

ADMINISTRATIVE DOCUMENT

PENNSYLVANIA DEPARTMENT OF HEALTH
BUREAU OF LABORATORIES
DIVISION OF LABORATORY IMPROVEMENT

CLIA #:		LABORATORY ID #:	
NAME OF LABORATORY:			
DATE OF SURVEY:	START TIME:	EXAMINER:	
PERSON(S) INTERVIEWED:			
NAME:		TITLE:	
COMMENTS:			
DEFICIENCIES:			
DIRECTOR PRESENT AT EXIT INTERVIEW? Y N			

REVISED 2/2007

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
ADMINISTRATIVE				
	<p>A. Hours of Testing:</p> <p style="text-align: center;">M T W Th F Sa Su</p> <p>From _____</p> <p>To _____</p>			
	B. Are all lab activities covered by a single state laboratory permit and CLIA certificate (e.g. blood gas lab, nuclear med lab, POC testing, OR lab, ER lab, etc.)?			
	C. Are all lab activities under common direction?			
	1. If no, does each laboratory site have a separate state permit and CLIA certificate?			
	D. Has there been a change of director?			
	1. If yes, is a personnel form or Curriculum Vitae available?			
	2. Does the individual meet the personnel requirements to fill this position?			
	3. How many laboratories does this individual direct, including this facility?			
	E. Has there been a change in ownership of the lab?			
	1. If yes, has a new Disclosure of Ownership form (HCFA-1513) been submitted?			
	F. Has there been a change of name, address, and/or phone number?			
	1. New Name:			
	2. New Address:			
	3. New Phone Number:			
	G. Did the laboratory notify the State within 30 days after any of the above changes?			
	H. Does the information in the STATE/CLIA system match (name, director, address, testing categories)?			

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TEST MENU				
	A. Have there been any changes to the test menu?			
	1. Did the lab notify the State prior to adding a new specialty/subspecialty?			
	2. Request a list of the tests/analytes performed			
	3. Request annual test volumes for all MODERATE and HIGH complexity tests (including PPMP)			
D4068 D4069	K. If a test was discontinued, are procedures/records available for 2 years?			
	L. If a test or new instrumentation was added, are written procedures available?			
D4065	1. Have they been reviewed and approved by the director?			
	a. Signed and dated?			
	2. Have they been reviewed/signed by all testing personnel?			
D4074 D4083	3. Have verification/validation procedures been completed (precision, accuracy, etc.)?			
D2000 D6088	4. Is the lab enrolled in Proficiency Testing (PT) for added tests?			
PERSONNEL				
	A. Are the following personnel qualified by the correct combination of education/training/experience at the appropriate complexity level?			
D6078	Director			
D6135	Clinical Consultant(s)			
D6034	Technical Consultant(s)			
D6111	Technical Supervisor(s)			
D6143	General Supervisor(s)			
D6171	Testing Personnel			
	B. Do the director and technical supervisor(s):			
D6080	1. Remain accessible for consultation as needed?			
	2. Ensure that:			
	a. Delegated duties are properly performed?			
D6082 D6085	b. Test methodologies are appropriate and provide quality patient results?			

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D6086 D6115	c. Verification procedures for each test are adequate to determine performance characteristics, including precision and accuracy (as appropriate)?			
D6093 D6094	d. Quality control and quality assurance programs are established and maintained to assure the quality of laboratory services?			
D6087 D6120	e. Lab personnel are performing the test methods as required to ensure accurate and reliable results?			
	f. The laboratory is enrolled in the PaNEDSS for electronic processing of reportable conditions? For information, go to www.health.state.pa.us			
	C. Does the clinical consultant:			
D6137 D6138	1. Ensure that consultation is available to the facility's clients for proper test ordering?			
D6139	2. Ensure that test result reports contain pertinent information for specific patient interpretation?			
D6140	3. Ensure that consultation is available to clients for interpretation of test results reported?			
D6145	D. Is there a general supervisor present during all hours of patient testing and do they:			
D6147	1. Remain accessible?			
D6148	2. Monitor testing to ensure that test performance is at an acceptable level?			
	3. As delegated by the director or technical supervisors:			
D6149	a. Ensure that corrective action is taken when test systems deviate from the lab's performance specifications?			
D6150	b. Ensure that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly?			
D6151	c. Provide orientation to all testing personnel?			
D6151	d. Annually evaluate and document the competency of all testing personnel?			
	E. Are personnel records current and do they contain:			

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D6107	1. A written job description?			
D6102	2. Education/training documents?			
D6103	3. Evaluation/competency reports?			
FACILITIES AND SAFETY				
D4012 D4016 D4017	A. Are the space, ventilation, and utilities adequate and well maintained for all phases of patient testing?			
D4018	B. Safety procedures:			
	1. Does the lab have a written plan to protect its employees from chemical hazards in the lab?			
	2. Are personnel made aware of the hazardous chemicals in the lab (MSDS sheets)?			
	3. Does the lab have a written plan to protect its employees from infectious agents and from those specimens generally considered to be infectious, such as those identified in the federal Bloodborne Pathogens Standard?			
	4. Are employees advised of their right to have blood of a patient tested in the event they have significant exposure to that blood (Act 148)?			
	5. Are basic electrical/fire/physical safety practices followed?			
	6. Are employees trained in appropriate procedures and practices prior to working with hazardous chemicals and/or infectious agents? Is the training documented?			
	7. Are infectious and hazardous wastes handled and disposed of according to DER regulations?			
PATIENT TEST MANAGEMENT				
	A. Does the lab maintain and follow a current client service manual from each reference lab used?			
	1. Which reference lab(s) are used?			
	2. Does the lab have a mechanism to track which specimens are still pending from their reference lab(s)?			

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	B. Does the laboratory have and follow a procedure manual that includes written instructions for:			
D3000	1. Patient identification?			
D3001	2. Patient preparation?			
D3004	3. Specimen collection?			
D3007	4. Specimen labeling?			
D3010	5. Specimen preservation?			
D3013	6. Specimen transport?			
D3014	7. Specimen processing?			
	C. Does the lab supply a current client service manual (if acting as a reference lab)?			
	1. If the laboratory is located within a hospital, is a manual distributed to all specimen-collecting areas within the hospital?			
	D. Does the laboratory offer courier services to its clients?			
	1. If yes, does the lab have a written courier policy?			
	2. Does the lab supply lock boxes to its clients?			
D3010 D3013	3. Does the laboratory supply instructions for the use of the lock boxes (kept locked, location, specimen preservation, etc.)?			
D3000	E. Does the laboratory have a written policy for specimen receiving and accessioning?			
	1. Are there written criteria for specimen rejection (e.g. specimen received unlabelled, QNS, wrong tubes)?			
D3017	F. Are all specimens accompanied by a written requisition?			
D3018	1. If verbal orders are accepted, does the lab attempt to obtain written or electronic authorization within 30 days? attempts to obtain confirmation documented?			
	2. Are requests for testing accepted only from a licensed practitioner of the healing arts, or other person authorized by statute?			
	G. Do test requisitions include the following information:			
D3022	1. Patient name or other unique identifier?			
D3023	2. Name and address of person ordering the test?			
D3024	3. Test(s) ordered?			

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D3025	4. Date of collection (and time of collection, if applicable)?			
D3029	5. Other pertinent information?			
D3029	6. Patient age/sex where applicable?			
	H. Do test records include the following information:			
D3037	1. Patient name or unique identifier?			
D3038	2. Date and time specimen was received?			
D3040	3. Reason for specimen rejection?			
D3041	4. The date the test was performed?			
D3042	5. Identity of personnel performing the test(s)?			
	a. If multiple tests have the same lab accession number, is the testing person identified for each test?			
	b. Is the testing person identified for POC testing?			
	I. Do test reports include the following information:			
D3056	1. Name and address of lab performing the test(s)?			
D3056	2. Test result with unit of measure?			
D3061	3. Reason for specimen rejection, if applicable?			
D3062	4. Reference or normal ranges?			
	a. If no, how is this information made available to clinicians?			
	J. Does the laboratory have a written policy for reporting:			
D3063	1. Routine test results?			
D3064	2. Critical values?			
	a. Are phoned “panic” or critical reports documented?			
D4002 D4054	3. Test results that are outside the reportable range established by the lab?			
	4. Communicable and noncommunicable diseases to the appropriate agency?			
	K. Does the test reporting system ensure that patient results are reported:			
D3050	1. In a timely, accurate, and reliable manner?			
	a. Does the lab have a policy for notifying clinicians when testing is delayed?			

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	b. Does the lab have a mechanism to track which tests are still pending?			
D3054	L. Does the reporting system ensure receipt of results by only the authorized person(s)?			
D3034	M. Does the laboratory keep all records/reports for at least 2 years (including instrument print-outs and reference lab reports)?			
	Immunochemistry 5 years? Cytology slides 5 years? Bone marrow slides 10 years? Histopathology Slides 10 years? Blocks 2 years? Tissue Until examined and diagnosis made?			
D6031 D6106	N. Is a procedure manual available to testing personnel at all times of testing?			
D4065	O. Did the director review, sign and date the procedure manual?			
	P. If the laboratory tests for creatinine, does it calculate and report the glomerular filtration rate?			
LABORATORY COMPUTER SERVICES				
	A. Does the laboratory utilize a Laboratory Information System (LIS)?			
D6106	1. If yes, are procedures for computer use available?			
D6102	2. Have the individuals who use the system been properly trained in the use of the system? Documented?			
	3. Is there a list of individuals who may have access to computer files?			
D3054 D3063	4. Is there a mechanism in place to prevent unauthorized access to patient sensitive data?			
	5. Is there a system in place protecting access codes?			
D3050	B. How does the laboratory determine if a new or revised LIS program performs acceptably before it is integrated into routine operation?			

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	1. Does the laboratory have a mechanism to maintain patient identity throughout the entire testing process (Is there a mechanism to link the patient identifier to test run, specimen analyzer position)?				
	2. Are all test results verified prior to release?				
D3050	3. Is there a mechanism in place to periodically verify that patient test results are received by the ordering physician as transmitted by the lab performing the test?				
	4. Are corrected results specified as such on all reports?				
	5. Is there a mechanism to identify the individuals entering patient data?				
	C. Does the laboratory have a back-up system when the LIS is down?				
	1. Are there written procedures to follow if the LIS becomes inoperable?				
	2. Are there procedures in place to preserve the data in the event of a software failure, hardware failure, or fire?				
	3. Are there procedures to ensure data integrity during computer down-time?				
	D. Does the lab perform maintenance procedures according to manufacturer's instructions (for modems, printers, monitors)?				
	E. Electronic storage of lab requisitions:				
	1. Can the lab assure that the data has not been altered and is retrievable for up to 2 years?				
	F. Electronic storage of lab results:				
	1. If lab results are stored in a computer system after being visually scanned, is there a mechanism to prevent altering of results?				
	2. Are results retrievable after 2 years? Immunohematology 5 years? Histopathology 10 years?				
PROFICIENCY TESTING					
D2000	A. Is the lab enrolled in PT for all specialties/subspecialties?				

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	B. Which program or programs is the lab enrolled in?			
	1. Is the lab releasing PT results to the State agency?			
	C. For regulated analytes , if the same test is performed at different sites under common direction, is PT performed at each site?			
D7043	1. If no, does the lab verify the accuracy at each site at least twice a year? Documented?			
D7047	D. Does the lab evaluate tests for which no PT is performed (unregulated analytes) at least once every 6 months?			
	1. Is the evaluation reviewed by the director or designee? Documented?			
	E. Are State PT requirements met?			
	F. Are there written instructions to staff:			
D2006 D2007	1. To test PT samples exactly the same as patient samples (with the regular workload by staff who routinely perform that testing and using the facility's routine test method)?			
D2011	2. Prohibiting discussion of PT results with any other laboratory?			
D2013	3. Prohibiting sending PT samples out for testing?			
	G. Do personnel follow these procedures?			
D2015	H. Does the lab maintain a copy of the signed attestation statement?			
D6018 D6091	I. Are all proficiency testing reports reviewed and signed by the director or another qualified person? Documented?			

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
	<u>Proficiency Testing Performance</u> ___ Bacteriology ___ Syphilis Serology ___ Mycobacteriology ___ General Immunology ___ Mycology ___ Parasitology ___ Routine Chemistry ___ Virology ___ Urinalysis ___ Endocrinology ___ Hematology ___ Toxicology ___ Immunohematology			
D2128 D2129	J. Is corrective action taken for unsatisfactory or unsuccessful PT results? Documented?			
	1. Does the lab review patient testing performed at the time of the PT failure to determine any negative impact the reason for failure had on the accuracy of patient testing?			
	a. Is corrective action taken? Documented?			
QUALITY ASSURANCE				
D7001	A. Does the laboratory have a complete written quality assurance policy that addresses each section of the laboratory?			
	1. Is compliance monitored?			
	2. Are all monitoring activities (quality control, proficiency testing, instrument calibrations, function checks, competency reviews, etc.) documented?			
	3. Are all instances when a monitoring activity shows a deficiency or unexpected result investigated and the results of the investigation documented?			
	Personnel Assessment:			
D6031 D6103	1. Does the laboratory have a policy and procedure for assuring employee competence at least annually?			
	a. Documented?			
D7055	b. Is this consistent with the QA policy			
	Communications:			

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D7057 D7058	1. Does the laboratory have a system for communicating new procedures, changes in procedures, and problems encountered to both the medical and lab staffs?			
	a. Is this system regularly reviewed?			
	Complaints:			
D7059	1. Does the laboratory have a system to document complaints reported to the laboratory?			
D7060	2. Are complaints investigated, when appropriate?			
	3. Is corrective action taken? Documented?			
	Quality Assurance Review with Staff:			
D7062	1. Does the laboratory have a system to review QA findings with staff?			
	Quality Assurance Records:			
D7066	1. Are quality assurance records maintained for 2 years?			
D7067	2. Are records available for review?			