SUNY Downstate Medical Center -University Hospital of Brooklyn Network
Department of Pathology Policy and Procedure

Subject: DOCUMENT CONTROL SYSTEM

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SUNY DOWNSTATE MEDICAL CENTER
DEPARTMENT OF PATHOLOGY
POLICY AND PROCEDURE

☒ CLINICAL LABORATORIES ☒ BAY RIDGE

Subject: DOCUMENT CONTROL SYSTEM

Policy No.: LAB-35

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JC Standards:

Issued by: Pathology

Review Date	Revisions		Director	Designee	Comments / Revisions
	No	Yes			

Discontinuation Date: _____

PURPOSE:

Provide a document control system to comply with Regulatory Agency Standards.

POLICY:

- Policies and Procedures are approved by the Laboratory Director or designee before the implementation of a procedure.
- Policies and Procedures are reviewed annually by the Laboratory Director or designee and revised as necessary.
- Discontinued Policies and Procedures are removed from manuals and stored for a minimum of 2 years after the date of discontinuation.
- Laboratory performance improvement records are maintained under the document control system.
- Laboratory records, slides, blocks and tissues will be retained for appropriate times should the Laboratory cease operations.

I. **POLICIES AND PROCEDURES:**

Polices and Procedures are maintained in three categories:

a. Hospital-wide Policies are available on the SUNY Downstate Intranet and the originals are maintained by the Department of Regulatory Affairs. www.uhb.org/pnp/lab
b. Departmental Policies for the Clinical and Anatomical labs are available on the SUNY Downstate Intranet and originals with signatures are maintained in Lab Administration. www.uhb.org/pnp/lab/p&p.asp (See Attachment A: Policies and Procedures). These are reviewed annually by the laboratory director.
c. Hardcopies of documents provided via the Laboratory Website will have an embedded watermark and date of print foot note. This will function as a warning to always refer to the website and not to printed documents for the most current version.
d. Laboratory section Procedures are reviewed annually by the laboratory director or designee and are maintained as hard copies in the Laboratory section.
e. The laboratory maintains a Document Control database which will be managed on a shared directory on the laboratory's shared local area network.

II. **PROFICIENCY TESTING RECORDS:**

a. Reports from the New York State Department of Health (Clinical Laboratory Improvement Program) and the College of American Pathologists (CAP) are received and date stamped in the Laboratory Administration office.
b. Reports are screened by Laboratory Administration and copies of a less than 100% successful survey are addressed to the lab section supervisor or designee.
c. Lab section supervisor completes Survey Exception Review Form (SER) for review and approval, within 10 days of date initially stamped as received.
d. All reports are reviewed and approved by the Laboratory Director or designee.
e. Report copies are approved by the Laboratory Director and addressed to the lab sections and the Pathology resident on rotation as tools for education.
f. If required, a response is submitted to the appropriate regulatory tester within 10 days of the stamped received date.

g. The original SER, approved by the Laboratory Director, is numbered and filed in the Laboratory Administration office and copies are provided to the Pathology P.I. committee and the responsible Laboratory Section Supervisor.

III. **INVESTIGATION REPORTS:**

a. An Investigation report (Attachment B: Incident / Action Form) is generated as a summary of an investigation, including the corrective action taken within five days of the incident.
b. Completed Reports are reviewed and approved by the laboratory director.
c. Reports are coded according to Laboratory sections and logged for tracking. (Attachment C: Laboratory Tracking Codes)
d. Report copies are provided to the Pathology P. I. Committee and the responsible Hospital Department for review and corrective action.
e. Responsible Departments / Services are expected to provide responses within 14 days when requested. An incomplete response is forwarded to the Quality Management Department for follow-up if a response is not received from the applicable Department within 30 days of the date of the Incident Report.

IV. **PERFORMANCE IMPROVEMENT DOCUMENT:**

a. Reports are submitted to the Pathology P. I. Committee and laboratory sections present to the committee on a scheduled basis.
b. Laboratory indicators are presented to the Executive Performance Improvement Council (EPIC) quarterly, by the Laboratory Director.

V. **REFERENCE LABORATORIES:**

CLIA Laboratory permits for reference laboratories utilized by UHB are reviewed annually by the Laboratory Administrator and updated permits are requested in writing if the current is outdated.

VI. **PRODUCT RECALLS AND INFORMATION MANAGEMENT:**

All products recalled by the manufacturer or any regulatory agency should be removed from use or corrected within 24 hours.

a. Alert coordinator is responsible for the evaluation alerts, ensuring action is dispose of recalled products, notifying end users of recalls/alerts and documenting actions taken. These activities are performed electronically in the RASMAS website. There is an Alert Coordinator for each RASMAS domain, who receives notification of an alert by email from RASMAS. (Proactively, the Alert Coordinator can also review the RASMAS website for new recalls/alerts.) Depending on the nature of the alert, the Alert Coordinator may respond directly to the alert, assign the alert to an Alert Responder(s) or re-assign the alert to another Domain Coordinator.

RASMAS (Risk and Safety Management Alert System) is a web-based subscription service from Noblis, Inc., which provides healthcare product alerts electronically to healthcare providers who subscribe to their service. It tracks all alerts and product recalls and documents all actions taken with regard to product safety information within University Hospital of Brooklyn. In place of the FDA Class I, Class II and Class III categories, RASMAS uses the terms :Urgent" and "Standard".
b. Laboratory related notices, recalls or alerts received outside of RASMAS by the Alert Coordinators are date stamped and copies distributed to appropriate supervisory personnel.
c. The Laboratory Section Supervisor or designee review the notice in conjunction with inventory records (i.e., reagent lot number)

d. The Supervisor prepares an Action Report reflecting the findings of the investigation if corrective action is applicable and submits the report to the Product Safety Coordinator.
e. The Laboratory Safety Coordinator provides a copy to the Institution's Risk Manager and the Pathology Performance Improvement Committee.
f. If Laboratory Section Supervisor receives such recall notices or alerts, the notification should be passed on to the Alert Coordinator immediately.
g. The Pathology Department has designated "The Clinical Lab Administrator" as an alternate in case the Alert Coordinator is not available.
h. All Laboratory staff members must be familiar with Hospital Policy No. RM-7.

VII. **RECORDS AND FORMS:**

a. Laboratory test results are stored indefinitely in the Laboratory Information Systems, CERNER and Co-Path for Clinical and Anatomical Pathology, respectively.
b. QC Accession Log, Instrument Work lists, Maintenance/Instrument Maintenance Records and assay runs are maintained by the individual Laboratory sections for a minimum of 2 years.
c. Laboratory reports for each procedure are reviewed annually by the Laboratory Director or designee and maintained in the LIS office.
d. Off-site storage is contractually available to store records, slides, blocks and tissues in accordance with the timeliness established in the Regulatory Standards (See attached).
e. List of approved Interdepartmental Forms initiated by the Department of Pathology. (Attachment D). The contractual arrangement will be maintained should the Laboratory cease to operate.

VIII. **REFERENCE:**

CAP: GEN.20100, GEN.20208, GEN.20372, GEN.20373; GEN.10000, GEN.10500
LAB/ LAB 9, LAB 10, LAB 12, LAB 14, LAB 8

Attachment A:

RETENTION OF LABORATORY RECORDS AND MATERIALS

The College of American Pathologists makes the following recommendations for the minimum requirements for the retention of laboratory records and materials. They meet or exceed the regulatory requirements specified in the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88). The College of American Pathologists urges laboratories to retain records and/or materials for a longer period of time than specified when such would be appropriate for patient care, education or quality improvement needs. Some state regulations as well as other federal mandates may require retention of records and/or materials for a longer time period than that specified in the CLIA-88 regulations; therefore any applicable state or federal laws should be reviewed carefully when individual laboratories develop their records retention policies.

MATERIALS/RECORD	PERIOD OF RETENTION
General Laboratory	
Accession log records	2 years
Maintenance/instrument maintenance	2 years
Quality control records	2 years
Surgical Pathology (including bone marrows)	
Wet tissue	2 weeks after final report
Paraffin blocks	10 years
Slides	10 years
Reports	10 years
Cytology	
Slides (negative-unsatisfactory)	5 years
Slides (suspicious-positive)	5 years
Fine needle aspiration slides	10 years
Reports	10 years
Non-Forensic Autopsy Records	
Wet tissue	3 months after final report
Paraffin blocks	10 years
Slides	10 years
Reports	10 years
Forensic Autopsy Records	
Wet stock tissue	3 years
Paraffin blocks	Indefinitely
Reports	Indefinitely
Slides	Indefinitely
Gross photographs/negatives	Indefinitely
Accession log records	Indefinitely
Body fluids and tissues for toxicology	1 year
Dried blood stain or frozen tissues for DNA	Indefinitely

Clinical Pathology Records

Patient test records	2 years
Serum/CSF/Body fluids (except urine)	48 hours
Urine	24 hours
Peripheral blood smears/body fluids smears	7 days
Permanently stained slides – microbiology (gram, trichrome, etc)	7 days

Cytogenetics Records

Permanently stained slides	3 years
Fluorochrome stained slides	At the discretion of the Laboratory director
Wet specimens/tissue	Until adequate metaphase Cells are obtained
Fixed cell pellet	2 weeks after final report
Final reports	20 years
Diagnostic images (digitized or negatives)	20 years

Blood Bank

Donor	10 years
Patient records	10 years
Records of employee signatures, initials, and identification codes	10 years
Quality control records	5 years
Records of indefinitely deferred donors, permanently deferred donors, or donors placed under surveillance for the recipient's protection (e.g., those donors that are Hepatitis B Core positive once, donors implicated in a hepatitis positive recipient)	Indefinitely
Specimens from blood donors units and recipients	7 days post-transfusion

Adopted 8/95
Revised 9/95
Reaffirmed 11/00
Revised 11/05

Summary of Regulations			
MATERIAL/RECORD	**CLIA**	**CAP**	**JCAHO**
Laboratory service requests, surgical pathology requests, Cytology requests and other laboratory test ordering documents.	2 years Medicare 6 years (42CFR1003 132)	2 years	2 years
Records of specimens received, tests, including identification of the patient, name of the submitter, dates of receipt and report; type of test performed; and test results, including instrument printouts and original test report or exact duplicate.	2 years	2 years	2 years
Bone Marrow – reports and smears.		10 years	
Records of inspection, validation, calibration, repair, and replacement to ensure proper maintenance and operation of equipment and proper reactivity of test materials.	2 years	2 years	2 years
Procedure manuals, card files, flow charts	2 years	2 years	2 years
Records of quality control procedures in use in the various technical areas of the laboratory, including results on standards and reference materials, and action limits, when appropriate	2 years	2 years	2 years
Blood-bank records; donor and recipient records; records of employee signatures, initials, and identification		10 years	
Cytology slides – negative and unsatisfactory	5 years	5 years	5 years
Cytology slides – positive and suspicious	5 years	5 years	5 years
Histopathology slides and fine-need aspiration slides	10 years	10 years	10 years
Blood films, permanently stained body fluid slides, and microbiology slides		7 days	
Serum/cerebrospinal fluid/body fluids		24 hours	
Specimens from blood-bank donors and recipients	7 days post-transfusion or 10 days post-crossmatch	7 days post-transfusion	
Specimen blocks	2 years	10 years	2 years
Wet-tissue specimen	Until diagnosis	2 weeks after final report	
Autopsy wet tissue		3 months after final report	
Surgical pathology accession log		2 years	
Pathology reports	10 years	10 years	10 years
Cytology reports	10 years	10 years	10 years
Cytology records indicating the daily accession of specimens, each of which is numbered, and an appropriate cross-filing system according to the patient's name		2 years	
Histologic or clinical confirmation of cytology findings on	10 years	10 years	10

abnormal cases and false-negative and false-positive results for each category of specimens, when such results are made available.			years
Proficiency-testing records	2 years	2 years	2 years
Immunohematology records, quality control, and test reports	5 years	5 years	5 years
Quality-assurance records	2 years	2 years	
Table provided by Robert Nakamura, MD, and the Quality Control staff at Scripts Clinic Laboratory			

Attachment B:

PRIVILEGED AND CONFIDENTIAL PEER-REVIEW QUALITY ASSURANCE MATERIAL
Confidential for Q.A. Purposes P.H.L. 2805

No.

UNIVERSITY HOSPITAL OF BROOKLYN

CONFIDENTIAL INVESTIGATION & ANALYSIS REPORT FOR QA PURPOSES
☐ LABORATORY ☐ RADIOLOGY

AN INCIDENT IS AN EVENT NOT CONSISTENT WITH THE DESIRED OPERATION OF THIS FACILITY, OR THE CARE OF PATIENTS

INSTRUCTIONS

1. **This form must be completed and forwarded within 24 hours.**
2. **Check box next to type of incident.**
3. **Write brief description of incident (See space below)**
4. **Describe patient's condition before and after the incident (See below)**

DATE OF INCIDENT	TIME: AM / PM	PREPARED BY:	LOCATION:

GENERAL. INCIDENTS

☐ **Wrong Encounter**	☐ **Lost Specimen**	☐ **Patient Incident**
☐ **Wrong Patient**	☐ **Medical Record / Financial Number Error**	☐ **Inability to Report Critical Values**
☐ **Equipment Malfunction**	☐ **Unlabelled Specimen**	☐ **Lab Management**
☐ **Physical Plant Failure**	☐ **Mislabeled Specimen**	☐ **Other**

☐ Sections Affected

_____
_____
_____
_____
_____
_____
_____
_____

PLACE PATIENT LABEL HERE OR FILL IN

PATIENT:
DOCTOR:
MR#:
DOB:

ACTION TAKEN:

OUTCOME:

RESPONSE FROM SERVICE/DEPARTMENT: **(Response to this issue is expected within 14 days of the report origination date)**

Responder Name:	Approved by:
Signature:	Signature:
Position:	Date:
Date:	Director:

Attachment C:

PATHOLOGY- CLINICAL LABORATORIES

INCIDENT REPORT CODING SYSTEM

The numbering system assigned is as follows:

2 digit – Month, followed by 2 digit – Year, followed by numbers assigned in order of receipt, followed by section code.

The assigned numbers will continue in numerical order until the end of the calendar year. i.e., 060501-HM …….. 120599-LS

Other examples shown below:

Month of Incident Report and the Originating Laboratory	Year	Month	No.	Section Code	Inc. Report Code No.
Hematology - June 26th, 2005	2005	06	01	HM	050601-HM
LIS - June 20th, 2005	2005	06	02	LS	050602-LS
Chemistry – July 10th, 2005	2005	07	03	CH	050703-CH
OPD - September 5th, 2005	2005	09	04	OP	050904-OP
Venipuncture - August 1st, 2005	2005	08	05	VP	050805-VP
Virology - October 2nd, 2005	2005	10	06	VR	051006-VR
Surgical Path - January 5th, 2005	2005	01	07	SP	050107-SP
Flow Cytometry - May 1st, 2005	2005	05	08	FC	050508-FC
Microbiology - July 20th, 2005	2005	07	09	MB	050709-MB
POC - November 13th, 2005	2005	11	10	PC	051110-PC
Central Access. - May 2nd, 2005	2005	05	11	CA	050511-CA
Blood Bank - July 12th, 2005	2005	07	12	BB	050712-BB

Clin Lab Admin - May 10th, 2006	**2006**	**05**	**10**	**CL**	**060510-CL**
Morgue – December 24th, 2005	**2005**	**12**	**11**	**MG**	**051211-MG**
Transplant–December 2nd, 2008	**2008**	**12**	**14**	**TP**	**081214-TP**
Bay Ridge – January 1st, 2009	**2009**	**01**	**01**	**BR**	**090101-BR**
Molecular Pathology – May 1st, 10	**2010**	**05**	**60**	**MP**	**100560-MP**