



**UNIVERSITY
OF MALAYA
MEDICAL CENTRE**

**DIVISION OF ANATOMICAL PATHOLOGY
DEPARTMENT OF PATHOLOGY**

DSI-APD-001

LABORATORY HANDBOOK

Version 004	Date of Issue 27 May 2015	
Prepared by Anthony Rhodes	Reviewed by Nazarina Abdul Rahman	Approved by Cheah Phaik Leng
Position Technical Consultant	Position Coordinator, Division of Anatomical Pathology	Position Head, Department of Pathology

DIVISION OF ANATOMICAL PATHOLOGY
DEPARTMENT OF PATHOLOGY



	DOCUMENT NAME:	LABORATORY HANDBOOK		
	DOCUMENT NO:	DSI-APD-001		
	PAGE	2/28	VERSION:	004
	DATE OF ISSUE:	27 May 2015	AMENDMENT:	00

TABLE OF CONTENTS

Title	Page
Table of Contents	2
Introduction	3
Objective & Scope	3
Definitions	4
Reference	4
General Information	5
The Clinical Procedure & Specimen Collection	6
Specimen Request Form Information	7
Histopathology Services Offered	8
Primary Sample Collection (Histopathology)	9
Primary Sample Identification (Histopathology)	10
Cytopathology Services Offered	11
Primary Sample Collection (Cytopathology)	12
Primary Sample Identification (Cytopathology)	18
Specimen Rejection Criteria	19
Expected Turn Around Times	20
Policy on Protection of Personal Information	21
The Laboratories Complaint Procedure	21
Appendices	22

DIVISION OF ANATOMICAL PATHOLOGY
DEPARTMENT OF PATHOLOGY

	DOCUMENT NAME:	LABORATORY HANDBOOK		
	DOCUMENT NO:	DSI-APD-001		
	PAGE	3/28	VERSION:	004
	DATE OF ISSUE:	27 May 2015	AMENDMENT:	00

DIVISION OF ANATOMICAL PATHOLOGY LABORATORY HANDBOOK

INTRODUCTION:


Pathological diagnosis provides a crucial role in patient management. The main aims of the laboratories are to process and test clinical specimens from patients, and to offer a high quality service in doing so. The patient is the primary concern of the laboratories. Therefore, to achieve quality results and optimal use of the services, a number of requirements are important and should be adhered to.

Firstly, appropriate samples should be collected using the correct containers, and transported to the laboratory under optimal conditions. This information can be found in the following pages. Secondly, each sample must be accompanied by a signed request form containing all the necessary information. In particular, relevant clinical details should be provided, to assist laboratories in performing the most appropriate tests and interpreting the results. Finally, users are encouraged to talk to the Head and consultants of the laboratories, whether to discuss tests or results, to get advice or to offer feedback. A close working relationship between the users and the laboratory will ultimately benefit the patients.

OBJECTIVE & SCOPE:

The directory provides details of the range of diagnostic tests offered by the Division of Anatomic Pathology as well as general guidance on procedures for sample collection specific to Anatomical Pathology but without prejudicing clinical procedures relevant to an individual patient.

DIVISION OF ANATOMICAL PATHOLOGY
DEPARTMENT OF PATHOLOGY

	DOCUMENT NAME:	LABORATORY HANDBOOK		
	DOCUMENT NO:	DSI-APD-001		
	PAGE	4/28	VERSION:	004
	DATE OF ISSUE:	27 May 2015	AMENDMENT:	00

DEFINITIONS

Consent: Informed consent obtained prior to a clinical or surgical procedure must include consent for histopathological / cytopathological examination. If verbal consent is obtained prior to a clinical procedure (e.g. fine needle aspiration), this should be documented in the patient's case record.

Requestor: Any qualified medical practitioner authorised to collect primary sample and sign the request form.

Patient name: Surname and initials of first and middle names. (for specimen collected in a container or on slides)

RN number: Hospital registration number of patient in full (for specimen collected in container).
Last three digits of hospital registration number (for specimen collected on slide).

(Request form must show patient's name and RN number in full. In case RN number is not available, as in referrals from outside UMMC, Patient's IC or Passport number is to be used on both container / slide and request forms.)


REFERENCES

Malaysian Standard ISO 15189:2014

UMMC PATHOLOGY DIAGNOSTIC LABORATORIES QUALITY MANUAL

Anatomical Pathology Divisional Policy (DPO-APD-013) on Pre-Examination Processes

DIVISION OF ANATOMICAL PATHOLOGY
DEPARTMENT OF PATHOLOGY

	DOCUMENT NAME:	LABORATORY HANDBOOK		
	DOCUMENT NO:	DSI-APD-001		
	PAGE	5/28	VERSION:	004
	DATE OF ISSUE:	27 May 2015	AMENDMENT:	00

GENERAL INFORMATION

Location

The Division of Anatomic Pathology facility is located on the 6th floor, Menara Timur (East Wing) with backup of some facilities at the Department of Pathology, UM, on the 3rd Floor of Blocks N and O of the Faculty of Medicine, University of Malaya adjoining the UMMC


Operation hours

The Division of Anatomic Pathology laboratory receives specimens from Monday to Friday, 8.00 am to 5.00 pm.

Contact numbers

Histopathology Laboratory : 03 – 7949 2230
Cytopathology Laboratory : 03 – 7949 2132
Medical Officer on duty : 03 – 7949 4780 / 4781
Pathologist on duty : Check with ext.2230

DIVISION OF ANATOMICAL PATHOLOGY
DEPARTMENT OF PATHOLOGY


	DOCUMENT NAME:	LABORATORY HANDBOOK		
	DOCUMENT NO:	DSI-APD-001		
	PAGE	6/28	VERSION:	004
	DATE OF ISSUE:	27 May 2015	AMENDMENT:	00

THE CLINICAL PROCEDURE AND SPECIMEN COLLECTION

The clinical team frequently require a specimen from the patient to make the most appropriate diagnosis and to aid in patient management. These investigations involve the taking of samples from the patient of body fluids such as blood or urine, or the taking of tissue biopsies. Tissue specimens, taken as biopsies at the hospitals clinics or excised during surgical procedures to treat the patient, are sent to the Anatomical Pathology Laboratory for microscopical examination. These samples are processed by the laboratory and reported by a medically qualified pathologist. The results of the investigations will then be sent to the clinical team treating the patient. All procedures carried out to obtain specimens require the informed consent of the patient by the requesting medical personnel. In order to most effectively treat the patient, at the time of consent the clinical team may also request details of any family history of similar or related illnesses.

The tests offered, specimen types and specimen containers are of various types and it is important that specimens are collected and transported properly. Deviations from the instructions given in this guide may result in pre-analytical errors with the specimens not being suitable for testing or giving test results that are of poor quality or are confusing. Specimens should be sent to the laboratory as soon as possible after collection.

DIVISION OF ANATOMICAL PATHOLOGY
DEPARTMENT OF PATHOLOGY


	DOCUMENT NAME:	LABORATORY HANDBOOK		
	DOCUMENT NO:	DSI-APD-001		
	PAGE	7/28	VERSION:	004
	DATE OF ISSUE:	27 May 2015	AMENDMENT:	00

SPECIMEN REQUEST FORM INFORMATION:

The request form should include the following:

- a) Patient identity; Name, Unique identification (RN), Gender, Date of Birth, Location or contact details of patient.
- b) Name of authorised clinical personnel making the request, destination of the report (the requesters address should be part of the request form information).
- c) Type of primary sample and the anatomic site of origin
- d) Examination requested.
- e) Relevant clinical information e.g. family history, communicable diseases,
- f) Date and time (where relevant) of sample collection
- g) Date and time (where relevant) of receipt of samples by the laboratory
- h) NB: i) Verbal requests for examinations are not allowed. ii) Patients should be aware of the information collected and the purpose of its collection

DIVISION OF ANATOMICAL PATHOLOGY
DEPARTMENT OF PATHOLOGY

	DOCUMENT NAME:	LABORATORY HANDBOOK		
	DOCUMENT NO:	DSI-APD-001		
	PAGE	8/28	VERSION:	004
	DATE OF ISSUE:	27 May 2015	AMENDMENT:	00


HISTOPATHOLOGY

The following describes the procedures and specimen collection guidelines specific to histopathological specimens (tissue biopsies and surgically resected tissues).

HISTOPATHOLOGY SERVICES OFFERED

- A. Routine histopathology diagnosis and reporting
- B. Special histopathology diagnosis and reporting
 - i. Renal biopsy interpretation
 - ii. Muscle biopsy interpretation
 - iii. Nerve biopsy interpretation
 - iv. Skin biopsy interpretations
- C. Frozen section reporting
- D. Processing formalin-fixed tissue and preparation of paraffin blocks
- E. Snap freezing of fresh tissue and preparation of frozen blocks
- F. Routine sections and haematoxylin & eosin staining
- G. Special stains (Refer to Appendix 2)
- H. Immunohistochemistry stains (Refer to Appendix 3)


DIVISION OF ANATOMICAL PATHOLOGY
DEPARTMENT OF PATHOLOGY

	DOCUMENT NAME:	LABORATORY HANDBOOK		
	DOCUMENT NO:	DSI-APD-001		
	PAGE	9/28	VERSION:	004
	DATE OF ISSUE:	27 May 2015	AMENDMENT:	00

1. Primary sample collection for histopathological examination:

- 1.1 Specimen for histopathological examination is collected by the clinician in accordance with standard clinical practices.
- 1.2 A properly identified request form shall accompany all specimens for histopathological examination.
- 1.3 All routine small biopsies shall be fixed in 10% buffered formalin (in a volume ratio of 1:10-20) in a plastic container with lid, and bearing the proper label which includes patient's particulars, nature of specimen and date of collection. Specimens **MUST NOT** be sent in normal saline.
- 1.4 All fresh specimens shall be sent in a double-bagged plastic bag with the proper label (on both bags) which includes patient's particulars, nature of specimen and date of collection. If the specimen cannot be sent to the laboratory on the same day, it must be stored in a refrigerator at 4^o C.
- 1.5 Biopsy specimens requiring special tests such as immunofluorescence (IF) or enzyme histochemical stains must be submitted to the laboratory fresh, unfixed and immediately after collection. E.g. Renal and skin biopsies for IF, muscle biopsy (Appendix 6) and rectal biopsy for enzyme histochemistry, peripheral nerve biopsies (Appendix 7 for immunocytochemistry and electron microscopy. **NB: Please see Appendix 5, for specific fixation guidelines for breast cancer specimens.**

DIVISION OF ANATOMICAL PATHOLOGY
DEPARTMENT OF PATHOLOGY

	DOCUMENT NAME:	LABORATORY HANDBOOK		
	DOCUMENT NO:	DSI-APD-001		
	PAGE	10/28	VERSION:	004
	DATE OF ISSUE:	27 May 2015	AMENDMENT:	00

1.6 For cases that require frozen section evaluation for intraoperative diagnosis, a request form must be sent to the laboratory at least one day prior to surgery. For unscheduled cases, the clinician must contact the pathologist on call directly and discuss.

1.7 Attendants of the Histopathology laboratory collect specimens from the major operating theatres twice during each working day.

1.8 Specimens from minor operating theatres (Minor OT), wards and clinics are sent to the Histopathology laboratory by attendants of the respective divisions.


Primary sample identification (Histopathology):

- a) Place biopsy obtained from one anatomical site within a container labelled with Patient name and RN number.

- b) If there is more than one biopsy obtained from a patient from different anatomical sites, these are placed within separate containers labelled as above. In addition, label the containers with the respective anatomical site. E.g: Omentum, L Obturator node, R Obturator node, etc.

- c) The accompanying request form must indicate the corresponding identification markers on the container labels and anatomical sites. (Request form is liable to be rejected if it is found to be otherwise)

DIVISION OF ANATOMICAL PATHOLOGY
DEPARTMENT OF PATHOLOGY

	DOCUMENT NAME:	LABORATORY HANDBOOK		
	DOCUMENT NO:	DSI-APD-001		
	PAGE	11/28	VERSION:	004
	DATE OF ISSUE:	27 May 2015	AMENDMENT:	00

CYTOPATHOLOGY

The following describes the procedures and specimen collection guidelines specific to cytological samples (gynaecological smears, FNA's, sputum, aspirate, washings and brushings etc).

CYTOPATHOLOGY SERVICES OFFERED


- A. Gynaecological cytology
(Cervical smears, vaginal/vault smears, endometrial/endocervical aspiration smears, vulval smear)
 - i) Processing & reporting
 - ii) Opinion on processed materials

- B. Non-gynaecological cytology
(Body fluids, sputum, endoscopic cytological samples)
 - i) Processing & reporting
 - ii) Opinion on processed materials

- C. Fine needle aspiration (FNA) cytology of palpable lesions
(Breast, thyroid, lymph nodes etc)
 - i) FNA procedure
 - ii) Reporting
 - iii) Opinion on processed material

- D. Fine needle aspiration (FNA) cytology of non-palpable lesions under mammographic, ultrasonogram, EUS or CT guidance
(Breast, chest and abdominal lesions etc)
 - i) Reporting
 - ii) Opinion on processed material

DIVISION OF ANATOMICAL PATHOLOGY
DEPARTMENT OF PATHOLOGY

	DOCUMENT NAME:	LABORATORY HANDBOOK		
	DOCUMENT NO:	DSI-APD-001		
	PAGE	12/28	VERSION:	004
	DATE OF ISSUE:	27 May 2015	AMENDMENT:	00

2. Primary sample collection for cytopathological examination

2.1 Gynaecological cytopathology

2.1.1 Conventional smears (including Cervical (Pap) smears, vaginal smears, vault smears, endocervical smears, endometrial smears, vulval smears etc.)

2.1.1.1 Label frosted end of slide with patient's name and RN number.

2.1.1.2 Keep 95% ethanol for smear fixation ready in screw cap plastic bottle.

2.1.1.3 Prepare the smear and immerse the slide immediately into alcohol, making sure that the smear is completely covered by alcohol.


2.1.1.4 If placing more than one slide into the same container, attach a paper clip to the frosted end of each slide to prevent them from sticking together.

2.1.1.5 A properly identified request form shall accompany all specimens for cytopathological examination (as specified in the section on identification of primary sample.)

2.1.2 Liquid based specimens (by Thinprep® method).

2.1.2.1 **Using spatula:** Select contoured end of plastic spatula and rotate it 360 degrees around the entire ectocervix while maintaining tight contact with ectocervical surface.

DIVISION OF ANATOMICAL PATHOLOGY
DEPARTMENT OF PATHOLOGY

	DOCUMENT NAME:	LABORATORY HANDBOOK		
	DOCUMENT NO:	DSI-APD-001		
	PAGE	13/28	VERSION:	004
	DATE OF ISSUE:	27 May 2015	AMENDMENT:	00

2.1.2.2 **Using endocervical brush:** Insert the brush into the cervix until only the bottom most fibers are exposed. Slowly rotate 1/4 or 1/2 turn in one direction. DO NOT OVER-ROTATE.

2.1.2.3 **Using the broom device:** Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the broom in a clockwise direction five times.

2.1.2.4 Rinse the collecting device as quickly as possible in the Thinprep solution by rotating it in the solution 10 times (while pushing against the Thinprep vial wall, if using brush or broom device). Swirl the device vigorously to further release material. Discard the collecting device.

2.1.2.5 Close the cap of the vial, label with patient identification details and send to Cytopathology laboratory in a specimen transport bag accompanied by a request form, duly filled in.


2.2 Non-gynaecological cytopathology

Non-FNA

2.2.1 Serous effusions, CSF, Washings, lavage etc.

2.2.1.1 Collect at least 30 ml of effusion fluid and at least 1 ml of CSF for cytopathological examination.

DIVISION OF ANATOMICAL PATHOLOGY
DEPARTMENT OF PATHOLOGY

	DOCUMENT NAME:	LABORATORY HANDBOOK		
	DOCUMENT NO:	DSI-APD-001		
	PAGE	14/28	VERSION:	004
	DATE OF ISSUE:	27 May 2015	AMENDMENT:	00

2.2.1.2 Place the fluid in clean screw-cap plastic containers and secure the cap. Do not use any fixatives.

2.2.1.3 Label the container as specified in the section on primary sample identification.

2.2.1.4 Place container in specimen transportation bag.

2.2.1.5 A properly identified request form must accompany all specimens for cytopathological examination (as specified in the section on identification of primary sample.)

2.2.1.6 The specimen and request form must reach the cytopathology laboratory within 2 hours and latest by 3.30 pm on the same day.

2.2.1.7 If there is a likelihood of delay, specimen must be stored in a refrigerator at 4⁰ C and submitted to the laboratory the next morning.


2.2.1.8 As far as possible avoid specimen collection in the afternoon on a Friday or before long holidays.

2.2.2 Sputum

2.2.2.1 Collect an early morning sample after a deep cough in a clean wide mouthed plastic container with screw-cap and secure the cap. Do not use any fixatives.

2.2.2.2 Label the container as specified in the section on primary sample identification.

DIVISION OF ANATOMICAL PATHOLOGY
DEPARTMENT OF PATHOLOGY

	DOCUMENT NAME:	LABORATORY HANDBOOK		
	DOCUMENT NO:	DSI-APD-001		
	PAGE	15/28	VERSION:	004
	DATE OF ISSUE:	27 May 2015	AMENDMENT:	00

2.2.2.3 Place container in specimen transportation bag.

2.2.2.4 A properly identified request form must accompany all specimens for cytopathological examination (as specified in the section on identification of primary sample.)

2.2.2.5 The specimen and request form must reach the cytopathology laboratory within 2 hours and latest by 3.30 pm on the same day.

2.2.2.6 As far as possible avoid specimen collection in the afternoon on a Friday or before long holidays.

2.2.3 Urine

2.2.3.1 Collect a random urine sample in a clean plastic container with screw-cap. Avoid early or first morning sample for cytopathological examination. It is preferable to have the patient collect the urine sample in the hospital.


2.2.3.2 Label the container as specified in the section on primary sample identification.

2.2.3.3 Place container in specimen transportation bag.

2.2.3.4 A properly identified request form must accompany all specimens for cytopathological examination (as specified in the section on identification of primary sample).

2.2.3.5 The specimen and request form must reach the cytopathology laboratory within 2 hours of collection.

DIVISION OF ANATOMICAL PATHOLOGY
DEPARTMENT OF PATHOLOGY

	DOCUMENT NAME:	LABORATORY HANDBOOK		
	DOCUMENT NO:	DSI-APD-001		
	PAGE	16/28	VERSION:	004
	DATE OF ISSUE:	27 May 2015	AMENDMENT:	00

2.2.4 Brush cytology smears: (Bronchial, bile duct, etc.)

2.2.4.1 Smears are prepared by gently rolling the brush on clean glass slides.

2.2.4.2 Prepare two sets of slides: One set of air-dried smears and one set of wet-fixed (in 95% ethanol) smears.

2.2.4.3 The wet-fixed smears are immersed in 95% alcohol immediately after smearing.

2.2.4.4 The air-dried smears are allowed to become completely dry

2.2.4.5 A properly identified request form with relevant endoscopy findings must accompany all specimens for cytopathological examination (as specified in the section on identification of primary sample).

2.2.4.6 The specimens and request forms must reach the cytopathology laboratory as soon as possible. If there is a likelihood of delay, store air-dried smears in a refrigerator at 4⁰ C and send the next morning.


2.3 Fine needle aspiration cytology (FNAC) samples:

2.3.1 FNAC performed by clinicians

2.3.1.1 Label slides on the frosted end with patient's details.

2.3.1.2 Prepare two sets of slides: One set of air-dried smears and one set of wet-fixed (in 95% ethanol) smears.

DIVISION OF ANATOMICAL PATHOLOGY
DEPARTMENT OF PATHOLOGY

	DOCUMENT NAME:	LABORATORY HANDBOOK		
	DOCUMENT NO:	DSI-APD-001		
	PAGE	17/28	VERSION:	004
	DATE OF ISSUE:	27 May 2015	AMENDMENT:	00

2.3.1.3 The wet-fixed smears are immersed in 95% alcohol immediately after smearing.

2.3.1.4 The air-dried smears are allowed to become completely dry

2.3.1.5 A properly identified request form with relevant clinical findings must accompany all specimens for cytopathological examination (as specified in the section on identification of primary sample.)

2.3.1.6 The specimens and request forms must reach the cytopathology laboratory as soon as possible. If there is a likelihood of delay, store in a refrigerator at 4⁰ C and send the next morning.


2.3.2 FNACs performed by Pathologist :

2.3.2.1 Phone the Cytopathologist on duty to fix the time and place for unscheduled procedures.(Note: FNACs of the Head & Neck lesions and others are performed on Tuesdays between 11 am and 12.00 pm in the Surgical Clinic, on prior appointment and breast FNACs on Wednesdays between 11.30 am and 12.30 pm)

2.3.2.2 Obtain consent from patient.

2.3.2.3 Complete the cytopathology request form and send to the laboratory.

DIVISION OF ANATOMICAL PATHOLOGY
DEPARTMENT OF PATHOLOGY

	DOCUMENT NAME:	LABORATORY HANDBOOK		
	DOCUMENT NO:	DSI-APD-001		
	PAGE	18/28	VERSION:	004
	DATE OF ISSUE:	27 May 2015	AMENDMENT:	00

2.3.3 FNACs performed by clinicians during endoscopy, CT/Ultrasound scanning:

2.3.3.1 Phone the Cytopathologist on duty to fix the time and place for unscheduled procedures.


2.3.3.2 Obtain consent from patient.

2.3.3.3 Complete the cytopathology request form and send to the laboratory.

Primary sample identification (Cytopathology):

- a) If the primary sample is collected in a specimen container, label the container with the Patient name and RN number. If there is more than one primary sample collected from different anatomical sites, these are placed in separate containers labelled as above. In addition, label the containers sequentially as A, B, C, D... etc.
- b) If the primary sample is collected on a glass slides, label the frosted end of each slide with Patient name and RN number.
- c) If primary sample is collected on glass slides from more than one anatomical site, label these sequentially as A, B, C, D... etc, in addition to Patient name and RN number.
- d) The accompanying request form must match the identification markers on the container / slide labels. (Request form is liable to be rejected if it is found to be otherwise)

DIVISION OF ANATOMICAL PATHOLOGY
DEPARTMENT OF PATHOLOGY

	DOCUMENT NAME:	LABORATORY HANDBOOK		
	DOCUMENT NO:	DSI-APD-001		
	PAGE	19/28	VERSION:	004
	DATE OF ISSUE:	27 May 2015	AMENDMENT:	00

SPECIMEN REJECTION CRITERIA


The following tables lists the criteria for rejection of samples sent to the Anatomical Pathology Laboratory (Histopathology and Cytopathology)

Rejection criteria for:		Code
SPECIMEN		
1	No specimen(s) received	RNS
2	Wrong specimen(s)	RWS
3	Incorrect number of specimen(s)	RIN
4	Specimen(s)/ slide(s) not labelled	RSL
5	Specimen(s)/ slide(s) wrongly labelled	RWL
6	Specimen description does not correspond to request form	RWD
7	Fresh specimen not double-bagged	RDB
8	Specimen bag (one or both), without patient's sticker	RBS
9	Specimen container leaking / broken slides	RLE
10	Slides not labelled with lead pencil	RLP
REQUEST FORM		
1	Wrong request form	RWR
2	No patient's sticker	RPS
3	Request form's mandatory fields incomplete	RND
4	Illegible handwriting on request form	RHW
5	Request form torn or defaced	RFD
6	Request form contaminated by body fluids, e.g. blood	RFC
7	No accompanying patient's stickers (4)	RS4
8	No biohazard label when specimen is infective	RBH

The following cytology specimens are also rejected.

- a. Specimen bottles or smears / slides without accompanying Cytopathology request forms.
- b. Non-gynae specimen containers and FNAC slides not properly labelled.
- c. Specimens received more than 3 days after collection.

DIVISION OF ANATOMICAL PATHOLOGY
DEPARTMENT OF PATHOLOGY

	DOCUMENT NAME:	LABORATORY HANDBOOK		
	DOCUMENT NO:	DSI-APD-001		
	PAGE	20/28	VERSION:	004
	DATE OF ISSUE:	27 May 2015	AMENDMENT:	00

Expected Turnaround Times:


Histopathology: It is our aim to provide diagnostic biopsy reports within 3 to 4 working days and uncomplicated large specimen reports within 7 working days. The time may be extended for those cases requiring histochemical, immunohistochemical staining or any other additional investigations.

Cytopathology: Most Fine Needle Aspiration Cytology (FNAC) will be reported within 7 working days, most gynae and non-gynae cytology will be reported within 5 working days and most cerebrospinal fluid cytology will be reported within 3 working days. However, this time may be extended for those cases requiring histochemical, immunohistochemical staining or any other additional investigations.

Urgent Samples: All samples are considered urgent and are treated accordingly. The pathologist will use his/her discretion to give further priority to a case taking into consideration the request i.e. those request forms stamped as urgent, and the clinical scenario.

Critical Alerts: The following samples are deemed critical and an interim report will be transmitted to the requester within 3 working days unless histochemical or immunohistochemical staining or any other specialized investigations are required for diagnosis; i) Abnormal findings in cerebrospinal fluid cytology, ii) Unexpected findings of malignancy in cases.

DIVISION OF ANATOMICAL PATHOLOGY
DEPARTMENT OF PATHOLOGY

	DOCUMENT NAME:	LABORATORY HANDBOOK		
	DOCUMENT NO:	DSI-APD-001		
	PAGE	21/28	VERSION:	004
	DATE OF ISSUE:	27 May 2015	AMENDMENT:	00


The Laboratories Policy on Protection of Personal Information:

All personnel adhere to security procedures while working in the laboratory including ensuring security of patient information (DPO-APD-10). The laboratory ensures that reports are released ONLY to clinical personnel who requested for the examination or a clinical personnel who is involved in the management of the patient. The Division does not issue reports directly to patients. In the rare circumstance when it is ascertained that the patient is seeking a second opinion or consultation that is relevant to his/her medical care, a DUPLICATE report may be released after approval by the reporting pathologist and Head of Department of Pathology, and the circumstance recorded. As this is done in good faith and with due consideration to care of the patient, the laboratory or patient will inform the requester (clinical personnel looking after the patient) to permit release of the duplicate report. This is in accordance with the Division's Policy on Release of Duplicate Reports, Tissue Sections (stained and unstained), Paraffin Blocks, Research Material. The laboratory does not permit any release of reports via telephone except for intraoperative frozen section reporting.

The Laboratories Complaint Procedure:

The Division looks into all complaints, incidents, suggestions and non-conformances in a positive manner and adheres to the University of Malaya and UMMC procedures for instituting corrective and preventive actions. For complaints, incidents, suggestions and non-conformances which are unique to the division, it adheres to Divisional policies and procedures. This procedure is used in the resolution of complaints, identification and control of non-conformities, implementation of corrective and preventive actions, as well as continual improvement activities which are unique to the Division of Anatomical Pathology, UMMC Pathology Diagnostic Labs. The Division of Anatomical Pathology uses the Complaint and Incident Notification Form as one of the ways to identify non-conformance. Staff and customers are encouraged to assist the Division by reporting any dissatisfaction or incidents. Complainants should complete the form, which is available in all the main working areas of the laboratory. The completed form should then be placed in the Complaints Box in the Pathology Office. The Academic staff in-charge or Quality Manager will review the investigation and classify the complaint or incident as a complaint, incident or non-conformity. On completion of the investigatory process the complainant shall be informed of the action taken.

DIVISION OF ANATOMICAL PATHOLOGY
DEPARTMENT OF PATHOLOGY

	DOCUMENT NAME:	LABORATORY HANDBOOK		
	DOCUMENT NO:	DSI-APD-001		
	PAGE	22/28	VERSION:	004
	DATE OF ISSUE:	27 May 2015	AMENDMENT:	00

LIST OF APPENDICES

No	Date of Issue	Title	Comment
1	06 Aug 2011	Amendment record for DSI-APD-001	Not Applicable
2	10 Jan 2014	List of special histochemical stains	
3	10 Jan 2014	List of immunohistochemical stains	
4	06 Aug 2011	Preparing a patient for primary sample collection	
5	10 April 2015	Fixation guidelines for breast cancer specimens	
6	10 April 2015	Muscle biopsy guidelines	
7	10 April 2015	Peripheral nerve biopsy guidelines	
8			
9			
10			
11			
12			
13			
14			
15			



APPENDIX 2: List of histochemical stains

- 01 Acetyl Cholinesterase [AChE]
- 02 Acid Phosphatase
- 03 Alcian blue
- 04 Alcian blue/PAS
- 05 ATPase
- 06 Bile stain [Fouchet's]
- 07 Chloroacetate esterase [CAE]
- 08 Congo red
- 09 Cytochrome oxidase [COX]
- 10 Giemsa
- 11 Gomori methanamine silver [GMS]
- 12 Gomori trichrome [GT]
- 13 Gram's stain [Taylor's]
- 14 Grimelius argyrophilic reaction
- 15 Iron haematoxylin [Heidenhain]
- 16 Iron [Perl's Prussian Blue]
- 17 Luxol Fast Blue
- 18 Martius Scarlet Blue
- 19 Masson Fontana
- 20 Masson Trichrome [MT]
- 21 Mucicarmine [Southgate's]
- 22 NADH Tetrazolium reductase [NADH-TR]
- 23 Nitroblue tetrazolium [NBT]
- 24 Oil Red O [ORO]
- 25 Orcein
- 26 Periodic Acid Schiff \pm Diastase [PAS/PAS-D]
- 27 Periodic Acid Silver - Jones [PAAG]
- 28 Phloxine tatrazine [Lendrum]
- 29 Phosphotungstic Acid Haematoxylin [PTAH]
- 30 Reticulin [Gordon and Sweet]
- 31 Rubeanic acid
- 32 Succinic dehydrogenase [SDH]
- 33 Touluidine blue
- 34 Von Kossa
- 35 Van Gieson
- 36 Van Gieson, Elastic
- 37 Warthin Starry
- 38 Ziehl-Neelsen: AFB (TB) & Fite-faraco (Lepae)

Note: The Division of Anatomical Pathology Laboratory reserve the right to alter this list at any time



APPENDIX 3: List of immunohistochemical stains

- 01 Actin, smooth muscle [Actin]
- 02 Adrenocorticotropin [ACTH]
- 03 ALK 1 protein [CD246]
- 04 Alpha-1 antitrypsin [AAT]
- 05 Alpha fetoprotein [AFP]
- 06 Alpha dystroglycan [α 1DG]
- 07 Alpha sarcoglycan [α Sarc]
- 08 Amyloid A [AA]
- 09 Bcl 2
- 10 Ber-EP4, Epithelial antigen
- 11 Beta human chorionic gonadotropin [β hCG]
- 12 Beta sarcoglycan [β Sarc]
- 13 Calcitonin
- 14 Calretinin
- 15 Carcinoembryonic antigen [CEA]
- 16 C 4d
- 17 CD 1a
- 18 CD 2
- 19 CD 3
- 20 CD 4
- 21 CD 5
- 22 CD 8
- 23 CD 10
- 24 CD 15
- 25 CD 20 [L26]
- 26 CD 21
- 27 CD 23
- 28 CD 30 [Ber-H2]
- 29 CD 31
- 30 CD 34 [QBEnd 10]
- 31 CD 43 [DF-T1]
- 32 CD 44
- 33 CD 45 [LCA]
- 34 CD 45RO [UCHL1]
- 35 CD 56



-
- 36 CD 61
 - 37 CD 68 [PGM1]

 - 38 CD 79a
 - 39 CD 99 [MIC2]
 - 40 CD 117 [c-kit]
 - 41 CD 138
 - 42 CD 141
 - 43 c-erb B2 [HER2, NEU]
 - 44 Chromogranin A [Chromo A]
 - 45 Collagen VI [Coll VI]
 - 46 Cyclin D1 [Cyc D1]
 - 47 Cytokeratin, AE 1/3
 - 48 Cytokeratin 5/6 [CK5/6]
 - 49 Cytokeratin 7 [CK7]
 - 50 Cytokeratin 20 [CK20]
 - 51 Cytokeratin, high molecular weight [HMWCK]
 - 52 Cytokeratin, MNF116
 - 53 Cytomegalovirus [CMV]
 - 54 Desmin
 - 55 Dysferlin
 - 56 Dystrophin 1 [Dys 1]
 - 57 Dystrophin 2 [Dys 2]
 - 58 Dystrophin 3 [Dys 3]
 - 59 EBER
 - 60 E-cadherin
 - 61 Epithelial membrane antigen [EMA]
 - 62 Estrogen receptor [ER]
 - 63 Gama sarcoglycan [γ Sarc]
 - 64 Glial fibrillary acidic protein [GFAP]
 - 65 Glucagon
 - 66 Growth hormone [GH]
 - 67 Granzyme B
 - 68 HBME1 [Mesothelial cell]
 - 69 Hepatitis B virus surface antigen [HbsAg]
 - 70 Herpes simplex virus-1 [HSV1]
 - 71 HMB45 [Melanosomes]
 - 72 IgA
 - 73 IgG



- 74 IgM
- 75 Inhibin α

- 76 Insulin
- 77 Kappa light chains [κ light chains]
- 78 Ki-67 [MIB 1]
- 79 Lambda light chains [λ light chains]
- 80 Merosin
- 81 MHC Class 1
- 82 Multiple myeloma MUM-1
- 83 Myeloperoxidase [MPO]
- 84 Myogenin
- 85 Neurofilament protein [Neurofil]
- 86 Neuron-specific enolase [NSE]
- 87 p53
- 88 p63
- 89 Pax5
- 90 Placental alkaline phosphatase [PLAP]
- 91 Progesterone receptor [PR]
- 92 Prolactin
- 93 Prostate-specific antigen [PSA]
- 94 pTEN
- 95 S100 antigen
- 96 Synaptophysin [Synap]
- 97 Tdt-339
- 98 Thyroglobulin [TG]
- 99 Thyroid transcription factor [TTF1]
- 100 Vimentin

Note: The Division of Anatomical Pathology Laboratory reserve the right to alter this list at any time



APPENDIX 4:

Preparing a patient for primary sample collection

Actions	Responsibility
<p>1. Sample collection for Histopathological examination</p> <p>Patients requiring histopathological examination such as a biopsy, excision or resection are prepared for the procedures by the attending clinicians.</p>	Requestor
<p>2. Sample collection for Cytopathological examination</p>	Requestor
<p>2.1 Fine needle aspiration cytology (FNAC)</p>	
<p>2.1.1 Explain the procedure clearly to the patient in a language understood by him/her, taking care to include the extent of discomfort anticipated and possible side effects.</p>	
<p>2.1.2 Obtain informed consent.</p>	
<p>2.1.3 No dietary restrictions or coagulation studies are required prior to FNAC.</p>	
<p>2.1.4 Local anaesthesia is not required for superficial swellings and lesions. Patient compliance can be ensured by clear explanation of the procedure and a caring and empathetic attitude.</p>	



- 2.1.5 Local anaesthesia may be used for deep seated swellings or when multiple aspirations are anticipated.
- 2.1.6 Sedation with appropriate medication is preferred for small children or agitated patients.
- 2.1.7 Simple disinfection by wiping the skin at and around the site of needle insertion and basic asepsis are sufficient for superficial swellings and lesions.
- 2.1.8 For deep-seated lesions, larger area of skin must be cleansed and draped.
- 2.1.9 It is preferable that a Cytopathologist performs the FNAC procedure. However, ultrasound, CT or endoscopy-guided FNAC procedures may be performed by the clinician or radiologist.
- 2.1.10 Apply firm pressure to the site of aspiration for a few minutes after the procedure to stop bleeding, if any.
- 2.1.11 Seal site of aspiration with adhesive plaster.

2.2 Non-gynaecological (effusion) cytology

- 2.2.1 Patients requiring cytopathological examination of effusion or other body fluids are prepared according to current and relevant clinical procedures.
 - 2.2.1.1 For sputum cytology, the first morning sample is collected in a wide mouthed container. A nebuliser



may be utilised to encourage expectoration.

2.2.1.2 For urine cytology, a random, ambulatory sample collected near the laboratory is preferred to morning sample collected at home.

2.3 Gynaecological cytology

2.3.1 Patients requiring gynaecological cytology examination are prepared according to current and relevant clinical procedures.

2.3.1.1 Ensure that the patient has maintained sexual abstinence for three days prior to collection.

2.3.1.2 Avoid sample collection if the patient is menstruating, unless there is overriding clinical need.

2.3.1.3 Avoid using synthetic gels for lubrication during instrumentation or sample collection. Preferably use saline.



DSI-1.2 App2 List of
histochemical stains

APPENDIX 5:

Specific fixation criteria for breast cancer specimens

Please note that it is a specific requirement of the laboratory's accreditation programme that the following fixation guidelines are communicated to clinical services;

- 1. Specimens should be immersed in fixative within 1 hour of the biopsy or resection procedure, in a volume of formalin that is at least 10 times the volume of the specimen.*
- 2. If delivery of a resection specimen to the pathology department is delayed (e.g. specimens from remote sites), the tumour should be bisected prior to immersion in fixative. In such cases, it is important that the surgeon ensures that the identity of the resection margins is retained in the bisected specimen; alternatively, the margins may be separately submitted.*
- 3. The time of removal of the tissue and the time of immersion of the tissue in fixative should be recorded and submitted to the laboratory*

The laboratory may monitor compliance with these guidelines and contact clients when they are not met as failure to implement them may significantly affect the performance of the tests and the interpretation of the results.



APPENDIX 6:

MUSCLE BIOPSY

1. The Site of muscle biopsy is determined by the attending clinician, with or without the Pathologist's advice.
2. Open biopsy: at least 1 cylinder, 0.5cm diameter x 1cm in length
3. Specimen shall be submitted fresh to the Anatomical Pathology Division laboratory in an air-tight, dry & clean container:
 - i. Do not place the muscle specimen on gauze, or tie it down or stretch it in any way.
 - ii. Do not submit in saline or formalin
4. If specimen cannot be sent to laboratory within 2 hr, store on ice:
 - i. Never use dry ice
 - ii. Never freeze the specimen
 - iii. Do not allow direct contact of the specimen with ice
5. Ensure request form has an attached Muscle Biopsy Form (refer DFR-APD-001).
6. Ensure correct specimen is attached to the form



APPENDIX 7:

PERIPHERAL NERVE BIOPSY

1. Nerve biopsy specimen should be about 2 cm in length and preferably from the sural nerve, and sent to the laboratory as a fresh (unfixed) specimen.
2. Fresh specimens should be sent immediately or within 2 hours in a clean, air-tight container (without fixative).
3. If specimen cannot be sent to laboratory within 2 hr, store in the fridge (4°C).
4. If specimen is from outside UMMC, put container in wet ice (not dry ice) for transport.
5. The laboratory is to be informed immediately so that the MLT is on standby to receive the specimen and begin processing immediately upon arrival