

IMMUNOLOGY 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			

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS								
ADMINISTRATIVE												
	A. What is the extent of services provided?											
	1. Syphilis Serology?	Y	N									
	2. General Immunology?	Y	N									
	B. Have there been any changes to the test menu (new test, instrument, or analyte put into use after April 24, 2003)?	Y	N									
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th data-bbox="367 378 569 410"><u>New Test</u></th> <th data-bbox="569 378 869 410"><u>Instrument/Kit</u></th> <th data-bbox="869 378 1079 410"><u>Complexity</u></th> <th data-bbox="1079 378 1281 410"><u>Volume</u></th> </tr> </thead> <tbody> <tr> <td style="height: 150px;"></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	<u>New Test</u>	<u>Instrument/Kit</u>	<u>Complexity</u>	<u>Volume</u>							
<u>New Test</u>	<u>Instrument/Kit</u>	<u>Complexity</u>	<u>Volume</u>									
	1. Did the lab notify the state prior to adding tests?	Y	N									
	2. Did the lab verify performance specifications (accuracy, precision, reportable range, and normal values for patient populations) for any test system put into use after April 24, 2003?	Y	N									
	3. Did the director review, sign, and date procedures and changes in procedures before use?	Y	N									
	4. Have testing personnel received appropriate training prior to testing patients' specimens? Documented?	Y	N									
	5. Has the lab enrolled in a proficiency testing program for all added tests?	Y	N									
FACILITY ADMINISTRATION												
	A. Are space, ventilation, utilities, and safety protocols adequate for performing all phases of patient testing?	Y	N									
	B. Does the lab have appropriate and sufficient equipment, reagents, and supplies for the type and volume of testing performed?	Y	N									
	C. Are all temperature-controlled areas and equipment monitored daily as needed? Documented?	Y	N									

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
	D. Does the lab retain the following records for at least 2 years:			
	1. Test procedures after they have been discontinued?	Y	N	
	2. Quality control and calibration records?	Y	N	
	3. Patient test records (including instrument printouts, unless the instrument is directly interfaced with an LIS)?	Y	N	
	4. Maintenance logs?	Y	N	
	5. Test/instrument verification studies (maintained for the life of the instrument, but not less than 2 years)?	Y	N	
PERSONNEL ASSESSMENT				
	A. Do all new testing personnel receive appropriate training prior to testing patients' specimens? Documented?	Y	N	
	B. Does the lab follow written policies and procedures to assess employee competency?	Y	N	
	1. Are competency assessments performed semi-annually during the first year and annually thereafter? Documented?	Y	N	
ANALYTIC SYSTEMS				
	A. Does the laboratory have and follow a written procedure manual, operator's guide, or package insert for all tests performed?	Y	N	
	1. Are procedures available to testing personnel in the work area?	Y	N	
	B. Is there documentation of an annual review of procedures by the director or a designee?	Y	N	
	1. Has the procedure manual been reviewed/signed by all testing personnel?	Y	N	
	C. Does the procedure manual contain:			
	1. Step-by-step procedure with calculations and interpretations of results?	Y	N	
	2. Preparation/storage of materials used for testing?	Y	N	
	3. Calibration and calibration verification?	Y	N	
	4. Reportable ranges?	Y	N	
	5. Control procedures?	Y	N	

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
	6. Corrective action that must be taken if calibration or control results fail to meet the lab's criteria for acceptability?	Y	N	
	7. Limitations, including interfering substances?	Y	N	
	8. Normal ranges?	Y	N	
	9. Panic values?	Y	N	
	10. References?	Y	N	
	11. The lab's system for reporting patient results, including the protocol for reporting a panic value?	Y	N	
	a. Does the manual include procedures for reporting communicable and noncommunicable diseases to the appropriate state agency?	Y	N	
	Is the lab enrolled in PA NEDSS for electronic processing of reportable conditions? (For additional information, go to www.health.state.pa.us)	Y	N	
	12. What to do if the test system is inoperable?	Y	N	
	13. Specimen storage and preservation?	Y	N	
	a. How long are specimens held before testing?			
	b. Is there a procedure defining specimen preservation for all tests when analysis is to be delayed?	Y	N	
	14. Criteria for specimen referral?	Y	N	
	D. Do test records include the following information:			
	1. Patient name or unique identifier?	Y	N	
	2. Date and time specimen was collected/received?	Y	N	
	3. Reason for specimen rejection?	Y	N	
	4. Date of test performance?	Y	N	
	5. Identity of the personnel performing the test(s)?	Y	N	
	E. If the lab performs the same test using different methodologies or instruments, is there a system in place that evaluates and defines the relationship between the methods at least twice a year?	Y	N	
	F. Does the lab have a policy that establishes values at which a test must be repeated and verified?	Y	N	

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
SYPHILIS SEROLOGY				
	A. RPR (18 mm) Circle Card Test:			
	Test System Used:			
	Control Material Used:			
	1. Are controls run each day of testing (Controls must include reactive, minimally reactive, and non-reactive materials)?	Y	N	
	2. Do quality control records contain:			
	a. The date the controls were run?	Y	N	
	b. All control results, whether acceptable or not?	Y	N	
	c. Expected control results?	Y	N	
	d. Documentation of corrective action?	Y	N	
	e. Indication of date of opening for kits, reagents, and controls?	Y	N	
	f. Expiration dates and lot numbers of kits, reagents and controls? (Note: Kits, reagents, and controls must not be used when they have exceeded their expiration date)	Y	N	
	3. Does the laboratory follow the instructions provided by the manufacturer for the following parameters:			
	a. Antigen delivery needle checks?	Y	N	
	b. Room incubation temperature?	Y	N	
	c. Rotator speed?	Y	N	
	d. Incubation time?	Y	N	
	4. Does the lab perform Quality Control assessment (QC review)? Documented?	Y	N	
GENERAL IMMUNOLOGY				
	A. Waived Test Kits:			
	1. Waived Test Kits Used:			

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
	2. For waived test kits, does the lab follow manufacturer's quality control instructions?	Y	N	
	3. Do quality control records contain:			
	a. The date the controls were run?	Y	N	
	b. All control results, whether acceptable or not (including internal controls)?	Y	N	
	c. Expected control results?	Y	N	
	d. Documentation of corrective action?	Y	N	
	e. Indication for date of opening for kits, reagents, and controls?	Y	N	
	f. Expiration dates and lot numbers of kits, reagents, and controls? (Note: Kits, reagents, and controls must not be used when they have exceeded their expiration date)	Y	N	
	4. Does the lab perform quality control assessment (QC review)? Documented?	Y	N	
	B. Non-Waived Test Kits:			
	1. Non-Waived Test Kits Used:			
	2. For non-waived test kits, are a positive and a negative external control run each day of testing and with each new lot (or at the frequency specified by the manufacturer, if more stringent)?	Y	N	

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
	3. For tests in which patient results are reported in terms of graded reactivity, e.g., 1+, 2+, minimally reactive, are controls of graded reactivity used?	Y	N	
	4. For tests in which patient results are reported as a titer, are controls of known titer used?	Y	N	
	<p>Equivalent Quality Control (EQC) Option:</p> <p>For test systems with internal/procedural controls, the lab may perform an evaluation process using positive and negative external controls for 30 consecutive days to determine the stability of the system. If all quality control results are acceptable, the lab may choose to reduce the frequency of performing external controls from daily to weekly.</p> <p>If the lab chooses to use the EQC Option, the lab must perform a positive and a negative external control each week of testing (and document internal procedural controls each day of testing).</p> <p>If weekly QC fails, the lab must determine if patient test results have been adversely affected and must repeat the evaluation process.</p>			
	5. Do quality control records contain:			
	a. The date the controls were run?	Y	N	
	b. All control results, whether acceptable or not?	Y	N	
	c. Expected control results?	Y	N	
	d. Documentation of corrective action?	Y	N	
	e. Indication of date of opening for kits, reagents, and controls?	Y	N	
	f. Expiration dates and lot numbers of kits, reagents and controls? (Note: Kits, reagents, and controls must not be used when they have exceeded their expiration date)	Y	N	
	6. Does the lab perform Quality Control assessment (QC review)? Documented?	Y	N	
	7. Does the lab perform equipment function checks (e.g. rotators, pipettes) as required? Documented?	Y	N	

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS	
	C. Instrumentation:	INSTRUMENT			
	1. Name of Analyzer:				
	2. Test(s) Performed:				
	3. Are manufacturer's calibration procedures being followed?				
	4. Are calibration verification procedures being performed according to manufacturer's instructions, but at least every 6 months at a minimal or zero value, a mid point value, and a maximum value near the upper limit of the reportable range? (Note: Calibration verification must also be performed if there is a complete change of reagents, there is major maintenance or replacement of critical parts, or if controls show a shift or trend)				
	5. Is there a mechanism to link the patient to test run and analyzer position?				
	6. If the analyzer is on-line with an LIS, are results verified prior to release?				

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS	
	C. Instrumentation (Continued):	INSTRUMENT			
	7. Are at least 2 levels of control material run each day of testing (or at the frequency specified by the manufacturer, if more stringent)?				
	8. Do all operators who perform testing perform quality control periodically?				
	9. Do quality control records contain:				
	a. The date the controls were 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 of reagents, controls, and calibrators?				
	f. Expiration dates and lot numbers of reagents, controls, and calibrators? (Note: Reagents, controls, and calibrators must not be used when they have exceeded their expiration date)				
	10. Is an acceptable QC protocol defined (e.g. Westgard)?				
	11. Does the lab perform Quality Control assessment (QC review)? Documented?				
	12. Are maintenance/function checks performed as per manufacturer's instructions? Documented?				

D-TAGS	REQUIREMENTS	QA	DOC	COMMENTS
MICROSCOPIC EXAMINATIONS				
	A. Does the laboratory perform fluorescent microscopic testing?	Y	N	
	1. Are hours of use of the tungsten lamp recorded?	Y	N	
	2. Is a control read with each batch of fluorescent stained slides?	Y	N	
	3. Are reference materials available to assist in the microscopic identification of fluorescent patterns?	Y	N	
	4. Does the lab have a defined system to ensure that all personnel report microscopic data in a similar fashion?	Y	N	
	B. FTA – ABS TEST:			
	1. Are slides placed in a moist chamber to prevent evaporation during incubation?	Y	N	
	2. Are slides examined within eight hours from cover slipping to reading?	Y	N	
	3. Does the fluorescent microscope contain ordinary sub stage tungsten light source to verify the presence or absence of treponemes?	Y	N	