



HEMATOLOGY 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:			
REPEAT DEFICIENCIES:			

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
PROFICIENCY TESTING				
	A. Which program is the laboratory enrolled in?			
D2000	B. Is the lab enrolled for all regulated analytes (including waived tests for State purposes)?			
	<u>REGULATED ANALYTES:</u> Cell ID or WBC Differential RBC Count WBC Count Platelet Count Hemoglobin Hematocrit (excluding spun microhematocrit) Fibrinogen PT APTT			
D2006	C. Are PT specimens handled like patient specimens?			
	1. Do reagents or kits used for PT match those used for patient testing?			
D2007	2. Are PT samples integrated within the routine workload and analyzed by personnel who routinely test patient samples?			
D2128 D2129	D. Is corrective action taken for unsatisfactory or unsuccessful PT results?			

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
	<p>Unsatisfactory (one of the following):</p> <ol style="list-style-type: none"> 1. Unacceptable analyte score 2. Unsatisfactory PT event or overall score for a subspecialty or specialty 3. Failure to participate in a testing event 4. Failure to return PT results within the time frames specified by the PT program 			
	<p>Unsuccessful (one of the following):</p> <ol style="list-style-type: none"> 1. Unsatisfactory performance for the same analyte or test in two or two out of three consecutive testing events 2. Unsatisfactory performance of a PT testing event or overall score for a specialty or subspecialty in two or two out of three consecutive testing events 			
D6092	1. Is corrective action documented?			
D6018 D6091	E. Are PT results reviewed by and discussed with the director? Documented?			
D7047	F. How are tests for which no PT is available evaluated every 6 months? Documented?			
	G. Does the laboratory perform the same tests at more than one location or by more than one method?			
D7043	1. If yes, do they compare test results at least twice a year? Documented?			
PATIENT TEST MANAGEMENT				
	A. Does the laboratory have and follow a procedure manual that includes written instructions for:			

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
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?			
	B. Do test records include the following information:			
D3037	1. Patient name or unique identifier?			
D3038	2. Date and time specimen was collected/received?			
D3040	3. Reason for specimen rejection?			
D3041	4. Date of test performance?			
D3043	5. Identity of personnel performing the test(s)?			
D3062	C. Are reference or normal ranges available to the person(s) using the test results?			
	D. Does the laboratory have a written procedure for:			
D3063	1. Reporting routine test results?			
D3064	2. Reporting critical values?			
D4002 D4054	3. Reporting test results when they exceed the reportable range established by the lab?			

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
	E. Does the test reporting system ensure that patient results are reported:			
D3050	1. In a timely, accurate, and reliable manner?			
D3054	2. In a confidential manner?			
D3034	F. Does the laboratory keep all records/reports for at least 2 years? (Including instrument print-outs and reference lab reports)			
D6031 D6106	G. Is a procedure manual available to testing personnel at all times of testing?			
	H. Does the procedure manual contain:			
D4046 D4048	1. Patient preparation, specimen collection and processing, including criteria for specimen rejection?			
D4049	2. Microscopic exam procedures (differential, semen analysis, blood parasites)?			
D4050	3. Step-by-step procedure with calculations and interpretations of results?			
D4051	4. Preparation/storage of materials used for testing?			
D4052	5. Calibration and calibration verification?			
D4054	6. Reportable ranges?			
D4055	7. Control procedures?			
D4056	8. Remedial action when QC is unacceptable?			

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
D4057	9. Limitations, including interfering substances?			
D4058	10. Normal ranges?			
D4059	11. Panic values?			
D4060	12. References?			
D4061	13. Specimen storage and preservation?			
D4062	14. System for reporting patient results (including protocol for reporting critical values)?			
D4063	15. What to do if test system is inoperable?			
D4064	16. Criteria for specimen referral?			
	NOTE: Manual must contain methods in use and all revisions (package inserts must be the most recent available)			
D4068 D4069	I. If a test was discontinued, are procedures available for 2 years?			
D4066 D4067	J. If a test was added, has the procedure been reviewed and approved by the director?			
D4065	K. Did the director review, sign, and date the procedure manual?			
AUTOMATED CBC SYSTEMS				
D4043	A. Is the procedure manual complete?			
	Instrument used: Back-up instrument:			

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
D4074	B. If the lab has added tests or has new instruments, are verification procedures complete?			
D4101	C. Are manufacturer's calibration procedures being followed?			
D4095	D. Is a background count performed each day of testing? Documented?			
D4084	E. Are electronic checks performed as per manufacturer's recommendations?			
D3050	F. Are CBC's run within 24 hours of collection?			
D3014 D4001	1. Are all blood specimens collected in anticoagulant mixed thoroughly before analysis?			
D3040	2. Are CBC specimens checked for clots (visual, applicator stick, autoanalyzer histogram) before reporting results?			
D4057	G. Are criteria established for CBC parameters which warrant further investigation? (repeat and verify, manual differential)			
D4057	H. Is there a procedure for detecting nucleated RBC's and correcting automated WBC counts when they are present?			
D3014 D3061	I. Are CBC specimens checked for lipemia or hemolysis before reporting results? Identified on report?			
D6014 D6087	1. Is there a written procedure to detect other misleading CBC instrument results that may be clinically significant (e.g. rouleaux, giant platelets, platelet clumps)?			
	J. Quality Control:			

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
D4300	1. Are at least one normal and one abnormal control material run each eight hour shift (or at the frequency specified by the manufacturer, if more stringent)?			
D4055	2. Is an acceptable QC protocol defined? (Westgard)			
D4182	3. Do QC records contain:			
	a. Date material run?			
	b. All control results, whether in range or not?			
	c. Ranges of acceptable control values?			
	d. Documentation of corrective action?			
	e. Indication of date of opening?			
	f. Expirations and lot numbers?			
D7033	4. Does the laboratory perform QC review?			
	a. Is documentation available?			
D4025	J. Are temperatures checked daily as needed? Documented?			
D4084	K. Are maintenance/function checks performed as per manufacturer's specifications? Documented?			
MANUAL CELL COUNTS				
	A. Are manual cell counts performed? (WBC, RBC, PLTS, Retics, body fluid cell counts) If yes:			

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
D4043	1. Is the procedure manual complete?			
D4084 D4090	2. Are the counting chamber, pipettes, and microscope in satisfactory working order?			
D3007 D4298	3. Are samples collected in capillary tubes obtained in duplicate whenever possible and adequately labeled with patient identification information throughout the analytical process? (Micro specimen containers need <u>not</u> be collected in duplicate)			
D4298	4. Are all manual cell counts using a hemocytometer (e.g. synovial fluids, CSF, semen) performed in duplicate?			
	a. Counting 2 hemocytometer chambers from one dilution satisfies this requirement.			
D4298	3. Is one control, assayed or procedural, performed every 8 hours?			
	a. Procedural Control:			

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
	<p>1. Duplicate dilutions of an assayed control or a previously assayed patient specimen. These may be assayed by the same individual or by different people and the results compared to previously defined acceptable limits for differences between duplicates.</p> <p>NOTE: This is the only acceptable procedural control for manual RBC counts</p>			
	<p>2. WBC and platelet counts may be compared with a value estimated from a blood smear.</p>			
D4182	<p>4. Is all QC documented?</p>			
D7033	<p>5. Does the lab perform QC review? Documented?</p>			
MICROSCOPIC EXAM PROCEDURES				
	<p>A. Manual Differential Smears:</p>			
D4043	<p>1. Is the procedure manual complete?</p>			
D4049	<p>2. Are the smear and staining procedures for differential leukocyte counts acceptable?</p>			
D3014	<p>3. Are all slides adequately identified?</p>			
D4049	<p>4. Are there written criteria for review of abnormal smears by a qualified person?</p>			

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS	
	B. Semen Analysis:				
	1. What is the extent of the analysis? _____ presence or absence _____ motility _____ count _____ morphology _____ other				
D4043	2. Is the procedure manual complete?				
	3. Are controls performed and documented?				
	4. Does the lab participate in a PT program for semen analysis?				
D7047	a. If no, how does the laboratory evaluate the accuracy of the procedure at least once every 6 months? Documented?				
	C. Blood Parasites:				
D4043	1. Is the procedure manual complete?				
	2. Are controls performed and documented?				
HEMOGLOBINOPATHIES					
	A. Are solubility or monoclonal antibody tests for sickling hemoglobin performed? If yes:				
D4043	1. Is procedure manual complete?				
D4006 D4300	2. Are a positive and a negative control run each 8 hour shift?				

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
D4182	a. Are all QC results documented?			
	B. Does the laboratory test for other hemoglobinopathies?			
D4043	1. Is the procedure manual complete?			
COAGULATION				
	A. PT/APTT:			
D4043	1. Is the procedure manual complete?			
D3004 D3010 D3013	a. Are special handling requirements for coagulation tests defined and followed (proper anticoagulant, specimen transportation/storage, temperature requirements)?			
	Instrument used: back-up instrument:			
D4074	2. If the lab has added tests or has new instruments, are verification procedures complete?			
D4308	3. Are all manual PT and APTT tests run and recorded in duplicate? (automated tests must be run in duplicate only if required by the manufacturer)?			
D4055 D4150	4. Are there written criteria for acceptable differences between duplicate values?			

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
	5. How is the Prothrombin Time reported: ___ seconds ___ % (percent) ___ INR ___ seconds and INR			
D-TAGS	REQUIREMENTS	QA	DOC	
	B. Quality Control:			
D4302 D4305	1. Are both a normal and an abnormal control material run each eight hour shift and with each change of reagents (or at the frequency specified by the manufacturer, if more stringent)?			
	a. If electronic controls are available from the manufacturer:			
	1. Does the laboratory run 1 electronic control plus one external liquid control each eight hour shift? OR			
	2. Does the laboratory run 2 electronic controls each eight hour shift?			
	NOTE: If electronic controls are used for daily QC, the laboratory must run 2 levels of external liquid control each week of testing and with each change of reagent lot. (STATE)			
D4182	2. Do QC records contain:			
	a. Date material run?			

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
	b. All control results, whether in range or not?			
	c. Ranges of acceptable control values?			
	d. Documentation of corrective action?			
	e. Indication of date of opening?			
	f. Expirations and lot numbers?			
D7033	3. Does the laboratory perform QC review?			
	a. Is documentation available?			
D4025	C. Are temperatures checked daily as needed? Documented?			
	1. Are PT/APTT's performed at 37 C?			
D4084	D. Are maintenance/function checks performed as per manufacturer's specifications? Documented?			
	E. Factor Assays:			
	1. If factor assays are performed, is a standard curve generated for each lot number or shipment?			
	2. Are at least three points included in each run? The points may be standards or controls but must cover the analytical range.			
PERSONNEL ASSESSMENT				
D6030 D6102	A. Have all personnel received appropriate training prior to testing patient specimens? Documented?			

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
	1. If a computer system (LIS) is used in the lab, have individuals been properly trained in the use of the system? Documented?			
D6031 D6103	A. Does the laboratory have a policy and procedure for assuring personnel competence?			
	1. Documented?			
QUALITY ASSURANCE				
D7001	A. Does the laboratory have a written quality assurance policy and conduct periodic quality assurance reviews?			
D7062 D7065	1. Does the laboratory utilize the data obtained from the quality assurance reviews to identify problems and improve lab performance?			