



MICROBIOLOGY 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			COMMENTS
ADMINISTRATIVE				
	A. What subspecialties of microbiology are performed?			
	1. Bacteriology?			
	Extent of services provided:			
	a. Definitive identification and susceptibility?	Y	N	
	b. Isolation and limited identification, sent to a reference lab for definitive identification?	Y	N	
	c. Growth/no growth, isolation and identification done by a reference lab?	Y	N	
	d. No bacteriology performed, all specimens sent to reference lab?	Y	N	
	2. Mycobacteriology?			
	Extent of services provided:			
	a. Definitive identification with or without susceptibility?	Y	N	
	b. Isolation and limited identification, sent to reference lab for definitive identification?	Y	N	
	c. Direct acid-fast smear and/or inoculation only, isolation and identification done by reference lab?	Y	N	
	d. No mycobacteriology performed, all specimens sent to a reference lab?	Y	N	
	3. Mycology?			
	Extent of services provided:			
	a. Definitive identification with or without susceptibility testing?	Y	N	
	b. Isolation and limited identification, with definitive identification by a reference lab?	Y	N	
	c. Direct specimen exam and isolation of fungus by culture, with identification by reference lab?	Y	N	
	d. No mycology performed, all specimens sent to a reference lab?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	4. Parasitology?			
	Extent of services provided?			
	a. Definitive identification?	Y	N	
	b. Definitive identification of organisms except when fixed, stained, and permanently mounted preps can be made and sent to a reference lab for identification?	Y	N	
	c. Presence of parasites, with referral to a reference lab for taxonomic identification?	Y	N	
	d. No parasitology performed, all specimens sent to a reference lab?	Y	N	
	5. Virology?			
	Extent of services provided:			
	a. Cell culture and viral isolation?	Y	N	
	b. Viral antigen/nucleic acid detection?	Y	N	
	c. Viral serology (antigen or antibody)?	Y	N	
	d. No virology performed, all specimens sent to a reference lab?	Y	N	
	6. Other?			
	B. Have there been any changes to the test menu (new test, instrument, or method put into use after April 24, 2003)?	Y	N	
	<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 population) for any test put into use after April 24, 2003?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	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	
	For Specialty/Subspecialty proficiency testing requirements, see the Administrative Survey Document			
FACILITY ADMINISTRATION				
	A. Are space, ventilation, and safety protocols adequate for performing all phases of patient testing?	Y	N	
	1. Are there policies and procedures for the safe handling and processing of specimens?	Y	N	
	2. Are Biological Safety Cabinets (BSC) available for handling specimens or organisms considered highly contagious by airborne routes?	Y	N	
	3. Are the BSC certified at least annually to ensure that filters are functioning properly and that airflow rates meet specifications?	Y	N	
	4. Are the BSC free of clutter or other items that may affect airflow?	Y	N	
	B. Does the lab have appropriate and sufficient equipment, reagents, and supplies for the type and volume of testing performed?	Y	N	
	1. Are there sufficient incubators available at specified temperature ranges?	Y	N	
	2. Does the laboratory have procedures for handling spills of contaminated materials?	Y	N	
	3. Are bench tops decontaminated daily?	Y	N	
	4. Are there written policies and procedures for the safe handling and processing of specimens?	Y	N	
	C. Are all temperature-controlled areas and equipment monitored daily as needed? Documented?	Y	N	
	1. Are all non-certified thermometers in-use checked against a NIST thermometer?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	2. Are thermometers present in all refrigerators, incubators, water baths, and heat blocks?	Y	N	
	D. Does the lab perform maintenance on equipment as required? Documented?	Y	N	
	1. Does the laboratory have maintenance records for microscopes, centrifuges, incubators, refrigerators, water baths, and autoclaves?	Y	N	
	2. Are pipettes, micro dilutors, and automatic dispensers checked for accuracy before being placed into use and at least every 6 months thereafter (if applicable)?	Y	N	
	E. 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 or as long as the test is performed, 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	
	Are competency assessments performed semi-annually during the first year and annually thereafter? Documented?	Y	N	
ANALYTIC SYSTEMS				
	A. Does the laboratory have a procedure manual available in the work area for each subspecialty and test performed?	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	

D-TAGS	REQUIREMENTS			COMMENTS
	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	
	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 or reference 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. Are criteria established for immediate notification of a physician or other clinical personnel when results are critical? Is the notification documented?	Y	N	
	b. Are preliminary reports generated to provide clinically useful information in a timely manner?	Y	N	
	c. Does the lab 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	
	d. Does the lab submit specimens to the state lab for further testing as mandated (e.g. salmonella, shigella, N. meningitidis, H. influenza, hemorrhagic E. coli)?	Y	N	
	12. What to do if the test system is inoperable?	Y	N	
	13. Specimen storage and preservation?	Y	N	
	a. Are there procedures defining specimen preservation for all tests when analysis is to be delayed?	Y	N	
	14. Criteria for specimen referral?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	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	
BACTERIOLOGY				
	A. MEDIA:			
	1. Is media prepared in-house or purchased?	Y	N	
	2. Is each lot/shipment of media visually inspected by the laboratory for cracked plates or bottles, unequal filling of plates or bottles, freezing, excessive bubbles, and contamination? Documented?	Y	N	
	a. Does the lab keep a record of rejected media?	Y	N	
	3. Is each shipment and/or lot number of media checked with appropriate control organisms for sterility, ability to support growth, and, if applicable, selectivity, and/or inhibition?	Y	N	
	a. Manufacturer's QC is acceptable except for media specified by the NCCLS.			
	4. If in-house QC is performed, does the laboratory maintain reference organisms for adequate verification of the media?	Y	N	
	Media that must be QC'd by the user lab: <ul style="list-style-type: none"> ▪ CAMPY agar, CHOC agar ▪ Media used for the selective isolation of <u>Neisseria</u> ▪ Mueller Hinton media for susceptibility tests ▪ Media commercially prepared and packaged as a unit or a test system consisting of 2 or more different substrates primarily used for microbial ID 			

D-TAGS	REQUIREMENTS			COMMENTS
	5. Do quality control records contain:			
	a. The date the controls were performed?	Y	N	
	b. All control results, whether acceptable or not?	Y	N	
	c. Acceptable control results?	Y	N	
	d. Documentation of corrective action?	Y	N	
	e. Indication of date of opening for media and controls?	Y	N	
	f. Expiration dates and lot numbers of media and controls? (Note: Media 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	
	B. STAINS:			
	1. Are Gram stain reagents checked each week of testing and with each new lot number with a known Gram positive and a known Gram-negative organism?	Y	N	
	2. Are all other stains checked each day of testing and with each new lot number with control materials that include both positive and negative reactivity?	Y	N	
	3. Are all special stains (fluorescent stains) checked with each patient run?	Y	N	
	4. Do quality control records contain:			
	a. The date the controls were performed?	Y	N	
	b. All control results, whether acceptable or not?	Y	N	
	c. Acceptable control results?	Y	N	
	d. Documentation of corrective action?	Y	N	
	e. Indication of date of opening for stains and controls?	Y	N	
	f. Expiration dates and lot numbers of stains and controls? (Note: Stains and controls must not be used when they have exceeded their expiration date)	Y	N	
	5. Does the lab perform Quality Control assessment (QC review)? Documented?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	C. REAGENTS:			
	1. Does the lab check each batch (if prepared in-house), lot number and shipment of reagents and disks when prepared or opened for positive and negative reactivity? (Note: XV discs or strips require only a positive control)	Y	N	
	2. Are beta-lactamase tests performed using methods other than Cefinase™?	Y	N	
	a. If yes, are they checked each day of use with a positive and a negative control?	Y	N	
	3. Are antisera (Salmonella/Shigella, Strep typing reagents) checked with positive and negative controls when prepared or opened, and once ever 6 months?	Y	N	
	a. Are polyvalent antisera tested with at least one organism from each polyvalent group?	Y	N	
	4. Do quality control records contain:			
	a. The date the controls were performed?	Y	N	
	b. All control results, whether acceptable or not?	Y	N	
	c. Acceptable control results?	Y	N	
	d. Documentation of corrective action?	Y	N	
	e. Indication of date of opening for reagents, discs, and controls?	Y	N	
	f. Expiration dates and lot numbers of reagents, discs, and controls? (Note: Reagents, discs, and controls must not be used when they have exceeded their expiration date)	Y	N	
	5. Does the lab perform Quality Control assessment (QC review)? Documented?	Y	N	
	D. SPECIMEN SOURCES/SITES CULTURED:			
	1. Does the procedure manual specify the primary isolation media used for each clinical site/specimen source?	Y	N	
	2. Does the laboratory follow its own procedure manual?	Y	N	
	3. Are the media listed in the procedure manual available for use?	Y	N	
	4. Are all media in-date?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	<u>Blood Cultures:</u>			
	1. What test system is in use for blood cultures?			
	2. Does the laboratory have a procedure for drawing and handling blood cultures (sterile technique)?	Y	N	
	3. Are adequate volumes of blood collected to detect sepsis (at least 20 ml per set for an adult)?	Y	N	
	4. Are the media used for blood cultures acceptable (one aerobic and one anaerobic)?	Y	N	
	5. Are blood cultures held at least 5 days (at 35-37 C)?	Y	N	
	6. Are initial positive results called to the physician immediately?	Y	N	
	<u>CSF Cultures:</u>			
	1. Are CSF cultures processed immediately after receipt in the laboratory?	Y	N	
	2. Are Gram stains routinely performed?	Y	N	
	3. Are positive results reported immediately to the physician?	Y	N	
	4. Is the media used appropriate for the recovery of bacteria expected in this type of specimen?	Y	N	
	5. If antigen detection methods are used, are back-up cultures performed on both positive and negative CSF specimens?	Y	N	
	<u>Respiratory Cultures:</u>			
	1. Is a Gram stain routinely performed on all expectorated sputum to determine the acceptability of the specimen?	Y	N	
	2. Does the media used permit recovery of bacteria (pathogens) expected in this type of specimen?	Y	N	
	<u>Urine Cultures:</u>			
	1. Are colony counts performed?	Y	N	
	2. Do the media used permit the isolation and identification of both Gram positive and Gram-negative bacteria?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	<u>GC Cultures:</u>			
	1. Are all cultures for <u>N. gonorrhoea</u> either inoculated directly or received in a suitable transport medium?	Y	N	
	2. Do the media used and method of incubation (35-37 C in CO ₂) permit the isolation of <u>N. gonorrhoea</u> ?	Y	N	
	3. Are procedures available for the isolation and identification of <u>N. gonorrhoeae</u> from throat cultures when indicated?	Y	N	
	4. Are procedures adequate to recover <u>N. gonorrhoea</u> from anal swabs when requested?	Y	N	
	<u>Stool Cultures:</u>			
	1. Do the media used permit the isolation of enteric pathogens?	Y	N	
	2. Is enrichment broth or selective media used to detect small numbers of enteric pathogens present?	Y	N	
	3. Does the final report list the organisms for which the specimen was cultured? (Note: It is unacceptable to report "No enteric pathogens isolated")	Y	N	
	<u>Wound Cultures:</u>			
	1. Are special procedures available to culture anaerobic organisms when indicated?	Y	N	
	2. Are both aerobic and anaerobic media inoculated with specimens from appropriate sites?	Y	N	
	3. Are anaerobic systems checked for adequacy (e.g. methylene blue strip)? Documented?	Y	N	
	E. KITS AND ID SYSTEMS:			
	1. What ID systems are in-use?			
	2. Are all reagents in-date?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	3. Is the laboratory following manufacturer's instructions for each ID system?	Y	N	
	4. Is each lot/shipment of ID systems checked prior to use with known organisms or reagents sufficient to give a positive and a negative reaction for each component of the kit?	Y	N	
	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 reagents and controls?	Y	N	
	f. Expiration dates and lot numbers of reagents and controls? (Note: 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	
	F. Waived Antigen Detection Test Kits:			
	1. Waived Test Kits Used:			
	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	

D-TAGS	REQUIREMENTS			COMMENTS
	G. Non-Waived Antigen Detection 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	
	<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>			
	3. 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	
	4. Does the lab perform Quality Control assessment (QC review)? Documented?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	H. SUSCEPTIBILITY TESTING:			
	1. Does the lab perform susceptibility testing using the Kirby Bauer method?	Y	N	
	a. Is Mueller Hinton medium used?	Y	N	
	b. Is there a desiccant in the disc dispenser?	Y	N	
	c. Is the turbidity standard in-date (or prepared semi-annually)?	Y	N	
	d. Are discs stored according to manufacturer's recommendations?	Y	N	
	e. After 30-day validation, is disc QC performed each week of testing with <u>S. aureus</u> , <u>E. coli</u> , and <u>Ps. aeruginosa</u> as appropriate?	Y	N	
	f. Is disc QC documented?	Y	N	
	2. Does the lab perform MIC testing?	Y	N	
	a. Methods used:			
	b. Are MIC control organisms appropriate to check the procedure?	Y	N	
	c. Are the MIC's within limits when checked with the appropriate reference organisms?	Y	N	
	3. Do quality control records contain:			
	a. The date the controls were run?	Y	N	
	b. All control results, whether in range or not?	Y	N	
	c. Ranges of acceptable control values?	Y	N	
	d. Documentation of corrective action?	Y	N	
	e. Indication of date of opening for discs?	Y	N	
	f. Expiration dates and lot numbers of discs? (Note: Discs 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	

D-TAGS	REQUIREMENTS			COMMENTS
	I. INSTRUMENT MAINTENANCE:			
	1. Does the laboratory perform instrument maintenance according to manufacturer's instructions?	Y	N	
	2. Is all maintenance documented?	Y	N	
MYCOBACTERIOLOGY				
	A. Specimen Collection and Handling:			
	1. Does the laboratory have written policies and procedures for proper patient preparation, specimen collection, identification, preservation, transportation, and processing?	Y	N	
	2. Does the laboratory system ensure optimum patient specimen integrity and positive identification throughout the total testing process?	Y	N	
	3. Are specimens for mycobacterial culture collected appropriately and transported to the lab without delay?	Y	N	
	a. Are specimens collected and/or received in sealed leak-proof containers?	Y	N	
	b. Does the lab recommend 3 first morning sputum specimens for patients with clinical findings consistent with tuberculosis?	Y	N	
	c. Are specimens delivered promptly to the lab (within 30 minutes of collection, but at least within 1 day of collection)? Specimens must be refrigerated within 1 hour of collection.	Y	N	
	4. Does the laboratory concentrate specimens before smear and culture are performed, if applicable (e.g. Sputum, urine)?	Y	N	
	a. When centrifuging specimens, are sealed screw caps tubes enclosed in sealed centrifuge carriers (double closure system) used to minimize aerosol hazards?	Y	N	
	5. Are mycobacterial cultures maintained at 35 - 37°C?	Y	N	
	B. MEDIA:			
	Mycobacteriology media used:			

D-TAGS	REQUIREMENTS			COMMENTS
	1. Does the laboratory use at least one solid medium?	Y	N	
	2. Is media prepared in-house or purchased?	Y	N	
	3. Is each lot/shipment of media visually inspected by the laboratory for cracked plates or bottles, unequal filling of plates or bottles, freezing, excessive bubbles, and contamination? Documented?	Y	N	
	4. Is each shipment and/or lot number of media checked with positive and negative controls, tested for sterility, ability to support growth, selectivity, and/or inhibition?	Y	N	
	a. Manufacturer's QC is acceptable except for media specified by the NCCLS.			
	5. Is documentation of media QC maintained?	Y	N	
	6. If in-house QC is performed, does the laboratory maintain reference organisms for adequate verification of the media?	Y	N	
	7. Does the laboratory use liquid media?	Y	N	
	a. If yes, what media is used?			
	C. STAINS:			
	Stains used:			
	1. For acid-fast stains (Ziehl-Neelsen, Kinyoun), does the lab perform a positive and a negative control each day of testing?	Y	N	
	2. For fluorescent acid-fast stains, does the lab perform a positive and a negative control each time of use?	Y	N	
	3. Do quality control records contain:			
	a. The date the controls were run?	Y	N	
	b. All 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 stains?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	f. Expiration dates and lot numbers of stains and controls? (Note: Stains 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	
	5. Are AFB stain results reported within 24 hours of specimen receipt by the laboratory?	Y	N	
	D. REAGENTS:			
	1. Are all reagents properly labeled as to contents, concentration, date prepared or received, and/or lot number, date placed in service, and expiration date as appropriate?	Y	N	
	<u>Biochemical Identification Procedures:</u>			
	1. What biochemical procedures are in use for the identification of mycobacteria?	Y	N	
	2. Are differential biochemical tests available for the extent of mycobacterial identification offered?	Y	N	
	3. Are all biochemical tests used checked each day of use with a positive and a negative control? Documented?	Y	N	
	4. If DNA probes are used for mycobacterial identification, are appropriate positive and negative controls tested each day of use? Documented?	Y	N	
	5. For the BACTEC NAP test, does the lab perform a positive and a negative control each week of testing? Documented?	Y	N	
	6. 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 of 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	

D-TAGS	REQUIREMENTS			COMMENTS
	7. Does the lab perform Quality Control assessment (QC review)? Documented?	Y	N	
	E. SUSCEPTIBILITY TESTING:			
	1. Does the lab check each batch of media and each lot number of antimycobacterial agents using an appropriate control organism?	Y	N	
	2. If susceptibility testing of <i>M. tuberculosis</i> is performed, does the lab check the procedure with an appropriate control strain (e.g. MTB H37rv) each week of testing?	Y	N	
	3. Do quality control records contain:			
	a. The date the controls were run?	Y	N	
	b. All control results, whether in range or not?	Y	N	
	c. Ranges of acceptable control values?	Y	N	
	d. Documentation of corrective action?	Y	N	
	e. Indication of date of opening for discs?	Y	N	
	f. Expiration dates and lot numbers of discs? (Note: Discs 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	
	F. REPORTING OF RESULTS:			
	1. Are TB cultures held at least 6 weeks before a negative result is reported?	Y	N	
	2. Does the laboratory retain positive cultures for at least 1 year?	Y	N	
	3. Are positive cultures reported to the appropriate State agency?	Y	N	
	G. SAFETY:			
	1. Does the laboratory have an isolated room for mycobacteriology testing?	Y	N	
	2. Does the laboratory keep lab doors closed when mycobacterial specimens are being processed?	Y	N	
	3. Does the laboratory have a one-pass ventilation system that establishes an airflow pattern moving from clean to the least clean area?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
MYCOLOGY				
	A. MEDIA:			
	1. For mycology specimens from body sites that are usually contaminated, does the laboratory use a medium with added antibiotics?	Y	N	
	2. Are media prepared in-house or purchased?	Y	N	
	3. Is each lot/shipment of media visually inspected by the laboratory for cracked plates or bottles, unequal filling of plates or bottles, freezing, excessive bubbles, and contamination? Documented?	Y	N	
	4. Is each shipment and/or lot number of media checked with positive and negative controls, tested for sterility, ability to support growth, selectivity, and/or inhibition?	Y	N	
	a. In-house QC is acceptable.			
	b. Manufacturer's QC is acceptable except for media that must be QC'd by the end-user, as specified by the NCCLS.			
	Media that must be QC'd by the user lab: ▪ DTM Media			
	B. STAINS:			
	1. Are stains checked with positive and negative controls each day of patient testing (e.g. Acid-fast, giemsa, PAS, Gomori methenamine silver, calcofluor white, India ink)?	Y	N	
	2. Does the lab check each batch, lot number, and shipment of lactophenol cotton blue when prepared or opened for intended reactivity with a control organism (e.g. Aspergillus sp.)?	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?	Y	N	
	c. Expected control results?	Y	N	
	d. Documentation of corrective action?	Y	N	
	e. Indication of date of opening for stains and controls?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	f. Expiration dates and lot numbers of stains and controls? (Note: Stains 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	
	C. REAGENTS:			
	1. Is nitrate assimilation checked each day of use with a peptone control? Documented?	Y	N	
	2. Are all other reagents checked weekly with a positive control? Documented?	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?	Y	N	
	c. Expected control results?	Y	N	
	d. Documentation of corrective action?	Y	N	
	e. Indication of date of opening for reagents and controls?	Y	N	
	f. Expiration dates and lot numbers of reagents and controls? (Note: 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	
	E. REPORTING OF RESULTS:			
	1. Are cultures held at least 3 weeks before reporting out a negative result?	Y	N	
	2. Are incubation temperatures defined and followed?	Y	N	
	3. If cultures are incubated at room temperature, is the ambient temperature monitored daily as required?	Y	N	
	F. SAFETY:			
	1. Are appropriate safety precautions taken to prevent the accidental opening of a plate (e.g. taping lid to plate)?	Y	N	
	2. When working with a colony exhibiting mycelial growth, are transfers performed within a biological safety cabinet?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	3. Is the use of slide-culture techniques limited to work with low virulence organisms; or if used for dimorphic fungi, are special safety precautions defined and rigidly adhered to?	Y	N	
	4. When preparing teased preps, are mycelia always submerged in some liquid medium (e.g. Lactophenol cotton blue)?	Y	N	
	5. Does the biological safety cabinet meet the minimum requirements for mycologic work?	Y	N	
PARASITOLOGY				
	A. PROCEDURE:			
	1. For labs doing definitive ID, does the complete exam include a direct microscopic exam, a direct macroscopic exam, and a concentration procedure?	Y	N	
	2. Does the laboratory make and read a permanent stained smear?	Y	N	
	3. Does the examination of liquid stools include a direct wet mount if submitted fresh?	Y	N	
	4. Are specimens examined immediately if not stored in PVA or formalin?	Y	N	
	B. STAINS:			
	1. Are all permanent stains checked each month of use with a fecal control that will demonstrate staining characteristics?	Y	N	
	2. Are stains that are used to detect specific parasites checked with appropriate control organisms each time the stain is used?	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?	Y	N	
	c. Expected control results?	Y	N	
	d. Documentation of corrective action?	Y	N	
	e. Indication of date of opening for stains and controls?	Y	N	
	f. Expiration dates and lot numbers of stains and controls? (Note: Stains and controls must not be used when they have exceeded their expiration date)	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	4. Does the lab perform Quality Control assessment (QC review)? Documented?	Y	N	
	E. BLOOD TEST FOR MALARIA:			
	1. Are both thick and thin films made to provide a thorough exam for malarial parasites?	Y	N	
	2. Are an adequate number of fields examined under oil immersion (300 fields)?	Y	N	
	3. Are results of initially positive smears reported to the physician immediately?	Y	N	
	F. SAFETY:			
	1. Are opened containers of ether or ethyl acetate stored on an open shelf in the smallest container possible?	Y	N	
VIROLOGY				
	A. LAB REQUISITION:			
	1. Does the test requisition include the following information important for the determination and selection of the proper host system:			
	a. Clinical symptoms of the patient?	Y	N	
	b. Age of the patient?	Y	N	
	c. Source of the specimen?	Y	N	
	d. Date of onset of clinical symptoms?	Y	N	
	e. Recent travel information of the patient?	Y	N	
	f. Tests requested by clinician?	Y	N	
	g. Date of specimen collection?	Y	N	
	B. SPECIMEN HANDLING AND PREPARATION:			
	1. Are specimens stored properly until work is begun?	Y	N	
	2. Are specimens for viral isolation treated with antibiotics?	Y	N	
	3. Is the pH of the specimen checked (near 7.2) prior to inoculation into cell culture?	Y	N	
	4. Are diluents checked for sterility and pH?	Y	N	
	C. MEDIA:			
	1. Is each component of cell culture media checked for sterility using bacterial culture techniques?	Y	N	
	2. Is fetal bovine serum checked for toxicity using cell culture systems?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	3. Are continuous cell lines checked for mycoplasma contamination?	Y	N	
	4. Does the laboratory have the appropriate minimal cell lines available for all virology testing performed?	Y	N	
	D. CULTURE TECHNIQUES:			
	1. How does the laboratory determine the specific cell culture to be used as the host system?	Y	N	
	2. Prior to the inoculation of the cell cultures, does the lab check the cell culture system for:	Y	N	
	a. The age of the cell culture monolayer (no more than 7-10 days post "seeding")?	Y	N	
	b. Maintenance media that is free from inhibitory substances?	Y	N	
	c. Sterility (visual observation for turbidity)?	Y	N	
	3. How many tubes from each cell line used are held as uninoculated controls?			
	4. How does the laboratory rule out <u>Clostridium difficile</u> toxin in those cell cultures in which the patient specimen exhibits non-specific effects unrelated to CPE?			
	5. Are tube monolayer cultures incubated for a sufficient time to recover the viruses for which service is offered?	Y	N	
	<u>Recommended times:</u> Herpes simplex (genital) 5 days Herpes simplex (other) 7 days Respiratory viruses 10 days Other viruses 14 days			
	6. Are inoculated cultures checked for cytopathic effect (CPE) at a frequency that optimizes the time to detect viral pathogens? (e.g. At least every other working day during the first 2 weeks of incubation)	Y	N	
	7. If presumptive reports are issued based on CPE, how does the laboratory confirm the identification reported?			

D-TAGS	REQUIREMENTS			COMMENTS
	<u>Direct Antigen Tests:</u>			
	1. For waived test kits, does the lab follow manufacturer's quality control instructions?	Y	N	
	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)? See EQC Option (Page 13)	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?	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	
	4. Does the lab perform Quality Control assessment (QC review)? Documented?	Y	N	
	<u>Neutralization Tests:</u>			
	1. If isolate identification in cell culture with specific immune anti-sera is performed, does the lab standardize its dilution of the viral isolate and control virus to the appropriate Tissue Culture Dose ₅₀ (TCD ₅₀), or equivalent, each time the test is performed?	Y	N	
	2. How many varieties of uninoculated cell cultures does the lab use to check each new lot of anti-serum or serum pool for toxicity?			

D-TAGS	REQUIREMENTS			COMMENTS
	<u>Hemagglutination Inhibition Test:</u>			
	1. Does the laboratory determine the working dilution of the viral isolate (usually 4 hemagglutination units) after having determined the hemagglutination titer?	Y	N	
	a. How does the lab ensure that this working dilution is correct for isolates and controls?			
	2. How many uninoculated cell controls (tubes or plates) does the lab use with each test?			
	3. How often and for which hemagglutination inhibition tests does the lab include a serum/cell/buffer control and a cell/buffer control?			
	4. Does the lab include one known virus or viral antigen specific to each antisera used in the test procedure?	Y	N	
	<u>Direct Immunofluorescence Tests:</u>			
	1. How does the laboratory determine which immune serum conjugate(s) to use when identifying viruses using antisera that react with viruses that are etiologically similar (e.g. An antigen test for specimens from patients with flu-like symptoms that identifies RSV, Influenza, and Parainfluenza)?			
	a. Does the lab assure the specificity of this conjugate for the specific virus being identified?	Y	N	
	2. Does the lab rule out non-specific reactivity for each conjugate used?	Y	N	
	<u>Indirect Immunofluorescence Tests:</u>			
	1. Does the laboratory determine the optimum dilution of its anti-species (antibody to host system or cell culture)?	Y	N	
	2. How does the lab determine the optimum dilution of the virus specific immune serum?			
	3. Does the laboratory check positive and negative reactivity using:			
	a. Uninoculated cells plus immune serum plus anti-species conjugate (negative control)?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	b. Viral antigen or known virus infected cells plus immune serum plus anti-species conjugate (positive control)?	Y	N	
	4. Does the laboratory check each new batch or shipment of conjugate using known virus infected cells plus PBS plus anti-species conjugate?	Y	N	