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GENERAL MICROBIOLOGY		
PROFICIENCY TESTING		
MIC.00350 PT Extent of Testing Phase II	Organisms in proficiency testing specimens are identified to the same level as those from patient samples. NOTE: If the laboratory's proficiency testing reports include incomplete identifications (e.g. "Gram positive cocci" or "Mycobacterium species, not tuberculosis"), it must document that this matches the information produced by the laboratory's internal capabilities in patient reports. In other words, patient reports cannot be more specific than the identification level reporting in proficiency testing, unless the former contain more specific information provided by reference laboratories.	Added to the Quality Laboratory Practices Procedure 5/17/13.
QUALITY MANAGEMENT AND QUALITY CONTROL - WAIVED TESTS		
MIC.10060 Documented QC Results - Waived Tests Phase II	Control results are documented for quantitative and qualitative tests, as applicable. NOTE: Quality control must be performed according to manufacturer instructions. To detect problems and evaluate trends, testing personnel or supervisory staff must review quality control data on days when controls are run. The laboratory director or designee must review QC data at least monthly. Because of the many variables across laboratories, the CAP makes no specific recommendations on the frequency of any additional review of QC data. With respect to internal controls, acceptable control results must be documented, at a minimum, once per day of patient testing for each device.* All unacceptable control results must be documented (see below). *Acceptable internal control results need not be documented, if (and only if) an unacceptableinstrument control automatically locks the instrument and prevents release of patient results.	The Acceva Rapid Strep assay is waived. However, the test is performed only by technical personnel. Patient results are only reported if internal control passes (refer to the test procedure). The IC result is documented on the test log.
MIC.10070 QC Corrective Action - Waived Tests Phase II	There is documentation of corrective action when quality control results exceed the acceptable range.	If a failure occurred, the IC would be documented on the test log. External control results are entered into LIS (see MQCR)
MIC.10080 QC Verification- Waived Tests Phase II	The results of controls are verified for acceptability before reporting results. Evidence of Compliance: ✓ Records showing verification of acceptability of QC	Refer to the Rapid Antigen Test Log for IC results

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QUALITY MANAGEMENT AND QUALITY CONTROL - GENERAL ISSUES		
MIC.11015 QC Handling Phase II	Control specimens are tested in the same manner and by the same personnel as patient samples. NOTE: QC specimens must be analyzed by personnel who routinely perform patient testing. This does not imply that each operator must perform QC daily, so long as each instrument and/or test system has QC performed at required frequencies, and all analysts participate in QC on a regular basis. To the extent possible, all steps of the testing process must be controlled, recognizing that preanalytic and postanalytic variables may differ from those encountered with patients. Evidence of Compliance: ✓ Records reflecting that QC is run by the same personnel performing patient testing	Refer to Microbiology Quality Laboratory Practices for written protocol. QC results in LIS have the tech ID number listed which shows that QC is done by the same personnel that perform patient testing.
MIC.11016 Commercial Product - QC Phase II	When using a commercial product, QC is performed precisely according to the manufacturer's recommendations.This includes, but is not limited to, Antimicrobial Susceptibility Testing/Identification (AST/ID) systems.	Refer to the QC Reference Guide or individual test procedures.
MIC.11017 QC Verification Phase II	Control results are reviewed for acceptability before reporting patient results. Evidence of Compliance: ✓ Written policy/procedure stating that controls are reviewed and acceptable prior to reporting patient results AND ✓ Evidence of corrective action taken when QC results are not acceptable	Written policy located in the Quality Laboratory Practice document and can be found in individual test procedures. Evidence of corrective action would be documented in LIS.
MIC.11018 QC Corrective Action Phase II	There is documentation of corrective action when control results exceed defined acceptability limits. NOTE: Patient/client test results obtained in an analytically unacceptable test run or since the last acceptable test run must be re-evaluated to determine if there is a significant clinical difference in patient/client results. Re-evaluation may or may not include re-testing patient samples, depending on the circumstances. Even if patient samples are no longer available, test results can be re-evaluated to search for evidence of an out-of-control condition that might have affected patient results.	Evidence of corrective action would be documented in LIS.

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MIC.11020 Monthly QC Review Phase II	Quality control data are reviewed and assessed at least monthly by the laboratory director or designee. NOTE: The QC data for tests performed less frequently than once per month should be reviewed when the tests are performed. Evidence of Compliance: ✓ Records of QC review with documented follow-up for outliers, trends or omissions	QC results are printed and reviewed monthly by the supervisor. See hanging files under bench outside of the supervisor's office. Phoenix QC is reviewed monthly by technical specialist. Records are located in: G:\LAB_SHARED\Micro Procedures\Phoenix Maintenance and QC. This file is accessible by AR, JC, and MM.
MIC.11025 Validation of Accuracy Phase II	If the laboratory performs test procedures for which calibration and control materials are not available, procedures have been established to validate the accuracy of patient test results.	Vaginal wet mount: Trichomonas results are verified by a second technologist.
MIC.11027 Comparability of Instrument Phase II	If the laboratory uses more than one instrument to test for a given analyte, the instruments are checked against each other at least twice a year for correlation of results. Evidence of Compliance: ✓ Written procedure for performing instrument correlation including criteria for acceptability AND ✓ Records of correlation studies reflecting performance at least twice per year with appropriate specimen types	BD Affirm weekly QC is alternated between instruments. Refer to BD Affirm procedure for written instructions. Records of alternating QC are loacated in: G:\LAB_SHARED\Micro Procedures\Molecular QA\BD Affirm QC and Correlation\Weekly QC - External Controls. This file is accessible by AR, JC, and MM. See also, QC logs for BioFire instruments.

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MIC.11350 Morphologic Observation Assessment Phase II	The microbiology laboratory at least annually assesses morphologic observations among personnel performing gram, trichrome and other organism stains, to ensure consistency. NOTE: Suggested methods to accomplish this include: 1. Circulation of organisms with defined staining characteristics, and/or 2. Multi-headed microscopy, and/or 3. Use of photomicrographs with referee and participant identifications (e.g. former CAP microbiology Surveys or other photomicrographs from teaching collections) 4. Use of digital images Evidence of Compliance: ✓ Written procedure defining the method and criteria used for evaluation of consistency AND ✓ Employee records documenting morphology assessment	Procedure for morphologic assessment (competency) is described in the: Quality Laboratory Practices. Evaluations are achieved using electronic images and scoring. Test scores < 80% require documentation that the employee has reviewed and understands the specific questions that were interpreted incorrectly." Results for individual technical staff are accessible by AR, JC, and MM in: G:\LAB_SHARED\Micro Procedures\QA and Competency\Competency Testing
SPECIMEN COLLECTION AND HANDLING		
MIC.13100 Specimen Acceptability Criteria Phase II	There are criteria for establishing specimen acceptability. NOTE: This could include important issues such as absence of gross external contamination, adequate specimen type/quantity, suitable preservation, prevention of dried swabs, and correct use of transport media when required. Evidence of Compliance: ✓ Records of rejected specimens	Described in individual test procedures and in the test directory. Records of rejected specimens are stored in CRM (PAML). Policy for specimen rejection: Lab General/Specimen Collection/Specimen Rejection Policy.
MIC.13200 Requisitions Phase I	Requests for analysis include source of specimen, test or tests requested and, when appropriate, type of infection and/or organism expected.	Cases of specimens without source are documented in CRM (PAML). See requisition.

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MIC.13250 Specimen Collection/Handling Phase II	There are documented instructions for microbiology specimen collection and handling that include all of the following. 1. Method for proper collection of culture specimens from different sources 2. Proper labeling of culture specimens 3. Use of transport media when necessary 4. Procedures for safe handling of specimens (tightly sealed containers, no external spillage) 5. Need for prompt delivery of specimens to ensure minimum delay and processing (e.g. CSF, wound cultures, anaerobes) 6. Method for preservation of specimens if processing is delayed (e.g. refrigeration of urines) NOTE: Manufacturer's recommendations must be followed when there is a delay in delivery or processing of specimens for automated instruments (e.g. blood culture instruments).	Specimen collection and transport information is outlined in many test procedures and described in the test directory.
MIC.13275 Specimens for Molecular Amplification Phase II	The laboratory has procedures for the handling of specimens that will also be tested using molecular amplification methods. NOTE: Special precautions must be taken to avoid sample cross-contamination that may not affect culture-based methods but may lead to false positive results when tested using molecular amplification methods. For example, proper procedures to prevent cross-contamination must be used when samples are processed in the same biohazard hood in which virus cultures are manipulated post-inoculation. Please refer to the Molecular Microbiology section of this checklist.	Work surfaces in biosafety cabinets are decontaminated prior to processing specimens. Specimens are opened one at a time. (see PCR Contamination Prevention, Environmental Monitoring, and Decontamination Procedure)
SPECIMEN COLLECTION AND HANDLING		
MIC.14583 Direct Antigen Test QC Phase II	For nonwaived direct antigen tests on patient specimens that DO include internal controls, a positive and negative external control are tested and documented with each new kit lot number or shipment, and as frequently as recommended by the manufacturer, or every 30 days (whichever is more frequent). Evidence of Compliance: ✓ Written QC procedures for each test consistent with the manufacturer's instructions AND/OR records documenting in-house acceptability studies of internal control systems	Refer to specific test procedures involving direct antigen testing with internal controls (FLU, RSV, Strep A). The requirement for 20 consecutive daily comparisons is effective for studies performed after 1/31/2012. These tests were brought on prior to this date.

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MIC.14616 Direct Antigen Test QC Phase II	For nonwaived direct antigen tests on patient specimens that do NOT include internal controls, a positive and negative control are tested and documented each day of patient testing.	See procedures for Cryptococcal antigen, Legionella DFA, Pertussis DFA, and Pneumocystis DFA. QC results can be accessed through function MQCR.
REPORTING OF RESULTS		
MIC.15000 Preliminary Reports Phase I	When indicated, preliminary reports are promptly generated. Evidence of Compliance: ✓ Written procedure(s) defining when preliminary results are issued	Refer to individual procedures for details (e.g., Stool Culture Procedure).
INSTRUMENTS AND EQUIPMENT		
MIC.16000 Instrument/Equipment Maintenance Schedule Phase II	Instruments (e.g. analyzers) and equipment (microscopes, centrifuges, etc.) are on a regular maintenance schedule and records of function checks are maintained.	Records are kept by Clinical Engineering. Each instrument is tagged with last maintenance date. The Phoenix instruments receive biannual PM by vendor. Refer to PCR procedures for details on the BD MAX maintenance schedule. The MIDI HPLC instrument receives annual PM (see documentation from vendor).
MIC.16100 Instrument/Equipment Service Records Phase II	Instrument and equipment maintenance, service and repair records (or copies) are promptly available to, and usable by, the technical staff operating the equipment.	Records for most instruments are kept by Clinical Engineering. Records of instruments serviced by vendors kept by the Micro supervisor.

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MIC.16150 Pipettors and Diluters Phase II	Pipettes, microtiter diluters or automatic dispensers that are used for quantitative dispensing of material are checked for accuracy and reproducibility at specified intervals, with results documented. NOTE: This requirement is not applicable for precalibrated inoculation loops that are used in the direct plating of clinical specimens such as urine cultures. Evidence of Compliance: ✓ Written procedure detailing method for checking the accuracy and reproducibility of automatic pipettes	Pipettes are checked annually by gravimetric verification (referenced in the microbiology Quality Lab Practices Procedure). The procedure for performing gravimetric verification can be found in the Pipette Calibration Procedure located in Chemistry. The Phoenix AP pipettors are also checked annually. Records for the AP instruments can be found in the electronic Phoenix maintenance log for each year.
MIC.16200 Thermometric Standard Device Phase II	An appropriate thermometric standard device of known accuracy is available (guaranteed by manufacturer to meet NIST standards). NOTE:Thermometers should be present on all temperature-controlled instruments and environments and checked daily. Thermometric standard devices should be recalibrated or recertified prior to the date of expiration of the guarantee of calibration. Evidence of Compliance: ✓ Thermometer certificate of accuracy	Refer to the Non-Certified Thermometer Check procedure.
MIC.16250 Non-Certified Thermometers Phase II	All non-certified thermometers in use are checked against an appropriate thermometric standard device before being placed in service. Evidence of Compliance: ✓ Written procedure defining criteria for verification of non-certified thermometers AND ✓ Records of verification prior to being placed in service	Criteria are referenced in the micro Quality Lab Practices Procedure and the general lab procedure Non Certified Thermometer Check. Verification Records are accessible by AR, JC, and MM in: G:\LAB_SHARED\Micro Procedures\Thermometer Verification Records or in the reagent prep room.

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MIC.16275 Microscopes Phase I	Microscopes used for immunofluorescent testing contain the appropriate filter(s) recommended by the manufacturer.	We currently have 3 fluorescent microscopes. Each contains appropriate filters and are labeled for the specific type of smear they are intended for.
TEMPERATURE-DEPENDENT EQUIPMENT		
MIC.16290 Temperature Range Phase II	Acceptable ranges have been defined for all temperature-dependent equipment.	Ranges are posted on equipment and are built into the LIS QC.
MIC.16300 Temperature-Dependent Equipment Phase II	Thermometers are placed in, or integrated in all of the following equipment. 1. Refrigerators 2. Incubators 3. Water baths 4. Heating blocks 5. Freezers	Refer to specific equipment for examples.
MIC.16500 Temperature Checks Phase II	Temperatures are checked and recorded daily.	Records for specific equipment can be accessed through the MQCR function or viewed with monthly reports.
MIC.16525 Temp. Corrective Action Phase II	There is evidence of corrective action taken if acceptable temperature ranges for temperature-dependent equipment are exceeded, including evaluation of contents for adverse effects.	Corrective actions are documented in MQCE and reviewed by supervisor.
MIC.16550 Adequate Incubators Phase I	There are sufficient, clean, and well-maintained incubators available at specified temperature ranges.	See equipment in lab.
MATRIX-ASSISTED LASER DESORPTION IONIZATION TIME-OF-FLIGHT (MALDI-TOF) MASS SPECTROMETRY		
MIC.16575 Instrument Operation Phase II	Procedures are documented for operation, calibration and maintenance of the mass spectrometer.	N/A
MIC.16585 Instrument Maintenance Phase II	The documented procedure requires that the mass spectrometer be maintained at regular intervals as suggested by the manufacturer, or if different criteria or procedures from the manufacturer are used, these procedures have been validated and the records maintained on file.	N/A

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MIC.16595 Mass Spectrometer Calibration Phase II	A calibration control is run each day of patient/client testing, with each change in target plate, or according to manufacturer's recommendations and these records are maintained.	N/A
MIC.16605 Mass Spectrometer Controls Phase II	Appropriate control organisms are tested on a daily basis.	N/A
MIC.16615 Mass Spectrometer Reagent Grade Phase II	Reagents and solvents are of appropriate grade. NOTE: Only the manufacturer's specified grade of solvents are used for this procedure. This may be HPLC-grade or other reagent grades as indicated.	N/A
MIC.16625 Mass Spectrometer Consumables Phase II	Consumables are of appropriate manufacturing type to function as required.	N/A
PERSONNEL		
MIC.17000 Personnel - Bench Testing Supervision Phase II	The person(s) in charge of bench testing/section supervisor in microbiology has education in microbiology equivalent to an associate's degree (or beyond) in a chemical, physical or biological science or medical technology and at least 4 years experience (one of which is in microbiology) under a qualified section director.	Records in HR
MIC.17050 Visual Color Discrimination Phase I	Personnel working in microbiology are checked for visual color discrimination. NOTE: Testing is not required for personnel who do not perform laboratory tests requiring color discrimination. This does not mean that visually color-impaired technical personnel cannot be employed, only that they be tested, with job assignments and responsibilities evaluated accordingly. Evidence of Compliance: ✓ Record of color discrimination testing OR functional assessment, if indicated	Records in HR

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BIOSAFETY		
MIC.18968 Agents of Bioterrorism Phase II	The microbiology laboratory has policies and procedures for the recognition and safe handling of isolates that may be used as agents of bioterrorism.	Hard copies of procedures are located in the Bioterrorism Procedure Manual in the main Microbiology lab. Added "Do not subject these isolates to identification utilizing automated instruments." to the Microbiology Biohazards and Safety Procedure.
MIC.18976 Bioterrorism Response Plan Phase I	The laboratory participates in the institution's bioterrorism response plan. Evidence of Compliance: ✓ Organizational bioterrorism plan describing the role of the laboratory	See Bioterrorism Manual and Infection Control/PSHMC Policies/Anthrax.
MIC.18985 Spill Handling Phase II	There are documented policies for handling spills of contaminated materials.	Refer to the Microbiology Biohazards and Safety Procedure. Also in Lab General - Chemical Spill: Located in the Laboratory Chemical Hygiene Plan and Hazard Communication Program (located in Lab Safety). Infectious Material Spill: Located in the Lab Infection Control Plan.
MIC.19010 Bench Top Decontamination Phase II	There is documentation of daily decontamination of bench tops.	Documented in LIS - view under MQCR or see monthly reports.
MIC.19035 Safe Specimen Processing Phase II	There are documented policies and procedures for the safe handling and processing of specimens.	Refer to the Microbiology Biohazards and Safety Procedure.
MIC.19060 Biosafety Levels Phase II	Policies and procedures have been developed to minimize the occupational risk of exposure to infectious agents handled in the microbiology laboratory, in accordance with current recommendations regarding the biosafety levels for working with different organisms.	Refer to the Microbiology Biohazards and Safety Procedure.

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MIC.19160 Biosafety Levels Phase II	Engineering and work practice controls appropriate to the Biosafety level of the laboratory are defined and implemented.	Evidenced by BSL 3 AFB/Mycology negative airflow and use of class II biosafety cabinets.
MIC.19840 Biological Safety Cabinet Phase II	A biological safety cabinet (BSC) or hood is available for handling specimens or organisms considered highly contagious by airborne routes. Evidence of Compliance: ✓ Maintenance schedule of BSC function checks AND ✓ Records of testing and certification	Records of testing and certification are kept by the departmental supervisor and clinical engineering.
MIC.20520 Biological Safety Cabinet Phase II	The biological safety cabinet (BSC) is certified at least annually to ensure that filters are functioning properly and that airflow rates meet specifications. Evidence of Compliance: ✓ Maintenance schedule of BSC function checks AND ✓ Records of testing and certification	Records of testing and certification are kept by the departmental supervisor and clinical engineering.
BACTERIOLOGY		
MEDIA		
MIC.21200 Media Supplier Phase II	The laboratory has documentation that its media supplier carries out the quality assurance guidelines enumerated in CLSI/NCCLS Document M22-A3.	CLSI M22-A3 document is located in Michael's office. Certificates from each media vendor are located in the QA procedure manual.
MIC.21220 Media Visual Inspection Phase I	The laboratory has documentation that each shipment of purchased media is examined for breakage, contamination, appearance, and evidence of freezing or overheating.	Receiving records are stored in binders above Specimen Processing CRM desk.
MIC.21240 Media QC - Purchased Phase II	The laboratory has documentation that an appropriate sample of each purchased medium that is not listed in M22-A3 as exempt from testing is checked for each of the following: 1. Ability to support growth (where applicable) by means of stock cultures or by parallel testing with previous batches 2. Biochemical reactivity, where appropriate	Refer to the QC Reference Guide Specific examples of media QC can be viewed via function MQCR.

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MIC.21300 Media QC In-House Prepared Phase II	For microbiology media prepared in-house, there is documentation that an appropriate sample of each medium prepared by the laboratory is checked for each of the following: 1. Sterility (following introduction of additives after sterilization) 2. Ability to support growth (where applicable) by means of stock cultures or by parallel testing with previous batches 3. Biochemical reactivity (where appropriate) Evidence of Compliance: ✓ Written procedure for testing media prepared in-house	N/A
MIC.21420 Media Visual Examination Phase II	All media are in visibly satisfactory condition (with expiration date, plates smooth, adequately hydrated, uncontaminated, appropriate color and thickness, tubed media not dried or loose from sides).	Described in the Quality Lab Practices procedure. Receiving records are stored in binders above Specimen Processing CRM desk.
MIC.21460 Quality Control Organisms Phase II	Quality control organisms are used to check stains, reagents and susceptibility test methods. NOTE: 1. Quality control organisms may be ATCC strains or well characterized laboratory strains unless specified by the manufacturer 2. Quality control organisms are maintained in a manner to preserve their bioreactivity, phenotypic characteristics and integrity	See QC Reference Guide for reference strains used as QC for each test. See QC Organism Maintenance Procedure.
STAINS		
MIC.21530 Direct Gram Stain Procedures Phase I	The laboratory has protocols in place to use Gram stain results to provide a preliminary identification of organisms, evaluate specimen quality when appropriate, and to guide work-up of cultures. Evidence of Compliance: ✓ Written procedure for Gram stain (laboratories may use the correlation of Gram stain results with the final culture results as a component of the QC program)	Refer to Gram Stain Procedure

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MIC.21540 Gram Stain QC Phase II	Quality control of Gram stain reagents is performed for intended reactivity and recorded for each new batch of stains and at least weekly against known gram-positive and gram-negative quality control organisms. Evidence of Compliance: ✓ Written procedure for Gram stain QC	Refer to Gram Stain Procedure and the QC Reference Guide
MIC.21560 Non-Immunofluorescent Stain QC Phase II	Quality control of all non-immunofluorescent, non-immunologic-based stains (other than Gram stains) is performed and recorded with a positive and negative quality control organism for intended reactivity each day of use, and for each new batch, lot number and shipment. Evidence of Compliance: ✓ Written procedure for QC of non-immunofluorescent stains	Refer to QC Reference Guide for Modified Kinyoun for Nocardia QC.
MIC.21570 Fluorescent Stain QC Phase II	Quality control of fluorescent stains is performed for positive and negative reactivity each time of use. Evidence of Compliance: ✓ Written procedure QC of fluorescent stain	Refer to QC Reference Guide for Auramine-Rhodamine Stain QC.
REAGENTS		
MIC.21624 Reagent QC Phase II	Positive and negative controls are tested and results recorded for each new batch, lot number, and shipment of reagents, disks/strips and stains.	Specific QC results can be viewed via function MQCR.
MIC.21626 Identification System QC Phase II	Appropriate positive and negative control organisms are tested and results recorded for each new lot and shipment of reagents used in bacterial identification systems. Evidence of Compliance: ✓ Written procedure for QC on new lot numbers or shipments of reagents for each MIS using the conventional QC method (a positive and negative control for each substrate) OR a written procedure for streamlined QC AND ✓ Records of test system verification and historical QC review used to qualify for streamlined QC, if applicable	Refer to the Phoenix Test Procedure for QC instructions. Records of QC are accessible by AR, JC, and MM in: G:\LAB_SHARED\Micro Procedures\Phoenix Maintenance and QC. QC results can also be accessed in Epicenter. QC for other identification systems, such as API, are entered in LIS.
MIC.21628 Antisera QC Phase I	Positive and negative controls are tested and results recorded for each new batch, lot number and shipment of antisera when prepared or opened and once every 6 months thereafter (e.g. Salmonella/Shigella antisera).	Refer to the QC Reference Guide for Wellcolex and O157 Kits. We typically use up kits within 6 months.

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MIC.21632 Beta-Lactamase QC Phase II	Positive and negative controls are tested and results recorded for beta-lactamase (other than Cefinase ®) on each day of use.	QC for Cefinase disks is performed for each new lot/shipment, when opened (see QC Reference Guide)
MIC.21812 Anaerobic Incubation Conditions QC Phase I	There is documentation that anaerobic incubation systems (e.g. jars, chambers, bags) are checked for adequate anaerobic conditions with methylene blue strips, fastidious anaerobic organisms or other appropriate procedures.	Refer to the Quality Lab Practices document. Records can be found in MQCR.
MIC.21813 CO2 Incubator Levels Phase I	CO2 incubators are checked daily for adequate CO2 levels, with recording of results.	Quality Lab Practices: "CO2 incubators must be checked daily by the digital reading and weekly using a Fyrite device." Results are entered in LIS.
MIC.21815 QC Campylobacter Incubation Conditions	Campylobacter incubation conditions are checked using QC organisms or other appropriate methods to ensure adequate environmental conditions to support growth of Campylobacter jejuni.	Conditions are checked with each new lot/shipment of media. (Contacted CAP to verify that this was acceptable)
ANTIMICROBIAL SUSCEPTIBILITY TESTING, QC REQUIREMENTS, AND RESULTS REPORTING		
MIC.21820 Susceptibility Testing - Pure Cultures Phase II	Only pure cultures are used for performance of antimicrobial susceptibility testing (i.e. susceptibility testing is not performed on mixed cultures). Evidence of Compliance: ✓ Written procedure describing the use of pure cultures for susceptibility testing, including the use of purity plates broth (reference or commercial methods) or agar dilution for Minimum Inhibitory Concentration (MIC) tests	Refer to the Phoenix Test Procedure
MIC.21840 Susceptibility Test QC Phase II	Quality control is performed on each new lot of disks and media and each new lot of MIC panels before or concurrent with initial use with appropriate QC organisms. Evidence of Compliance: ✓ Records of new lot susceptibility disk QC	QC Results for disk diffusion are documented in LIS. Phoenix QC results are stored in G:\LAB_SHARED\Micro Procedures\Phoenix Maintenance and QC which is accessible by AR, JC, and MM.

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MIC.21910 Susceptibility Test QC Frequency Phase II	For antimicrobial susceptibility testing by either disk or dilution (MIC) methods, control organisms are tested with each new lot number or shipment of antimicrobials or media, and each day the test is performed thereafter. Evidence of Compliance: ✓ Records of susceptibility QC results documented at defined frequency and meeting defined acceptability criteria	QC Results for disk diffusion are documented in LIS. Phoenix QC results are stored in G:\LAB_SHARED\Micro Procedures\Phoenix Maintenance and QC which is accessible by AR, JC, and MM.
MIC.21930 Susceptibility Test Endpoint Determination Phase II	For antimicrobial susceptibility testing systems, there are documented criteria for measuring and determining the MIC endpoint or zone size.	E-test end points are based on CLSI standards. These are available at each bench. The Phoenix/Epicenter endpoints are also based on CLSI standards and can be viewed in Epicenter under the Configuration module.
MIC.21940 Standardized Inoculum Phase II	The inoculum used for antimicrobial susceptibility testing (i.e. inoculum size) is controlled using a turbidity standard or other acceptable method. Evidence of Compliance: ✓ Written procedure for standardizing susceptibility inoculum	The Phoenix test procedure describes standardized inoculum preparation using the AP instrument (automated) or the Phoenix Spec (manual). Inoculum preparation for disk diffusion testing using the BBL Prompt System is outlined in the Disk Diffusion Susceptibility Test Procedure.
MIC.21943 Selection of Antimicrobial Agents to Report Phase II	Guidelines are established to ensure that only antimicrobial agents appropriate for the organism and body site are routinely reported. Evidence of Compliance: ✓ Documentation of reporting of antimicrobial agents for different body sites AND ✓ Documentation that the antimicrobial reporting protocols have been reviewed on an annual basis	Panels of drugs reported for specific organisms are posted at each bench. Infection control committee reviews reporting protocols.

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MIC.21944 Testing and Reporting Supplemental Antimicrobial Agents Phase I	There are protocols for testing supplemental agents when needed on isolates resistant to routinely tested antimicrobial agents. Evidence of Compliance: ✓ Patient testing reports demonstrating additional testing or referral	Cascading rules are built into LIS. See AST bench sheet for examples. We also offer other drugs to be tested by request (e.g., tigecycline).
MIC.21946 Cum. Susceptibility Data Phase I	For hospital based microbiology laboratories, cumulative antimicrobial susceptibility test data are maintained and reported to the medical staff at least yearly.	Refer to annual antibiograms
MIC.21950 Inconsistent Antimicrobial Results Phase I	The procedure manual addresses unusual or inconsistent antimicrobial testing results. Evidence of Compliance: ✓ Records of investigation for unusual/inconsistent results	Refer to the Susceptibility Profiles and High Score Testing Procedure. Records of investigation/repeat testing are documented in Epicenter and LIS under specific accession numbers.
PROCEDURES AND TESTS - RESPIRATORY SPECIMENS		
MIC.22100 Sputum Gram Stain Phase I	A gram-stained smear is performed routinely on expectorated sputa to determine acceptability of a specimen for bacterial culture and as a guide for culture workup. Evidence of Compliance: ✓ Policy defining acceptable specimens	Sputum gram stain protocol can be found in the Gram Stain Procedures. Protocol for working up cultures can be found in the Lower Respiratory Tract Culture Procedure.

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MIC.22110 Unacceptable Sputum Specimens Phase I	Specimens deemed unacceptable by Gram stain review are not cultured for routine bacteria (or cultured only by special request) and the health care provider or submitting laboratory is notified so another specimen can be collected without delay, if clinically indicated. Evidence of Compliance: ✓ Records of specimen rejection such as rejection log or patient report	Poor quality specimens are processed due to the inherent delays in serving a large geographic area and the difficulties of reculturing patients. However, minimal identification and no susceptibility testing of potential pathogens is performed on these poor quality specimens to avoid the reporting of clinically misleading information. The following comment is appended to each gram stain report for unacceptable specimens: Squamous cells in the specimen indicate the presence of superficial material that may contain contaminating or colonizing bacteria unrelated to infection. Collection of another specimen is suggested, avoiding superficial sources of contamination.
PROCEDURES AND TESTS - URINE SPECIMENS		
MIC.22200 Urine Colony Count Phase II	Quantitative cultures (colony counts) are performed. NOTE: Urine cultures should include an estimate of CFU/volume. Evidence of Compliance: ✓ Written procedure for colony counts	Refer to the Urine Culture Procedure
MIC.22210 Urine Culture Procedure Phase II	The media and procedures used permit the isolation and identification of both gram-positive and gram-negative bacteria. NOTE: This does not require the use of gram-positive selective media.	Refer to the Urine Culture Procedure for details on CHROMagar Orientation medium

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PROCEDURES AND TESTS - GENITAL SPECIMENS		
MIC.22273 Group B Strep Screen Phase II	Group B streptococcus screens from pregnant women are collected and cultured in accordance with the current guidelines.	Refer to the Genital Culture Procedure
MIC.22280 Bacterial Vaginosis Phase I	When Gram stains are performed to make the laboratory diagnosis of bacterial vaginosis, the smear is scored and interpreted according to published criteria.	Refer to the Gram Stain Procedure for genital specimens.
MIC.22285 Genital Pathogens Phase II	Appropriate protocols are established to ensure the recovery of genital pathogens such as Neisseria gonorrhoeae.	Refer to the Specimen Processing and Genital Culture Procedures
PROCEDURES AND TESTS - STOOL SPECIMENS		
MIC.22330 Clostridium Difficile Phase II	The laboratory has protocols for the timely detection and reporting of C. difficile or its toxins.	Testing performed on 1st and 2nd shift each day. See Notifiable Conditions Procedure (listed as an alert value).
MIC.22336 Stool Specimen Reporting Phase I	The final report for stool cultures submitted for routine bacterial pathogen examination lists the organisms for which the specimen was cultured (e.g. Salmonella, Shigella, Vibrio, etc.).	Refer to the Stool Culture Procedure
MIC.22410 Stool Culture Enrichment/Selective Media Phase I	Appropriate methods are used routinely to recover enteric pathogens.	Refer to the Stool Culture Procedure
MIC.22440 Stool Specimen Number/Timing Phase I	The laboratory has guidelines for the number and/or timing of collection of stool specimens submitted for routine bacterial testing.	Refer to the Stool Culture Procedure and the Test Directory
PROCEDURES AND TESTS - CEREBROSPINAL & OTHER BODY FLUID SPECIMENS		
MIC.22495 Centrifugation of Body Fluids Phase I	If plated media are used for sterile body fluids, the fluid is centrifuged and the sediment used to inoculate media. NOTE: When inadequate volume is received, the report should note that the culture results may be compromised by the limited volume of specimen received. Equivalent methods are acceptable, if validated by the laboratory.	Refer to the Specimen Processing Procedure for Body Fluids. Inadequate volume is not defined. Often, it is not possible for more fluid to be collected.

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MIC.22500 CSF Processing Phase II	CSF samples for culture are processed immediately on receipt. NOTE: Bacterial meningitis is a critical condition that requires immediate attention. Samples must be processed upon receipt when meningitis is suspected. The laboratory may choose to handle surveillance cultures, e.g. involving neurosurgical implants, differently. Evidence of Compliance: ✓ Policy and procedure for CSF processing AND ✓ Culture log or patient records	Refer to the Specimen Processing Procedures and patient records
MIC.22520 CSF Media/Incubation Phase II	The procedure (media and incubation conditions) permits recovery of fastidious bacteria expected in this type of specimen (N. meningitidis, S. pneumonia, H. influenzae).	Refer to the Specimen Processing Procedures
MIC.22550 CSF Back-Up Cultures Phase II	If bacterial antigen-detection methods are used, back-up cultures are performed on both positive and negative CSF specimens. Evidence of Compliance: ✓ Written procedure stating that CSF cultures are performed in conjunction with bacterial antigen tests OR procedure describing testing at another location AND ✓ Records of back-up CSF cultures performed on-site OR records indicating that cultures are performed at another location OR documentation that order for CSF bacterial antigen was blocked by the computer due to no order for a culture	N/A
PROCEDURES AND TESTS - BLOOD CULTURES		
MIC.22600 Blood Culture System Phase II	The blood culture system in use is designed to recover both aerobic and, when indicated or if intended to be part of the routine procedure, anaerobic organisms. NOTE:This criterion is not intended to imply that anaerobic cultures must be performed on all blood cultures if circumstances where anaerobic cultures are not indicated are specifically delineated (e.g. on neonates where volume is of concern).	Refer to the Blood Culture Procedure

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MIC.22610 Manual Blood Culture Systems Phase II	For non-automated systems, macroscopically negative aerobic blood cultures are stained and/or subcultured within 12-48 hours of incubation. NOTE: Subcultures and/or stains need not be done on blood cultures performed by automated methods if bottles are monitored for at least 5 days. Evidence of Compliance: ✓ Records of staining and/or subculture of macroscopically negative cultures	N/A
MIC.22620 Blood Culture Examination Phase II	Blood cultures are examined (macroscopically if manual method) for evidence of growth at least twice daily for the first two days of incubation, then at least daily for the remainder of the incubation period. NOTE:The time to detection of positive blood cultures, whether processed by manual or automated methods, depends on the schedule of inspection for evidence of growth.The means of the inspection may include visual examination, gram staining, subculturing, or electronic analysis by continuous monitoring instruments. Because most significant positive blood cultures may be detected within 48 hours of incubation, it is recommended that blood cultures be examined for evidence of growth at least two times on the first two days of incubation, then at least once daily through the remainder of the laboratory's routine incubation period. Evidence of Compliance: ✓ Patient records/worksheet with result of examination for manual methods documented at defined frequency	Automated instrument monitors bottles conitnuously. Manual testing is only performed for bottles that are falsely positive twice. See Blood Culture Procedure.
MIC.22630 Blood Culture Collection Phase II	Sterile techniques for drawing and handling of blood cultures are defined, made available to individuals responsible for specimen collection and practiced. NOTE: It is recommended that blood culture statistics, including number of contaminated cultures, be maintained and reviewed regularly by the laboratory director. The laboratory should establish a threshold for an acceptable rate of contamination. Tracking the contamination rate and providing feedback to phlebotomists or other persons drawing cultures has been shown to reduce contamination rates. Other measures to monitor include types of skin disinfection, volume of blood drawn, number of culture sets drawn, number of single cultures and line draws.	Blood culture collection instructions are located in the test directory

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MIC.22640 Blood Culture Volume Phase I	The laboratory has a system for monitoring blood cultures for adequate volume and feeding back the results to blood collectors. NOTE: Larger volumes of blood increase the yield of true positive cultures. In adults, optimally 20 mL of blood per culture set (2 bottles) should be collected for culture. The laboratory should periodically monitor collected blood volumes and provide feedback to clinical staff. Automated blood culture systems approved or cleared by the FDA may use smaller volumes per culture set and are acceptable. Evidence of Compliance: ✓ Documentation of monitoring of volume at a defined frequency AND ✓ Documentation of feedback to the clinical staff	Refer to the Blood Culture Procedure
PROCEDURES AND TESTS - WOUND SPECIMENS		
MIC.22700 Wound/Anaerobic Cultures Phase II	Special procedures are defined to culture anaerobic organisms when indicated.	Refer to the Specimen Processing Procedures
MIC.22710 Direct Smear Gram Stain Phase I	Gram stains of direct smears are examined and results reported, when indicated. NOTE: Gram stains are recommended to evaluate specimen quality and guide the work-up of the specimen. Examination of the smear may reveal quantity and morphotypes of the organisms present, acute inflammatory cells and squamous epithelial cells.	Refer to the Gram Stain Procedure for wound specimens.
LABORATORY SAFETY		
MIC.23200 Hazardous Waste Disposal Phase II	Microbiology specimen residuals and contaminated media are disposed of in a manner to minimize hazards to all personnel handling the material. NOTE: Sterilization or decontamination within the microbiology section before disposal is preferred. If such material is transported before treatment, it must be placed into a leak-resistant rigid container, and appropriately labeled. Evidence of Compliance: ✓ Written procedure for the handling and disposal of microbiology waste	Refer to the infection control plan in the Lab General Procedures.

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MYCOBACTERIOLOGY		
SPECIMEN HANDLING		
MIC.31100 Specimen Collection/Transport Phase I	Specimens for mycobacterial culture are collected appropriately and transported to the laboratory without delay. NOTE: The laboratory should recommend collecting 3 sputum specimens for acid-fast smears and culture in patients with clinical and chest x-ray findings compatible with tuberculosis. These three samples should be collected at 8-24 hour intervals (24 hours when possible) and should include at least one first morning specimen. Specimens must be delivered to the laboratory promptly; specimens that cannot be processed within one hour of the time of collection should be refrigerated during transport to and storage in the laboratory prior to processing. This will decrease overgrowth with contaminating organisms likely to be present. Laboratories are encouraged to process acid-fast specimens in their laboratory or obtain results from referral laboratories as soon as possible so that smear results can be available within 24 hours of collection (see MIC.31200 below). Evidence of Compliance: ✓ Written procedure describing specimen collection and handling requirements	Refer to the Specimen Collection section of the AFB manual and the test directory.
REPORTING OF RESULTS		
MIC.31200 Acid Fast Stain Results Phase I	When clinically indicated, results of acid-fast stains are reported within 24 hours of specimen receipt by the testing laboratory. Evidence of Compliance: ✓ Written procedure defining turnaround time for reporting acid-fast stain results	Refer to the AFB Smear Procedure in the AFB procedure manual.
MIC.31220 Mtb Susceptibility Test Results Phase I	Susceptibility test results for M. tuberculosis are available in a timely manner. NOTE: The rapid recognition of drug-resistant organisms is essential to the control of multidrug-resistant tuberculosis. For isolates of M. tuberculosis complex, the CDC and Prevention Laboratory work group recommends that laboratories use methods that may allow susceptibility test results to be available within 28 days of specimen receipt. From a CAP accreditation perspective, 28 days is a goal, not a requirement.	Refer to the Antimycobacterial Susceptibility Testing of M. tuberculosis BACTEC MGIT 960 Procedure.

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MEDIA		
MIC.31400 Media QC Phase II	An appropriate sample of each medium and additive prepared by the laboratory is checked for all of the following elements. 1. Sterility (if additives are introduced after initial sterilization) 2. Ability to support growth (when applicable) by means of stock cultures or by parallel testing with previous batches 3. Biochemical reactivity (where appropriate) NOTE: This checklist requirement does not apply to commercially prepared additives that are reconstituted when added to mycobacterial media. Evidence of Compliance: ✓ Records of media QC for laboratory-prepared media and additives	We purchase commercially prepared media.
MIC.31460 Media Visual Examination Phase II	All media are in satisfactory condition (adequately hydrated, tubed media not dried or loose from sides).	Receiving records are stored in binders above Specimen Processing CRM desk. Also refer to the Quality Lab Practices document which describes visually inspecting media.
CONTROLS AND STANDARDS		
MIC.31630 QC Verification Phase II	The results of controls are reviewed for acceptability before reporting patient results. Evidence of Compliance: ✓ Records showing verification of acceptability of QC	Access results in LIS under function MQCR.
MIC.31635 QC Corrective Action Phase II	There is documentation of corrective action when control results exceed the acceptability limits. NOTE: Patient test results obtained in an analytically unacceptable test run or since the last acceptable test run must be re-evaluated to determine if there is a significant clinical difference in patient/client results. Re-evaluation may or may not include retesting samples, depending on the circumstances.	Access results in LIS under function MQCR.
MIC.31640 AFB Stain QC Phase II	AFB stains are checked each day of use with appropriate positive and negative controls, and results documented.	Refer to QC Reference Guide for Kinyoun Stain QC instructions. QC results can be viewed in MQCR.

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MIC.31650 Fluorescent Stain QC Phase II	Fluorescent stains are checked with positive and negative controls each time of use and results documented.	Refer to QC Reference Guide for Auramine-Rhodamine Stain QC instructions. QC results can be viewed in MQCR.
MIC.31660 NAP Test QC - Phase I	A known strain of M. tuberculosis is tested whenever the NAP (p-nitro-a-acetylamino-beta-hydroxypropiophenone) test is performed.	N/A
MIC.31670 Nucleic Acid Probe QC Phase II	If nucleic acid probes are used for identification of mycobacteria grown in culture, appropriate positive and negative controls are tested on each day of use. Evidence of Compliance: ✓ Records of nucleic acid probe QC documented at defined frequency	Currently N/A. Previously: Access results in LIS under function MQCR (item codes GPMAI, GPMG, GPMTB)
MIC.31680 M.tb Susceptibility QC Phase II	If the laboratory performs susceptibility testing of M. tuberculosis, a control strain sensitive to all antimycobacterial agents is run each week of patient testing, and with each new batch/lot number of media and antimicrobial agents. Evidence of Compliance: ✓ Records of routine and new lot M.tb QC results documented at defined frequency	Access results in LIS under function MQCR (item codes: AFETH, AFISO1, AFISO4, AFPZA, AFRIF, AFSTR1, AFSTR4)

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PROCEDURES AND TESTS - RAPID METHODS		
MIC.32100 Fluorochrome Stain Phase II	Fluorochrome staining is performed on mycobacterial smears prepared from primary specimens, either in the laboratory or by the reference laboratory. NOTE: Such smears are easier to read than those stained with a conventional carbol-fuchsin based stain. Fluorescing organisms stand out prominently against the background of the smear, and the smears can be examined at a lower power than conventionally-stained smears, so that a larger amount of material can be examined in a given period of time. As with the interpretation of Ziehl-Neelsen- and Kinyoun-stained smears, expertise is needed for interpretation of smears stained with a fluorescent stain; not everything that fluoresces in such a stain is necessarily a mycobacterium. Particularly when only a few organism-like structures are seen, it is important to pay careful attention to their morphology before interpreting them as Mycobacteria. Evidence of Compliance: ✓ Written procedure for including fluorochrome staining on primary specimens for mycobacterial culture OR written policy for referral of specimens to a reference laboratory for fluorochrome staining AND ✓ Patient reports/worksheets with fluorochrome stain results OR reference laboratory reports with results	Refer to the AFB Smear Procedure in the AFB manual.
MIC.32140 Rapid Method Phase I	Nucleic acid probes, chromatography, the NAP test, or other rapid method (e.g. nucleic acid amplification or sequencing) is employed for identification of mycobacterial isolates. Evidence of Compliance: ✓ Written procedure defining method(s) in use for identification of mycobacterial isolates	Refer to the MIDI HPLC Procedure.
PROCEDURES AND TESTS - CONCENTRATION, INOCULATION, INCUBATION		
MIC.32200 AFB Concentration Phase II	Certain specimens (e.g. sputum) are concentrated before AFB smear examination and culture. Evidence of Compliance: ✓ Documentation of specimens requiring concentration	Refer to the Processing of AFB Specimens procedure in the AFB manual.

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MIC.32250 Specimen Inoculation Phase I	Specimens (other than blood) are routinely inoculated on media that support optimal growth of the majority of clinically relevant mycobacterial species. NOTE:The use of two types of media (for specimens other than blood), including one liquid medium (when possible) or a comparable culture method, is recommended for optimal isolation of mycobacteria.	Routine set-up includes LJ and MGIT broth. Room temp CHOC and LJ are added for specific sources.
PROCEDURES AND TESTS - CULTURES		
MIC.32320 Incubation Temperature Phase II	Mycobacterial cultures are maintained at 35-37°C. NOTE: The optimal incubation temperature for most mycobacterial specimens is 35 to 37° C. Exceptions to this include specimens obtained from skin or soft tissue suspected to contain M. marinum (incubate at 30-32° C) or M. xenopi (incubate at 42° C). These specimens should be held at 35 – 37° C in addition to the lower or higher temperature. Evidence of Compliance: ✓ Temperature records	Temperature records for the AFB incubators can be accessed in MQCR (item codes BAC02 and BAO224)
PROCEDURES AND TESTS - DIFFERENTIAL BIOCHEMICAL PROCEDURES		
MIC.32420 Differential Biochemical Test Phase II	Differential biochemical tests are appropriate for the extent and manner of mycobacterial identification. Evidence of Compliance: ✓ Written procedure detailing tests performed and identification scheme appropriate for the extent of testing	Refer to MQCR for the Niacin accumulation and Nitrate reductase QC results.
MIC.32480 Biochemical Test QC Phase II	All biochemical tests employed are checked each day of use with appropriate positive and negative controls and results recorded.	N/A

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PROCEDURES AND TESTS - HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) FOR MICROBIAL IDENTIFICATION		
MIC.32518 HPLC Calibrators/Standards Phase II	Appropriate calibrators or standards are run with each analytic batch. NOTE: Either calibration standards or organisms of known identity must be run with each analytic batch, and criteria must exist for acceptance of runs based on mobility of internal standards, ability to identify significant peaks, baseline noise, peak symmetry of internal standards, detection of low-quantity peaks, and similar criteria. Evidence of Compliance: ✓ Written procedure defining calibrators/standards appropriate for the test system used AND ✓ Records of calibration/calibration verification with each batch	Refer to the MIDI HPLC Procedure. Refer to the PQ Tables for the calibration records.
MIC.32556 HPLC Controls Phase II	Appropriate controls are extracted and run through the entire procedure. NOTE: Control organisms must be extracted and carried through the entire procedure with each run or batch. Appropriate positive (e.g. mycobacterial) and negative controls (organisms such as Candida from which no mycolic acids are expected) must be included with each run. Evidence of Compliance: ✓ Written procedure defining QC requirements AND ✓ QC records documented at defined frequency	Refer to the MIDI HPLC Procedure. Refer to the PQ Tables for the QC records.
MIC.32594 Chromatogram Controls Phase I	External chromatogram pattern controls are available. NOTE: Patterns for known strains should be established in those laboratories using HPLC. In addition laboratories should have access to the standard method manuals containing comparable chromatographic patterns for comparison.	Refer to the reference patterns kept in the MIDI testing area.
MIC.32632 Column Verification Phase II	New columns are verified for performance before use. NOTE: Column verification must include assessment of flow, consistency, and carryover. If the HPLC-method interpretive software uses a peak-naming table, it must be calibrated with each change of column. Generally the basic performance of new columns is certified by the manufacturer. HPLC analysis requires columns be equilibrated with about 10 column volumes of solvent followed with a blank run to test pressure and solvent flow. Evidence of Compliance: ✓ Written procedure for column verification AND ✓ Records of column verification	Refer to the MIDI HPLC Procedure. Refer to the PM notebook with the vendor's column verification records.

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MIC.32670 Column/Detector Monitoring Phase II	The performance of the column and detector are monitored on each day of use. NOTE: Unextracted standard organisms and extracted calibrators or controls, typically containing a range of mycolic acids (or other appropriate targets) of known relative retention times, may be analyzed to monitor critical aspects of HPLC performance. Appropriate criteria for evaluating such parameters as retention time of specific standards, relative retention compounds time, separation of closely eluting peaks of interest, detection of known low-quantity peaks, column pressure, chromatography quality and detector response should be established and monitored. Column temperatures and pump pressures are monitored with each run to ensure they met specified criteria for analysis. The column and detector operations are monitored with a blank run prior to use and during batch runs. Positive and negative control samples supplement the blank run when samples are analyzed. Evidence of Compliance: ✓ Records for column and detector monitoring documented at defined frequency	Refer to the MIDI HPLC Procedure. The MIDI software includes a blank run. Positive and negative controls are included with each batch.
MIC.32708 Carryover Detection Phase II	There is a procedure for the detection and evaluation of potential carryover. NOTE: No matter what type of injection is used, the procedure must address criteria for the evaluation of potential carryover from a preceding elevated (high concentration) sample to the following sample, either periodically, or in each analytical batch analysis. Evidence of Compliance: ✓ Records of reassessment of samples with potential carryover	Refer to the MIDI HPLC Procedure. Refer to the PQ tables for negative control QC records.
MIC.32746 HPLC Growth Media Phase II	The laboratory procedures define which growth media may be used for organisms to be analyzed by HPLC. NOTE: Final results can be influenced by conditions of growth. For reliable results, standard conditions of analysis must be met, including growth media.	Refer to the MIDI HPLC Procedure.
MIC.32784 Peak Verification Phase II	There is a procedure for verifying calibration of the peak-naming table, if used. NOTE: In order to insure that peaks are correctly identified by interpretive software, the table must be verified at least annually with standard materials or organisms with known characteristics.	Vendor performs post-maintenance test runs for peak verification with annual PM. See PM notebook in testing area.

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MIC.32822 HPLC Method Validation Phase II	The HPLC method has been validated using known strains of bacteria, including strains expected to be encountered in routine clinical use. Evidence of Compliance: ✓ Record of method validation with appropriate strains	Refer to the MIDI HPLC Procedure under the test validation section.
MIC.32860 HPLC Result Review Phase II	There is a procedure for review of HPLC results in conjunction with other laboratory data prior to reporting results. NOTE: HPLC is only one tool for microbial identification. When results of HPLC analysis conflict with growth characteristics, pigmentation, or the results of biochemical or molecular testing, identification decisions must be based on all the information available.	Refer to the MIDI HPLC Procedure under the Purity Check section.
MIC.32898 HPLC Analysis - Pure Isolates Phase II	There are procedures to check the purity of cultures used as a source for HPLC analysis. NOTE: Results of HPLC analysis may be unreliable if mixed cultures are tested. If HPLC is performed on an isolate from liquid culture and an interpretable chromatogram is obtained, it is not necessary to await the results of the purity check before reporting results, but a purity check must still be performed.	Refer to the MIDI HPLC Procedure under the Purity Check section.
MIC.32936 HPLC Reagent Storage/Grade Phase I	Reagents and solvents are stored correctly and of appropriate grade, and solvent purity is assessed when needed. NOTE: Only HPLC grade solvents are recommended for this procedure. Degradation begins once ultra-pure solvents are opened. Degradation can be slowed by storing solvents in tightly capped, amber bottles in the dark. Solvent purity verification is suggested when a degradation-related problem is suspected. Evidence of Compliance: ✓ Reagent logs	Refer to the PQ tables for reagent documentation.
MIC.32974 Instrument Operation Phase II	Procedures are documented for operation, calibration, and maintenance. NOTE: Basic principles of HPLC analysis require continual monitoring of analysis conditions, including maintenance, standard operating procedures, and system calibration. System problems and corrective actions must be appropriately documented.	Refer to the PQ tables. System problems or corrective actions are documented and stored with PQ table records.

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MIC.33012 Instrument Performance Phase II	Instrument performance (e.g. retention times, detector response) is checked after major instrument maintenance. NOTE: Instrument performance must be verified by control runs after major maintenance. Evidence of Compliance: ✓ Instrument performance records	Refer to the MIDI HPLC Procedure. Refer to the PM notebook from the vendor.
LABORATORY SAFETY		
MIC.33050 Specimen Collection Phase II	All specimens for mycobacterial culture are collected and/or received in sealed leak-proof containers.	Refer to the test directory.
MIC.33100 Centrifuge Safety Phase II	In centrifuging specimens, sealed screw-capped tubes are enclosed in sealed safety centrifuge carriers (i.e. a double closure system) used to minimize aerosol hazards.	See centrifuge in AFB room.
MIC.33300 Biological Safety Cabinet Phase II	The biological safety cabinet meets minimum requirements for mycobacterial work. NOTE: Exhaust air from a class I or class II biological safety cabinet must be filtered through high efficiency particulate air (HEPA) filters. Air from Class I and IIB cabinets is hard-ducted to the outside. Air from Class IIA cabinets may be recirculated within the laboratory if the cabinet is tested and certified at least every 12 months. It may be exhausted through a dedicated stack that protects against backflow of air from adverse weather conditions or through the building exhaust air system in a manner (e.g. thimble connection) that avoids any interference with the air balance of the biological safety cabinet or building exhaust system. Evidence of Compliance: ✓ Written procedure defining the types of safety cabinets, filtration systems and exhaust systems used AND ✓ Maintenance schedule of BSC function checks AND ✓ Records of testing and certification AND ✓ Records of HEPA filters used for filtration of all BSC classes AND ✓ Records of exhaust mechanism OR recirculation, if appropriate	Refer to the Biosafety Cabinet Operation and Maintenance Procedure. Maintenance and certification records are kept by the supervisor and clinical engineering.

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MYCOLOGY		
MEDIA		
MIC.41200 Media QC Phase II	An appropriate sample of each medium prepared by the laboratory or purchased but not excluded from testing in NCCLS M22-A3 is checked for each of the following. 1. Sterility (following introduction of additives after sterilization) 2. Ability to support growth and biochemical reactivity (where applicable) by means of stock cultures or by parallel testing with previous batches Evidence of Compliance: ✓ Records of media QC for laboratory-prepared or non-exempt purchased media	Records can be accessed in LIS via function MQCR. Nonexempt fungal media that we use includes Birdseed agar, CGB agar, CHROMagar Candida, and Potato Flakes agar.
CONTROLS AND STANDARDS		
MIC.41250 Reference Organisms Phase II	Reference cultures are used to check stains and reagents at appropriate intervals.	Refer to the QC Reference Guide for examples of control strains used for media and identification tests.
MIC.41270 Nucleic Acid Probe/Exo-antigen QC Phase II	If nucleic acid probes or exo-antigen tests are used for identification of fungi isolated from culture, appropriate positive and negative controls are tested on each day of use. Evidence of Compliance: ✓ Written procedure defining QC for nucleic acid probe or exo-antigen tests AND ✓ Records of nucleic acid probe or exo-antigen QC documented at defined frequency	N/A
MIC.41330 QC Verification Phase II	The results of controls are reviewed for acceptability before reporting patient results. Evidence of Compliance: ✓ Written policy/procedure stating that controls are reviewed and acceptable prior to reporting patient results AND ✓ Evidence of corrective action taken when QC results are not acceptable	Refer to the Quality Lab Practices document: Quality Control Failures & Corrective Action. Refer to MQCR for QC results and any corrective actions.
MIC.41345 QC Corrective Action Phase II	There is documentation of corrective action when quality control results exceed the acceptability limits.	QC failures and corrective actions are entered in LIS and can be reviewed with function MQCR.

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MIC.41370 Direct Smear Stain QC Phase II	Direct patient specimen stains (e.g. acid fast, PAS, Giemsa, Gomori's methenamine silver, India ink) are checked with positive and negative controls on each day of patient sample testing. NOTE: For certain stains such as GMS and Giemsa, the slide itself serves as the negative control. Controls for KOH preparations are not required. Evidence of Compliance: ✓ Records of stain QC documented at defined frequency	See next item.
MIC.41390 Fluorescent Stain QC Phase II	Fluorescent stains (such as calcofluor white) are checked with positive and negative controls each time of use and results documented.	Records of calcofluor white stain QC are in LIS and can be viewed with function MQCR (item code CFWST).
PROCEDURES AND TESTS		
MIC.42025 Cryptococcal Antigen Phase II	If cryptococcal antigen-detection methods are used on CSF, back-up cultures are performed on positive CSF specimens submitted for diagnosis. Evidence of Compliance: ✓ Written procedure stating that CSF cultures are performed in conjunction with initial cryptococcal antigen tests OR procedure describing testing at another location AND ✓ Records of back-up CSF cultures performed on-site OR records indicating that cultures are performed at another location	Add-on testing must be ordered by the clinician. Positive CSF reports have a comment attached: A fungus culture should be ordered to determine the species of Cryptococcus and to recover the organism for potential susceptibility testing.
MIC.42050 Selective Media Phase II	Suitable selective media are used for the growth and isolation of ermatophytes and/or systemic fungi. Evidence of Compliance: ✓ Written procedure for mycology culture defining the media used for growth and isolation	Refer to the Specimen Processing Procedures.
MIC.42100 Selective Media Phase II	Media with antimicrobial agents are used to suppress the growth of contaminants. NOTE: Antimicrobial agents may inhibit some yeasts and the yeast phase of dimorphic organisms. Both types of media (with and without antimicrobials) should be available and used when indicated. Evidence of Compliance: ✓ Written procedure for mycology culture defining the use of media to suppress contaminants	Refer to Processing Fungal Cultures in the Mycology manual or the Specimen Processing procedures.

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MIC.42150 Incubation Temperature Phase II	Incubation temperatures for the growth and isolation of dermatophytes and systemic fungi are defined and followed under culture conditions. Evidence of Compliance: ✓ Temperature records	Refer to the Specimen Processing Procedures for incubation temperatures. Temperature records for each incubator can be accessed via function MQCR (item codes BF301, BF302, BF303, BF304, and BF24)
MIC.42200 Incubation Temperature Phase II	If cultures are incubated at room temperatures, actual ambient temperature (22-26° C) is checked daily to determine if proper growth conditions are being maintained.	Records can be reviewed in LIS via function MQCR (item code BF24)
MIC.42250 Differential Tests Phase II	Procedures for the differentiation and identification of fungi (differential tests) are adequate for the needs of the laboratory. NOTE: Laboratories offering full identification must have sufficient procedures to do so. Smaller laboratories with limited services should have an arrangement with an approved reference laboratory for back-up and complete identification of mycology specimens. Evidence of Compliance: ✓ Written procedure detailing tests performed and identification scheme appropriate for the extent of testing	Refer to the Mycology Manual.
MIC.42350 Differential Tests Phase II	Differential tests include biochemical tests (e.g. urease, carbohydrate assimilation and/or fermentation).	Refer to the Mycology Manual.
MIC.42400 Differential Tests Phase I	Differential tests include slide cultures (when appropriate).	Refer to the Mycology Manual.
MIC.42450 Differential Tests Phase I	Differential tests include nutritional studies for dermatophytes when identification is carried to the species level.	N/A
MIC.42550 Dimorphic Fungi Phase I	The identification of dimorphic fungal isolates is confirmed by exo-antigen, molecular, yeast-mold conversion or tissue phase detection tests.	Suspect isolates are sent to ARUP for DNA probe testing

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LABORATORY SAFETY		
MIC.43050 Safety Precautions Phase II	If plate culture media is used in mycology, appropriate safety precautions are taken (such as taping lid to plate on both sides when not in use or other appropriate measures) to prevent the accidental opening of a plate. Evidence of Compliance: ✓ Written procedure defining safety precautions for handling mycology culture plates	Refer to the Safety document in the Mycology manual.
MIC.43100 Safety Precautions Phase II	When working with a colony exhibiting mycelial growth, transfers are performed within a biological safety cabinet.	Refer to the Safety document in the Mycology manual.
MIC.43150 Safety Precautions Phase II	The use of slide culture techniques is limited, where possible, to work with low virulence organisms; or if used for dimorphic fungi, special safety precautions are defined and rigidly adhered to.	Refer to the Safety document in the Mycology manual.
MIC.43200 Safety Precautions Phase II	When preparing teased preparations or "scotch" tape preps, mycelia are always submerged in some liquid medium (such as lactophenol cotton blue).	Refer to the Lactophenol Cotton Blue procedure.
MIC.43250 Biological Safety Cabinet Phase II	A biological safety cabinet (BSC) or hood is available for handling specimens or organisms considered to be highly contagious by airborne routes. Evidence of Compliance: ✓ Maintenance schedule of BSC function checks AND ✓ Records of testing and certification	Records of maintenance and certification are kept by supervisor/clinical engineering.
MIC.43300 Biological Safety Cabinet Phase II	The biological safety cabinet (BSC) is certified annually to ensure that filters are functioning properly and that airflow rates meet specifications. Evidence of Compliance: ✓ Maintenance schedule of BSC function checks AND ✓ Records of testing and certification	Records of maintenance and certification are kept by supervisor/clinical engineering.
MIC.43350 Biological Safety Cabinet Phase II	The BSC meets minimum requirements for mycologic work. Evidence of Compliance: ✓ Written procedure defining the types of safety cabinets, filtration systems and exhaust systems used AND ✓ Maintenance schedule of BSC function checks AND ✓Records of testing and certification AND ✓ Records of HEPA filters used for filtration of all BSC classes AND ✓ Records of exhaust mechanism OR recirculation, if appropriate	Refer to the Biosafety Cabinet Operation and Maintenance Procedure. Maintenance and certification records are kept by the supervisor/clinical engineering.

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PARASITOLOGY		
QUALITY CONTROL		
MIC.45900 QC Verification Phase II	The results of controls are reviewed for acceptability before reporting patient results. Evidence of Compliance: ✓ Written policy/procedure stating that controls are reviewed and acceptable prior to reporting patient results AND ✓ Evidence of corrective action taken when QC results are not acceptable	Refer to the Quality Lab Practices document. Records can be found in MQCR.
MIC.48450 QC Corrective Action Phase II	There is documentation of corrective action when control results exceed the acceptability limits.	Records can be found in MQCR.
MIC.51000 Reference Materials Phase I	Reference materials, such as permanent mounts, photomicrographs, NCCLS documents M15-A and M28-A2, or printed atlases are available at the work bench to assist with identifications.	Parasitology reference materials are located on the shelf above the Parasitology bench.
REAGENTS		
MIC.51120 Reagents Phase II	If zinc sulfate is used, the solution is stored in a tightly-stoppered bottle and checked for specific gravity (1.18 for fresh specimens and 1.20 for formalin-fixed specimens) with a hydrometer whose scale is large enough to differentiate the two values. Evidence of Compliance: ✓ Records for specific gravity checks on the zinc sulfate solution	N/A
MIC.51160 Permanent Stain QC Phase II	All permanent parasitology stains are checked for intended reactivity with controls or reference materials at least monthly (or with each test if performed less frequently than every month). Evidence of Compliance: ✓ Records of permanent stain QC documented at defined frequency	Trichrome QC is entered in LIS. Access records via MQCR under item code TRCHST.
MIC.51170 Special Stain QC Phase II	Stains that are used to detect specific parasites (e.g. acid fast, fluorescent) are checked with appropriate control organisms each time that stain is used. Evidence of Compliance: ✓ Records of special stain QC each time of use	Modified Kinyoun QC is entered in LIS. Access records via MQCR under item code CRYPST.

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INSTRUMENTS AND EQUIPMENT		
MIC.51210 Ocular Micrometer Phase II	An ocular micrometer is available for determining the size of eggs, larvae, cysts, trophozoites, and microfilaria or other bloodborne parasites.	Ocular micrometers are available on the Parasitology microscope and the double-headed microscope.
MIC.51220 Calibration/Recalibration - Ocular Micrometer Phase II	The ocular micrometer has been calibrated for the microscope(s) in which it is used and it is recalibrated each time the eyepieces or objectives are changed. NOTE: Calibrations can be checked against a micrometer or other objects of known dimensions. If there are no changes to a particular microscope's optical components, there is no need to recheck calibration. Evidence of Compliance: ✓ Records of initial calibration and recalibration if applicable	Calibration records for ocular micrometers are posted near the parasitology and double-headed microscopes.
PROCEDURES AND TESTS - STOOLS FOR OVA AND PARASITES		
MIC.52100 Ova/Parasite Exam Phase II	The microscopic examination of all stools submitted for an ova and parasite (O&P) examination includes a concentration procedure and a permanent stain. Evidence of Compliance: ✓ Written procedures for stool for O&P AND ✓ Patient reports/worksheets with concentration and permanent stain results	Refer to the Ova and Parasite Procedure.
MIC.52190 Stool Number/Timing Phase I	The laboratory has guidelines (developed with clinicians) for the number and/or timing of collection of stool specimens submitted for routine parasitology testing. NOTE: Suggestions made by the authors of a 1996 CAP Q-Probes study (Valenstein et al) include: 1. Accept no more than 2 or 3 specimens/patients without prior consultation with an individual who can explain the limited yield provided by additional specimens 2. Do not accept specimens from inpatients after the fourth hospital day, without prior consultation These recommendations are for diagnostic testing. Different guidelines may apply to tests ordered for follow-up.	Refer to the Ova and Parasite Procedure. Also described in the test directory under test code OP.

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BLOOD FILMS FOR MALARIA AND OTHER PARASITES		
MIC.52193 Blood Parasite Detection Phase II	The microscopic examination of blood films submitted for detection of blood parasites allows for detection of parasites responsible for malaria, babesiosis, trypanosomiasis and filariasis.	Performed in Hematology
MIC.52195 Percentage Parasitemia Reporting Phase I	When blood films are positive for malaria parasites (Plasmodium spp.), the percentage parasitemia is reported along with the organism identification. Evidence of Compliance: ✓ Written procedure for performing and reporting parasitemia percentage with identification	Performed in Hematology
MIC.52200 Thick and Thin Films Phase II	Both thick and thin films (routine blood films and/or buffy coat films), or methods of equivalent sensitivity, are made to provide thorough examination for blood parasites.	Performed in Hematology
MIC.52220 Malaria Stain Procedure Phase I	There is documentation that malaria stains are washed with a buffer of a pH appropriate for the stain used (e.g. pH 6.8-7.2 for Giemsa), or the range specified by the manufacturer.	Performed in Hematology
MIC.52260 Slide Review Procedure Phase II	An adequate number of fields are examined under oil immersion using the 100X oil immersion objective (e.g. 300 fields). Evidence of Compliance: ✓ Written procedure defining criteria for assessment of malaria slides including objective and number of fields examined	Performed in Hematology
LABORATORY SAFETY		
MIC.53050 Formalin Safety Phase II	If a procedure uses formalin, formaldehyde vapor concentrations are maintained below the following maxima, expressed as parts per million. Evidence of Compliance: ✓ Written safety procedure for formalin including action limits, criteria for discontinuation of monitoring and criteria for resumption of monitoring AND ✓ Record of initial formalin monitoring AND ✓ Records of resumption of formalin monitoring when action limits are exceeded	Refer to the Formaldehyde Exposure Control Plan. Records of monitoring are kept bythe supervisor.
MIC.53150 Ether Safety Phase II	If a procedure uses ether, the diethyl ether is stored on open shelves in a well ventilated room using the smallest can feasible (as shipped by manufacturer).	N/A

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VIROLOGY		
QUALITY CONTROL - REAGENTS		
MIC.62400 Order Information Phase I	For viral screening tests by direct antigen detection (direct immunofluorescence or EIA), rapid cell culture or molecular methods, reports and test order information indicates thespecific viruses sought/detected by the assay.	See FilmArray Respiratory Panel Procedure and patient reports.
LABORATORY SAFETY		
MIC.63050 Biological Safety Cabinet Phase II	A biological safety cabinet (BSC) or hood is available for handling specimens or organisms considered to be highly contagious by airborne routes. Evidence of Compliance: ✓ Maintenance schedule of BSC function checks AND ✓ Records of testing and certification	Records of testing and certification are kept by the departmental supervisor and clinical engineering.
MIC.63100 Biological Safety Cabinet Phase II	The BSC is certified annually to ensure that filters are functioning properly and that airflow rates meet specifications. Evidence of Compliance: ✓ Maintenance schedule of BSC function checks AND ✓ Records of testing and certification	Records of testing and certification are kept by the departmental supervisor and clinical engineering.
MIC.63150 Biological Safety Cabinet Phase II	The BSC meets minimum requirements for virology work. Evidence of Compliance: ✓ Written procedure defining the types of safety cabinets, filtration systems and exhaust systems used AND ✓ Maintenance schedule of BSC function checks AND ✓ Records of testing and certification AND ✓ Records of HEPA filters used for filtration of all BSC classes AND ✓ Records of exhaust mechanism OR recirculation, if appropriate	Refer to the Procedure - Biosafety Cabinet Operation and Maintenance.
MIC.63200 Specimen Handling/Processing Phase II	There are written procedures for the safe handling and processing of virology specimens. Evidence of Compliance: ✓ Written policies for safe handling/processing of specimens	Refer to the FilmArray Respiratory Panel Procedure
MIC.63220 Specimen Handling/ Processing Phase II	There are written procedures for the safe handling and processing of samples that are suspected to contain avian influenza virus, SARS coronavirus, or other similar emerging pathogens.	Refer to the FilmArray Respiratory Panel Procedure for specimen processing in a BSC.

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MIC.63250 Hazardous Waste Disposal Phase II	Specimens and used media are disinfected, sterilized or contained in a manner to minimize the hazard of an accident during transportation to a remote autoclave or incinerator.	Specimens are discarded into specially marked biohazard bins and transported for incineration.
MOLECULAR MICROBIOLOGY - GENERAL REQUIREMENTS		
Quality Management		
MIC.63252 Statistics Phase I	When appropriate, appropriate statistics (e.g. percentage of results that are positive for Chlamydia trachomatis and/or Neisseria gonorrhoeae) are maintained and monitored. NOTE: An increase above the expected positive rate within a run or over multiple runs should prompt investigation for potential false positive results. Evidence of Compliance: ✓ Written procedure for calculating statistics including thresholds AND ✓ Records of statistical data, evaluation and corrective action if indicated	Statistics are compiled for each month and published on the intranet. Thresholds for positive rates within runs can be found in the Environmental Monitoring and Decontamination Procedure.
MIC.63256 Turnaround Times Phase I	There is evidence that the laboratory monitors sample turnaround times and that they are appropriate for the intended purpose of the test. NOTE: There are certain clinical situation in which rapid completion is essential. An example is detection of HSV in CSF. Evidence of Compliance: ✓ Written policy defining turnaround time and mechanism for monitoring AND ✓ Records showing that times defined in the policy are routinely met	TATs are published in the Test Directory. We have not historically monitored TATs for molecular tests because testing is performed on both 1st and 2nd shift. Per AR 11/30/12, "None of our PCR testing qualifies as critical or "essential", as indicated in the item note."

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QUALITY CONTROL		
MIC.63262 Daily QC Phase II	Controls are run daily for quantitative and qualitative tests. NOTE 3: Daily controls may be limited to electronic/procedural/built -in (e.g. internal, including built-in liquid) controls for tests meeting the following criteria: 2. For qualitative tests, the test system includes an electronic/procedural /built-in internal control run daily 3. For laboratories subject to US regulations, the system is FDA-cleared or approved, and not modified by the laboratory 4. The laboratory has performed studies to check the adequacy of limiting daily QC to the electronic/procedural/built-in controls. Studies must include daily comparison of external controls to built-in controls for at least 20 consecutive days when patient samples are tested. For checking of multiple identical devices, the minimum of 20 consecutive daily comparisons applies to the initial device; the laboratory director is responsible for determining the extent of the comparison studies for the other devices. Acceptable results are required before daily quality control can be limited to built-in controls. The laboratory director is responsible for determining criteria for acceptability. Records must be retained while an instrument/method is in service, and for two years afterwards. The requirement for 20 consecutive daily comparisons is effective for verification studies performed after 1/31/2012. Corrective action must be taken if either the internal or external control is out of acceptable range during or after the evaluation process. Repeating controls or re-evaluation of the internal control system may be necessary to achieve acceptable results. 5. External surrogate sample controls are run for each new lot number or shipment of test materials; after major system maintenance; and after software upgrades.** Regarding the positive external control for qualitative tests, best practice is to run a weak positive control maximize detection of problems with the test system. 6. External surrogate sample controls are run as frequently as recommended by the test manufacturer, or every 30 days, whichever is more frequent. Evidence of Compliance: ✓ Records of QC results including external and electronic/procedural/built-in control systems AND ✓ Records documenting in-house validation of electronic/procedural/built-in control systems, if used	External control QC results can be accessed in LIS under function MQCR.
MIC.63264 Multiplex QC Phase II	For multiplex tests, controls for each analyte are either included in each run or rotated so that all analytes are tested periodically. Evidence of Compliance: ✓ Written procedure defining multiplex test QC AND ✓ Records of multiplex test QC	Refer to the FilmArray procedures. QC is documented in LIS (item codes FILMBL & FILMR)

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MIC.63274 QC Verification Phase II	Results of controls are reviewed for acceptability prior to reporting patient results. NOTE: Conditions causing unacceptable control results must be investigated and corrective action must be documented. Evidence of Compliance: ✓ Written policy/procedure stating that controls are reviewed and acceptable prior to reporting patient results AND ✓ Evidence of corrective action taken when QC results are not acceptable	Refer to the molecular test procedures for the written policy. Corrective actions would be documented in LIS.
MIC.63275 QC Acceptability Limits Phase II	Acceptability limits are defined for all control procedures, control materials, and standards. NOTE: Acceptability limits must be defined for all control procedures, control materials, and standards. These controls must be appropriate for the range of sensitivities tested and should, ideally, focus on result ranges that are near clinical decision points. Evidence of Compliance: ✓ Written QC procedure(s) defining acceptability limits	Refer to the molecular test procedures for the written policy.
MIC.63276 QC Corrective Action Phase II	There is documentation of corrective action when control results exceed defined acceptability limits.	Corrective actions would be documented in LIS.
MIC.63277 QC Statistics Phase II	For quantitative assays, quality control statistics are performed monthly to define analytic imprecision and to monitor trends over time. Evidence of Compliance: ✓ Written procedure for monitoring of analytic imprecision including statistical analysis of data	N/A
MIC.63278 Inhibition Assessment Phase II	For assays without an internal control, the laboratory has a procedure to assess inhibition for each specimen type.	N/A
MIC.63282 Equivocal QC Phase II	If results of negative controls are positive or equivocal, the laboratory has a written procedure in place to investigate and resolve the problem.	Refer to the molecular test procedures.
PROCEDURE MANUAL		
MIC.63297 Analytic Interpretation Phase II	There are written guidelines for analytic interpretation of results, as applicable.	N/A

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MIC.63298 Calculating Quant. Values Phase II	For quantitative molecular tests, methods for calculating quantitative values are adequately described and units clearly documented.	N/A
SPECIMEN HANDLING & PROCESSING		
MIC.63318 Specimen Collection Manual Phase II	Procedures are in place to prevent specimen loss, alteration, or contamination during collection, transport, processing and storage.	Specimen collection, processing and storage are listed in the Test Directory. Refer to the molecular test procedures for details regarding processing samples in Microbiology.
MIC.63322 Specimen Aliquots Phase II	If aliquoting of specimens is performed, there is a written procedure to prevent any possible cross-contamination of the aliquot containers.	N/A Specimens for molecular testing are not transferred to aliquot containers.
MIC.63324 Residual Samples Phase I	If residual samples are used for amplification-based testing, policies and procedures ensure absence of cross-contamination of samples. NOTE: An example of a residual sample is a liquid based cytology sample that is tested post-cytologic processing using amplified C. trachomatis or N. gonorrhoeae tests.	N/A
MIC.63327 Specimen ID Phase II	There is a system to positively identify all patient specimens, specimen types and aliquots through all phases of the analysis, including specimen receipt, nucleic acid extraction, nucleic acid quantification, hybridization, detection, documentation, and storage.	Refer to the molecular test procedures and the test logs that illustrate the number identification system.
MIC.63328 Specimen Processing/ Storage Phase II	Patient samples are processed promptly or stored appropriately to minimize degradation of nucleic acids. NOTE: Frost-free freezers may not be used to store patient samples unless freezer temperature is monitored by a continuous monitoring system, or a maximum/minimum thermometer. Evidence of Compliance: ✓ Written procedure for processing and storage of specimens	Refer to the molecular test procedures for processing and storage instructions.
RESULTS REPORTING		
MIC.63330 Final Report Phase I	The final report includes a summary of the test method and information regarding clinical interpretation if appropriate.	See molecular test procedures for reporting protocol. Sample reports can also be provided.

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REAGENTS		
MIC.63350 Reagent Storage Phase II	All test reagents and controls are stored properly and in a manner which minimizes target DNA/RNA contamination and degradation. Evidence of Compliance: ✓ Written procedure defining storage requirements for reagents and controls	Refer to the molecular test procedures for reagent storage instructions.
MIC.63580 New Reagent Lot - Multiplex Tests Phase II	For multiplex tests, all analytes detected by the assay are individually verified for each new shipment and/or lot. NOTE: Verification of new shipments and/or lots may be difficult for rare organisms or subtypes. In these situations, verification may be performed annually. Evidence of Compliance: ✓ Written procedure for new lot/shipment validation of all analytes detected by each multiplex assay AND ✓ Records of new lot/shipment validation	Refer to the FilmArray test procedures. Analytes are verified using multi-marker controls. Results are documented in LIS and can be viewed in MQCR (item codes FILMBL & FILMR)
PROCEDURES & TESTS		
MIC.63800 Carryover Phase II	Nucleic acid amplification procedures (e.g. PCR) are designed to minimize carryover (false positive results) using appropriate physical containment and procedural controls. NOTE: This item is primarily directed at ensuring adequate physical separation of pre- and post-amplification samples to avoid amplicon contamination.The extreme sensitivity of amplification systems requires that the laboratory take special precautions. For example, pre- and post-amplification samples should be manipulated in physically separate areas; gloves must be worn and frequently changed during processing; dedicated pipettes (positive displacement type or with aerosol barrier tips) must be used; and manipulations must minimize aerosolization. Enzymatic destruction of amplification products is often helpful, as is real-time measurement of products to avoid manual manipulation of amplification products. Evidence of Compliance: ✓ Written procedure that defines the use of physical containment and procedural controls as applicable to minimizing carryover	Refer to the PCR Contamination Prevention, Environmental Monitoring, and Decontamination Procedure.

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MIC.64025 Isolation/Preparation Phase II	The adequacy of nucleic acid isolation/preparation procedures are evaluated. NOTE: Adequacy of nucleic acid isolation/preparation procedures (manual or automated) must be evaluated with each assay by the use of positive and negative controls run in parallel with patient samples.To the extent possible, controls must be processed through all steps of the assay, including the extraction phase. Evidence of Compliance: ✓ Written procedure for evaluating adequacy of nucleic acid AND ✓ Records of controls used to assess adequacy	Each assay is evaluated when a new lot/shipment is received and every 30 d thereafter. Positive and negative external control materials are used and QC is entered into LIS (see MQCR).
MIC.64350 Temp. Range Defined Phase II	For each step of the procedure all incubation temperatures are defined and documented. NOTE: For some instruments this function is performed automatically by software provided by the manufacturer.	N/A No incubation steps are included with the sample preparation. The instrument software monitors parameters during amplification.
MIC.64450 Incubations - Manufacturer Specs. Phase II	Incubations (reactions) performed using baths/blocks/instruments meet manufacturer specifications. NOTE: Bath/blocks/instruments must be able to maintain the appropriate temperature throughout the incubation (reaction) within the range specified by the manufacturer of the assay. Evidence of Compliance: ✓ Written procedure for incubation performance consistent with manufacturer specifications	N/A
MIC.64550 Temp. Corrective Action Phase II	If any incubation temperature is out of range, the deviation is reported to the supervisor or designee and corrective action documented.	N/A

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INSTRUMENTS		
MIC.64614 Thermocycler Temperature Checks Phase II	Individual wells (or a representative sample thereof) of thermocyclers are checked for temperature accuracy before being placed in service and at least annually thereafter. NOTE: A downstream measure of well-temperature accuracy (such as productivity of amplification) may be substituted to functionally meet this requirement. For closed systems this function should be performed as a component of the manufacturer-provided preventative maintenance. Evidence of Compliance: ✓ Written procedure for verification of thermocycler accuracy AND ✓ Records of thermocycler verification	BD MAX Instrument is serviced and checked by the vendor every 6 months.
LABORATORY SAFETY		
MIC.64620 Specimen Handling/Processing Phase II	There are documented policies for the safe handling and processing of samples from patients with suspected infections due to avian influenza, SARS, or similar emerging pathogens.	Refer to the Microbiology Safety Guidelines
PERSONNEL		
MIC.64631 Personnel Training Phase II	There is an adequate training program for supervisory personnel and technologists. Evidence of Compliance: ✓ Documented training program AND ✓ Records of training by the institution or appropriate outside organization	See training records for the BD MAX on the G drive (accessible by director, supervisor and technical specialist).
MIC.64634 Bench Testing Supervision Phase II	If the laboratory performs laboratory-developed or modified FDA-cleared/approved molecular testing, the person in charge of bench testing/section supervisor of molecular microbiology has education equivalent to an associate's degree (or beyond) in a chemical, physical, biological science or medical technology and at least 4 years experience (one of which is in molecular diagnostic testing)) under a qualified section director. Evidence of Compliance: ✓ Records of qualifications including degree or transcript, certification/registration, current license (if required) and work history in related field	N/A

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MOLECULAR MICROBIOLOGY - FDA CLEARED/APPROVED NON-AMPLIFICATION METHODS (BD Affirm)		
QUALITY CONTROL		
MIC.64710 ISH QC Phase II	Appropriate positive and negative controls are run in parallel and results documented for each microbial in situ hybridization (ISH) analysis.	N/A
MIC.64720 QC Corrective Action Phase II	Corrective action is documented when microbial ISH (in situ hybridization) results do not correlate with culture findings.	N/A
MIC.64730 Slide Usage - Manufacturer Rec. Phase II	For microbial fluorescence in situ hybridization (FISH) testing, the laboratory uses only the microscope slides and filters recommended by the manufacturer.	N/A
MIC.64750 Group B Screening Phase II	Negative results obtained for Group B streptococcus intrapartum screening by direct DNA probe are followed up with a selective broth culture method.	N/A
ASSAY VERIFICATION		
MIC.64760 Verification Study Phase II	There is documentation that the laboratory has performed a verification study prior to reporting patient results.	Refer to verification studies included at the end of each test procedure.
MIC.64770 Validation Studies - Sample Type/Collection Phase II	If the laboratory tests sample types or uses collection devices other than those listed in the package insert, the laboratory performs validation studies to document adequate performance of the test.	N/A
MOLECULAR MICROBIOLOGY - FDA CLEARED/APPROVED TARGET & SIGNAL AMPLIFICATION METHODS		
QUALITY CONTROL		
MIC.64810 Test Performance - Manufacturer Instructions Phase II	Tests are performed and results reported as specified in package inserts without substitution of reagents or modification of testing protocol.	Yes, refer to the test procedures. Tests are performed as specified in the PI.

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MIC.64815 Validation Studies - Sample Type/Collection Phase II	If the laboratory tests sample types or uses collection devices other than those listed in the package insert, the laboratory performs validation studies to document adequate performance of the test.	Refer to the BD MAX MRSA test procedure. Validation of a different collection device is outlined in the verification section at the end of the test procedure.
MIC.64817 Pre-enrichment - GBS Phase II	A pre-enrichment step using a selective broth enrichment culture is performed for antepartum (35-37 weeks gestation) vaginal/rectal swab screening for Group B streptococci (GBS) colonization by nucleic acid amplification testing (NAAT).	Refer to the BD MAX GBS test procedure. Lim broth is used for pre-enrichment.
MIC.64820 M.tb Molecular Testing Phase II	When performing molecular testing for the detection of M. tuberculosis directly from clinical specimens, culture is performed on all samples regardless of the molecular test result. Evidence of Compliance: ✓ Patient reports or worksheets	N/A
MIC.64825 Modified Cut-Off Phase II	If the laboratory has modified the manufacturer's cut off-value for a positive result, the new cut-off value has been validated. Evidence of Compliance: ✓ Records of cut-off validation when different cut-off values are utilized	N/A
MIC.64830 Test Calibration Phase II	For quantitative tests, test calibration is performed according to the manufacturer's specifications. Evidence of Compliance: ✓ Records of calibration	N/A
MIC.64832 AMR Verification Phase II	Verification of the analytical measurement range (AMR) is performed with matrix-appropriate materials that include the low, mid and high range of the AMR, and the process is documented. Evidence of Compliance: ✓ Written procedure for AMR verification defining the types of materials used and acceptability criteria consistent with manufacturer's instructions	Contacted CAP on 3/12/14 at 1044. Kathy indicated that this checklist item only applies to quantitative assays. We do not have any quantitative assays.
MIC.64834 AMR Verification Criteria Phase II	Criteria are established for verifying the analytical measurement range and compliance is documented. Evidence of Compliance: ✓ Written procedure defining the method, frequency and acceptability criteria for AMR verification	Contacted CAP on 3/12/14 at 1044. Kathy indicated that this checklist item only applies to quantitative assays. We do not have any quantitative assays.

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SEQUENCING		
MIC.64835 Sequencing Data Criteria Phase II	Criteria are established for the acceptability and interpretation of primary sequencing data.	N/A
MIC.64840 Sequence Data Interp. Phase I	The laboratory has a process in place to assure that interpretation of sequence data is based on the latest version of the manufacturer's interpretive software.	N/A
MIC.64845 Alternative Sequencing Interpretive DB Phase II	If the laboratory uses alternative sequence interpretive databases, either alone or in conjunction with manufacturer's software, the alternative databases have been validated for the interpretation of the sequence data. Evidence of Compliance: ✓ Records of validation study if alternative interpretive databases are utilized, if applicable	N/A
MIC.64850 Sample/Amplicon Contamination Phase II	There is a procedure to prevent or detect potential cross-contamination of samples and/or amplicons.	N/A
MIC.64855 Sample/Amplicon Contamination Phase II	If results of fingerprint analysis or negative control indicate a potential for sample and/or amplicon contamination, the laboratory has a written procedure in place to investigate and resolve the problem.	N/A
ASSAY Validation/VERIFICATION		
MIC.64860 Validation/Ver. Study Phase II	There is documentation that the laboratory has performed a validation/verification study prior to reporting patient results.	Refer to verification studies included at the end of each test procedure.
MOLECULAR MICROBIOLOGY - LABORATORY-DEVELOPED OR MODIFIED FDA CLEARED / APPROVED TESTS		
QUANTITATIVE ASSAYS: CALIBRATION & STANDARDS		
MIC.64868 Calibration Procedures Phase II	Calibration procedures for each test system are adequate, and the calibration records are reviewed for acceptablility.	N/A
MIC.64870 Calibration Materials Phase II	High quality materials with test-system and matrix-appropriate target values are used for calibration and calibration verification whenever possible. Evidence of Compliance: ✓ Written procedure defining the use of appropriate calibration/calibration verification materials	N/A

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MIC.64872 Calibration Materials Phase II	All calibration materials used for non-FDA cleared/approved tests are documented as to quality. NOTE: Commercial standards used to prepare calibrators require certificates of analysis. The laboratory should document the accuracy of a new lot of calibrators by checking the new lot against the current lot.	N/A
MIC.64874 Calibration Material Labeling Phase II	All calibration materials are properly labeled as to content, calibration values, dates placed in service, and expiration dates. NOTE: Complete values need not be recorded directly on each vial of calibrator material, so long as there is a clear indication where specific values may be found for each analyte tested and each analyzer used by the laboratory. The dates may be recorded in a log (paper or electronic), rather than on the containers themselves, providing that all containers are identified so as to be traceable to the appropriate data in the log. Evidence of Compliance: ✓ Written procedure defining elements required for labeling of calibration material	N/A
MIC.64880 Calibration Verification Criteria Phase II	Criteria are established for frequency of calibration or calibration verification, and the acceptability of results. Evidence of Compliance: ✓ Written procedure defining the method, frequency and limits of acceptability of calibration verification for each instrument/test system AND ✓ Records of calibration verification documented at defined frequency	N/A
MIC.64882 Recalibration Phase II	The system is recalibrated when calibration verification fails to meet the established criteria of the laboratory. Evidence of Compliance: ✓ Written procedure defining criteria for recalibration AND ✓ Records of recalibration, if calibration or calibration verification has failed	N/A
MIC.64884 AMR Validation Phase II	Verification of the analytical measurement range (AMR) is performed with matrix-appropriate materials that include the low, mid and high range of the AMR, and the process is documented. Evidence of Compliance: ✓ Written procedure for AMR validation defining the types of materials used and acceptability criteria consistent with manufacturer's instructions	N/A

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MIC.64886 AMR Verification Criteria Phase II	Criteria are established for verifing the analytical measurement range and compliance is documented. Evidence of Compliance: ✓ Written procedure defining the method, frequency and acceptability criteria for AMR validation	N/A
QUALITY CONTROL		
MIC.64910 Probe Characteristics Phase II	Sufficient information is documented regarding the nature of any probe or primer used in an assay to permit interpretation and troubleshooting of test results. Evidence of Compliance: ✓ Records of probe details including oligonucleotide sequence, target, concentration, or purity, as applicable	N/A
MIC.64912 Current Primers/Probes Phase II	The laboratory has a method in place whereby the sequences of primers and probes are evaluated for compatibility with currently circulating microbial strains.	N/A
MIC.64915 Qualitative Cut-Off Phase II	For qualitative tests that use a cut-off value to distinguish positive from negative, the cut-off value is established initially, and verified with every change in lot or at least every 6 months. Evidence of Compliance: ✓ Written procedure for initial establishment and verification of the cut-off value AND ✓ Records of initial establishment and verification documented at defined frequency	N/A
SEQUENCING		
MIC.64920 Sequencing Data Criteria Phase II	Criteria are established for the acceptability and interpretation of primary sequencing data.	N/A
MIC.64922 Sequencing Data Interp. Phase II	The laboratory has a process in place to assure that appropriate databases are used for the interpretation of sequencing data.	N/A
MIC.64924 Seq. Data Correlation Phase II	The sequence data are correlated with available phenotypic data. Evidence of Compliance: ✓ Records of result review including correlation with phenotypic data	N/A

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MIC.64926 Sample/Amplic Contam Phase II	Procedures are in place to prevent or detect potential cross-contamination of samples and/or amplicons and to resolve problems from contamination of sequencing reactions.	N/A
TEST PROCEDURES		
MIC.64930 Nucleic Acid Extraction/Purification Phase II	Nucleic acids are extracted and purified by validated methods. Evidence of Compliance: ✓ Records to support nucleic acid extraction/purification is performed by a validated method	N/A
MIC.64934 Melting Temperature Phase II	For tests that generate a result based on a melting temperature (Tm), appropriately narrow temperature ranges (+/- 2.5º C) are defined and monitored.	N/A
MIC.64938 Autoradiograph Resolution/Gel Criteria Phase II	The autoradiographs and electrophoretic gel photographs are of sufficient resolution and quality (low background, clear signal, absence of bubbles, etc.) to permit the reported interpretation using objective criteria. Evidence of Compliance: ✓ Written procedure including interpretive criteria for autoradiographs or gels	N/A
MIC.64940 Molecular Weight Markers Phase II	Known molecular weight markers that span the range of expected bands are used for each electrophoretic run. Evidence of Compliance: ✓ Records of appropriate markers documented with each run	N/A
MIC.64944 Visual/Fluorescent Markers Phase II	Visual or fluorescent markers are used to determine the endpoint of gel electrophoresis.	N/A
ASSAY VALIDATION		
MIC.64952 Validation Study Phase II	There is documentation that the laboratory has performed a validation study prior to reporting patient results.	N/A
MIC.64956 Modified FDA-Cleared/Approved Assay Phase II	If the laboratory modifies an FDA-cleared/approved assay, the modified procedure has been validated to yield equivalent or superior performance. Evidence of Compliance: ✓ Records of validation studies for modified approved assays	N/A

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MIC.64960 Validation Studies - Specimen Selection Phase II	Validation studies were performed with an adequate number and representative (reasonable) distribution of samples for each type of specimen (e.g. blood, fresh/frozen tissue, paraffin-embedded tissue). Evidence of Compliance: ✓ Records of validation studies	N/A
MIC.64964 Validation Studies - Specimen Selection Phase II	Validation studies include specimens representing each strain or genotype, when appropriate. Evidence of Compliance: ✓ Records of validation studies	N/A
MIC.64968 Validation Study Comparison Phase II	The results of each validation study were compared to another valid test, such as a comparison to another test method or specimen exchange with a laboratory performing the same type of test in a similar fashion. Evidence of Compliance: ✓ Records of comparison and evaluation of each validation study to another test method OR records of comparison using specimen exchange with another laboratory	N/A
MIC.64972 Reference/Reportable Range Qualitative Phase II	For qualitative assays, the reference value and reportable range are defined. Evidence of Compliance: ✓ Written procedure defining reference and reportable range for each test	N/A
MIC.64976 Reference/Reportable Range - Quantitative Phase II	For quantitative assays, the reference and reportable ranges are defined. Evidence of Compliance: ✓ Written procedure defining reference and reportable range for each test	N/A
MIC.64980 Validation Study Phase II	Validation studies document test accuracy, analytical sensitivity, analytical specificity, precision, and linear range (quantitative tests only).	N/A
MIC.64984 LDT Report Phase I	Reports for laboratory-developed assays contain a description of the method, a statement that the assay was developed by the laboratory, and appropriate performance characteristics.	N/A

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MIC.64988 ASR Report Phase II	If patient testing is performed using analyte-specific reagents (ASRs) obtained or purchased from an outside vendor, the patient report includes the disclaimer required by federal regulations.	N/A