

Statewide Pricing Guideline

Research Services

Version 2.1

for all of

www.pathology.health.nsw.gov.au





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1. Introduction

In ensuring NSW Health Pathology continues to deliver better services and outcomes, NSW Health Pathology has developed a standardised approach to pricing pathology services for external research, across all NSW.

The following is indicative pricing for NSW Health Pathology services to non-NSW Health Pathology research. The pricing is broken down into:

- 1. Non-commercial research avoidable cost recovery.
- 2. Commercial research full cost recovery for all activity surrounding the service.

In cases where NSW Health Pathology is a **collaborating partner**, or NSW Health Pathology **employees are involved as an investigator in a research project**, NSW Health Pathology views this as a <u>research collaboration</u>, not services for research.

For research collaborations, a NSW Health Pathology investigator must be added to the research ethics application (through REGIS) listing the site as NSW Health Pathology. This will create a site-specific assessment form for NSW Health Pathology's research governance office. For further information please go to our <u>Research Governance website</u>.

2. Definitions

Research Sponsor means the company, institution or organisation, body or individual that takes overall responsibility for the conduct of the research undertaken for Non-Commercial or Commercial Research Purposes and usually initiates, organises and supports the research.

Commercial Research Purposes means the use of a product/process/subject matter for research or scholarly purposes under a commercial contract for commercial benefit or exploitation of Intellectual Property rights that includes, but is not limited to:

- (a) consulting arrangements;
- (b) contract research for government, non-government and/or private sector entities; or
- (c) collaborative research with government, non-government and/or private sector entities.

Please note in referring to 'Commercial' and 'Non-commercial' costings it is the Research Sponsor not the Funder that is being referred to.



3. Statewide Pricing Guide

The below costs are to be used for indicative pricing only. For a formal quote please contact your local NSW Health Pathology research service coordinator listed on page 12.

Description	Unit	Commercial	Non-Commercial
PROJECT START-UP	Unit	Commercial	Non-Commercial
Site project establishment fee	Per application	\$500 (initial operational area) \$100 (each additional operational area)	\$100 (each operational area)
PROJECT RELATED ACTIVITES	Unit	Commercial	Non-Commercial
A. Specimen collection ¹	Unit	Commercial	Non-Commercial
For research (children >5 years and adults)	Per case ²	\$15	\$15
• Paediatric ³			
- Babies age <1 year		\$40	\$40
- Children aged 1 to 5 yrs.		\$25	\$25
B. Specimen retrieval	Unit	Commercial	Non-Commercial
I. Non-histological specimen retrieval:Bloods (or other)	Per sample	\$5	\$5
 II. Histological specimen retrieval (tissue): Block & slide retrieval Access fee (off-site) 	Per visit	\$75	\$50
• Block and slide retrieval ⁴ \leq 50 cases ²	Per case ²	\$7.50	\$5
• Block and slide retrieval ⁴ > 50 cases ²	Per case ²	Contact local research serv	ice coordinator
C. Data Entry, Handling and Processing	Unit	Commercial	Non-Commercial
I. Data entry and handling only ⁵	Per case ²	\$11	\$11
 II. Non-histological specimens: Data entry, handling, and processing (Local Lab) 	Per case ²	\$20	\$15
 Data entry, handling, and processing (Central Lab) 	Per case ²	Commercial	Non-Commercial



-	Bloods (or other) - Simple (routine)		\$25	\$20
	Bloods (or other) - Intermediate (non- routine)		\$35	\$25
-	Bloods (or other) - Complex		\$50	\$45
111.	Retrieve, culture, and supply microbic isolates	Per case ²	\$110	\$42
IV.	Histology specimen processing			
	Histology embedding	Per block	\$7.50	\$5
	Histology (time-critical)	Per case ²	\$80	Negotiable
V.	Microtomy	Per slide/scroll	\$7.50	\$5
VI.	Cryo sectioning	Per slide/scroll	\$30	\$20
VII.	Snap freezing of tissue	Per case ²	\$15	\$10
VIII.	Fresh specimen triage	Per case ²	\$35	\$30
Histo	ology staining (including microtomy)	Unit	Commercial	Non-Commercial
١.	H&E Staining (including microtomy)	Per slide	\$10	\$7
П.	Special Staining	Per slide	\$30	\$20
111.	IHC staining			
	Excluding Ab	Per slide	\$40	\$25
	Including Ab	Per slide	\$100	\$70
IV.	IHC Antibody (Ab)			
	Optimisation	Per Ab	\$200	\$100
	Additional slides	Per Ab	\$40	\$25
V.	ISH staining			
	Excluding probe	Per slide	\$100	\$70
	Including probe	Per slide	\$200	\$120
Spec	imen Testing	Unit	Commercial	Non-Commercial



Specimen testing ^{6, 7, 8, 9}		MBS	120%	85%
		Non-MBS	Contact local research service coordina	
NSW	/ Health Statewide Biobank ¹⁰	Unit	Commercial	Non-Commercial
Biob	anking (end to end)			
-	imen collection, data entry & sport to NSW Health Statewide ank	Per case ²	\$25	\$25
Who	le Slide Imaging	Per image	\$4.35	\$2.90
PRO.	IECT CLOSE	Unit	Commercial	Non-Commercial
Stora	age ¹¹	Per case ²	\$15	\$10
Tran	sport (Local Courier)	Per case ²	At cost	At cost
Pack	aging &/ Dispatch	Per case ²	Contact local research service coordinator	
	SP		H SERVICES	
FOR	ENSIC	Unit	Commercial	Non-Commercial
I.	Forensic toxicology and therapeutic drug monitoring on urine, blood, serum, and oral fluids.			
II.	Environmental testing in water and other environmental samples.	– Per test		
III.	Drug and pharmaceutical screening, identification, and purity.	- Per lest		
IV.	Chemical and unknown materials identifications and comparisons.		Contact local research service coordinate	
V.	Biological fluid and DNA testing, and expert systems.			
VI.	Forensic medical imaging			
VII.	Other forensic & analytical science services for research			



Toxicology and therapeutic drug monitoring on urine, blood, serum, and oral fluids	Per test	Contact local research service coordinator		
Liquid chromatography (LC), Liquid Chromatography-Mass Spectrometry (LC-MS) and Gas Chromatography-Mass Spectrometry (GC-MS)				
Analysis using established methods	Unit	Commercial	Non-Commercial	
a. Data acquisition, analysis, and report	Per case ²	Contact LC-MS/MS research coordinator		
b. Sample Preparation	Per case ²	Contact LC-MS/MS research coordinator		
Analysis requiring method development	Unit	Commercial	Non-Commercial	
a. Pilot acquisition, analysis, and report	Per project	Contact LC-MS/MS research coordinator		
 b. Sample preparation (pilot investigation) 	Per project	Contact LC-MS/MS research coordinator		
c. Method validation	Per project	Contact LC-MS/MS research coordinator		

GENOMICS			
Whole Exome Sequencing (WES)	Per case ²	Contact Clinical Genomics Operations Manager	
Whole Genome Sequencing (WGS)	Per case ²	Contact Clinical Genomics Ope	erations Manager
Genomics Panels undertaken by Statewide Sequencing Service	Per case	Contact Clinical Genomics Operations Manager	
Data Storage and Transfer	Per case or project	Contact Clinical Genomics Operations Manager	
Other genomics services		Contact local research service coordinator	
POINT OF CARE TESTING (PoCT)			
New or established technology: technology verification, validation, and pilot evaluation		Contact local research service coordinator	
ADDITIONAL SERVICES	Unit	Commercial	Non-Commercial
Data Management	Unit	Commercial	Non-Commercial



Data management	Per hour	\$100	\$100
Data analytics/informatics	Per hour	\$130	\$110
Reporting	Unit	Commercial	Non-Commercial
Assessment of adequacy by pathologist	Per case ⁵	Contact local research c	coordinator
Macroscopic dictation (Project-based, no images)	Per case⁵	\$75	\$50
Microscopic report (Project-based)	Per case ⁵	\$450	\$300
Staff time (consultation, analytical work and/or administration)	Unit	Commercial	Non-Commercial
Senior Staff Specialist	Per hour	\$220	\$220
Senior Scientist	Per hour	\$150	\$150
Scientific Officer	Per hour	\$100	\$100
Out of hours Per hour Contact local research coordinat		coordinator	

¹Collection fee is for NSWHP to collect samples. If the collection is piggy backing off a standard of care test, then this fee may be reduced, or waived, depending on consumables. This is up to the discretion of the local NSWHP clinical research coordinator. Paediatric blood collection may attract an addition cost.

²Per case" refers to a specific patient episode

³Only available at a few sites

⁴If AP blocks are supplied for research it is expected that they will be returned at the cost of the applicant. ⁵Should you require data entry and handling out of normal business hours, please contact local research coordinator to discuss fees and possibility for this.

⁶No research activity can be funded in any part by the MBS.

⁷Costs outlined in this table 'for research tests only'.

⁸Tests for research activity that are part of standard of care are billable to MBS and will not be charged back to the applicant (not applicable to research activity initiated by commercial companies).

⁹Trials may include tests not defined in the MBS. These tests will be assigned non-MBS item numbers (NSWHP assigned numbers) with fees based on actual cost recovery.

¹⁰NSW Health Statewide Biobank offers a range of additional research services incl. slide imaging, PBMC preparation & DNA extraction, please see contact <u>NSWPATH-biobanking@health.nsw.gov.au</u> for further information.

¹¹Storage is only available in some laboratories. For laboratories where storage is available, the annual fee for storage of samples held past 6 months are up to the discretion of local laboratory manager.

Please note: Pricing may be negotiable at local level, to cater for large scale opportunities with discounts for economies of scale. Batched studies can also be negotiated at local level. AP blocks are supplied for research it is expected that they will be returned at the cost of the applicant.



4. Description of inclusions in pricing

DESCRIPTION	INCLUSIONS
PROJECT START-UP	
Site project establishment fee	Protocol, ethics and laboratory manual review, discussions with clinical directors and lab managers, request form development, billing system setup. Ongoing administration including access to current Accreditation documents (NATA, Medicare, IATA), access to current Reference Interval documentation, monitoring and troubleshooting, as well as laboratory access for site visits & audits.
PROJECT RELATED ACTIVITIES	
Central lab – Kit supplied; collection, processing & storage (may be additional charges for PK sampling)	This is the total cost for specimen collection, processing, and storage.
Data analytics/informatics	Includes data extraction and cleaning of test results.
Data entry & processing	Administration costs involved in tracking sample from collection to supply and return (if appropriate), including putting in place a MTA. Also includes any routine processing such as a spinning or aliquoting.
	Non-routine is when the protocol involves more complex or time critical processing.
Data Management	Includes data extraction, collation, and cleaning of test results.
Handling	Sample handling that is not processing.
Histological	Microscopic anatomy of biological tissue; the study of tissues and cells under a microscope.
Non-Histological	Samples other that biological tissue and cells, i.e., blood, urine, microbes, etc.
Processing	The performance of a mechanical or chemical operation on a sample in order to change or preserve it.
Specimen collection	Blood collection by NSW Health Pathology phlebotomists. Other sample collections e.g., swabs, urine or stool samples including directing patients to collect samples.
	Application of collection fee when collecting in addition to standard care samples will be at the discretion of the NSWHP Research Coordinator.
Specimen testing	Cost to perform the test and is based on the MBS item rebate.
Specimen collection, data	Specific to the Statewide Biobank collections.
entry & transport to NSW Health Statewide Biobank	Samples to be collected by NSWHP collection staff, tracked, and transported to the Statewide Biobank.



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Toxicology and therapeutic drug monitoring	The cost to conduct toxicology testing or therapeutic drug monitoring in urine, blood, serum, or oral fluid samples.		
MICROBIOLOGY/VIROLOGY			
Microbic isolation	Separation of a strain from a natural, mixed population of living microbes as present in a patient sample.		
Retrieval of isolates	Retrieval of isolates for patients on a research project (based on estimated hours required to retrieve results).		
TISSUE PATHOLOGY	There is no policy yet to the supply of blocks without return.		
Administration			
Diack & clicke retrieval (on cite	This includes the time it takes to locate and retrieve a block or slide.		
Block & slide retrieval (on-site or off-site)	Off-site means from a location different to where you are requesting the service from.		
Processing			
Cryo sectioning	Cutting of frozen tissue sections.		
	Processing of non-gynaecological samples onto glass slides, stained and covered or cytology samples for cell block.		
Cytology processing	May be direct smears from samples or smears prepared via cytocentrifugation or centrifugation.		
Bone marrow in formalin	Bone marrow is placed in formalin for preservation.		
Microtomy	Cutting thin sections of tissue from the block		
Snap freezing of tissue	Selection of fresh tissue and snap freezing via individual laboratory processes e.g., liquid nitrogen, CO2 etc. To include short term storage until collection arranged.		
Time-critical sample	Means a sample that has requirement so important that if it is not met immediately, the outcome will become or approach a state of material risk.		
Tissue processing & embedding	The process to prepare and embed tissue into a paraffin block.		
Staining			
H&E Staining	Hematoxylin and eosin stain includes cutting and mounting thin sections of tissue from the block and staining with haematoxylin and eosin stain. H&E is the most used stain.		
IHC Ab Optimisation	Immunohistochemistry (IHC) involving anything outside standard IHC		
additional slides	staining requires specialised skills for optimisation / value-add. This is time it takes a specialist to optimise the antibody.		



IHC staining - including Ab - excluding Ab	Immunohistochemistry (IHC) is dependent on antibody / clone repertoire. The costs in the pricing are only for a standard test repertoire.		
ISH staining - including probe - excluding probe	In situ hybridization (ISH) staining preparation depends on the probe being used. The probe is a high-cost consumable and in some cases, researchers may supply their own probe. This price enables with or without NSWHP probes.		
Special Staining	Includes staining of tissue as part of slide preparation with a non-routine stain		
Slide scanning			
Whole Slide Imaging (at NSW Health Statewide Biobank)	Imaging of clean, good quality slides. Note: additional costs apply if slides are poor quality (e.g., dirty, broken cover slips etc).		
Reporting			
Assessment of adequacy by pathologist	For a pathologist to review the block or slide to ensure there is adequate tissue available for the research project and is charged per hour.		
Macroscopic dictation (Project-based no images)	Cut-up of the fresh tissue and dictation of the description of the collected sample including measurements etc.		
Microscopic report (Project- based)	Review of the tissue slide and description of the pathology present at the cellular level. This may include microscopic photography at extra costs.		
PROJECT CLOSE			
Packaging & preparation for	Costs to package the sample and prepare it for transport.		
dispatch	Does not include courier fees.		
	Storage of research samples for a maximum of 6 months after which time there is an annual fee to hold the samples.		
Storage	NSWHP has limited space available to store samples in local laboratories. If long-term storage is required NSWHP encourages sample storage within the Statewide Biobank.		
Transport (Local Courier)	Cost to courier the sample(s) to the research group.		
ADDITIONAL SERVICES			
Data management (retrieval of test results)	Retrieval of test results for patients on a research project (based on estimated hours required to retrieve results).		
Data analytics/informatics (data extraction and collation)	Manual extraction and collation of routine patient care data based on a predefined dataset.		



5. NSW Health Pathology Research Service Coordinators

Our Research Coordinators will be processing submitted <u>Access Request</u> forms which has to be submitted for NSW Health Pathology to provide you with access to biospecimens, data and/or research services. If you need to contact any of them, please check out their contact details on our website <u>here</u>.

6. Version History

The approval and amendment history for this document must be listed in the following table.

Version No	Effective Date	Approved By	Approval Date	Document Author	Risk Rating	Sections Modified
1.0	01/01/2021	Roger Wilson	01/07/2020	Amanda Koegelenberg	Low	New pricing model for research services
2.0	05/09/2022	Robert Lindeman Paul Dunn	12/08/2022	Bente Talseth- Palmer	Low	Updated pricing guideline
2.1	03/01/2023	Shaun Roman	31/03/2023	Bente Talseth- Palmer	Low	Minor updates to section 3 and 5
2.2	09/01/2024	Shaun Roman	09/01/2024	Bente Talseth- Palmer	Low	Minor updates in section 4 and 5