for specimens and records are based on the National Pathology Accreditation Advisory Council of Australia 7th Edition 2018 (NPAAC) and DHB General Authority (GDA), Disposal authority number DA262, Public Records Act.

Preanalytical		
Paper Record / Electronic Record	Reference document/ Retention requirement	Actual retention times
Original paper request form Hastings – paper originals Wairoa – paper originals, Wairoa retains NHC – paper originals sent to Hastings CHB - paper originals sent to Hastings	NPAAC 1.5 4 years ³	1 month hard copy, then scanned RFI (see below for RFI retention)
Microbiology – paper front face RFI, worksheet rear face RFI	NPAAC 1.5 4 years ³	4 years ^{2,3}
Transfusion Medicine – paper originals	NZBS 108I015 → NPAAC 8.1 20 years	20 years
Histology & Cytology – paper originals	NPAAC 1.5 4 years ³	Indefinitely
Future paper request forms Request forms for future collects held in collection rooms	Local practice	12 months from request date

Version: 3

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Locations: Hastings 2, Wairoa, CHB

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	Reference document/ Retention requirement	Actual retention times
Scanned request form images into RFI¹ <i>Haematology</i> <i>Biochemistry</i> <i>Microbiology</i>	NPAAC 1.5 4 years ³	Indefinitely as zip file from 2008-2015 2016 on, 4 years as an image file
<i>Histology & Cytology</i>	NPAAC 1.5 4 years ³	25 years as an image file
Scanned images as pdf² Worksheets, QC/QA documents, Manuals, Methods	NPAAC 1.2, 1.5, 1.6 4 years ³	4 years ³
Medico-legal documentation Paper request, Chain of Evidence paperwork	10 years forensic/medio-legal	10 years hard copy

1. RFI files ¹Electronic request form records

File stored: \\rfiserver\rfimages.

All J, L, K series except J0, indefinitely as zip file from 2008-2015, backup monthly 2016-2018, backup daily 2019
Histology J0 series indefinitely

2. Pdf files

Any quality documentation relating to laboratory records such as records of analysis, calculations and observations from which the result is derived; is retained for 4 years (from Nov 2018)

3. NPAAC 7th Ed 2018

Year retention from Nov 2018

General Laboratory		
Record	Reference guide/ Retention requirement	Actual retention times
Copy of original paper report or ability to reprint the information content of an original report (unless specified within departmental guide)	NPAAC 1.8 7 years from date report created	At least 10 years Delphic implemented 1 Apr 2003
Original paper report - Cytogenetics	NPAAC 6.1 100 years effectively indefinite	100 years
Worksheets ² Test verification documentation Calculations influencing the result QA & QC records Supply inventory	NPAAC 1.2, 1.5 4 years ³	4 years ³
Personnel records (incl. Rosters)	NPAAC 1.1 Period of employment + 4 years ³	Employment period plus 4 years ³
Equipment maintenance records	NPAAC 1.3 Life of equipment + 4 years ³	Life of the equipment plus 4 years ³
Laboratory methods, procedures and manuals	NPAAC 1.4 4 years ³	While current plus 4 years ³
Internal & external laboratory assessments; Quality, Health and Safety, QIF	Linked to 4 yearly external assessment cycle	4 years ³
HBDHB Incident/Accident/event reports	GDA 10.1 7 years after date of last action	15 years (held by Q&R)

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Anatomical Pathology/Cytology Laboratory		
Record	Reference guide/ Retention requirement	Actual retention times
Copy of original report or ability to reprint the information content of an original report	NPAAC 2.1 10 years	25 years ⁴
Digital images used for diagnostic analysis	NPAAC 2.3 4 years	Image scanned & retained with report in DelphicAP
Histology slides and blocks (incl. Special stains)	NPAAC 2.2, 2.4 10 years	25 years ⁴
Frozen section tissue (blocks, frozen & paraffin sections)	NPAAC 2.5 10 years	25 years ⁴
Containers with no residual tissue	NPAAC 2.7 1 month from date of report issue	1 month
Containers with residual tissue / Unblocked tissue removed at surgery	NPAAC 2.7 1 month from date of report issue	1 month after reporting of results

4. Histology/Cytology records and material retention times

Reports, blocks, slides and tissue shall be retained for 10 years but where refers to a paediatric sample, the retention should be until the person reaches the age of 25 years of age. HBDHB do not distinguish between paediatric samples and adult samples therefore minimum retention follows as if paediatric.

Transfusion Medicine Laboratory		
Record	Reference guide/ Retention requirement	Actual retention times
Records – including administration of blood & blood products	NZBS 108I015 → NPAAC 7.1 20 years records of blood products received and issued	20 years
Blood samples	NZBS 136P001	21 days 2-8°C WB ≤ -30°C plasma 2 month

Haematology Laboratory		
Record	Reference guide/ Retention requirement	Actual retention times
Samples	NPAAC 1.7 7 days from date of receipt	7 days 2-8°C
Blood films	NPAAC 7.1 Clinically significant 1 year Not clinically significant 1 month	1 year
Bone Marrow slides	NPAAC 7.4 10 years for adults 7 years from the age of majority ⁵	10 years

5. Bone Marrows on paediatric patients

Paediatric patients are referred to Starship hospital, therefore no bone marrows are performed on minors in HBDHB.

Biochemistry Laboratory		
Record	Reference guide/ Retention requirement	Actual retention times
Samples	NPAAC 1.6 7 days from date of receipt	7 days 2-8°C

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Microbiology Laboratory		
Record	Reference guide/Requirement	Actual Retention times
Sputa/Swabs/Faeces	NPAAC 1.7 7 days from date of receipt	7 days
Urines	NPAAC 10.4 3 days from date of issue of report, under refrigeration	7 days
CSF/Body Fluids	Local policy	3 months
Wet Preparations	NPAAC 10.1 Discard	Discarded after testing
Gram satins	NPAAC 10.1 2 weeks	2 weeks
TB Slides	NPAAC 10.1 6 weeks	2 month
Cultures – clinically significant	NPAAC 10.2 Isolates clinically significant: 5 days	1 week
Cultures – Not clinically significant	NPAAC 10.2 Isolates not clinically significant: discard	Discarded after testing
Sera for infectious disease	NPAAC 10.3 All sera: 4 months	4 months
Sera for infectious disease - Antenatal	NPAAC 10.3 12 months	1 year
Positive Sera for infectious disease: Syphilis (reactive), Hepatitis B&C, HIV	NPAAC 10.3 12 months	1 year
Needle sticks – Donor and Recipient	NPAAC 10.3 12 months	Local policy 10 years

5.0 Exception to retention times for Police and Coroners request

On occasions police may come to the laboratory requesting staff hand over diagnostic specimens on a particular patient(s). The specimens required may include the original specimen tube/container and aliquots. A copy of the laboratory request form will also need to accompany the specimens.

Under no circumstances is staff to directly hand over any specimen. All requests must be directed to the Laboratory Manager or his delegate.

When testing has finished, place the specimens and a copy of the laboratory request form (all in a biohazard bag) in the Central Registration fridge. Inform the police that they will need to return with a search warrant or coroner's request which will need to be presented to the Laboratory Manager (or his delegate) who will then comply with their wishes.

The Laboratory Manager (or delegate) will:

- Obtain a copy of each of the laboratory request form(s).
- Retain the search warrant/coroner's request.
- Complete the form "Request by Police or Coroner for Laboratory Samples" *J:\Departments\Methods\Quality\Request by Police or Coroner for Laboratory Samples.doc* copies held in the appropriate file in the Laboratory Managers office.
- File all of the above into the appropriate folder kept in the Laboratory Manager's office.

5.1 Offsite storage

There are some records that are stored offsite with Crown Storage. Histology blocks and slides are stored offsite with Crown Storage.

The Histology department manages and maintains these records intimately; refer to *Lab/Department/Methods/Histology/Specimen Reception Manual/7) Storage*

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