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PROFICIENCY TESTING			
COM.01000 PT Procedure	The laboratory has written procedures for proficiency testing sufficient for the extent and complexity of testing done in the laboratory.	Phase II	Records of all surveys are kept in Lab QA/POCT office. The list is reviewed at least annually by Micro to ensure all areas are being tested when challenges are available. Lab General Policy Manual, Proficiency Testing section: 1. Proficiency Testing Program 2. Proficiency Testing and Peer Educational Materials Program/ Sample Handling Protocol
COM.01100 Ungraded PT Challenges	The laboratory has a procedure for assessing its performance on PT challenges that were intended to be graded, but were not. Evidence of Compliance: ✓ Records of review and evaluation of ungraded PT challenges	Phase II	A results evaluation review is supplied with all CAP PT results and is kept in Gail's office.
COM.01200 Activity Menu	The laboratory's current CAP Activity Menu accurately reflects the testing performed.	Phase I	Reviewed annually for accuracy. Record kept in Lab QA/POCT office.
COM.01300 PT Participation	The laboratory participates in the appropriate required proficiency testing (PT)/external quality assessment (EQA) program accepted by CAP for the patient testing performed. Evidence of Compliance: ✓ Records such as CAP order form or purchase order indicating that the laboratory is enrolled in CAP PT Programs for all analytes that CAP requires PT OR record of completed/submitted result forms for all analytes on the activity menu	Phase II	CAP is sole source of external PT in Micro. Records kept in Lab QA/POCT office.
COM.01400 Attestation Page	The proficiency testing attestation statement is signed by the laboratory director or designee and the individual performing the testing. Evidence of Compliance: ✓ Appropriately signed attestation statement from submitted PT result forms	Phase II	Records kept in Micro supervisor's office.

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COM.01500 Alternative Performance Assessment	For tests for which CAP does not require PT, the laboratory at least semi-annually exercises an alternative performance assessment system for determining the reliability of analytic testing. Evidence of Compliance: ✓ Records of completed external PT OR alternative assessments	Phase II	Records found on G drive/Micro/PT
COM.01600 PT Integration Routine Workload	The laboratory integrates all proficiency testing samples within the routine laboratory workload, and those samples are analyzed by personnel who routinely test patient/client samples, using the same primary method systems as for patient/client/donor samples. Evidence of Compliance: ✓ Written policy describing proper handling of PT specimens AND ✓ Instrument printout and/or work records AND ✓ Completed attestation pages from submitted PT result forms	Phase II	Refer to policies “Proficiency Testing Program” and “PT Sample Handling Protocol” which can be found in the Proficiency Testing section of the Lab General P&P manual on the intranet. Work records and attestation pages can be found in the Micro supervisor's office.
COM.01700 PT Evaluation	There is ongoing evaluation of PT and alternative assessment results, with prompt corrective action taken for unacceptable results. Evidence of Compliance: ✓ Records of ongoing, timely review of all PT reports and alternative assessment results by the laboratory director or designee AND ✓ Records of investigation of "unacceptable" PT and alternative assessment results including records of corrective action that is appropriate to the nature and magnitude of the problem	Phase II	Records of completed external PT are kept in the CAP binders in the Lab QA/POCT office, or can be viewed from the CAP web site at cap.org.
COM.01800 PT Interlaboratory Communication	There is a policy that prohibits interlaboratory communication about proficiency testing samples until after the deadline for submission of data to the proficiency testing provider.	Phase II	Refer to policy “Proficiency Testing Program” which can be found in the Proficiency Testing section of the Lab General P&P manual and on the intranet under Lab General

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COM.01900 PT Referral	There is a policy that prohibits referral of proficiency testing specimens to another laboratory or acceptance from another laboratory.	Phase II	Refer to policy "Proficiency Testing Program" which can be found in the Proficiency Testing section of the Lab General P&P manual and on the intranet under Lab General
QUALITY MANAGEMENT - GENERAL ISSUES			
COM.04000 Documented QM/QC Plan	The laboratory has a written quality management/quality control (QM/QC) program. Evidence of Compliance: ✓ Records reflecting conformance with the program as designed AND ✓ Results of quality surveillance	Phase II	Located in Lab General and addressed in the Microbiology Quality Laboratory Practices Document.
COM.04050 Unusual Laboratory Results	There is a documented system in operation to detect and correct significant clerical and analytical errors, and unusual laboratory results, in a timely manner. Evidence of Compliance: ✓ Records of review of results OR records of consistent implementation of the error detection system(s) defined in the procedure AND ✓ Records of timely corrective action of identified errors	Phase II	Clerical error checks are in place for the rapid antigen, immunology, and molecular assays (refer to procedures). Phoenix Epicenter have high score rules in place for infrequent AST results to be verified.
COM.04100 Supervisory Result Review	In the absence of on-site supervisors, results of tests performed by personnel are reviewed by the laboratory director or supervisor/general supervisor within 24 hours. Evidence of Compliance: ✓ Written policy defining the review process and personnel whose results require review AND ✓ Records of result review for specified personnel	Phase II	N/A All "high complexity testing" in Micro is performed by MLS/MLT.
COM.04150 Specimen Collection Manual	There is a documented procedure describing methods for patient identification, patient preparation, specimen collection and labeling, specimen preservation, and conditions for transportation, and storage before testing, consistent with good laboratory practice.	Phase II	SHMC Department of Laboratory Medicine Specimen Identification Policy (refer to Administrative Policy). Collection instructions for individual tests can be found in the test directory.

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COM.04200 Instrument Maintenance Evaluation	There is documentation of monthly evaluation of instrument maintenance and function, including temperatures of refrigerators/freezers in which reagents or patient specimens are kept.	Phase II	Instrument maintenance and function checks, temperatures are recorded daily and reviewed at the end of the month by the supervisor. Some instruments, such as the Phoenix and AP have maintenance logs rather than records in LIS.
PROCEDURE MANUAL			
COM.10000 Procedure Manual	A complete procedure manual is available at the workbench or in the work area.	Phase II	Hard copies or electronic copies are available.
COM.10100 Procedure Manual Review	There is documentation of review of all technical policies and procedures by the current laboratory director or designee at least every two years.	Phase II	Documentation is kept with the procedures.
COM.10200 New Procedure Review	The laboratory director reviews and approves all new technical policies and procedures, as well as substantial changes to existing documents, before implementation.	Phase II	Documentation is kept with the procedures.
COM.10250 New Procedure Review	For laboratories not subject to US regulations, the laboratory director or designee reviews and approves all new technical policies and procedures, as well as substantial changes to existing documents before implementation.	Phase II	N/A
COM.10300 Knowledge of Procedures	The laboratory has a system documenting that all personnel are knowledgeable about the contents of procedure manuals (including changes) relevant to the scope of their testing activities. Evidence of Compliance: ✓ Records indicating that the testing personnel have read the procedures, new and revised, OR records of another documented method approved by the laboratory director	Phase II	Personnel are required to review and sign off on all procedures electronically.
COM.10400 New Director Procedure Review	If there is a change in laboratory directorship, the new laboratory director reviews and approves (over a reasonable period of time) that laboratory procedures are current.	Phase II	N/A
COM.10500 Discontinued Procedure	When a procedure is discontinued, a paper or electronic copy is maintained for at least 2 years, recording initial date of use, and retirement date.	Phase II	See hard copies in Micro supervisor's office. Electronic copies are stored on the G drive.

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RESULTS REPORTING			
COM.29950 Reference Intervals	All patient/client results are reported with reference (normal) intervals or interpretations as appropriate.	Phase II	N/A
COM.30000 Critical Result Notification	The laboratory has procedures for immediate notification of a physician (or other clinical personnel responsible for the patient's care) when results of designated tests exceed established "alert" or "critical" values that are important for prompt patient management decisions.	Phase II	Refer to the Microbiology Critical Results, Notifiable Conditions, and Select Agents. Also refer to Lab General "Laboratory Critical Value List."
COM.30100 Critical Result Read-Back	When critical results are communicated verbally or by phone, there is a policy that laboratory personnel ask for a verification “read-back” of the results. Evidence of Compliance: ✓ Records of critical result notification with documented read-back	Phase I	Refer to the Procedure for Reporting Critical Values located in Lab General.
REAGENTS			
COM.30250 Reagent Handling/Storage - Waived Tests	For waived tests, the laboratory follows manufacturer instructions for handling and storing reagents, cartridges, test cards, etc. Evidence of Compliance: ✓ Written procedure consistent with manufacturer's instructions for each waived test	Phase II	N/A
COM.30300 Reagent Labeling	Reagents, calibrators, cellular controls, and solutions are properly labeled, as applicable and appropriate, with the following elements. 1. Content and quantity, concentration or titer 2. Storage requirements 3. Date prepared or reconstituted by laboratory 4. Expiration date Evidence of Compliance: ✓ Written policy defining elements required for reagent labeling	Phase II	Reagent policy in Lab General
COM.30350 Reagent Storage	All reagents and media are stored as recommended by the manufacturer. Evidence of Compliance: ✓ Records of reagent and media storage consistent with manufacturer's instructions, including refrigerator, freezer and room temperature monitoring, as applicable	Phase II	Records of temperature monitoring for reagent storage conditions can be found in the monthly QC folder in Micro.

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COM.30400 Reagent Expiration Date	All reagents and media are used within their indicated expiration date. Evidence of Compliance: ✓ Written policy for evaluating reagents and media lacking manufacturer's expiration date	Phase II	Refer to the Reagent Receiving and Labeling Policy in Lab General - Quality Management
COM.30450 New Reagent Lot Confirmation of Acceptability	New reagent lots and/or shipments are checked against old reagent lots or with suitable reference material before or concurrently with being placed in service. Evidence of Compliance: ✓ Written procedure for the verification of new lots and shipments prior to use AND ✓ Records of verification of new reagents/shipments	Phase II	Refer to the QC Reference Guide or individual test procedures. Documented results can be found in MQCR.
COM.30500 Reagent Kit Components	If there are multiple components of a reagent kit, the laboratory uses components of reagent kits only within the kit lot unless otherwise specified by the manufacturer. Evidence of Compliance: ✓ Written documentation defining allowable exceptions for mixing kit components from different lots	Phase II	Refer to the Reagent Receiving and Labeling Policy in Lab General - Quality Management
TEST METHOD VALIDATION/VERIFICATION			
COM.40000 Method Validation/Verification Approval	There is a summary statement, signed by the laboratory director (or designee who meets CAP director qualifications) prior to reporting patient results, documenting review of validation/verification studies and approval of each test for clinical use.	Phase I	Refer to Method Validation procedure in Method Evaluation section of the Lab General Policies and Procedures Manual
METHOD PERFORMANCE SPECIFICATIONS			
COM.40100 Intermittent Testing	When a test is put back into production, the following requirements must be met: 1. PT or alternative assessment performed within 30 days prior to restarting patient testing 2. Method performance specifications verified, as applicable, within 30 days prior to restarting patient testing 3. Competency assessed for analysts within 12 months prior to restarting patient testing	Phase II	Refer to the the Method Validation policy.
COM.40200 Laboratory-Developed Tests	The laboratory documents the list of tests it has developed and implemented during the previous 2 years.	Phase I	N/A

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COM.40250 Manufacturer Instructions	The laboratory follows manufacturer instructions or provides documentation of validation study(ies) if the test has been modified.	Phase II	See specific test procedures. No modified assays in use.
COM.40300 Analytic Accuracy/Precision	The laboratory verifies or establishes analytic accuracy and precision for each test. Evidence of Compliance: ✓ Written procedure for determining method performance characteristics, including accuracy/precision AND ✓ Records of verification or establishment of analytic accuracy and precision for each test	Phase II	Refer to the test verification section of specific test procedures.
COM.40400 Analytic Sensitivity	The laboratory verifies or establishes the analytic sensitivity (lower detection limit) of each assay, as applicable. Evidence of Compliance: ✓ Written procedure for determining method performance characteristics, including analytic sensitivity AND ✓ Records of verification or establishment of analytic sensitivity for each assay	Phase II	Refer to the test verification section of specific test procedures.
COM.40450 Analytical Specificity/Interfering Substances	For modified FDA-cleared/approved tests or LDT's, the results of each validation study include a sufficient number of samples to establish the test's analytical specificity.	Phase II	HPLC validation summary located at the end of the test procedure.
COM.40500 Analytic Interferences	The laboratory understands the analytic interferences for each test, and has an appropriate plan of action when they are present. Evidence of Compliance: ✓ Written procedure for determining method performance characteristics, including analytic interferences AND ✓ Records of verification or establishment of analytic interferences for each test	Phase II	Refer to Method Validation procedure in Method Evaluation section of the Lab General Policies and Procedures. When applicable, refer to the test verification section of specific test procedures.
COM.40600 Reportable Range	The reportable range (analytic measurement range) is verified/established for each analytic procedure before implementation. Evidence of Compliance: ✓ Written policy for determining method performance characteristics, including reportable range AND ✓ Records of verification or establishment of reportable ranges for each test	Phase II	N/A

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COM.40620 Body Fluid Validation	Testing of body fluid specimens using methods intended for other specimen types (e.g. blood or other fluid) have been validated by the laboratory for accuracy, precision, analytic sensitivity, analytic interferences, and reportable range.	Phase II	N/A
COM.40630 LDT Reporting	Reports for laboratory-developed tests (LDT) contain a description of the method, a statement that the assay was developed by the laboratory, and appropriate performance characteristics.	Phase I	Refer to the HPLC procedure for Mycobacteria (non-MTB)
COM.40640 LDT Clinical Claims Validation	All clinical claims made by the laboratory about a laboratory-developed test are validated.	Phase II	N/A
COM.40700 Method Performance Specifications Availability	The laboratory's current test methods, including performance specifications and supporting validation/verification data (analytic accuracy, precision, analytic sensitivity, interferences, reference range, and reportable range, as acceptable), are available to clients of the laboratory and to the inspection team upon request.	Phase II	Refer to validation/verification summaries.
COM.40800 Analytic Methodology Changes	If the laboratory changes its analytic methodology so that test results or their interpretations may be SIGNIFICANTLY different, the change is explained to clients. Evidence of Compliance: ✓ Records such as directed mailings, laboratory newsletters or comment on the patient report advising of the change	Phase II	N/A
REFERENCE INTERVALS			
COM.50000 Reference Intervals Established/Verified	The laboratory establishes or verifies its reference intervals (normal values). Evidence of Compliance: ✓ Record of reference range study OR records of verification of manufacturer's stated range when reference range study is not practical (e.g. unavailable normal population) OR other methods approved by the laboratory director	Phase II	N/A
COM.50100 Reference Interval Evaluation	The laboratory evaluates the appropriateness of its reference intervals and takes corrective action if necessary. Evidence of Compliance: ✓ Records of evaluation and corrective action, if indicated	Phase II	N/A