CAP General Laboratory Common Checklist ver.06.04.2020

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- Laboratory (LAB)
- Pathology Data System(PDS)/Laboratory Information System (LIS)
- Organizational Policies Johns Hopkins Medical Institutions (JHMI)/ Johns Hopkins Medical Laboratories (JHML)-/CQI office
- JHH Safety Manual
- Shared function between LIS and Laboratory
- Requirement # w/ N= New standard
- Requirement # w/ R= Revised standard/information

Requirement (ID)	Phase	Standards	Notes	Evidence of Compliance Required	Policy Manual Note: Number or Name of Policy	Links	Comments
			Please note that due to variations in different laboratory disciplines, there are some situations where the same requirement continues to exist in both the COM Checklist and in a discipline-specific checklist, but with a different checklist note that has specific requirement. In these situations, the discipline-specific requirement takes precedence over the COM requirement.				
			PROFICIENCY TESTING				
COM.01000 R	2	**PT Procedure** The laboratory has written procedures for proficiency **PT** testing sufficient for the extent and complexity of testing done in the laboratory.	NOTE: The laboratory must have written procedures for: ● Proper handling, analysis, review and reporting of *PT* materials. ● Investigation *of each* unacceptable *PT result to evaluate the impact on patient sample* results *and to correct problems identified in a timely manner.*		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A- QUALITY MANAGEMENT ∞ HPO; QM (004) Proficiency Testing Guidelines	https://hpo.johnshopkins.edu/pathology-enterprise/policies/905/40925/policy_40925.pdf?_=0.585249828423?_=0.936429333289	
COM.01100 R	2	**Ungraded PT Challenges** The laboratory assesss its performance on proficiency testing (PT) challenges that are ungraded.	NOTE: Examples include but are not limited to: ● PT challenges that were intended to be graded, but were not, for reasons such as: • The laboratory submitted its results after the cut-off date, • The laboratory did not submit results, • The laboratory did not complete the result form correctly (eg, submitted the wrong method code or recorded the result in the wrong place). • The laboratory's result was not graded because of lack of consensus. ● Educational PT challenges	** Written procedures for assessing PT performance AND * Records of review and evaluation of ungraded PT challenges*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A- QUALITY MANAGEMENT ∞ HPO; QM (004) Proficiency Testing Guidelines	https://hpo.johnshopkins.edu/pathology-enterprise/policies/905/40925/policy_40925.pdf?_=0.585249828423?_=0.936429333289	
COM.01200 R	1	**Activity Menu** The laboratory's current CAP Activity Menu accurately reflects the testing performed.	NOTE: The laboratory's CAP Activity Menu must include all patient/client testing, performed by the laboratory. • For laboratories with a CLIA certificate, it includes all testing and activities performed under that CLIA certificate. • For laboratories not subject to CLIA, it includes all testing and activities meeting all of the following criteria: 1) performed under the same laboratory director, 2) under the same laboratory name, and 3) at the same physical premises (contiguous campus). The testing and activities must be listed on the laboratory's CAP of the Activity Menu regardless of whether it is also accredited by another organization. The laboratory must update its CAP Activity Menu when tests are added or removed. by logging into e-LAB Solutions Suite on cap.org and going to Organization Profile - Sections/Departments. In order to ensure proper customization of the checklists, the laboratory must also ensure ***its*** activity menu is accurate for non-test activities, such as methods and types of services offered. Some activities are included on the Master Activity Menu using more generic groupings or panels instead of listing the individual tests. The Master Activity Menu represents only those analytes that are directly measured. Calculations are not included, with a few exceptions (eg. INR, hematocrit). Laboratories are not required to include testing performed solely for the purpose of research on their activity menus, but may opt to include such testing if the laboratory wants it to be inspected by the CAP. Testing performed for research is defined as laboratory testing on human specimens where patient-specific results are not reported for, the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. If patient-specific results are reported from the laboratory, the testing is subject to CLIA and must be reported to the CAP. If an inspector identifies that a laboratory is performing tests or procedures not included on the laboratory's CAP Activity Menu, the inspector must do the following:				
cont. COM.01200 R			● Contact the CAP (800-323-4040) inspectionfor instructions as requirements may be missing from a laboratory's customized checklist ● Record whether those tests/ procedures were inspectedon the appropriate section page in the Inspector's Summation Report (ISR)				
COM.01300 R	2	**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.	NOTE 1: Information on analytes that require enrollment and participation in a CAP-accepted PT program is available on the CAP website http://www.cap.org/ Solutions Suite under CAP Accreditation Resources, Master Activity Menu Reports. Also, the inspection packet includes a report with this information for each laboratory section/department. The CAP Office audits PT participation to assure that accredited laboratories participate in appropriate PT. NOTE 2: This checklist requirement applies to both waived and nonwaived tests. NOTE 3: For laboratories subject to US regulations, participation in proficiency testing may be through CAP PT Programs or another proficiency testing provider accepted by CAP. Laboratories will not be penalized if they are unable to participate in an oversubscribed program. If unable to participate, however, the laboratory must implement an alternative performance assessment procedure for the affected analytes. For regulated analytes, if the CAP and CAP-accepted PT programs are oversubscribed, CMS requires the laboratory to attempt to enroll in another CMS-approved PT program. NOTE 4: For laboratories not subject to US regulations, participation in proficiency testing must be through CAP PT Programs only. Laboratories may use acceptable alternatives when the CAP is unable to deliver PT due to oversubscribed programs, stability issues or customs denial, contingent on CAP approval. If unable to participate, however, the laboratory must implement an alternative performance assessment procedure for the affected analytes.	** Records such as CAP PT order confirmation 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*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A- QUALITY MANAGEMENT ∞ HPO; QM (004) Proficiency Testing Guidelines	https://hpo.johnshopkins.edu/pathology-enterprise/policies/905/40925/policy_40925.pdf?_=0.585249828423?_=0.936429333289	
COM.01300 R	2	**PT Participation**	NOTE 5: Refer to COM.01520 for PT and alternative performance assessment requirements for predictive marker testing performed using immunohistochemistry in situ hybridization methods. NOTE 6: For purposes of photograph/image identification in CAP PT Programs, it is strongly recommended that current educational resource be available to the bench technologist. Examples include the bench top resources guide, color atlases, and the Surveys Hematology Glossary, as applicable.				
COM.01400	2	**PT Attestation Statement** The proficiency testing attestation statement is signed by the laboratory director or qualified designee and all individuals involved in the testing process.	NOTE: Physical signatures must appear on a paper version of the attestation form. A listing of typed names on the attestation statement does not meet the intent of the requirement. The signature of the laboratory director or designee need not be obtained prior to reporting results to the proficiency testing provider. Designees must be qualified through education and experience to meet the defined regulatory requirements associated with the complexity of the testing as defined in the Personnel section of the Laboratory General Checklist. * For high complexity testing, it may be delegated to an individual meeting the qualifications of a technical supervisor or section director (GEN.53400). For the specialties of Histocompatibility, Cytogenetics, and Transfusion Medicine, refer to specific requirements for the qualifications of section directors/technical supervisors in the associated checklists (HSC.40000, CYG.50000, and TRM.50050). * For moderate complexity testing, it may be delegated to an individual meeting the qualifications of a technical consultant (GEN.53625).	** Appropriately **signed** attestation statement from submitted PT result forms*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A- QUALITY MANAGEMENT ∞ HPO; QM (004) Proficiency Testing Guidelines	https://hpo.johnshopkins.edu/pathology-enterprise/policies/905/40925/policy_40925.pdf?_=0.585249828423?_=0.936429333289	
COM.01500	2	**Alternative Performance Assessment** For tests for which CAP does not require *proficiency testing* (PT), the laboratory at least semiannually exercises an alternative performance assessment system for determining the reliability of analytic testing.	NOTE 1: Appropriate alternative performance assessment procedures include participation in an external PT program not required by CAP; participation in an ungraded/educational PT program; split sample analysis with referral or other laboratories, split sample analysis with an established in-house method, use of assayed materials, clinical validation by chart review, or other suitable and documented means. It is the responsibility of the laboratory director to define such alternative assessment procedures and the criteria for successful performance in accordance with good clinical and scientific laboratory practice. NOTE 2: For *in situ hybridization* testing other than predicitive marker testing, and othe complex molecular and sequencing-based tests (including but not limited to microarray-based tests, multiplex PCR-based tests, and next generation sequencing-based tests), alternative performace assessment may be performed by method or specimen type rather than for each analyte or tested abnormality. For tests such as allergen testing, alternative performance assessment may be performed in batches of analogous tests. NOTE 3: Semiannual alternative performance assessment must be performed on tests for which external PT is not available. NOTE 4: This checklist requirement applies to both waived and nonwaived tests. The list of analytes for which CAP requires enrollment and participation in a CAP-accepted PT program is available on CAP.Org through e-LAB Solutions Suite under CAP Accreditation Resources, Master Activity Menu Reports. Also, the inspection packet includes a report with this information for each laboratory section/department. A form, Alternative Performance Assessment (APA) Test List, is available on cap.org through e-LA [http://www.cap.org/] oratories track compliance with this requirement.	** List of tests defined by the laboratory as requiring alternative assessments AND * Records of those assessments*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A- QUALITY MANAGEMENT ∞ HPO; QM (004) Proficiency Testing Guidelines	https://hpo.johnshopkins.edu/pathology-enterprise/policies/905/40925/policy_40925.pdf?_=0.585249828423?_=0.936429333289	
COM.01520 R	2	**PT and Alternative Performance Assessment for IHC and ISH Predictive Marker Interpretation** The laboratory participates in the appropriate required proficiency testing (PT) program/external quality assessment (EQA) program accepted by CAP or performs alternative performance assessment for all predictive marker interpretation performed using immunohistochemistry (IHC) and in situ hybridization (ISH) methods, as required in the note.	NOTE: The term predictive marker is used to refer to immunohistochemical (IHC) and in situ hybridization (ISH) tests used to predict responsiveness to a specific treatment independent of other histopathologic findings. Rather than confirming a specific diagnosis, these tests differentiate predicted responsiveness to a target therapy. The following requirements for participation in proficiency testing or alternative performance assessment must be followed: • HER2, and/or ER breast predictive marker IHC interpretation - participation in CAP Surveys or CAP-accepted PT programs is required. IHC slides may be sent to another facility for staining only and be interpreted at the originating laboratory. • HER2 breast predictive marker ISH interpretation - participation in CAP Surveys or CAP-accepted PT programs is required, unless hybridization (ISH) is performed at a different laboratory (different CAP/CLIA number). If hybridization and interpretation are performed at different laboratories, the interpreting laboratory must perform alternative performance assessment at least semiannually and must not participate in formal (external) PT. • HER2 PT for breast predictive marker testing is method specific. Laboratories interpreting HER2 results performed by multiple methods must participate in the required PT or perform alternative performance assessment as described above for each method. • Semiannual alternative performance assessment is required for other predictive marker tests for which CAP does not require proficiency testing. Examples of alternative performance assessment include but are not limited to participation in a PT or external assessment program if available (eg, PD-L1); split sample analysis with another method or another laboratory; use of assayed materials, or clinical validation by chart review. • For predictive markers performed by methods other than ISH and IHC, refer to COM.01300 and COM.01500.	**Records such as CAP PT order confirmation for HER2, ER testing for breast predictive markers OR record of completed/submitted result forms OR * Records of alternative performance assessment for IHC and ISH predictive markers for which the CAP does not require participation in a PT program*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A- QUALITY MANAGEMENT ∞ HPO; QM (004) Proficiency Testing Guidelines	https://hpo.johnshopkins.edu/pathology-enterprise/policies/905/40925/policy_40925.pdf?_=0.585249828423?_=0.936429333289	
COM.01600	2	**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.	NOTE: Repetitive analysis of any proficiency sample by one or more individuals is acceptable only if patient/client specimens are routinely analyzed in the same manner. With respect to morphologic examinations (identification of cell types and microorganisms; review of electrophoretic patterns, etc.), group review and consensus identifications are permitted only for unknown samples that would ordinarily be reviewed by more than one person on an actual patient sample. Laboratories that are subject to regulation by the Centers for Medicare and Medicaid Services (CMS) are not permitted to test the same analyte from the same PT product on more than one instrument or method unless that is how the laboratory tests patient specimens and laboratory procedures are written to reflect that process. If the laboratory (under one CLIA license) uses multiple methods for an analyte, proficiency samples must be analyzed by the primary method at the time of the PT event, or rotated among primary methods each PT shipment. Laboratories subject to CMS regulation are not allowed to order multiple PT kits for the purpose of testing the same sample/analyte on multiple instruments or methods prior to the due date for submitting results to the provider. The educational purposes of proficiency testing are best served by a rotation that allows all testing personnel to be involved in the proficiency testing program. Proficiency testing records must be retained and can be an important part of the competency and continuing education records in the personnel files of the individuals. When external proficiency testing materials are not available, the semiannual alternative performance assessment process should also be integrated within the routine workload, if practical.	** Written policy describing proper handling of PT specimens AND * Instrument printout and/or work records AND * Completed attestation pages from submitted PT result forms*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A- QUALITY MANAGEMENT ∞ HPO; QM (004) Proficiency Testing Guidelines	https://hpo.johnshopkins.edu/pathology-enterprise/policies/905/40925/policy_40925.pdf?_=0.585249828423?_=0.936429333289	
cont.COM.01600		**PT Integration Routine Workload**	The US Department of Defense (DOD) and the Department of Veterans Affairs (VA) laboratories are subject to different regulations. For both the DOD and the VA, multiple proficiency testing kits may be ordered, with results reported, from the same proficiency testing provider on the same analyte; however, laboratories may not compare results from multiple kits until after the deadline for submission of results to the provider.				

COM.01700	2	**PT and Alternative Performance Assessment Result Evaluation** There is ongoing evaluation of *proficiency testing* (PT)and alternative performance assessment results, with appropriate corrective action taken for each unacceptable result.	NOTE: Each unacceptable PT or alternative performance assessment result (any result or sample not meeting defined acceptability criteria) must be evaluated. It is recommended that the laboratory investigate acceptable results that show significant bias or trends. Primary records related to PT and alternative performance assessment testing are retained for at least two years (five years for transfusion medicine). These include all instrument tapes, work cards, computer printouts, evaluation reports, evidence of review, and records of follow-up or corrective action. For laboratories outside the US, PT failures relating to problems with shipping and specimen stability should include working with local customs and health regulators to ensure appropriate transit of PT specimens.	** Records of ongoing review of all PT reports and alternative assessment results by the laboratory director or designee AND * Records of investigation of each "unacceptable" PT and alternative assessment result including records of corrective action appropriate to the nature and magnitude of the problem*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A- QUALITY MANAGEMENT ∞ HPO; QM (004) Proficiency Testing Guidelines	https://hpo.johnshopkins.edu/pathology-enterprise/policies/905/40925/policy_40925.pdf?_=0.585249828423?_=0.936429333289	
COM.01800	2	**PT Interlaboratory Communication** There is no interlaboratory communication about proficiency testing samples until after the deadline for submission of data to the proficiency testing provider.	NOTE: Proficiency testing (PT) must be performed by personnel at the laboratory (CAP/CLIA number) for which PT was ordered. In addition, results must be reported by personnel atthe laboratory where PT was performed. The written PT policies must strictly prohibit interlaboratory communications about PT samples or results until after the deadline for submission of data to the PT provider. The laboratory director is responsible for enforcing this prohibition. Records of training on the handling of PT samples and prevention of interlaboratory communication are strongly recommended. The laboratory must retain the records of the proficiency testing event, including a copy of the proficiency testing program's report forms, instrument printouts, and work records. PT records must not be shared with and should be inaccessible to personnel of other laboratories, including an affiliated laboratory until after the deadline for submission of results. Laboratories that share a common computer system or personnel have strict policies and procedures to ensure that personnel do not access proficiency testing records from other laboratories.	** Written policy prohibiting interlaboratory communication about PT specimens AND * PT records*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A- QUALITY MANAGEMENT ∞ HPO; QM (004) Proficiency Testing Guidelines	https://hpo.johnshopkins.edu/pathology-enterprise/policies/905/40925/policy_40925.pdf?_=0.585249828423?_=0.936429333289	
COM.01900* R	2	**PT Referral** Proficiency testing specimens are not referred to other laboratories and are not accepted from other laboratories for analysis.	NOTE 1: The written proficiency testing policies must strictly prohibit referral or acceptance of proficiency testing specimens for analysis from other laboratories. This applies even if the second laboratory is in the same health care system. This prohibition takes precedence over the requirement that proficiency testing specimens be handled in the same manner as patient specimens. For example, a laboratory's routine procedure for review of patient abnormal CBC blood smears might be referral of the smear to a pathologist located at another site (different CAP/CLIA number). For proficiency testing specimens, the laboratory must NOT follow its routine procedure,to refer the specimen. If the PT sample meets laboratory defined criteria for referral to a pathologist prior to reporting and the pathologist is at another site, the pathologist must review the PT sample at the physical location of the laboratory performing the PT. Alternatively, the laboratory must refer to the PT provider kit instructions on how to record a result for a test not performed in the laboratory. It is the responsibility of the laboratory director to ensure that this prohibition is enforced. . NOTE 2: Laboratories that perform testing using a distributive testing model where portions of the process are performed at another laboratory with a different CAP/CLIA number must not participate in formal PT, as this is considered PT referral by CMS and is strictly prohibited. An alternative performance assessment must be performed at least semiannually in lieu of formal PT in these situations. Common examples of distributive testing include:	** Written policy prohibiting PT specimen referral or acceptance from other laboratories AND * Proficiency testing records*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A- QUALITY MANAGEMENT ∞ HPO; QM (004) Proficiency Testing Guidelines	https://hpo.johnshopkins.edu/pathology-enterprise/policies/905/40925/policy_40925.pdf?_=0.585249828423?_=0.936429333289	
COM.01900*R cont.	2	**PT Referral**	• In situ hybridization and slide interpretation performed at separate laboratories. • Next generation sequencing wet bench process, bioinformatics processes, and/or interpretation performed at different laboratories. • Leukemia/lymphoma flow cytometry panels and pathologist interpretation of the data at different laboratories. Immunohistochemistry (IHC) slides are permitted to be sent to another facility for staining only. NOTE 3: Records of training on referral and acceptance of PT samples is strongly recommended. Refer to 'Tips for Avoiding Proficiency Testing Referral' on the CAP website through e-LAB Solutions Suite. (http://www.cap.org)				
COM.01950	2	**Cease Patient Testing for Repeat PT Failures.** If the laboratory was instructed by the CAP to cease patient testing for an analyte or subspecialty due to repeat unsuccessful proficiency testing, laboratory records demonstrate that no patient results were released until after the laboratory received approval from the CAP to resume patient testing.	NOTE: In order to resume patient testing, the laboratory must meet the conditions as outlined in the cease patient testing notification.	** Records of communication notifying staff/physicians that testing is suspended for the required period of time OR * LIS report verifying that no patient results were reported for the affected analyte or subspecialty during the cease testing time frame OR * Patient reports indicating name and address of laboratory where testing was performed during the affected period OR * Send-out log to referral laboratory*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL: -∞HPO- Pathology volume II-Quality Management- Quality Management Program.	http://www.insidehopkinsmedicine.org/hpo/policies/68/3577/policy_3577.pdf	
			QUALITY MANAGEMENT - GENERAL ISSUES				
COM.04000	2	**QM Program** The laboratory quality management (QM) program is implemented in each section (department) of the laboratory.	NOTE: The program must ensure quality throughout the pre-analytic, analytic, and post-analytic (reporting) phases of testing, as appropriate for each section (department) of the laboratory. The QM program should address key indicators of quality, in particular those relating to activities that are of high patient impact and/or are of high risk for error.	** Records reflecting conformance with the program as designed AND * Results of quality surveillance*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL: -∞HPO- Pathology volume II-Quality Management- Quality Management Program.	http://www.insidehopkinsmedicine.org/hpo/policies/68/3577/policy_3577.pdf	
COM.04050	2	**Error Detection and Correction** There is a written procedure for the detection and correction of significant clerical and analytical errors, and unusual laboratory results, in a timely manner.	NOTE: One common method is review of results by a qualified person (technologist, supervisor, pathologist) before release from the laboratory, but there is no requirement for supervisory review of all reported data for tests that do not include interpretation. In computerized laboratories, there should be automatic "traps" for improbable results. The system for detecting clerical errors, significant analytical errors, and unusual laboratory results *must* provide for timely correction of errors, ie. before results become available for clinical decision making. For confirmed errors detected after reporting, corrections must be promptly made and reported to the ***appropriate clinical personnel*** or referring laboratory, as applicable. If laboratories use delta checks as a mechanism to detect errors prior to the reporting of patient results, the laboratory must have written procedures describing the actions to be taken when acceptability criteria are exceeded and a process for approval of new or changed delta checks by the laboratory director or designee. Each procedure must include a listing of common situations that may cause analytically inaccurate results, together with a procedure to address such analytic errors or interferences. This may require alternate testing methods; in some situations, it may not be possible to report results for some or all of the tests requested. The intent of this requirement is NOT to require verification of all results outside the reference *interval* .	** 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*			
COM.04100	2	**Supervisory Result Review** In the absence of on-site supervisors, high complexity testing performed by trained high school graduates qualifying as high complexity testing personnel is reviewed by the laboratory director or supervisor/general supervisor within 24 hours.	NOTE: The CAP does NOT require supervisory review of all test results before or after reporting to patient records. Rather, this requirement is intended to address only that situation for "high complexity testing" performed by trained high school graduates qualifying under the CLIA regulation 42CFR493.1489(b)(5)(i) when a qualified supervisor/general supervisor is not present. The qualifications to perform high complexity testing can be accessed using the following link: . CAP Personnel Requirements by Testing Complexity	** Written policy defining the personnel and test results requiring review AND * Records of result review for specified personnel*			
COM.04200	2	**Instrument/Equipment Record Review** Instrument and equipment maintenance and function check records are reviewed and assessed at least monthly by the laboratory director or designee.	NOTE: There must be records of corrective action if problems are identified (eg, maintenance not performed as scheduled). The review of the records related to tests that have an approved IQCP must include an assessment of whether further evaluation of the risk assessment and quality control plan is needed based on problems identified (e.g. trending for repeat failures, etc.).				
COM.04250 R	2	**Comparability of Instruments and Methods - Nonwaived Testing** If the laboratory uses more than one nonwaived instrument/method to test for a given analyte, the instruments and methods are checked against each other at least twice a year for comparability of results	NOTE: This requirement applies to tests performed on the same or different instrument makes/models or by different methods, even if there are different reference intervals or levels of sensitivity. It includes primary and back up methods used for patient testing. The purpose of the requirement is to evaluate the relationship between test results using different methodologies, instruments, or testing sites. The laboratory must establish a written procedure for this check that includes acceptance criteria. This requirement is not applicable to: ● Calculated parameters ● Waived methods ● Laboratories with different CAP numbers The following types of materials may be used to generate data for comparability studies: ● Patient/client specimens (pooled or unpooled) are preferred to avoid potential matrix effects ● Quality control materials for tests performed on the same instrument platform, with both control materials and reagents of the same manufacturer and lot number. ● Alternative protocols based onquality control or reference materials for cases when availability or pre-analytical stability of patient/client specimens is a limiting factor. The must be validated (when applicable) to have the same response as fresh human specimens for the instruments and methods involved. This requirement only applies when the instruments/reagents are producing the same reportable result. For example, some laboratories may use multiple aPTT reagents with variable sensitivity to the lupus anticoagulant to perform different tests, such as aPTT for heparin monitoring and a lupus-like anticoagulant screen. .	** Written procedure for performing instrument and method comparison AND * Records of comparability studies reflecting performance at least twice per year with appropriate specimen types*			
COM.04250 *cont.*	2	**Comparability of Instruments and Methods - Nonwaived Testing**	If these are defined as separate tests, then this requirement does not apply unless each type of aPTT test is performed on more than one analyzer. For Microbiology testing, this requirement applies when two instruments (same or different manufacturers) are used to detect the same analyte. Two or more detectors or incubation cells connected to a single data collection, analysis and reporting computer need not be considered separate systems (e.g. multiple incubation and monitoring cells in a continuous monitoring blood culture instrument, two identical blood culture instruments connected to a single computer system, or multiple thermocycler cells in a real time polymerase chain reaction instrument). This checklist requirement does not apply to multiple analytical methods (e.g. antigen typing versus culture or detection of DNA versus a biochemical characteristic) designed to detect the same analyte				
COM.04300	2	**Comparability Criteria - Non-waived Testing** Acceptability criteria are defined for comparability of nonwaived instruments and methods used to test the same analyte, with records of action when the criteria are not met.	NOTE: Statistically defined acceptability limits should be used for quantitative assays.	** Records of comparability studies with evidence of review and action taken, as appropriate*			
			SPECIMEN COLLECTION AND HANDLING				
COM.06000	2	**Specimen Collection Manual** There are written procedures 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.	NOTE: The proximity of the patient to the test site does not preclude the need for proper identification systems to prevent reporting of one patient's result to another's record. Refer to the Specimen Collection section of the Laboratory General Checklist for additional information on patient identification. The procedure may be in paper or electronic form.				
COM.06100	2	**Primary Specimen Container Labeling** All primary specimen containers are labeled with at least two patient-specific identifiers.	NOTE: A primary specimen container is the innermost container that holds the original specimen prior to processing and testing. This may be in the form of a specimen collection tube, cup, syringe, swab, slide or other form of specimen storage. Data files received from other laboratories for analysis are considered a specimen and must contain acceptable patient identifiers. Criteria for acceptable specimen labeling and the handling of sub-optimal specimens must be defined in laboratory policy. Examples of acceptable identifiers include, but are not limited to: patient name, date of birth, hospital number, social security number, requisition number, accession number, unique random number. A location (e.g. hospital room number) is not an acceptable identifier. Identifiers may be in a machine readable format, such as a barcode. For prepared slides submitted to the laboratory, if the slides only contain one identifier, they must be securely submitted in a container labeled with two identifiers. In limited situations, a single identifier may be used if it can uniquely identify the specimen. For example, in a trauma situation where a patient's identification is not known, a specimen may be submitted for testing labeled with a unique code that is traceable to the trauma patient. Other examples may include forensic specimens, coded or de-identified research specimens, or donor specimens labeled with a unique code decryptable only by the submitting location.	** Written policy with criteria for acceptable labeling of primary specimen containers AND * Specimen collection procedures with defined labeling specifications OR * Records of compliance audits for specimen labeling*			

COM.06100 cont.	2	**Primary Specimen Container Labeling**	For specimens where site of origin is critical to the analysis (e.g. site specific cultures, surgical and cytology specimens), the primary specimen container and/or the requisition must clearly identify the site of origin, and as appropriate, the laterality of the specimen (right versus left). If more than one specimen container is submitted with one requisition, each container must be labeled in a manner to ensure linkage of the specimen to the site of origin and laterality. This requirement does not apply to the labeling of specimens collected for immediate bedside patient testing performed in the presence of the patient. If the specimens are (or may be) utilized for testing away from the patient, the labeling criteria defined in this requirement apply.					
COM.06200	2	**Secondary Specimen Container Labeling** Adequate specimen identification is provided on specimen containers throughout all phases of testing, including, but not limited to aliquots, dilution, tubes, slides, blocks, culture plates, reaction units, nucleic acids and other extracts, data extract files, images, and other secondary specimens created during the processing or testing of a specimen.	NOTE: A single, unique identifier may be used to label materials derived from the primary specimen for use in subsequent phases of testing. The specimen identification system used must provide reliable identification of the secondary specimen and be linked to the full particulars of patient identification, collection date, specimen type, etc. The specimen identifier(s) must be indelible, legible, and able to withstand all stages of processing and conditions of storage. Identification may be text-based, numeric, bar-coded, etc. The form of this system is entirely at the discretion of each laboratory and must be defined in laboratory procedure. Slides prepared from specimens in the laboratory are considered secondary specimen containers. Slides prepared in the patient setting and brought to the laboratory (e.g. fine needle aspiration, bone marrow preparations) are considered primary specimen containers and must follow the labeling requirements for primary specimen containers. For histology specimens, each block of tissue must be identified by a unique identifier traceable to the primary specimen (e.g. accession number) assigned to the case and by any descriptive letter(s)/number(s) added by the prosector during the dissection. If additional blocks are prepared later, all lists and logs must reflect these additions. Identification number and letter(s)/number(s) must be affixed to all blocks in a manner that remains legible. Each slide must be identified by the unique identifier traceable to the primary specimen and descriptive letters unique to the block from which it is cut. Other appropriate identifiers should be included as applicable (e.g. levels of sectioning). Automated prelabeling systems are acceptable.					
COM.06300 R	2	**Specimen Rejection Criteria** There are written criteria for the rejection of unacceptable specimens, instructions for the special handling of sub-optimal specimens, and records of disposition of all unacceptable specimens in the patient/client report and/or quality management records.	NOTE: The test report must indicate information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This requirement applies to specimens received for all types of testing and does not imply that all "unsuitable" specimens are discarded or not analyzed. If there is a problem with a specimen (e.g. improperly collected or stored, insufficient quality/quantity of specimen, inadequate labeling or requisition information, broken slides, hemolysis, lipemia, gross contamination, etc.), there must be a mechanism to notify clinical personnel responsible for patient care. If the treating physician desires the result, and the laboratory agrees to perform testing, the laboratory must note the condition of the specimen on the report. Some or all tests may be incorrect on such a specimen. The laboratory may wish to record that a dialogue was held with the physician, when such occurs. For newborn screening specimens, rejection criteria must be consistent with the criteria defined in the current edition of the CLSI NBS01 Standard, Blood Collection on Filter Paper for Newborn Screening Programs.	** Records of rejected specimens AND * Instructions for special handling of sub-optimal specimens AND * Records of disposition of unacceptable specimens*				
PROCEDURE MANUAL ***All laboratory testing, functions, and/or processes must be addressed in written policies and/or procedures, with appropriate approval, to assure clarity and consistency.The procedure manual should be used by personnel at the workbench and must include the following elements, when applicable to the test procedure:*** ***1.*** *Principle and clinical significance;* ***2.*** *Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection;* ***3.*** *Microscopic examination, including the detection of inadequately prepared slides;* ***4.*** *Step-by-step performance of the procedure, including test calculations and interpretation of results;* ***5.*** *Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing* ***6.*** *Calibration and calibration verification procedures;* ***7.*** *The analytic measurement range for test results for the test system, if applicable*;* ***8.*** *Control procedures;* ***9.*** *Corrective action to take when calibration or control results fail to meet the laboratory's criteria foracceptability;* ***10.*** *Limitations in the test methodology, including interfering substances;* ***11.*** *Reference intervals (normal values);* ***12.*** *Imminently life-threatening (critical) test results;* ***13.*** *Pertinent literature references* ***14.*** *The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the procedure for reporting imminently life-threatening (critical) results;* ***15.*** *Description of the course of action to take if a test system becomes inoperable.* *(*The analytic measurement range may not apply to qualitative or semi-quantitative tests.)* *The manual should address relevant pre-analytic and post-analytic considerations, as well as the analytic activities of the laboratory. The specific style and format of procedure manuals are at the discretion of the laboratory director*								
COM.10000	2	**Procedure Manual** A complete procedure manual is available in a paper-based, electronic, or web-based format at the workbench or in the work area.	NOTE 1: The use of inserts provided by manufacturers is not acceptable in place of a procedure manual. However, such inserts may be used as part of a procedure description, if the insert accurately and precisely describes the procedure as performed in the laboratory. Any variation from this printed or electronic procedure must be detailed in the procedure manual. **In all cases, procedures must match the laboratory's practice, the laboratory's practice must follow written procedure, and appropriate reviews must occur**. NOTE 2: A manufacturer's procedure manual for an instrument/reagent system may be acceptable as a component of the overall departmental procedures. Any modification to or deviation from the manufacturer's manual must be clearly recorded and approved. NOTE 3: Card files or similar systems that summarize key information are acceptable for use as quick reference at the workbench provided that: * A complete manual is available for reference * The card file or similar system corresponds to the complete manual and is subject to document control □		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL: -∞HPO- Pathology volume II-Laboratory -Documents and Records-	https://hpo.johnshopkins.edu/hopkins/policies/68/10572/policy_10572.pdf?_=0.337667600621		
COM.10000 cont.	2	**Procedure Manual**	NOTE 4: Electronic manuals accessed by computer are fully acceptable. There is no requirement for paper copies to be available for the routine operation of the laboratory, as long as the electronic versions are readily available to all personnel and personnel have been trained on how to access them. However, procedure manuals must be available to laboratory personnel when the electronic versions are inaccessible (e.g. during laboratory information system or network downtime); thus, the laboratory must maintain paper copies, electronic copies on CD or other digital media, or have an approved alternative mechanism to access web-based files during network downtimes. All procedures, in either electronic or paper form, must be readily available for review by the inspector at the time of the CAP inspection Electronic procedure manuals and electronic copies of procedures are subject to proper document control (see GEN.20375), and there must be records of biennial review. Review of electronic procedures may be recorded by including statements such as "reviewed by [name of reviewer] on [date of review]" in the electronic record. Records of review by a secure electronic signature are NOT required. Alternatively, paper review sheets may be used to record review of electronic procedures.					
COM.10100	2	**Procedure Manual Review** There are records of review of all technical policies and procedures by the current laboratory director or designee at least every two years.	NOTE: The laboratory director must ensure that the collection of testing policies and technical procedures is complete, current, and has been thoroughly reviewed by a knowledgeable person. Technical approaches must be scientifically valid and clinically relevant. To minimize the burden on the laboratory and reviewer(s), it is suggested that a schedule be developed whereby roughly 1/24 of all technical policies and procedures are reviewed monthly. Paper/electronic signature review must be at the level of each procedure, or as multiple signatures on a listing of named procedures. A single signature on a Title Page or Index is not a sufficient record that each policy or procedure has been carefully reviewed. Signature or initials on each page of a policy or procedure is not required. Only technical policies and procedures are addressed in this requirement. Biennial review is not required for other controlled documents.		Departmental Manual for Hopkins Policy Online: _ Path Volume II General Policy Manual- Quality Management - Document Management (QM013)	https://hpo.johnshopkins.edu/hopkins/policies/68/10572/policy_10572.pdf?_=0.337667600621		
COM.10200	2	**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.	NOTE: This review may not be delegated to designees in laboratories subject to the CLIA regulations. Paper or electronic signature review of records is required. A secure electronic signature is desirable, but not required.	** Policy on procedure review AND * Records of new policy or procedure approval*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL: -∞HPO- Pathology volume II-Laboratory -Documents and Records-Document Management (ADM013)	https://hpo.johnshopkins.edu/hopkins/policies/68/10572/policy_10572.pdf?_=0.337667600621		
COM.10250	2	**New Procedure Review (Not Subject to US Regulations)** For laboratories not subject to US regulations, the laboratory director or designee who meets CAP director qualifications reviews and approves all new technical policies and procedures, as well as substantial changes to existing documents before implementation.	NOTE: Paper or electronic signature review of records is required. A secure electronic signature is desirable, but not required.	** Policy on procedure review AND * Records of new policy or procedure approval*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL: -∞HPO- Pathology volume II-Laboratory -Documents and Records-Document Management (ADM013)	https://hpo.johnshopkins.edu/hopkins/policies/68/10572/policy_10572.pdf?_=0.337667600621		
COM.10300	2	**Knowledge of Policies and Procedures** The laboratory has a defined process and records indicating that all personnel are knowledgeable about the contents of the policies and procedures (including changes) relevant to the scope of their testing activities.	NOTE: The form of this system is at the discretion of the laboratory director. Annual procedure sign-off by testing personnel is not specifically required.	** Records indicating that the testing personnel have read the policies and procedures, new and revised, OR records of another written method approved by the laboratory director*				
COM.10500	2	**Discontinued Policies and Procedures** When a policy or procedure is discontinued, a paper or electronic copy is ***retained*** for at least two years (five years for transfusion medicine), recording initial date of use, and retirement date.	NOTE: Discontinued policies and procedures must be appropriately archived using the document control system and must generally be inaccessible to the working areas of the laboratory (GEN.20375). For testing on minors (under the age of 21), stricter national, federal state (or provincial), or local laws and regulations may apply to retention of discontinued policies and procedures.					
			RESULTS REPORTING					
COM.29950	2	**Reference Intervals** All patient/client results are reported with reference (normal) intervals or interpretations as appropriate.	NOTE: The laboratory must report reference intervals or interpretations with patient/client results, where such exist. This is important to allow proper interpretation of patient/client data. Age- and/or sex-specific reference intervals or interpretive ranges must be reported with patient test results, as applicable. In addition, the use of high and low flags (generally available with a computerized laboratory information system) is recommended. It is not necessary to include reference intervals when test results are reported as part of a treatment protocol that includes clinical actions, which are based on the test result. Under some circumstances it may be appropriate to distribute lists or tables of reference intervals to all users and sites where reports are received. This system is usually fraught with difficulties, but if in place and rigidly controlled, it is acceptable.					
COM.30000	2	**Critical Result Notification** The laboratory has written procedures for immediate notification of a physician (or other clinical personnel responsible for the patient's care) when results of designated tests exceed established "critical" values that are important for prompt patient management decisions. Records of notification are ***retained.***	NOTE: Alert or critical results are those results that may require rapid clinical attention to avert significant patient morbidity or mortality. Each laboratory may define the critical values and critical results that pertain to its patient population. The laboratory may establish different critical results for specific patient subpopulations (for example, dialysis clinic patients). Critical results should be defined by the laboratory director, in consultation with the clinicians served. An appropriate notification includes a direct dialog with the responsible individual or an electronic communication (eg, secure email or fax) with confirmation of receipt by the responsible individual.For communication of significant and unexpected surgicalpathology and cytopathology findings, refer to ANP.12175 and CYP.06450 instead. Allowing clinicians to "opt out" of receiving critical results is strongly discouraged. Records must be retained showing prompt notification of the appropriate clinical individual after obtaining results in the critical range. These records must include the following: ● Date of communication; ● Time of communication ● Responsible laboratory individual, ● Person notified (the person's first name alone is not adequate documentation), and ● Test results. Any problem encountered in accomplishing this task should be investigated to prevent recurrence. .		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL: -∞HPO- Pathology volume II-Customer Focus -•Laboratory Critical Action Value Reporting (ICPM - PAT032) (APPENDIX A) // •Laboratory Critical Action Value List ((APPENDIX A))	http://www.insidehopkinsmedicine.org/hpo/policies/39/75/policy_75.pdf		
cont. COM.30000	2	**Critical Result Notification**	Referral laboratories may report critical results directly to clinical personnel, or to the referring laboratory. The referral laboratory should have a written agreement with the referring laboratory that indicates to whom the referral laboratory reports critical results. In the point-of-care setting, the identity of the testing individual and person notified need not be recorded when the individual performing the test is the same person who treats the patient. In this circumstance, however, there must be a record of the critical result, date, and time in the test report or elsewhere in the medical record					

COM.30100	1	**Critical Result Read-Back** When critical results are communicated ***verbally,*** "read-back" of the results is requested and recorded.	NOTE: Transmission of critical results by electronic means (***eg*** ,FAX or computer) is acceptable. If critical results are transmitted electronically, the laboratory must confirm receipt of the result by the intended recipient (***eg.*** by a phone call); however, no read-back is necessary.	** Records of critical result notification, including read-back as necessary*			
			REAGENTS				
COM.30250	2	**Reagent *Storage and* Handling - Waived Tests** For waived tests, the laboratory follows manufacturer instructions for handling and storing reagents, cartridges, test cards, etc.	NOTE: There is no requirement to routinely label individual containers with "date opened"; however, a new expiration date must be recorded if opening the container changes the expiration date, storage requirement, etc. If the manufacturer defines a required storage temperature range, the temperature of storage areas must be monitored daily. Refer to the Temperature-Dependent Instruments, Equipment, and Environment section of the checklist for requirements for monitoring and recording temperature. If the laboratory identifies a problem with a reagent that was used for patient testing (***eg*** . expired vial or reagent subjected to unacceptable storage conditions, etc.), the laboratory must evaluate the potential impact on patient test results and ***retain*** records of the evaluation and actions taken.	** Records of reagent storage and handling consistent with manufacturer's instructions, including refrigerator, freezer and room temperature monitoring*			
			The remaining checklist requirements in the REAGENTS section do not apply to waived tests.				
COM.30300 R	2	**Reagent Labeling** Reagents, calibrators, controls, stains, chemicals, 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, filtered or reconstituted by laboratory 4. Expiration date	NOTE: The above elements may be recorded in a log (paper or electronic), rather than on the containers themselves, providing that all containers are identified so they are traceable to the appropriate data in the log. While useful for inventory management, labeling with "date received" is not routinely required. There is no requirement to routinely label individual containers with "date opened"; however, a new expiration date must be recorded if opening the container changes the expiration date, storage requirement, etc.For containers with multiple individual reagent units (eg, cartridges), the expiration date must be recorded on each unit if stored outside of the original container This requirement also applies to the labeling of chemicals used in the laboratory to prepare reagents or during the preanalytic and analytic phases of the testing process. Requirements relating to precautionary labeling for hazardous chemicals are included in the Chemical Safety section of the Laboratory General Checklist.	** Written procedure defining elements and requirements for reagent labeling*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL: -∞HPO- Pathology volume II - Gneral Policy Manual:Safety and Facilities Chemical Labeling Policy (LES005)	https://hpo.johnshopkins.edu/hopkins/policies/68/9303/policy_9303.pdf?_=0.0767870914206	
COM.30350	2	**Reagent Storage and Handling** All reagents (eg, chemicals, stains) media are stored and handled as defined by the laboratory and following the manufacturer's instructions.	NOTE: Reagents and media must be stored and handled in a manner that will prevent environmentally-induced alterations that could affect reagent stability and test performance. Prepared reagents must be properly stored, mixed, when appropriate, and discarded when stability parameters are exceeded. If the manufacturer defines a required storage temperature range, the temperature of storage areas must be monitored daily. Refer to the Temperature-Dependent Instruments, Equipment, and Environment section of the checklist for requirements for monitoring and recording temperature. If the laboratory identifies a problem with a reagent that was used for patient testing (***eg*** . expired vial or reagent subjected to unacceptable storage conditions, etc.), the laboratory must evaluate the potential impact on patient test results and ***retain*** records of the evaluation and actions taken.	** Records of reagent storage and handling consistent with manufacturer's instructions, including refrigerator, freezer and room temperature monitoring*			
COM.30400 R	2	**Reagent Expiration Date** All reagents (eg, chemicals, stains, media, antibodies)) are used within their indicated expiration date.	NOTE: Expiration dates assigned by a manufacturer must be observed. The laboratory must assign an expiration date if an expiration date is not provided by the manufacturer. The laboratory must base the assigned expiration date on known stability, frequency of use, storage conditions, and risk of deterioration. Transfusion service laboratories may use rare reagents (ie, rare antisera and selected panel red cells to determine the specificity of red cell antigens and antibodies) beyond their expiration date if appropriate positive and negative controls are run each day of use and react as expected. The laboratory must have in-date reagents for routine antigen typing and antibody panel testing For histology and cytology, laboratories may satisfy confirmation of ongoing acceptable performance of stains until the expiration date by technical assessment of case material containing suitable material for evaluation of stains, or by use of suitable control specimens. Laboratories not subject to US regulations and military laboratories in overseas locations, may use expired reagents only under the following circumstances: 1) The reagents are unique, rare or difficult to obtain; or 2) Delivery of new shipments of reagents is delayed through causes not under control of the laboratory. The laboratory must retain records of verification of the performance of expired reagents in accordance with written laboratory procedure. The laboratory must also retain records of its efforts to obtain reagents in a timely manner and the rationale for continuing to perform the test instead of referring it to another laboratory. Laboratories subject to US regulations must not use expired reagents.	** Written procedure for evaluating reagents and media lacking manufacturer's expiration date AND * Records confirming acceptability of any reagent used beyond its expiration date (in jurisdictions where allowed)*			
COM.30450 R	2	**New Reagent Lot Confirmation of Acceptability** New reagent lots and shipments are checked against ***previous*** reagent lots or with suitable reference material before or concurrently with being placed in service.	NOTE: The purpose of this check is to confirm that the use of new reagent lots and shipments do not affect patient results. Matrix interferences between different lots of reagents may impact the calibration status of instruments and consistency of patient results. Improper storage conditions during shipping of reagents may have a negative impact on their ability to perform or exhibit the same levels of reactivity as intended. The minimum extent of the reagent check is described below; however, the check must be at least as extensive as described in the manufacturer's instructions. **Qualitative**: For qualitative nonwaived tests, minimum cross-checking includes retesting at least one positive and negative sample with known reactivity against the new reagent lot. A weakly positive sample *is recommended* in systems where patient results are reported in that fashion. Examples of suitable reference materials for qualitative tests include: 1. Positive and negative patient samples tested on a previous lot; 2. Previously tested proficiency testing materials; 3. External QC materials tested on the previous lot; 4. Control strains of organisms or previously identified organisms for microbiology reagents used to detect or evaluate cultured microorganisms. ***5.*** If none of the above options is available, control material provided by the assay manufacturer with the new test kit. For flow cytometry reagents, please refer to the Reagents section of the Flow Cytometry Checklist.	** Written procedure for the confirmation of acceptability of new lots and shipments, with defined acceptability criteria AND * Records for the introduction of new lots and shipments, including lot number(s) tested and comparison of results to the acceptability criteria*			
COM.30450 R cont.	2	**New Reagent Lot Confirmation of Acceptability**	**Quantitative**: For quantitative nonwaived tests, patient specimens should be used to compare a new lot against the previous lot, when possible. Manufactured materials, such as proficiency testing (PT) or QC materials may be affected by matrix interference between different reagent lots, even if results show no change following a reagent lot change. method specific The use of patient samples confirms the absence of matrix interference. The following materials may also be used: 1. Patient samples tested on a previous lot; 2.Reference materials or QC products provided by the method manufacturer with and reagent lot specific target values; 3. Proficiency testing materials with peer group established means; 4. QC materials with peer group established means based on interlaboratory comparison that is method specific and includes data from at least 10 laboratories; 5. Third party general purpose reference materials if the material is affirmed in the package insert or by the method manufacturer to be commutable with patient specimens for the method. 6. QC material used to test the current lot is adequate alone to check a new shipment of the same reagent lot, as there should be no change in potential matrix interactions between the QC material and different shipments of the same lot number of reagents. For hematology analyzers, reservoirs containing testing reagents and cleaning/decontaminating solutions must be checked according to manufacturer's instructions.				
COM.30500	2	**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.		** Written policy defining allowable exceptions for mixing kit components from different lots*			
			INSTRUMENTS AND EQUIPMENT *A variety of instruments and equipment are used to support the performance of analytical procedures. Examples of equipment include, but are not limited to centrifuges, microscopes, incubators, heat blocks, refrigerators, freezers, biological safety cabinets, fume hoods, glassware, pipettes, etc. This section contains general requirements that apply to most laboratory sections and types of testing. The laboratory is also responsible for any additional instrument and equipment requirements found in the discipline-specific checklists, as applicable*				
			INSTRUMENT AND EQUIPMENT MAINTENANCE/FUNCTION CHECKS				
COM.30525	2	**Maintenance and Function Checks - Waived Tests** For waived tests, the laboratory follows manufacturer's instructions for instrument and equipment maintenance and function checks.		** Written procedure consistent with manufacturer's instructions for each waived test AND * Records for instrument/equipment maintenance and function checks as required by the manufacturer*			
		The remaining checklist requirements in the INSTRUMENT AND EQUIPMENT MAINTENANCE/FUNCTION CHECK section do not apply to waived tests.					
COM.30550	2	**Instrument/Equipment Performance Verification** The performance of all instruments and equipment is verified prior to initia*l use,* and after major maintenance or service, *an* d after relocation to ensure that they run according to expectations.	NOTE: Instrument/equipment performance verification (NOT to be confused with validation or verification of the test method performance specifications) includes processes to verify that the instruments and equipment perform according to expectations for the intended use and within defined tolerance limits. If instruments or equipment are moved, the laboratory must perform appropriate function checks to ensure that they were not adversely affected by the relocation process or changes due to the new environment. This does not apply to portable equipment used following the manufacturer's instructions.	** Written procedure to verify proper functioning of instruments and equipment prior to initial use, after major maintenance or service, and after relocation AND * Records of appropriate function checks*			
COM.30575	2	**Instrument Operation** There are written procedures for start-up, operation and shutdown of instruments and equipment, as applicable	NOTE: These procedures must readily be available to the operator in the immediate vicinity of the instrument, and ideally should include a procedure for emergency shutdown and for handling workload during instrument downtime. These may be separate approved procedures or included in the testing procedure for a specific analyte.				
COM.30600	2	**Maintenance/Function Checks** Appropriate maintenance and function checks are performed and records retained for all instruments (*eg.* analyzers) and equipment (e.g. centrifuges) following a defined schedule, at least as frequent as specified by the manufacturer.	NOTE: There must be a schedule and procedure available to testing personnel for appropriate function checks and maintenance. These may include (but are not limited to) cleaning, electronic, mechanical and operational checks. The procedure and schedule must be as thorough and as frequent as specified by the manufacturer. Function checks should be designed to detect drift, instability, or malfunction, before the problem is allowed to affect test results. For equipment that has no standard frequency or requirement for maintenance and function checks, each laboratory should establish a schedule and procedure that reasonably reflects the workload and specifications of its equipment.				
COM.30625	2	**Function Check Tolerance Limits** Tolerance limits for acceptable function are defined for specific instruments and equipment wherever appropriate, with records of action when the limits are exceeded.	NOTE: The defined tolerance limits must follow the manufacturer's specified limits. Function checks must be within the defined tolerance limits prior to use for testing patient samples. The action related to tests that have an approved Individualized Quality Control Plan (IQCP) must include an assessment of whether further evaluation of the risk assessment and quality control plan is needed based on problems identified (e.g. trending for repeat failures, etc.).				
COM.30650	2	**Instrument Troubleshooting** Instructions are provided for minor troubleshooting and repairs of instruments (such as manufacturer's service manual).					
COM.30675	2	**Instrument and Equipment Records** Instrument and equipment maintenance, function check, performance verification, and service and repair records (or copies) are promptly available to, and usable by, the technical staff operating the equipment	NOTE: Effective utilization of instruments and equipment by the technical staff depends upon the prompt availability of the records (copies are acceptable) to detect trends or malfunctions. Off-site storage, such as with centralized medical maintenance or computer files, is acceptable if the inspector is satisfied that the records can be promptly retrieved.				
COM.30680	2	**Microscope Maintenance** Microscopes are clean, adequate (e.g. low, high dry and oil immersion lenses as appropriate for the intended use), optically aligned, and properly maintained with records of preventive maintenance at least annually	*NOTE:* Koehler illumination must be maintained for optimal resolution. Phase contrast microscopy should be available when indicated (e.g. manual platelet counting, urinalysis microscopy).				

COM.30685	2	**Microscopes for Fluorescence Testing** The microscopes used for fluorescence testing are monitored to ensure sufficient light source intensity, and are used with filters and slides appropriate to, and verified in conjunction with, the test(s) being performed.	*NOTE:* Having a process to track the length of time the bulb is in use and limit bulb usage based on the manufacturer's recommendations (as applicable), is an example of an acceptable process to monitor the adequacy of the source intensity. The use of filters or slides not matched properly to the assay(s) performed can lead to erroneous results. Written procedures must specify the excitation and emission filters used for fluorescence microscopy. Fluorescence microscopes should be used in an area where ambient lighting can be minimized.	** Records of microscope monitoring AND * Written test procedures describing the filters and slides used*				
COM.30690 N	2	**Calibration/Recalibration - Ocular Micrometer** The ocular micrometer (when required) is calibrated for the microscope(s) and the specific objective(s) with which it is used.	NOTE: An ocular micrometer is required for certain types of testing, including: ● Parasitology identification when determining the size of eggs, larvae, cysts, trophozoites, and microfilaria or other bloodborne parasites ● Sperm morphology for use of certain sperm morphology classification methods (Kruger Strict and World Health Organization (WHO) methods references in the 3rd and 4th editions). ● Surgical pathology when accurate microscopic measurements are needed (eg, measuring depth or extent of invasion and margins in various cancers, extent of involvement in needle core biopsies, size of organisms or other microscopic findings) Calibrations must be checked against a calibrated stage micrometer slide or other object(s) of known dimensions appropriate to the use of the ocular micrometer. Any change in the optics of the microscope (eg, change in objective or ocular lens) requires recalibration. If there are no changes to a particular microscope's optical components, there is no need to recheck calibration.	**Written policy for ocular micrometer calibration and recalibration AND * Records of initial calibration and recalibration, if applicable*				
			Thermometers					
COM.30700	2	**Thermometric Standard Device** An appropriate thermometric standard device of known accuracy (certified to meet NIST Standards or traceable to NIST Standards) is available.	NOTE: Thermometric standard devices must be recalibrated, recertified, or replaced prior to the date of expiration of the guarantee of calibration or they are subject to requirements for non-certified thermometers. Thermometers should be periodically evaluated for damage (e.g. separation of columns). Thermometers with obvious damage must be rechecked for continued use.	** Thermometer certificate of accuracy AND * Policy for the use of thermometers after the date of expiration of the guarantee of calibration and records of recertification*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL: -∞HPO- Pathology volume II - General Policy Manual:Operations: Temperature Monitoring Systems (OPER003)	https://hpo.johnshopkins.edu/hopkins/policies/68/22952/policy_22952.pdf?_=0.432993311223		
COM.30725	2	**Non-certified Thermometers** All non-certified thermometers in use are checked against an appropriate thermometric standard device before initial use and as defined by laboratory policy.	NOTE: Non-certified thermometers used in transfusion medicine, including blood-warmer thermometers, must be checked at least annually. If digital or other displays of temperatures on equipment are used for daily monitoring, the laboratory must verify that the readout is accurate. The display must be checked initially and following manufacturer's instructions.	** Written procedure defining verification of non-certified thermometers AND * Written policy for rechecking of non-certified thermometers AND * Records of verification*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL: -∞HPO- Pathology volume II - General Policy Manual:Operations: Temperature Monitoring Systems (OPER003)	https://hpo.johnshopkins.edu/hopkins/policies/68/22952/policy_22952.pdf?_=0.432993311223		
			Temperature-Dependent Instruments, Equipment, and Environments					
COM.30750	2	**Temperature Checks** Temperatures are checked and recorded each day of use for all temperature-dependent equipment and environments using a calibrated thermometer.	NOTE: Temperature-dependent equipment (***eg*** . refrigerators, freezers, incubators) containing reagents and/or patient/client specimens must be monitored daily, as equipment failures could affect accuracy of patient/client test results. Items such as water baths and heat blocks used for procedures need only be checked on days of patient/client testing. For heat blocks or dry baths, thermocouple probes may be used as an alternative method for checking the temperature. If specific instruments, equipment, kits, or supplies have specified ambient temperature ranges for proper operation, storage, or use, there must be records that the specified ambient temperature is maintained and corrective action taken when tolerance limits are exceeded. Temperatures may be recorded either manually, or using a recording device or system by: 1) recording the numerical temperature, or 2) placing a mark on a graph that corresponds to a numerical temperature. If temperatures are recorded manually, the identity of the individual recording the temperature(s) must be recorded (initials of the individual are adequate). If an automated (including remote) temperature monitoring system is used instead of manual temperature monitoring, laboratory personnel must have ongoing immediate access to the temperature data so that appropriate corrective action can be taken if a temperature is outside of the acceptable range. System records must demonstrate daily functionality of the system.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL: -∞HPO- Pathology volume II - General Policy Manual:Operations: Temperature Monitoring Systems (OPER003)	https://hpo.johnshopkins.edu/hopkins/policies/68/22952/policy_22952.pdf?_=0.432993311223		
COM.30750 cont.	2	**Temperature Checks**	If a minimum/maximum thermometer is used to perform continuous monitoring of temperatures between daily temperature readings or following a laboratory downtime (eg. laboratory closure for weekend or holiday), both the low and high temperatures must be recorded. To ensure correct temperature readings, the minimum/maximum thermometer device must be reset prior to the monitoring period A frost-free freezer may be used to store reagents and controls provided that the function of these materials is not compromised. Storage conditions must remain within the specifications of the manufacturer of the reagent or control. Temperatures may be recorded using a continuous monitoring system or a maximum/minimum thermometer. Thermal containers within the freezer may be used. . Patient samples may be stored in a frost-free freezer only if protected from thawing. The laboratory must ***retain*** records showing that the temperatures stay within the defined range.					
COM.30775	2	**Temperature Range** Acceptable ranges have been defined for all temperature-dependent equipment and environments (including test-dependent ambient temperature) in accordance with the manufacturer's instructions.		** Temperature log or record with defined acceptable range*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL: -∞HPO- Pathology volume II - General Policy Manual:Operations: Temperature Monitoring Systems (OPER003)	https://hpo.johnshopkins.edu/hopkins/policies/68/22952/policy_22952.pdf?_=0.432993311223		
COM.30800	2	**Temperature Corrective Action** There is evidence of corrective action taken if acceptable temperature ranges for temperature-dependent equipment and environmental temperatures are exceeded, including evaluation for adverse effects.	NOTE: If acceptable temperature ranges are exceeded, stored reagents, controls, calibrators, etc. must be checked to confirm the accuracy or quality of the material before use, with records retained. The check should follow a defined procedure.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL: -∞HPO- Pathology volume II - General Policy Manual:Operations: Temperature Monitoring Systems (OPER003)	https://hpo.johnshopkins.edu/hopkins/policies/68/22952/policy_22952.pdf?_=0.432993311223		
			VOLUMETRIC GLASSWARE AND PIPETTES					
COM.30810	2	**Volumetric Glassware Accuracy and Reproducibility** Glass volumetric pipettes and other glassware used for volumetric dispensing purposes are of certified accuracy (Class A); or if non-Class A pipettes and glassware are used, they are checked for accuracy and reproducibility initially and according to the manufacturer's recommended interval, or at least annually if not specified, and the results are recorded.	NOTE: The following Table shows the American Society for Testing and Materials' calibration (accuracy) specifications for Class A volumetric pipettes Nominal Capacity (mL) Variation (± mL) 0.5 - 2 0.006 3 - 7 0.01 8 - 10 0.02 15 - 30 0.03 40 - 50 0.05 100 0.08 For Non-Class A pipettes: Pipette checks must be performed following manufacturer's instructions, at minimum and as defined in laboratory procedure. Such checks may be done by gravimetric, colorimetric or other validation procedures. Alternative approaches include spectrophotometry and the use of commercial kits. If initial calibration is performed by the manufacturer or other outside facility, sufficient information must be provided to justify acceptance of the pipette's calibration based on the laboratory's written specifications of acceptable bias and imprecision. The outside facility must also provide a record of the technique used to check calibration and ship the pipette in a manner that protects it from damage in transit.	** Pipettes and glassware marked Class A OR a NIST certificate OR * Records of initial and ongoing verification of non-Class A pipette and glassware accuracy and reproducibility*				
COM.30820	2	**Quantitative Pipette Accuracy and Reproducibility** Pipettes used for quantitative dispensing (eg, adjustable volume, micropipettes, dilutors, and analytic instruments with integral automatic pipettors) are checked for accuracy and reproducibility initially and according to the manufacturer's recommended interval, or at least annually if not specified, and the results are recorded.	NOTE: The initial calibration may be performed by the manufacturer or other outside facility, but in such cases the laboratory must have a record from the manufacturer or other facility that includes the technique used to check calibration, the method of shipment to prevent damage in transit, and the bias and precision of the pipette(s). The bias and imprecision must meet the specification established by the laboratory. If the facility performs pipette checks in house, they must be performed following manufacturer's instructions, at minimum, and as defined in laboratory procedure. Such checks may be done by gravimetric, colorimetric or other validation procedures. Alternative approaches include spectrophotometry and the use of commercial kits. For analytic instruments with integral automatic pipettors, this checklist requirement applies, unless such checks are not practical for end-user laboratory. Manufacturers' recommendations must be followed. This requirement is not applicable for pre-calibrated inoculation loops that are used in the direct plating of clinical specimens such as urine cultures.:	** Written procedure for checking the accuracy and reproducibility of pipettes AND * Records of initial and ongoing verification of pipette accuracy and reproducibility*				
COM.30830	1	**Measuring Devices** The use of less precise measuring devices such as serological plastic pipettes and graduated cylinders are limited to situations where the accuracy and precision of calibrated glass pipettes are not required.	NOTE: In contrast with the more stringent accuracy requirements of glass pipettes, ASTM requirements for plastic pipettes are ± 3% of the stated volume. The procedure manual must specify when the use of non-class A measuring devices is permissible.					
COM.30840	2	**Pipette Carryover** The laboratory evaluates its automatic pipetting systems for carryover.	NOTE: The laboratory must have written procedures for evaluating whether carryover effects are present. This requirement applies to both stand-alone pipette systems and to sample pipettes integrated with analytic instruments. One suggested method to study carryover is to run known high patient samples, followed by known low samples to see if the results of the low-level material are affected. If carryover is detected, the laboratory must determine the analyte concentration above which subsequent samples may be affected, and define this value in the procedure. Results of each analytical run must be reviewed to ensure that no results exceed this level. If results that exceed the defined level are detected, then the appropriate course of action must be defined (repeat analysis of subsequent samples, for example). Carryover studies must be performed, as applicable, as part of the initial evaluation of an instrument. (The laboratory may use the data from carryover studies performed by instrument manufacturers, as appropriate.) Carryover studies should be repeated after major maintenance or repair of the pipetting assembly of the instrument. Evaluation for carryover is not required for automatic pipettes that use disposable tips. This requirement is not applicable to coagulation.	** Record of carryover studies at defined frequency*				
			Analytical Balances					
COM.30860	1	**Analytical Balance Maintenance** Analytical balances are cleaned, serviced and checked at least annually by qualified service personnel.		** Records of analytical balance maintenance AND * Service contract or records of technical training of in-house personnel*				
COM.30870	1	**Analytical Balance Mounting** Analytical balances are mounted such that vibrations do not interfere with readings.						
COM.30880	2	**Analytical Balance Accuracy** Standard weights of the appropriate ANSI/ASTM Class are available and used for verifying accuracy of analytical balances at defined intervals, with records retained.	NOTE: The verification of accuracy of the analytical balance must be performed at a defined interval to ensure accurate creation of analytical calibrators and/or weighed-in controls from standard materials, as well as when gravimetrically checking the accuracy of pipettes. Accuracy must be verified at least every six months if used for weighing materials to make standard solutions for method calibration. Accuracy must be verified at the time of installation and whenever a balance is moved. Acceptable ranges must be defined. External verification of accuracy requires the appropriate class of ASTM specification weights. ASTM Class 1 weights are appropriate for calibrating high precision analytical balances (0.01 to 0.1 mg limit of precision). ASTM Class 2 weights are appropriate for calibrating precision top-loading balances (0.001 to 0.01 g precision). ASTM Class 3 weights are appropriate for calibrating moderate precision balances, (0.01 to 0.1 g precision). Laboratories located outside of the United States may use equivalent certified weights if ANSI/ASTM class standard weights are not available.	** Written procedure defining criteria for the use of standard weights for accuracy checks of analytical balances*				
COM.30890	2	**Weight Maintenance** Calibration weights for analytical balances are well-maintained (clean, in a covered container, free of corrosion) and appropriate lifting or handling devices are available.	NOTE: Weights must be well-maintained (covered when not in use, free of corrosion) and only be handled by devices that will not leave residual contaminants on the weights. Certified weights will only meet their specifications if maintained in pristine condition.					
			WAIVED TEST IMPLEMENTATION ***This section applies to waived testing performed following the manufacturer's instructions, without modification. The current list of tests waived under CLIA may be found at*** https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm					

COM.30980	2	***Waived Test Implementation and Approval*** For each waived test, the laboratory follows manufacturer's instructions for the introduction of the instrument or device and there are records that the test(s) is approved for use by the laboratory director, or designee meeting CAP director qualifications, prior to use in patient testing.	NOTE: Waived testing must be performed following the manufacturer's instructions. If the laboratory modifies a waived test, the checklist requirements for high complexity testing apply, including the requirements for validation of the method performance specifications. The laboratory director's signature on the written test procedure may be used to show approval of the test for use in patient testing.	** Records of test approval*			
			TEST* METHOD *VALIDATION AND VERIFICATION* - NONWAIVED TESTS *see next Tab				
COM.40250 R	2	**Manufacturer's Instructions** The laboratory follows manufacturer's instructions or provides validation records if the test has been modified.	NOTE: Following manufacturer's instructions includes performing quality control, calibration, calibration verification, and related functions as applicable to the scope of testing. Reagents, fluids, and disposable materials supplied by the laboratory must meet the specifications in the instructions. If the laboratory modifies manufacturer's instructions, the test is no longer FDA-cleared/approved, and the modification(s) must be validated by the laboratory. This requirement also applies to laboratories not subject to US regulations for tests approved by an internationally recognized regulatory authority that are modified by the laboratory. Changes in the specimen type or collection device are examples of common modifications (see "modification of manufacturer's instructions" in the Definition of Terms). Additional requirements for validation/verification may be found in the discipline-specific checklists. For waived and moderately complex tests, if manufacturer instructions are modified, requirements for high complexity testing apply.	*Evidence of Compliance:* ** Validation records of established performance specifications (accuracy, precision, analytical sensitivity, analytical specificity, interferences, reference range, and reportable range) of any test that has been modified.*			
COM.40300 R	2	**Verification of Test Performance Specifications - FDA-cleared/approved Tests** Prior to clinical use of each unmodified FDA-cleared or approved test, the laboratory has performed a verification study and prepared a written assessment of each of the following test method performance specifications, as applicable, *using a sufficient number of characterized samples.* ***1*** . Analytical accuracy; ***2*** . Analytical precision; ***3*** . Reportable range	NOTE 1: Accuracy *verifie* by comparing results to a definitive or reference method, or an established comparative method. Use of matrix-appropriate reference materials, patient specimens (altered or unaltered), or other commutable materials with known concentrations or activities may be used to verify accuracy. The use of routine quality control materials or calibrators that were used to calibrate the method is not appropriate. NOTE 2: Precision is verified by repeat measurement of samples at varying concentrations or activities within run and between run over a period of time. NOTE 3. The reportable range of an assay is the range of values that the laboratory reports for that assay. NOTE 4: If multiple identical instruments or devices are in use, there must be records (data and written assessment) showing that the method performance specifications have been separately verified for each test and instrument or device. NOTE 5: If a method is verified by someone other than the laboratory's personnel (eg, manufacturer's representative), the laboratory must have records to show that the verification correlates with its in-house test performance by showing confirmation of performance specifications by the laboratory personnel testing known specimens.. NOTE 6: The requirement for a written assessment applies to all tests implemented after June 15, 2009; however, all nonwaived tests must have records of completed analytical verification, regardless of the implementation date. The written assessment must include an evaluation of each component of the verification study, including the acceptability of the data. If data include discordant results, there must be a record of the discordance and investigation of any impact on the approval of the test for clinical use.	** Written procedure for verifying test method performance specifications AND* ** Records of verification and written assessment of each component of the test method performance specifications for each test*			
COM.40325 N	2	**Verification of Test Performance Specifications - Tests Approved by an Internationally Recognized Regulatory Authority - Laboratories not Subject to US Regulations** For laboratories not subject to US regulations, prior to clinical use of each test approved by an internationally recognized regulatory authority (eg, the European Union's Conformité Européenne (CE) Marking), the laboratory has performed a verification study and prepared a written assessment of each of the following test method performance specifications, as applicable, using a sufficient number of characterized samples: 1. Analytical accuracy 2. Analytical precision 3. Reportable range 4. Any other performance characteristic required to ensure analytical test performance	NOTE 1: Accuracy is verified by comparing results to a definitive or reference method, or an established comparative method. Use of matrix-appropriate reference materials, patient specimens (altered or unaltered), or other commutable materials with known concentrations or activities may be used to verify accuracy. The use of routine quality control materials or calibrators used to calibrate the method is not appropriate NOTE 2: Precision is verified by repeat measurement of samples at varying concentrations or activities within run and between run over a period of time. NOTE 3: The reportable range of an assay is the range of values that the laboratory reports for this assay. NOTE 4: The laboratory must also validate analytic sensitivity (lower detection limit) and analytic specificity (interferences) if the test manufacturer has not documented these test characteristics. Data on interferences may be obtained from manufacturers or published literature, as applicable. The laboratory must validate other relevant analytic characteristics not documented by the test manufacturer, as appropriate. NOTE 5: If multiple identical instruments or devices are in use, there must be records (data and written assessment) showing that the method performance specifications have been separately verified for each test and instrument or device.	** Written procedure for verifying test method performance specifications AND* ** Records of the test method performance specifications for each test*			
cont.COM.40325 N		**Verification of Test Performance Specifications - Tests Approved by an Internationally Recognized Regulatory Authority - Laboratories not Subject to US Regulations**	NOTE 6: If a method is verified by someone other than the laboratory's personnel (eg, manufacturer's representative), the laboratory must have records to show that the verification correlates with in-house test performance by showing confirmation of performance specifications by the laboratory personnel testing known specimens. NOTE 7: The requirement for a written assessment applies to all tests implemented after June 15, 2009; however, all nonwaived tests must have records of completed analytical verification, regardless of the implementation date. The written assessment must include an evaluation of each component of the verification study, including the acceptability of the data; If data include discordant results, there must be a record of the discordance and investigation of any impact on the approval of the test for clinical use.				
COM.40350 R	2	**Validation of Test Performance Specifications - Modified FDA-cleared/approved Test and LDTs** Prior to clinical use of each modified FDA-cleared or approved test and laboratory-developed tests (LDTs), the laboratory has performed a validation study and prepared a written assessment of each of the following test method performance specifications, as applicable, using a sufficient number of characterized samples: 1. Analytical accuracy 2. Analytical precision 3. Reportable range 4. Analytical sensitivity (lower detection limit) 5. Analytical specificity 6. Any other performance characteristic required to ensure analytical test performance	NOTE 1:For laboratories not subject to US regulations, this requirement also applies to: ● Tests that are not approved by an internationally recognized regulatory authority ● Approved tests that have been modified by the laboratory NOTE 2 Accuracy is validated by comparing results to a definitive or reference method, or an established comparative method. Use of matrix-appropriate number of samples reference materials, patient specimens (altered or unaltered), or other commutable materials with known concentrations or activities may be used to validate accuracy. The use of routine quality control materials or calibrators used to calibrate the method is not appropriate. For laboratory-developed tests, an appropriate number of samples to demonstrate analytical accuracy is defined as the following: * For quantitative tests, a minimum of 20 samples with analyte concentrations distributed across the analytical measurement range should be used. Proportionate mixtures of samples may be used to supplement the study population. * For qualitative tests, a minimum of 20 samples, including positive, negative, and low-positive samples with concentrations near the lower level of detection should be used; equivocal samples should not be used.	** Written procedure for validating test method performance specifications AND* ** Records of validation and written assessment of each component of the test method performance specifications*			
cont. COM.40350 R	2	**Validation of Test Performance Specifications - Modified FDA-cleared/approved Test and LDTs**	* For certain methods that test multiple analytes (e.g. next-generation sequencing, FISH, HPLC, GC-MS, MALDI-TOF, etc.), analytic accuracy may be established for each method (not necessarily each analyte), as appropriate. If the laboratory uses fewer samples, the laboratory director must record the criteria used to determine the appropriateness of the sample size. In many cases, a validation study with more samples is desirable. For LDTs in use prior to July 31, 2016, for which limited validation studies are recorded, ongoing data supporting acceptable test performance may be used to meet the above minimum sample requirement, unless the laboratory director has recorded the criteria used to determine the acceptability of a smaller sample size. Examples of such ongoing data include records of proficiency testing, alternative performance assessment, and quality control, and correlation with clinical data.				
COM.40350 R		**Validation of Tests Performance Specifications cont.**	NOTE 3: Precision is validated by repeat measurement of samples at varying concentrations/ activities within-run and between-run over a period of time. NOTE 4: The reportable range of an assay is the range of values that the laboratory reports for that assay. . NOTE 5: If multiple identical instruments or devices are in use, there must be records (data and written assessment) showing that the method performance specifications have been separately verified for each test and instrument or device. NOTE 6: If a method is verified by someone other than the laboratory's personnel (eg, manufacturer's representative), the laboratory must have records to show that the verification correlates with its in-house test performance by showing confirmation of performance specifications by the laboratory personnel testing known specimens. NOTE 7:The requirement for a written assessment applies to all tests implemented after June 15, 2009; however, all nonwaived tests must have records of completed analytical verification, regardless of the implementation date. The written assessment must include an evaluation of each component of the verification study, including the acceptability of the data. If data include discordant results, there must be a record of the discordance and investigation of any impact on the approval of the test for clinical use. NOTE 8:This checklist requirement does not apply to LDTs that employ the following methods: ● Manual microscopy (eg, histopathologic and cytologic interpretation, microscopic examination of blood or body fluids, Gram stains) ● Conventional microbiologic cultures and disc/broth/tube susceptibility studies				
COM.40475	2	**Method Validation and Verification Approval - Nonwaived Tests** Prior to clinical use of each nonwaived test, the laboratory director, or designee meeting CAP director qualifications, has signed the laboratory's written assessment of the validation or verification study (accuracy, precision, etc.) to confirm the acceptance of the study data and written assessment, and to approve each nonwaived test for clinical use.	NOTE: This checklist requirement is applicable only to nonwaived tests implemented after June 15, 2009; however, all nonwaived tests must have records of completed analytical validation or verification, regardless of their implementation date. The approval must include: 1) a review of the written assessment of the validation or verification study, including the acceptability of the data and investigation of any discordant results; 2) signed approval statement, such as, "I have reviewed the verification (or validation) data for the performance specifications listed below for the (insert instrument/test name), and the performance of the method is considered acceptable for patient testing. . If a validation or verification study (accuracy, precision, reportable range, etc.) was not performed or is missing required components, the appropriate, related checklist requirements must also be cited (e.g. COM.40300, COM.40350). If multiple identical instruments or devices are in use, there must be records (data and written assessment) showing that the method performance specifications have been separately validated/verified for each test and instrument or device.	** Records of approval of validation and verification studies and approval for clinical use*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL: -∞HPO- Pathology volume II - General Policy Manual:Quality Management: Test Method Validation (QM015)	https://hpo.johnshopkins.edu/hopkins/policies/68/8917/policy_8917.pdf?_=0.0895125456227	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL: -∞HPO- Pathology volume II - General Policy Manual:Quality Management: Test Method Validation (QM015)
COM.40500	2	**Analytical Interferences** The laboratory understands the analytical interferences for each test, and has an appropriate plan of action when they are present.	NOTE: Interfering substances may pose a significant problem to the clinical laboratory and healthcare providers who may be misled by laboratory results that do not reflect patient clinical status. The laboratory must be aware of common interferences by performing studies or referencing studies performed elsewhere (such as by the instrument-reagent manufacturer).	** Written procedure for determining method performance characteristics, including analytical interferences AND* **Document listing known interferences for each test and plan of action when they are present*			
COM.40605	2	**Reference Intervals** The laboratory verifies or establishes or verifies its reference intervals.	NOTE: Reference intervals are important to allow a clinician to assess patient results against an appropriate population. The reference *intervals* must be established or verified for each analyte and specimen source (e.g. blood, urine, cerebrospinal fluid), when appropriate. For example, a reference interval can be verified by testing samples from 20 healthy representative individuals; if no more than two results fall outside the proposed reference interval, that interval can be considered verified for the population studied If a formal reference interval study is not possible or practical, then the laboratory should carefully evaluate the use of published data for its own reference *intervals* , and retain records of this evaluation. For many analytes (e.g. therapeutic drugs, *cholesterol* and CSF total protein), literature references or a manufacturer's package insert information may be appropriate.	** Record of reference interval study OR records of verification of manufacturer's stated interval when reference interval study is not practical (eg, unavailable normal population) OR other methods approved by the laboratory/section director*			
COM.40615	2	**Reference Interval Evaluation** The laboratory evaluates the appropriateness of its reference intervals and takes corrective action if necessary.	NOTE: Criteria for evaluation of reference intervals include: 1. Introduction of a new analyte to the test repertoire 2. Change of analytic methodology 3. Change in patient population If it is determined that the range is no longer appropriate for the patient population, corrective action must be taken.	** Records of evaluation and corrective action, if indicated*			

COM.40620	2	**Body Fluid Analysis** Methods for body fluid analysis have been validated or verified and metrics for interpretation have been established.	NOTE: This requirement applies directly to body fluid testing that the laboratory offers as a routine, orderable test. If the test is routinely performed on the fluid, there must be a written procedure. The requirement COM.40000 for a method validation or verification approval applies. Method performance specifications for blood specimens may be used for body fluids if the laboratory can reasonably exclude the existence of matrix interferences affecting the latter either by reference in the procedure manual to published literature or by evaluation for interferences due to matrix effects by performing an appropriate study (eg, a dilution study using admixtures of samples, spiking samples, further dilution). Alternative performance assessment is required (COM.01500) and may be performed using clinical assessment by chart review. The reference intervals must be defined and reported with the results, unless the concentration of the analyte is reported in comparison to its concentration in a contemporaneously collected blood specimen. If the result is to be interpreted by comparison to the patient's blood, serum, or plasma, such results must be accompanied by an appropriate comment such as, "The reference intervals and other method performance specifications are unavailable for this body fluid. Comparison of this result with the concentration in the blood, serum, or plasma is recommended." Reference intervals citations from the manufacturer's insert or published literature citations may be used to determine the reference intervals (COM.**40605**). However, reference intervals have not been published for many body fluid analytes, and obtaining normal fluids to establish reference intervals may not be feasible.	** Records of validation or verification studies with review and approval; AND* ** Records of reference interval study OR records of verification of manufacturer's stated interval or published literature OR other methods approved by the laboratory/section director*			
cont. COM.40620		**Body Fluid Analysis**	A request for a test on a body fluid specimen that is not listed on the laboratory's test menu that requires clearance by the section director or designee is considered a clinically unique specimen, rather than a routine, orderable test. Typically, these specimens are submitted due to an unusual clinical concern in a specific patient or situation (e.g. pathologic states where the analyte is not normally found in the fluid type) and it may not be possible to establish a comparative metric. In such cases, the result must be accompanied by a comment such as, "The reference intervals and other method performance specifications have not been established for this body fluid. The test result must be integrated into the clinical context for interpretation."				
COM.40640 R	2	**Clinical Claims Validation** All clinical claims made by the laboratory are validated for the following types of tests: * Laboratory-developed tests (LDTs) * FDA-cleared/approved tests for which the laboratory makes a clinical claim(s) not included in manufacturer instructions * In laboratories not subject to US regulations, tests approved by an internationally recognized regulatory authority (eg, CE marking) for which the laboratory makes a clinical claim(s) not included in the manufacturer's instructions	NOTE: Clinical claims include statements about a test's diagnostic sensitivity and specificity, ability to predict the risk of a disease or condition, clinical usefulness, or cost-effectiveness. Clinical claims may be found on the test report or in other information distributed by the laboratory (websites, test catalogues, newsletters, memoranda, advertisements, etc.). Laboratories are not required to make clinical claims about a test, but any claims made by the laboratory must be validated. The laboratory director must review and approve the validation of clinical claims for FDA-cleared/approved tests not included in manufacturer's instructions and laboratory-developed tests, as applicable In order to adequately support a claim about diagnostic sensitivity and specificity and/or ability to predict risk of a disease or condition, the laboratory must perform a clinical validation study, unless the clinical validity of the test is documented in peer-reviewed literature or textbooks. The clinical validation study must include at least 20 samples and must include both positive and negative samples. If the laboratory uses fewer samples, the laboratory director must record the criteria used to determine the appropriateness of the sample size.	** Records of clinical studies performed by the laboratory OR peer-reviewed literature that reasonably substantiates all claims made by the laboratory about a test*			

COM.40700	2	**Method Performance Specifications Availability** For current test methods, the laboratory makes the following available to clients and the inspection team upon request: * Summary of the analytical performance specifications for each method, validated or verified by the laboratory to include analytical accuracy, precision, analytical sensitivity, analytical specificity (test method interferences), reference range, and reportable range, as applicable; and * Supporting data for clinical performance claims, if applicable, validated or verified by the laboratory or obtained from peer-reviewed literature.	NOTE: Information may be provided to clients, in a summary format referring to the supporting data, statistics, and published studies, as appropriate. Clients include healthcare entities, other laboratories, and licensed independent practitioners. This requirement does not apply to patients or their authorized representatives. The laboratory may require clients to treat the data as confidential and not to use such proprietary information for its own test development or share such data with any other party except as required by law. The CAP inspection team is instructed to treat all such data as confidential and to review them solely for accreditation purposes.				
COM.40800	2	**Analytical Methodology Changes** If the laboratory changes its analytical methodology so that test results or their interpretations may be SIGNIFICANTLY different, the change is explained to clients.	NOTE: This requirement can be accomplished in any of several different ways, depending on local circumstances. Some methods include directed mailings, laboratory newsletters or part of the test report itself.	** Records such as directed mailings, laboratory newsletters or comment on the patient report advising of the change*			
COM.40805	2	**Intermittent *or Seasonal* Testing** For tests taken out of production, for a period of time (eg, seasonal testing for influenza), the laboratory meets the following requirements prior to resuming patient testing: 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	NOTE: A test is considered to be taken out of production when (1) patient testing is not offered AND (2) PT or alternative assessment, as applicable, is suspended. It does not apply to situations where a proficiency testing challenge is not performed due to a temporary, short-term situation, such as a reagent back order or an instrument breakdown. In those situations, the laboratory must perform alternative assessment for that testing event. The laboratory should have written procedures for putting intermittent tests into production. For tests for which PT is required by CAP, if a PT challenge is not offered during the 30-day period prior to restarting patient testing, the laboratory may perform an alternative assessment of the test. The laboratory must participate in the next scheduled PT event, if the Laboratory Accreditation Program requires external PT for that analyte.				
COM.40830 R	1	**Test List Modified FDA-cleared/approved Tests *and LDTs*** The laboratory maintains a list of laboratory-developed tests (LDTs) and modified FDA-cleared/approved tests implemented by the laboratory.	NOTE: For laboratories not subject to US regulations, the list must aslo include tests approved by an internationally recognized regulatory authority that have been modified by the laboratory. A form is available on the CAP website that may be used for maintaining this list and can be downloaded from the CAP website (cap.org) through e-LAB Solutions Suite.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL: -∞HPO- Pathology volume II - General Policy Manual:Quality Management: Test Method Validation (QM015) •Laboratory-Developed & Modified FDA-Cleared/Approved Test List	https://hpo.johnshopkins.edu/hopkins/policies/68/22952/policy_22952.pdf?_=0.432993311223	
COM.40840 R	2	**Calibration and Quality Control Procedures - Modified FDA-cleared/ approved Tests and LDTs** For laboratory-developed tests and modified FDA-cleared/approved tests, the laboratory defines written procedures for calibration and quality control based on the studies performed to evaluate the method performance specifications.	NOTE: The procedures must define the frequency, number, and concentration of calibrators and controls to be used. For laboratories not subject to US regulations, this requirement also applies to tests that are not approved by an internationally recognized regulatory authority and to approved tests that have been modified by the laboratory.				
COM.40850 R	2	**LDT and Class I ASR Reporting** Reports for laboratory-developed tests (LDTs) including those performed using class I analyte-specific reagents (ASRs), contain the following: ● A statement that the assay was developed by the laboratory. AND ● A brief description of the method and performance characteristics needed for clinical use, unless the information is readily available to the clinician in another format (eg, test catalog, policy to provide upon request).	NOTE: TheFor laboratories subject to US regulations, thefollowing disclaimer statement must be included on the patient report: "This test was developed and its performance characteristics determined by <insert laboratory/company name>. It has not been cleared or approved by the US Food and Drug Administration." Laboratories not subject to US regulations do not need to use the above disclaimer but must include a statement that the test was developed by the laboratory. The laboratory may put a single disclaimer on the patient report for all studies (eg, immunostains, in situ hybridization, or flow cytometry) collectively used in a particular case. Separately tracking each reagent used for a case and selectively applying the disclaimer is unnecessary. The CAP also recommends (but does not require) including additional information in the patient report, such as the following: ● The FDA does not require this test to go through premarket FDA review. ● This test is used for clinical purposes. It should not be regarded as investigational or for research. ● This laboratory is certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical laboratory testing. This requirement does not apply to laboratory-developed tests that aretraditional methods, such as manual microscopy, conventional microbiologic cultures, conventional cytogenetics, and manual hematology and immunology tests.				
cont. COM.40850 R	1	**LDT and Class I ASR Reporting**	The FDA defines ASRs as reagents (eg, antibodies, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid sequences), which through specific binding or chemical reaction with substances in a specimen are intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens. An ASR is the manufacturer-provided active ingredient in a laboratory-developed test system. Class I ASRs are not subject to preclearance by the US Food and Drug Administration or to special controls by the FDA. When manufacturers have assembled ingredients towards the development of a test, the product is no longer an ASR. The following types of reagents do not meet the FDA's definition of an ASR: reagents that are sold in kit form with other materials and/or an instrument, and/or with instructions for use, and/or when labeled by the manufacturer as Class I for in vitro diagnostic use (IVD), Class II IVD, or Class III IVD. A class I ASR is the manufacturer-provided active ingredient in a laboratory-developed test system. Class I devices are those classified by the FDA as posing the lowest patient risk. Class I ASRs are therefore exempt from FDA clearance/approval. A class I ASR is provided by the manufacturer as a single reagent and is not combined with other materials, nor does the manufacturer provide instructions for use. Reagents subject to FDA clearance or approval are not class I ASRs; therefore, this checklist requirement does not apply. Examples include: ● Reagents that are sold as kits in combination with other materials and/or an instrument, or with manufacturer's instructions for use ● Class I, II and III products labeled "for in vitro diagnostic use (IVD)"				
	INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP) This section applies to laboratories using an IQCP approved by the laboratory director for nonwaived testing to reduce external control analysis to a frequency less than the limits defined in the CLIA regulations and CAP checklists. Laboratories are not required to implement an IQCP however, one is required if the laboratory decides to perform QC at a frequency less than specified in the CLIA regulations. A laboratory may not implement an IQCP that allows for quality control to be performed less frequently than indicated in the manufacturer's instructions. This section does not apply if the type and frequency of external quality control already meets or exceeds minimum quality control requirements defined in the CLIA regulations and CAP checklist requirements. If a laboratory is located in a state that does not accept IQCP as an option for reducing the frequency of external quality control, the laboratory must follow the state regulations and perform external quality control following the frequency defined in the state regulations and CAP checklists. Eligibility for use of an IQCP is limited to testing meeting **all** of the following criteria: ● Nonwaived tests that employ an internal (electronic/procedural/built-in) quality control system ◦ Exception: Microbiology media and reagents used for microbial identification and susceptibility testing may implement an IQCP as defined in the *Microbiology Checklist* ● Tests performed in specialties other than Anatomic Pathology and Cytopathology. ◦ Exception: If an Anatomic Pathology or Cytopathology test can be assigned to a different CMS subspecialty, it may qualify. Testing performed using microbiology media and reagents used for microbial identification and susceptibility testing is eligible for IQCP as defined in the Microbiology Checklist IQCP https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm *the FDA website to confirm the complexity of tests performed and can be accessed at* The CAP has a variety of tools available on cap.org through e-LAB Solutions Suite under Checklist Resources, IQCP Toolbox, including frequently asked questions, examples, forms, and links to CMS and CDC resources. Note that development of an IQCP only impacts quality control requirements. All other checklist requirements remain unchanged and applicable. For a listing of specialties/subspecialties and general regulations which are designated as "eligible" for IQCP refer to the Centers for Medicare and Medicaid State Operations Manual (www.cms.gov) interpretive guidelines for regulation 42CFR493.1256(d), Table 1: Eligibility for IQCP.						
COM.50200	2	***List of Individualized Quality Control Plans*** The laboratory has identified all tests using an IQCP *on* the CAP's List *of Individualized Quality Control Plans form*.	***NOTE: The forms*** may be downloaded from cap.org through e-LAB Solutions Suite under Checklist Resources,IQCP Toolbox. The use of the *CAP form* is required, even if standardized forms and templates are used by the laboratory.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL: -∞HPO- Pathology volume II - General Policy Manual:Compliance:Individualized Quality Control Plan (COP005)	https://hpo.johnshopkins.edu/hopkins/policies/68/18141/policy_18141.pdf?_=0.481359751669	
COM.50300	2	**Risk Assessment** The IQCP for a test/device/instrument includes a risk assessment to evaluate potential sources of error to include all of the following: ● Preanalytic, analytic, and postanalytic phases of the testing process ● Intended medical uses of the test and impact if inaccurate results are reported (clinical risk) ● Components of the tests including reagents, environment, specimen, testing personnel, and test system ● Variations in the components based on use of the tests (e.g. use in different environments, by different personnel, or multiple identical devices) ● Data from the laboratory's own environment, instrument/equipment performance, and testing personnel demonstrating acceptable performance over the maximum time interval between external quality control runs defined in the IQCP ● Manufacturer's instructions and recommendations	NOTE: The risk assessment must include a process to identify the sources of potential failures and errors for a testing process, and evaluate frequency and impact of those failures and sources of error. The laboratory director must consider the laboratory's clinical and legal responsibilities for providing accurate and reliable patient test results. Published data and information may be used to supplement the risk assessment, but are not substitutes for the laboratory's own studies and evaluation. The laboratory must involve a representative sample of testing personnel in the process of conducting the risk assessment. It is not necessary for all personnel to be involved. **The risk assessment for laboratories with multiple identical devices must show that an evaluation was performed if there are differences in testing personnel or environments where testing is performed, with customization of the quality control plan, as needed**. The QC study to assess the performance and stability of the tests must support the QC frequency and elements defined in the laboratory's quality control plan study must include laboratory data representing, the maximum interval between runs of external quality control. Consecutive days, of data collection are not specifically required if testing is done sporadically, or is not performed seven days a week. Laboratories may use historical data for tests already in place. and may supplement the study with data from published literature.*For new tests, devices, and instruments introduced into the laboratory, the laboratory must collect in-house data and may need to define a more frequent QC interval until sufficient data is available to support a longer time interval between runs of external QC* .For susceptibility testing guidance, refer to MIC.21910.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL: -∞HPO- Pathology volume II - General Policy Manual:Compliance:Individualized Quality Control Plan (COP005)	https://hpo.johnshopkins.edu/hopkins/policies/68/18141/policy_18141.pdf?_=0.481359751669	
cont. COM.50300	2	**Risk Assessment**	For affiliated laboratories (e.g. systems) with integrated procedures, each accredited laboratory must have its own IQCP approved by the laboratory director. There must be records demonstrating that risks specific to the site were evaluated involving a representative sample of local testing personnel to conduct the risk assessment and that laboratory-specific QC data were used in the study to support the defined frequency of quality control. Laboratories may use data from other sites to supplement risk assessments and to support their findings.				
COM.50400	2	**Quality Control Plan Approval** The IQCP includes a written quality control plan approved by the laboratory director prior to implementation.	NOTE: The quality control plan may be part of a test procedure or be a separate written plan. As an efficiency, a single plan may address multiple tests performed on one device. A separate, quality control plan approved by the laboratory director must be in place for each laboratory with a separate CAP and CLIA number.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL: -∞HPO- Pathology volume II - General Policy Manual:Compliance:Individualized Quality Control Plan (COP005)	https://hpo.johnshopkins.edu/hopkins/policies/68/18141/policy_18141.pdf?_=0.481359751669	
COM.50500	2	**Quality Control Plan Elements** The individualized quality control plan must define all aspects monitored based on the potential errors identified during the risk assessment, including the following parameters as applicable: * The number, type (external and internal quality control systems), and frequency of quality control * Criteria for acceptable performance * Monitoring of the testing environment and reagents * Specimen quality * Instrument calibration, maintenance, and function checks * Training and competency of testing personnel * Provisions for multiple identical devices and variation for uses covered under one IQCP	NOTE: The components of the quality control plan must meet regulatory and CAP accreditation requirements and be in compliance with the manufacturer instructions, at minimum. The quality control plan must control the quality of the test process and ensure accurate and reliable test results. External control material samples must be analyzed with new lots and shipments of reagents or more frequently if indicated in the manufacturer's instructions.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL: -∞HPO- Pathology volume II - General Policy Manual:Compliance:Individualized Quality Control Plan (COP005)	https://hpo.johnshopkins.edu/hopkins/policies/68/18141/policy_18141.pdf?_=0.481359751669	

COM.50600	2	**Ongoing Quality Assessment Monitoring** Ongoing quality assessment monitoring is performed by the laboratory to ensure that the quality control plan is effective in mitigating the identified risks for the IQCP and includes records of the following: * Review of quality control and instrument/equipment maintenance and function check data at least monthly * Evaluation of errors relating to preanalytic, analytic and post analytic phases of the testing process * Review of complaints from clinicians and other healthcare providers regarding the quality of testing to confirm the clinical efficacy of testing * Evaluation of corrective actions taken when problems are identified *Re-evaluation of the quality control plan if changes to the reagents, environment, specimen, testing personnel, or test system elements of the risk assessment occur * Reapproval of the quality control plan by the laboratory director or designee at least biennially	NOTE: If ongoing assessments identify failures in one or more components of the quality control plan, the laboratory must investigate the cause and consider if modifications are needed to the quality control plan to mitigate potential risk. Common examples of failures include unacceptable proficiency testing results, recurrent out-of-range reagent storage or room temperatures, unacceptable quality control results, use of unvalidated specimen types, and the IQCP not being followed as written. An example form is available on cap.org through e-LAB Solutions Suite under Checklist Resources IQCP Toolbox that may be used for recording ongoing assessments of the IQCP.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL: -∞HPO- Pathology volume II - General Policy Manual:Compliance:Individualized Quality Control Plan (COP005)	https://hpo.johnshopkins.edu/hopkins/policies/68/18141/policy_18141.pdf?_=0.481359751669	

ALL COM 6_4_2020

NEW Checklist Requirements	
Effective Date	***Requirement***
6/4/2020	COM.30690
6/4/2020	COM.40325

REVISED Checklist Requirements	
Effective Date	**Requirement**
6/4/2020	COM.01000
6/4/2020	COM.01100
6/4/2020	COM.01200
6/4/2020	COM.01300
6/4/2020	COM.01520
6/4/2020	COM.01900
6/4/2020	COM.04250
6/4/2020	COM.06300
6/4/2020	COM.30300
6/4/2020	COM.30400
6/4/2020	COM.30450
6/4/2020	COM.40250
6/4/2020	COM.40300
6/4/2020	COM.40350
6/4/2020	COM.40640
6/4/2020	COM.40830
6/4/2020	COM.40840
6/4/2020	COM.40850

TEST METHOD VALIDATION AND VERIFICATION - NONW

NOTE: This *section* does not apply to waived tests *performed following manufacturer's instructions.*

ANALYTICAL VALIDATION/VERIFICATION

Analytical verification is the process by which a laboratory determines that an unmodified FDA-cleared/c
. Analytical validation is the process used to confirm with objective evidence that a laboratory-developec
See below for requirements for laboratories not subject to US regulations.

Laboratories are required to perform analytical validation or verification of each nonwaived test, metho
including instruments of the same make and model and temporary replacement (loaner) instruments. ***T***
laboratory must have data for the validation or verification of the applicable method performance specij

If an FDA-cleared or approved method was verified by someone other than the laboratory's personnel (e
its in-house test performance by showing confirmation of performance specifications by laboratory per

The method performance specifications (ie.the applicable analytic performance characteristics of the tes
If an instrument is moved, the laboratory is responsiblefor determining that the method performance sp
such as set-up limitations, environmental conditions, etc.). The laboratory must follow manufacturer's in
the performance of instruments and equipment to confirm that they function according to expectations
and Function Checks section (COM.30550, COM.30600).

QUALITATIVE TESTING

Not all method performance specifications apply to qualitative tests. For qualitative tests, the laboratory

LABORATORIES SUBJECT TO US REGULATIONS:

- *For unmodified FDA-cleared or approved tests, the laboratory may use information from ma*
  on accuracy, precision, reportable range and reference intervals.
- *For modified FDA-cleared or approved tests and laboratory-developed tests (LDTs), the labor*
  specificity, (interferences), reportable range, and reference intervals,as applicable; data on ir

LABORATORIES NOT SUBJECT TO US REGULATIONS:

- *For laboratories performing tests approved by an internationally recognized regulatory auth*
  or published literature, but the laboratory must verify such outside information on accuracy,
  and local laws and regulations for approval and usage of such tests. These instruments and c
- *For tests not approved by an internationally recognized regulatory authority, the laboratory*
  (interferences), reportable range, and reference intervals, as applicable; data on interference

LABORATORY-DEVELOPED TESTS:

For the purposes of interpreting the checklist requirements, a laboratory-developed test (LDT) is defined

1 *The test is performed by the clinical laboratory in which the test was developed wholly or in p*
   AND
2 *The test is neither FDA-cleared nor FDA-approved (or, for laboratories not subject to US regu*

EMERGENCY USE AUTHORIZATION (EUA)

For laboratories subject to US regulations, an emergency use authorization (EUA) is the legal mechanisr
of an approved medical product during an emergency to diagnose, treat, or prevent a serious or life thr

A laboratory that uses an EUA assay may not be able to establish accuracy, precision, analytical sensitivi
the assay or test system's protocol as authorized by the FDA without modification and document the alt
Information on current EUA assays can be found on the FDA website at the following link;

'AIVED TESTS

approved test performs according to the specifications set forth by the manufacturer when used as direct
d or modified FDA-cleared/approved test method or instrument system delivers reliable results for the int

d, or instrument system before use in patient testing, regardless of when it was first introduced by the la
here is no exception for analytical validation or verification of tests introduced prior to a specific date
fications and retain the records as long as the method is in use and for at least two years after discontinu

g, manufacturer's representative), the laboratory must ensure that the verification correlates with
sonnel testing known specimens.

st, such as accuracy, precision, etc) must be validated or verified in the location in which patient testing w
pecifications are not affected by the relocation process or any changes due to the new environment (e.g.
nstructions for instrument set up, maintenance, and system verification. Separate requirements for verify
for the intended use and within the defined tolerance limits are found in the Instrument and Equipment I

y must verify or establish the method performance specifications that are applicable and clinically relevai

nufacturers, or published literature, but the laboratory must verify such outside information

atory must establish accuracy, precision, analytical sensitivity, analytical
nterferences may be obtained from manufacturers or published literature, as applicable.

ority (eg, the European Union's Conformité Européenne (CE) Marking), the laboratory may use informati
precision, reportable range, and reference intervals. Analytical verification must also follow national, fec
devices are not considered laboratory-developed tests in laboratories not subject to US regulations.
must perform analytic validation to establish accuracy, precision, analytic sensitivity, analytical specificit
es may be obtained from manufacturers or published literature, as applicable.

as follows: A test used in patient management that has both of the following features:
part;

ulations, the test is not approved by an internationally recognized regulatory authority).

n used by the FDA to allow the use of an unapproved medical product (e.g. diagnostic device) or an unap
eatening disease condition caused by a chemical, biological, radiological, or nuclear agent (CBRN).

ity, interferences, analytical specificity, (interferences) reportable range and reference interval studies. Lo
ternative mechanism employed to ensure accurate test results.

ttps://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm

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vill be performed.
refer to the manufacturer's manual regarding critical requirements,
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Maintenance

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on from manufacturers,
deral, state (or provincial),

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pproved use

aboratories using an EUA assay must follow