Clinical Departments: Pathology/Laboratory

Name of Hospital: _____

Date: _____ Hospital Contact: _____

Always/ Yes	Sometimes	Never/ No	N/A	
				DEPARTMENT MANAGEMENT
				Physicians
☐	☐	☐	☐	1. All pathologists are board certified.
☐	☐	☐	☐	2. Pathologists participate in quality improvement (QI) committees at the facility, including:
☐	☐	☐	☐	a. institutional clinical-pathological conferences (CPC) and morbidity-mortality reviews as requested, and
☐	☐	☐	☐	b. tumor board.
☐	☐	☐	☐	3. A peer review process is in place and includes:
☐	☐	☐	☐	a. review and documentation of significant concerns or complaints regarding a pathologist;
☐	☐	☐	☐	b. criteria for action to be taken, including proctoring; and
☐	☐	☐	☐	c. a disciplinary process, including termination.
				4. If the pathologist is contracted, there is an agreement defining:
☐	☐	☐	☐	a. frequency of visits by the consulting pathologist, and
☐	☐	☐	☐	b. responsibilities during on-site visits by the consulting pathologist.
				Leadership
☐	☐	☐	☐	5. A laboratory director is present at each location.
☐	☐	☐	☐	a. The hospital provides written responsibilities for the director.
☐	☐	☐	☐	b. Laboratory policies and procedures are reviewed annually by the current director or designee.
☐	☐	☐	☐	6. One pathologist is at each facility/satellite.
☐	☐	☐	☐	7. Pathologists participate in inspections and laboratory audits.
☐	☐	☐	☐	8. A pathologist is on call 24/7 for surgical pathology frozen section analysis.

Clinical Departments: Pathology/Laboratory

Always/ Yes	Sometimes	Never/ No	N/A	
☐	☐	☐	☐	9. New pathologists have 100 percent review of at least 100 cases.
☐	☐	☐	☐	a. Discordant cases are reviewed with the pathologist.
☐	☐	☐	☐	10. There is ongoing quality review of a percentage (determined by the hospital) of every pathologist's findings and reports to check their accuracy and completeness.

Policies and Procedures

☐	☐	☐	☐	11. There are policies and procedures at each location, including:
☐	☐	☐	☐	a. specimen collection, labeling, preservation, and handling procedures;
☐	☐	☐	☐	b. a method to identify blood or blood products;
☐	☐	☐	☐	c. procedures to ensure that each test is performed for accurate and reliable results;
☐	☐	☐	☐	d. specimen rejection criteria and procedures;
☐	☐	☐	☐	e. established limits for critical or panic values and method for reporting to clinician with documentation of report;
☐	☐	☐	☐	i. reporting of critical values requires read-back verification;
☐	☐	☐	☐	f. retention of specimens, logbooks, and reports for 10 years;
☐	☐	☐	☐	g. a proper method for responding to subpoenas or requests for specimens;
☐	☐	☐	☐	h. procedures to ensure that original slides never leave the facility; and
☐	☐	☐	☐	i. procedures for documentation and communication of report addenda.
☐	☐	☐	☐	12. Policies and procedures are reviewed annually for revisions and approved by the medical director.

General

				13. The laboratory is:
☐	☐	☐	☐	a. Clinical Laboratory Improvement Amendments (CLIA) certified (date of last review/certification_____)
☐	☐	☐	☐	b. College of American Pathologists (CAP) accredited (date of last review/ accreditation_____)
☐	☐	☐	☐	c. Commission on Office Laboratory Accreditation (COLA) accredited (date of last review/accreditation_____)

Clinical Departments: Pathology/Laboratory

Always/ Yes	Sometimes	Never/ No	N/A	
☐	☐	☐	☐	d. The Joint Commission (TJC) accredited (date of last review/ accreditation_____)
☐	☐	☐	☐	e. All identified deficiencies or recommendations have been resolved.
☐	☐	☐	☐	14. The lab is open 24 hours a day, seven days a week.
☐	☐	☐	☐	15. There is a designated safety officer.
☐	☐	☐	☐	16. There is a biohazard/waste management program.
☐	☐	☐	☐	17. Computer templates for diagnoses and reports are periodically reviewed and upgraded to ensure that the data is complete.
				18. Substantive corrections for typographical and transcription errors or those reports requiring amendments are reported to:
☐	☐	☐	☐	a. the department director,
☐	☐	☐	☐	b. the patient's attending/primary care physician, and
☐	☐	☐	☐	c. the patient.

HUMAN RESOURCES

☐	☐	☐	☐	19. Training and licensure are verified prior to employment.
☐	☐	☐	☐	20. Staff is supervised in performance of duties and testing.
☐	☐	☐	☐	21. Staff competence is evaluated per CLIA, CAP, COLA, or TJC standards.
☐	☐	☐	☐	22. All personnel are familiar with the facility's policies and procedures.

PATIENT CARE

Blood Bank

☐	☐	☐	☐	23. The blood bank is approved by AABB, TJC, or CAP.
☐	☐	☐	☐	a. If not, the blood bank is inspected by the FDA.
☐	☐	☐	☐	24. The blood bank is directed by a pathologist.
☐	☐	☐	☐	25. The blood bank's alarm system is monitored continuously, e.g., at the switchboard, nursing station, or maintenance department, in addition to being monitored by the blood bank.
☐	☐	☐	☐	26. Emergency power is supplied for both the blood bank and the blood bank alarm system.
☐	☐	☐	☐	27. Major cross matches are made prior to transfusions, per the AABB.

Clinical Departments: Pathology/Laboratory

Always/ Yes	Sometimes	Never/ No	N/A	
☐	☐	☐	☐	28. The hospital draws blood donors and processes the blood for administration to patients.
				If yes,
☐	☐	☐	☐	a. Donors are screened by health history to exclude individuals who may be in the high-risk group for AIDS.
☐	☐	☐	☐	b. The hospital screens the units of blood for hepatitis.
☐	☐	☐	☐	c. The hospital screens the units of blood for HIV antibodies.
☐	☐	☐	☐	d. If a donor's blood tests positive for HIV antibodies, there are procedures established for notifying the donor of the test results.
				If no,
☐	☐	☐	☐	a. The hospital gets blood to administer to patients from an agency approved by the AABB, TJC, or CAP (or inspected by the FDA). (Name of agency: _____)
☐	☐	☐	☐	b. This agency performs hepatitis and HIV antibody testing.
☐	☐	☐	☐	c. The hospital performs repeat testing for hepatitis and HIV antibodies.
☐	☐	☐	☐	29. The hospital makes a program available for patients to use autologous (self-donated) units of blood.
				30. If the hospital acts as a test center for individuals concerned about their HIV antibody status:
☐	☐	☐	☐	a. testing is done at the hospital,
☐	☐	☐	☐	b. testing is done at a reference lab,
☐	☐	☐	☐	c. staff members follow policies and procedures for notifying patients of results, and
☐	☐	☐	☐	d. staff members receive annual updates on privacy and confidentiality.

Laboratory

☐	☐	☐	☐	31. All personnel having direct contact with body fluids have received education on precautionary measures and the application of standard precautions.
☐	☐	☐	☐	32. Lab staff routinely uses personal protective equipment, such as gloves, gowns, masks, and safety shields.
☐	☐	☐	☐	33. The lab has discontinued use of plain glass capillary tubes for specimen collection and specimen handling.

Clinical Departments: Pathology/Laboratory

Always/ Yes	Sometimes	Never/ No	N/A	
☐	☐	☐	☐	34. Lab personnel who perform blood draws have had specific training in intravenous access with demonstration and documentation of appropriate proficiency.
☐	☐	☐	☐	35. There is a program for follow-up procedures for employees after possible and known exposure to HIV, HBV (hepatitis B), or HCV (hepatitis C).
☐	☐	☐	☐	36. Specimens removed during a surgical procedure are routinely sent to a pathologist for examination.
☐	☐	☐	☐	37. There is a list of specimens that do not need to be sent to the lab for examination.
☐	☐	☐	☐	38. The specimens received from surgery are logged in.
☐	☐	☐	☐	39. Two patient identifiers are used to correctly identify all specimens.
☐	☐	☐	☐	40. All blood specimens are appropriately labeled with patient information and the name of the person drawing the specimen. (Identifying information on computer-generated labels should be verified by the individual drawing the specimen.)
☐	☐	☐	☐	41. The department has a policy that limits the number of times (two or three) that a phlebotomist may attempt to draw blood before seeking assistance.

Surgical Pathology: Preanalytic

☐	☐	☐	☐	42. Histology quality controls are completed according to certification and accreditation standards.
☐	☐	☐	☐	43. Positive and negative controls of immunohistochemical stains are monitored.
☐	☐	☐	☐	a. Control results are documented in the final report.
☐	☐	☐	☐	b. Discordant or substandard results are referred to appropriate supervisory personnel for follow-up and resolution.

Surgical Pathology: Analytic

				44. There is consistent monitoring of performance by pathology assistants that includes:
☐	☐	☐	☐	a. adequacy of gross descriptions,
☐	☐	☐	☐	b. anatomic dissection,
☐	☐	☐	☐	c. gross photography, and
☐	☐	☐	☐	d. selection of sections for submission.

Clinical Departments: Pathology/Laboratory

Always/ Yes	Sometimes	Never/ No	N/A	
☐	☐	☐	☐	45. Frozen section intraoperative consultation diagnoses are correlated with final diagnoses.
☐	☐	☐	☐	a. There is a system in place to track them.
☐	☐	☐	☐	46. Surgical tissue diagnoses are made by a pathologist.
☐	☐	☐	☐	47. During an operative procedure, the pathologist communicates directly with the surgeon (not with anyone else in the operating room) regarding verbal reports on specimens.
				48. Surgical pathology criteria include the following:
☐	☐	☐	☐	a. The frozen section turnaround time is within 20 minutes (CAP benchmark).
☐	☐	☐	☐	i. Substantial or consistent deviations are addressed by the pathologist.
☐	☐	☐	☐	b. The turnaround time for 80 percent of specimens is within two working days (CAP benchmark).
☐	☐	☐	☐	c. The random review of at least 1 percent of all specimens collected is encouraged.
☐	☐	☐	☐	d. Discordant cases or inappropriate deferrals are reviewed for final classification and are designated as:
☐	☐	☐	☐	i. no discrepancy found on review,
☐	☐	☐	☐	ii. gross or microscopic sampling error,
☐	☐	☐	☐	iii. minor interpretive error with no significant potential for adverse clinical outcome,
☐	☐	☐	☐	iv. interpretive error with potential for or actual minor adverse clinical consequence, or
☐	☐	☐	☐	v. major interpretive error with potential for serious adverse clinical consequence.
☐	☐	☐	☐	e. Intradepartmental consultations are monitored to ensure adequate peer review.
☐	☐	☐	☐	i. Concordant second reviews are documented in the final report or file copy.
☐	☐	☐	☐	ii. Discordant reviews are obtained and documented in the final report.

Clinical Departments: Pathology/Laboratory

Always/ Yes	Sometimes	Never/ No	N/A	
				Surgical Pathology: Postanalytic
☐	☐	☐	☐	49. Reports are monitored to ensure they include data elements from CAP cancer checklists/protocols.
☐	☐	☐	☐	50. All reports are reviewed and signed by the pathologist.
☐	☐	☐	☐	51. Case reviews by an outside pathologist are reviewed.
☐	☐	☐	☐	a. Discordant results are discussed within the group.
☐	☐	☐	☐	b. An addendum or amended report is issued with an immediate call to notify the clinician.
☐	☐	☐	☐	c. There is documentation of the notification.
☐	☐	☐	☐	52. Conference or multidisciplinary tumor board review is performed and includes:
☐	☐	☐	☐	a. discrepancies addressed by the pathologist; and
☐	☐	☐	☐	b. an amended report.
				Cytopathology: Preanalytic
☐	☐	☐	☐	53. A pathologist or supervisory-level cytotechnologist reviews the technical quality of cytological preparations daily.
☐	☐	☐	☐	54. Monitoring of cumulative PAP ASCUS/SIL ratio is performed for each pathologist.
☐	☐	☐	☐	55. Each pathologist participates in CAP's PAP proficiency testing.
				Cytopathology: Analytic
☐	☐	☐	☐	56. There is a 10 percent random rescreen of all negative lesions.
☐	☐	☐	☐	57. A mandatory five-year look-back occurs for new lesions that are high-grade or above.
☐	☐	☐	☐	58. There is a mandatory second review of malignancies and pre-sign-outs.
☐	☐	☐	☐	59. Intraprocedural touch preps and immediate fine needle aspiration interpretations are correlated with the final pathology.
☐	☐	☐	☐	a. There is a system in place to track them.
☐	☐	☐	☐	60. Intradepartmental consultations occur on difficult, unusual, or especially high-risk cases regardless of the specimen type or diagnosis.

Clinical Departments: Pathology/Laboratory

Always/ Yes	Sometimes	Never/ No	N/A	
☐	☐	☐	☐	61. Documented records of intra- and extradepartmental consultations are maintained.
☐	☐	☐	☐	62. Cytotechnologists review no more than 100 slides per 24 hours.

Cytopathology: Postanalytic

☐	☐	☐	☐	63. Turnaround time for reports is monitored for each pathologist.
☐	☐	☐	☐	64. Reports are reviewed and signed by the pathologist.
☐	☐	☐	☐	65. Reports include a correlation between a patient's history, histology, and findings.
☐	☐	☐	☐	66. Cytopathology reports include an interpretation of the morphologic findings.
☐	☐	☐	☐	67. Cytology findings are reported using standard descriptive diagnostic terminology.
☐	☐	☐	☐	68. A corrected report is issued when a significant discrepancy that would affect current patient care is found during a retrospective review.
☐	☐	☐	☐	a. The attending/primary care provider is notified.
☐	☐	☐	☐	b. There is documentation of notification.
☐	☐	☐	☐	69. There is a policy and procedure regarding retention and release of blocks/slides.

Autopsy Pathology: Preanalytic

70. Quality parameters include:

☐	☐	☐	☐	a. a complete permit for autopsy,
☐	☐	☐	☐	b. documentation of body identification, and
☐	☐	☐	☐	c. consistent and timely procurement of medical records for review prior to autopsy.
☐	☐	☐	☐	71. Deviations are noted on incident forms and reviewed by QI committee.
☐	☐	☐	☐	72. Findings from autopsies are incorporated into the quality management program.
☐	☐	☐	☐	73. Formal intra-and extradepartmental consultations are documented, and the reports are maintained with the patient's autopsy report.

Clinical Departments: Pathology/Laboratory

Always/ Yes	Sometimes	Never/ No	N/A	
				Autopsy Pathology: Analytic
☐	☐	☐	☐	74. Turnaround time for provisional anatomic diagnosis (PAD) is not more than two working days (CAP benchmark).
☐	☐	☐	☐	75. The majority of autopsy final reports are produced within 30 working days (CAP benchmark).
☐	☐	☐	☐	76. Turnaround time for the final autopsy report is 60 working days (CAP benchmark) and is no more than 13 weeks for complex cases.
				Autopsy Pathology: Postanalytic
☐	☐	☐	☐	77. Preliminary and final anatomic diagnoses are reviewed to ensure clear and relevant cause of death statements with feedback provided to the issuing pathologist.
				ENVIRONMENT OF CARE
☐	☐	☐	☐	78. Laboratory equipment is maintained and calibrated according to the manufacturer's recommendations.
☐	☐	☐	☐	79. Air quality testing has been performed (e.g., in tissue processing) to determine if staff is exposed to unacceptable levels of formaldehyde, xylene, toluene, and other hazardous chemicals.
☐	☐	☐	☐	80. Hazardous wastes are stored in closed containers away from public access.
☐	☐	☐	☐	81. Policy prohibits storing food in laboratory refrigerators and freezers.
☐	☐	☐	☐	82. Refrigerated storage areas are monitored for temperature control.
☐	☐	☐	☐	83. The morgue is equipped with a refrigerated cooler to store bodies for autopsies or until they are picked up by funeral homes.
				Protective Measures
☐	☐	☐	☐	84. The laboratory has a department-specific fire plan.
☐	☐	☐	☐	85. Supplies of flammable and combustible liquids are reasonable for the laboratory's needs, and they are properly stored.
☐	☐	☐	☐	86. Employees are trained on procedures to follow in case of clothing fires.
☐	☐	☐	☐	87. Door stops are prohibited for fire-resistant doors and smoke barriers.
☐	☐	☐	☐	88. A Chemical Hygiene Plan (CHP) is in place and includes:
☐	☐	☐	☐	a. standard procedures for safety when handling hazardous chemicals,
☐	☐	☐	☐	b. measures to reduce exposure to hazardous chemicals,

Clinical Departments: Pathology/Laboratory

Always/ Yes	Sometimes	Never/ No	N/A	
☐	☐	☐	☐	c. measures to ensure that chemical hoods and other protective equipment function properly,
☐	☐	☐	☐	d. decontamination procedures, and
☐	☐	☐	☐	e. designated individuals to oversee the operation of the CHP.
☐	☐	☐	☐	89. The CHP is reviewed annually.
				90. The lab is equipped with the following safety equipment that is immediately available:
☐	☐	☐	☐	a. eye wash,
☐	☐	☐	☐	b. fire extinguishers that are inspected on a monthly basis and retagged annually,
☐	☐	☐	☐	c. a shower, and
☐	☐	☐	☐	d. a hazardous materials spill kit.

PROCESS IMPROVEMENT/PATIENT SAFETY

☐	☐	☐	☐	91. Satisfaction by patients and referring physicians with the laboratory's service has been measured within the past two years.
☐	☐	☐	☐	92. A quality management or quality improvement plan is in place.
☐	☐	☐	☐	93. The quality management team meets at least monthly.
				94. The quality plan addresses:
☐	☐	☐	☐	a. surgical pathology,
☐	☐	☐	☐	b. cytopathology, and
☐	☐	☐	☐	c. autopsy pathology.
				95. The following quality and patient safety parameters are assessed:
☐	☐	☐	☐	a. patient identification,
☐	☐	☐	☐	b. specimen identification,
☐	☐	☐	☐	c. labeling errors,
☐	☐	☐	☐	d. specimen/requisition mismatch,
☐	☐	☐	☐	e. requisition omissions,
☐	☐	☐	☐	f. tissue lost in processing, and
☐	☐	☐	☐	g. courier specimen loss/misrouting.

Clinical Departments: Pathology/Laboratory

Always/ Yes	Sometimes	Never/ No	N/A	
☐	☐	☐	☐	96. Quality/patient safety parameters are monitored and reported by all pathologists and support staff.
☐	☐	☐	☐	97. Reports are reviewed for trends or increased sources of error with communication to the responsible pathologist.
☐	☐	☐	☐	98. Adverse events and near misses are reported according to policy.
☐	☐	☐	☐	a. The department provides constructive and timely feedback on each reported adverse event and near miss.
☐	☐	☐	☐	b. Staff members are able to describe how information on adverse events and near misses is used to improve patient safety.
☐	☐	☐	☐	99. The department has a patient safety plan with specific goals and objectives.
☐	☐	☐	☐	100. The department collects data needed to track progress toward the department patient safety goals.
☐	☐	☐	☐	a. Staff members are able to describe how they use data to determine which safety projects to adopt.
☐	☐	☐	☐	b. Staff members are able to describe how they use data to improve patient care.

Resource: The Centers for Disease Control and Prevention's (CDC) Laboratory Science, Policy and Practice Program Office: Laboratory Medicine Best Practices (LMBP) Initiative at https://www.futurelabmedicine.org.