



The Lab General Checklist

Lab General

- ▶ 129 potential pages of fun!
 - ▶ Customized to your lab and lab services so probably more like 50 for RLAP.
 - ▶ The Laboratory General (GEN) Checklist applies to all sections or departments of the laboratory.
 - ▶ One copy of the GEN Checklist is provided to the inspection team.
 - ▶ All inspectors must be familiar with the GEN Checklist requirements and ensure that all areas are in compliance.

Quality Management

- ▶ Probably the most cited area during inspections
- ▶ Items to be reviewed include:
 - ▶ Policy for communication of employee concerns
 - ▶ Sampling of quality indicators with follow-up actions when targets are not achieved
 - ▶ Annual appraisal of effectiveness of the QM Program
 - ▶ Document control policy
 - ▶ Record/specimen retention policy
 - ▶ Error, complaint and incident logs with corrective/preventative actions
 - ▶ Device-related adverse patient event procedure and records of reporting
 - ▶ Results of the laboratory's self-evaluation and correction of deficiencies
 - ▶ Records of manufacturer's recalls and records of follow-up

Quality Management

- ▶ GEN.13806 QM Program Phase II
- ▶ The laboratory has a written quality management (QM) program.
- ▶ NOTE: There must be a document that describes the overall QM program. The document need not be detailed, but should spell out the objectives and essential elements of the QM program.
- ▶ If the laboratory is part of a larger organization, the laboratory QM program is coordinated with the organization's QM plan.

Quality Management

- ▶ GEN.16902 QM Implementation Phase II
- ▶ For laboratories that have been CAP accredited for more than 12 months, the QM plan is implemented as designed and is **reviewed annually for effectiveness**.
 - ▶ NOTE: Appraisal of program effectiveness may be evidenced by an annual written report, revisions to laboratory policies and procedures, or revisions to the QM plan, as appropriate.
 - ▶ Evidence of Compliance:
 - ▶ ✓ Evidence that the plan has been implemented as designed requires all of the following:
 - ▶ quality measurements/assessments specified in the plan are being substantially carried out;
 - ▶ there is evidence of **active review** of quality measurements;
 - ▶ if target performance levels are specified in the plan and the targets are not being met, there are records of **follow-up action**;
 - ▶ any interventions/changes to operations that are specified in the plan have been carried out as scheduled, or the reason for delay recorded; AND
 - ▶ any **communication of information** that is required by the plan have taken place

Quality Management

- ▶ GEN.20100 QM Extent of Coverage Phase II
- ▶ The QM program covers all areas of the laboratory and all beneficiaries of service.
 - ▶ NOTE: The QM program must be implemented in all areas of the laboratory (Andrology, Embryology, Chemistry). The program must include all aspects of the laboratory's scope of care

Quality Management

- ▶ GEN.20208 QM Patient Care Services Phase II
- ▶ The QM program includes a process to identify and evaluate errors, incidents and other problems that may interfere with patient care services.
 - ▶ NOTE: There must be an organized process for recording of problems involving the laboratory that are identified internally, as well as those identified through outside sources such as complaints from patients, physicians or nurses. The process must be implemented in all sections of the laboratory, and on all shifts. Any problem that could potentially interfere with patient care or safety must be addressed. Clinical, rather than business/management issues, should be emphasized. The laboratory must record investigation and resolution of these problems.
 - ▶ Laboratories must perform root cause analysis of any unexpected event involving death or serious physical or psychological injury, or risk thereof (including “near misses” and sentinel events). Laboratories must be able to demonstrate appropriate risk-reduction activities based on such root cause analyses.

Quality Management

- ▶ ****REVISED**** 08/17/2016
- ▶ GEN.20316 QM Indicators of Quality Phase II
- ▶ The QM program includes monitoring key indicators of quality in the pre-analytic, analytic, and post-analytic phases.
- ▶ NOTE: Key indicators should monitor activities critical to patient outcome or that may affect many patients.
 - ▶ The laboratory must evaluate its indicators by comparing its performance against available benchmarks.
 - ▶ The laboratory should also evaluate the effectiveness of each corrective action.
 - ▶ The number of monitored indicators should be consistent with the laboratory's scope of care.

Quality Management

- ▶ Commonly Used Indicators of Care:
- ▶ 1. Patient/Specimen Identification: Percent of ordered tests with patient identification errors, or percent of results with identification errors
- ▶ 2. Test Order Accuracy: Percent of test orders correctly entered into a laboratory computer
- ▶ 3. Specimen Acceptability: Percent of specimens accepted for testing
- ▶ 4. Test Turnaround Time: Collection-to-reporting turnaround time or receipt in-laboratory-to-reporting turnaround time of tests, or the percent of specimens with turnaround time that falls within an established limit
- ▶ 5. Critical Value Reporting: Percent of critical results with written record that results have been reported to caregivers; percent of critical results for which the primary clinician cannot be contacted in a reasonable period of time

Quality Management

- ▶ 6. Customer Satisfaction: Standardized satisfaction survey tool with a reference
- ▶ database of physician, nurse, or patient respondents
- ▶ 7. Corrected Reports: Percent of reports that are corrected
- ▶ 8. Specimen Labeling: Percent of requisitions or specimen containers with one or more errors of pre-defined type
- ▶ 9. Culture Contamination: Percent of cultures that grow bacteria or yeast that represent contaminants

Quality Management

- ▶ Evidence of Compliance:
 - ▶ ✓ Listing of quality indicators that include the following:
 - ▶ indicators for pre-analytic, analytic, and post-analytic phases AND
 - ▶ indicators to address the scope of testing and laboratory services AND
 - ▶ frequency for monitoring each indicator AND
 - ▶ defined benchmarks for the performance of each indicator AND
 - ▶ ✓ Quality management data and reports for quality indicator monitoring and evaluation, including comparison against benchmark data, and corrective action when targets are not met

Quality Management

- ▶ GEN.20325 Employee and Patient Quality Communication Phase II
- ▶ The laboratory has a procedure for employees and patients to communicate concerns about quality and safety to management.
 - ▶ NOTE: The investigation and analysis of employee and patient complaints and suggestions, with corrective or preventive action as appropriate, should be a part of the laboratory quality management program and be specifically addressed in laboratory quality management records.
- ▶ Evidence of Compliance:
- ▶ ✓ Records of employee and patient complaints (if any) with appropriate follow up

Quality Management

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 - ▶ Evidence of Compliance:
 - ▶ ✓ Records of employee and patient complaints (if any) with appropriate follow up
 - ▶ Ask lab staff if they are aware of an employee complaint procedure and if they would feel comfortable lodging a complaint
 - ▶ Alert staff to the CAP sign and contact information

Quality Management

- ▶ GEN.20330 CAP Sign Phase II
- ▶ The laboratory posts the official CAP sign regarding reporting of quality concerns.
- ▶ NOTE: The laboratory must prominently post the official CAP sign regarding the reporting of quality concerns to CAP. While personnel should report concerns to laboratory management, the laboratory must ensure that all personnel know that they may communicate with CAP directly if they have a concern not addressed by laboratory management, and that **CAP holds such communications in strict confidence.**
- ▶ In addition, the laboratory must have a policy prohibiting harassment or punitive action against an employee in response to a complaint or concern made to CAP or other regulatory organization regarding laboratory quality or safety.

Quality Management

- ▶ ****REVISED**** 07/28/2015
- ▶ GEN.20335 Customer Satisfaction Phase I
- ▶ The laboratory has measured the satisfaction of healthcare providers or patients with laboratory services within the past two years.
 - ▶ NOTE: Satisfaction metrics are important for understanding the needs of clients (physicians, patients, referring laboratories, nurses, etc.) to improve laboratory services. Experience has shown that surveys are more informative if they are conducted anonymously and allow for open ended comments. The sample size should be adequate. A numeric satisfaction scale allows for calculation of statistics.
 - ▶ Evidence of Compliance:
 - ▶ ✓ Records of the design and results of satisfaction surveys

Quality Management

- ▶ GEN.20340 Notifications From Vendors Phase II
- ▶ The laboratory manages notifications from vendors of defects or issues with supplies or software that may affect patient care.
 - ▶ NOTE: Notifications may take the form of product recalls, market withdrawals, or software patches and upgrades. The laboratory should take action on those that have the potential to affect testing results or laboratory services.
 - ▶ Evidence of Compliance:
 - ▶ ✓ Records of manufacturer's recalls received AND
 - ▶ ✓ Records of follow-up

Quality Management

- ▶ GEN.20351 Adverse Patient Event Reporting Phase II
- ▶ The laboratory has a procedure for reporting device-related adverse patient events, as required by the FDA.
 - ▶ NOTE: When information reasonably suggests that any laboratory instrument, reagent or other device (including all instruments and accessory devices used for **phlebotomy or specimen collection**) has or may have caused or contributed to a patient death or serious patient injury, the FDA requires hospitals and outpatient diagnostic facilities, including independent laboratories, to report the event. If the event is death, the report must be made both to the FDA and the device manufacturer. If the event is serious patient injury, the report may be to the manufacturer only, unless the manufacturer is unknown, in which case the report must be submitted to the FDA. Reports must be submitted on the FDA Form 3500A (or an electronic equivalent) as soon as practical but no later than 10 days from the time medical personnel become aware of the event.
 - ▶ The FDA defines “serious patient injury” as one that is life threatening; or results in permanent impairment of a body function or permanent damage to a body structure; or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. **Device malfunctions or problems that are reportable may relate to any aspect of a test, including hardware, labeling*, reagents or calibration; or to user error (since the latter may be related to faulty instrument instructions or design)**. An adverse patient event that may have resulted from inherent limitations in an analytic system (e.g. limitations of sensitivity, specificity, accuracy, and precision) is not reportable.

Quality Management

- ▶ ****NEW**** 07/28/2015
- ▶ GEN.20361 CLIA Certificate Type Phase II
- ▶ For laboratories subject to US regulations performing patient testing subject to CLIA, the laboratory has registered with the Centers for Medicare and Medicaid Services (CMS) and obtained a CLIA certificate that corresponds to the complexity of testing performed, as applicable.
 - ▶ NOTE: This requirement does not apply to laboratories that are part of the Department of Defense. Laboratories located in CLIA exempt states, such as Washington and New York, must be able to show that they have obtained a CLIA number, when appropriate.
 - ▶ The CLIA regulations define a laboratory as a facility that performs testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

Quality Management

- ▶ GEN.20374 Federal/State/Local Regulations Phase I
- ▶ The laboratory has a policy for ensuring compliance with applicable federal, state and local laws and regulations.
 - ▶ NOTE: Applicable federal, state and local requirements may include but are not limited to the following areas: handling radioactive materials, shipping infectious or diagnostic materials, personnel qualifications, retention of specimens and records, hazardous waste disposal, fire codes, medical examiner or coroner jurisdiction, legal testing, acceptance of specimens only from authorized personnel, handling controlled substances, patient consent for testing, confidentiality of test results, and donation of blood. The checklists contain specific requirements on these areas.
 - ▶ The laboratory may obtain information on applicable federal, state and local laws and regulations from multiple sources, including hospital management, state medical societies and state departments of health.

Quality Management

- ▶ ****REVISED**** 07/28/2015
- ▶ GEN.20375 Document Control Phase II
- ▶ The laboratory has a document control system to manage policies, procedures, and forms that are subject to CAP accreditation.
 - ▶ NOTE: This includes documents relating directly to laboratory testing, as well as others, such as quality management, safety, specimen collection, personnel, and laboratory information systems. The document control system must ensure that only current policies, procedures (including derivative documents such as card files and summary charts), and forms are in use and that records for approval, review, and discontinuance are available.
 - ▶ It is recommended that the laboratory maintain a control log listing all current policies, procedures, and forms with the locations of copies. The control log may contain other information as appropriate, such as dates when policies and procedures were placed in service, schedule of review, identity of reviewer(s), and dates when policies and procedures were discontinued and/or superseded.

Quality Management

- ▶ ****REVISED**** 08/17/2016
- ▶ GEN.20377 Record/Specimen Retention Phase II
- ▶ Laboratory records and materials are retained for an appropriate time.
 - ▶ NOTE: Policies for retention of records and materials must comply with federal, state and local laws and regulations and with the retention periods listed below, whichever is most stringent. For testing on minors (under the age of 21), stricter state regulations may apply.
 - ▶ More specific requirements for certain laboratory records are found in the Reproductive Laboratory Medicine Checklist

Quality Management

- ▶ Two year retention:
 - ▶ Specimen requisitions (including the patient chart or medical record if used as the requisition)
 - ▶ Accession records
 - ▶ Quality management records
 - ▶ Proficiency testing records
 - ▶ Quality control records
 - ▶ Instrument maintenance and function check records
 - ▶ (Laboratories may wish to retain instrument maintenance records for longer than the two-year requirement (e.g. for the life of the instrument), to facilitate trouble-shooting)
 - ▶ Instrument printouts and worksheets
 - ▶ For data directly transmitted from instruments to the laboratory computer system via an interface (on-line system), it is not necessary to retain paper worksheets, printouts, etc., so long as the computer retains the data for at least two years.

Quality Management

- ▶ Two year retention (continued):
 - ▶ Personnel Records
 - ▶ Competency assessment records
 - ▶ Training records
 - ▶ Patient test results and reports, including original and corrected reports, and referral laboratory reports
- ▶ Two years after discontinuation
 - ▶ Validation/verification of method performance specifications
 - ▶ Policies and procedures

Quality Management

- ▶ Other retention requirements:
 - ▶ **Permanently** stained body fluid slides – 7 days
 - ▶ Laboratory Computer Services – 2 years beyond the life of the system
 - ▶ Computer system validation records
 - ▶ Records of changes to software, the test library, and major functions of laboratory
 - ▶ Information systems
 - ▶ Ongoing computer system checks (e.g. calculation verification)
- ▶ Evidence of Compliance:
 - ▶ ✓ Written policy for retention of records, specimens and slides

Quality Management

- ▶ GEN.20425 Record Retention Phase II
- ▶ The laboratory has a policy to ensure that all records, slides, blocks, and tissues are retained and available for appropriate times should the laboratory cease operation.

- ▶ **NEW** 08/17/2016
- ▶ GEN.20450 Correction of Laboratory Records Phase II
- ▶ The laboratory follows a written policy for the management and correction of laboratory records, including quality control data, temperature logs, and intermediate test results or worksheets.
 - ▶ NOTE: Laboratory records and changes to such records must be legible and indelible. Original (erroneous) entries must be visible (i.e. erasures, white and correction fluid are unacceptable) or accessible (e.g. audit trail for electronic records). Corrected data, including the identity of the person changing the record and when the record was changed, must be accessible to audit.

Quality Management

- ▶ GEN.23584 Interim Self-Inspection Phase II
- ▶ The laboratory conducts an interim self-inspection and records efforts to correct deficiencies identified during that process.
 - ▶ NOTE: The interim self-inspection is an important aspect of continuing education and laboratory improvement. The use of a variety of mechanisms for self-inspection (residents, technologists or others trained to perform inspections) is strongly endorsed. Self inspection by personnel familiar with, but not directly involved in, the routine operation of the laboratory section to be inspected is a best practice. Records of performance of the interim self-inspection with correction of deficiencies is a requirement for maintaining accreditation. The laboratory must have a record to demonstrate that personnel responsible for each laboratory section have reviewed the findings of the interim self-inspection.
- ▶ Evidence of Compliance:
 - ▶ ✓ Written evidence of self-inspection findings with records of corrective action

Quality Management

- ▶ ****REVISED**** 07/28/2015
- ▶ GEN.26791 Terms of Accreditation Phase II
- ▶ The laboratory has a policy that addresses compliance with the CAP terms of accreditation.
- ▶ NOTE: The CAP terms of accreditation are listed in the laboratory's official notification of accreditation. The policy must include notification of CAP regarding the following:
 - ▶ 1. Investigation of the laboratory by a government entity or other oversight agency, or adverse media attention related to laboratory performance; notification must occur **no later than two working days** after the laboratory learns of an investigation or adverse media attention. For laboratories subject to US regulations, this notification must include any complaint investigations conducted or warning letters issued by any oversight agency (e.g. CMS, State Department of Health, The Joint Commission, FDA, OSHA).
 - ▶ 2. A facility must notify the CAP as soon as it finds itself to be the subject of a validation inspection
 - ▶ 3. Discovery of actions by laboratory personnel that violate national, state or local regulations
 - ▶ 4. Change in laboratory test menu prior to beginning that testing or the laboratory permanently or temporarily discontinues some or all testing
 - ▶ 5. Change in laboratory directorship, location, ownership, name, insolvency, or bankruptcy; notification must occur no later than 30 days **prior** to the change(s); or, in the case of unexpected changes, **no later than two working days afterwards**. Laboratories subject to US regulations must also notify the US Department of Health and Human Services.

Quality Management

GEN.26791 Terms of Accreditation

- ▶ In addition, the policy must address:
 - ▶ 6. Provision of a trained inspection team comparable in size and scope if requested by CAP at least once every two-year accreditation period
 - ▶ 7. Cooperation with CAP and HHS when the laboratory is subject to a CAP or HHS complaint investigation or validation inspection
 - ▶ 8. Adherence to the Terms of Use for the CAP Certification Mark of accreditation
 - ▶ 9. For laboratories subject to US regulations, availability, on a reasonable basis of the laboratory's annual proficiency testing results upon request of any person

- ▶ Evidence of Compliance:
 - ▶ ✓ Records of notification, if applicable

Quality Management

- ▶ GEN.30000 Monitoring Analytic Performance Phase II
- ▶ There is a written quality control program that clearly defines policies and procedures for monitoring analytic performance.
- ▶ NOTE: There must be a written overall quality control program for the entire laboratory. It must include general policies and assignment of responsibilities.
- ▶ There must be clearly defined, written procedures for ongoing monitoring of analytic performance, including
 - ▶ (1) number and frequency of controls;
 - ▶ (2) establishment of tolerance limits for control testing; and
 - ▶ (3) corrective actions based on quality control data.
- ▶ Quality control records should be well-organized with a system to permit regular review by appropriate supervisory personnel (laboratory director, supervisor or laboratory quality control coordinator).

Specimen Collection, Handling, and Reporting

- ▶ Follow a patient specimen beginning with test ordering through patient identification, collection, labeling, transport, receipt and processing, delivery to test area, analysis, result review, and reporting. Determine if practice matches related policies and procedures.

Specimen Collection, Handling, and Reporting

- ▶ ****REVISED** 07/28/2015**
- ▶ GEN.40016 Specimen Collection Procedure Review Phase II
 - ▶ There are records of review of the specimen collection/handling procedures by the current laboratory director or designee at least every two years.
- ▶ ****REVISED** 07/28/2015**
- ▶ GEN.40032 New Specimen Collection Procedure Review Phase II
- ▶ The laboratory director reviews and approves all new specimen collection and handling procedures, as well as substantial changes to existing procedures before implementation.
 - ▶ NOTE: Current practice must match written procedures.

Specimen Collection, Handling, and Reporting

- ▶ GEN.40050 Distribution of Manuals Phase I
- ▶ The specimen collection manual is distributed to all specimen-collecting areas within the hospital (**nursing** stations, operating room, emergency room, out-patient areas) AND to areas outside the main laboratory (such as **physicians' offices** or other laboratories).
 - ▶ NOTE: It is acceptable for this information to be electronically available to users rather than in book format; there is no requirement for a paper-based specimen collection manual. Indeed, electronic manuals have the advantage of more accurately reflecting current requirements.

Specimen Collection, Handling, and Reporting

- ▶ GEN.40100 Specimen Collection Manual Elements Phase II
- ▶ The specimen collection manual includes instructions for all of the following elements, as applicable.
 - ▶ 1. Preparation of the patient
 - ▶ 2. Type of collection container and amount of specimen to be collected
 - ▶ 3. Need for special timing for collection (e.g. creatinine clearance)
 - ▶ 4. Types and amounts of preservatives or anticoagulants
 - ▶ 5. Need for special handling between time of collection and time received by the laboratory (e.g. refrigeration, immediate delivery)
 - ▶ 6. Proper specimen labeling
 - ▶ 7. Need for appropriate clinical data, when indicated

Specimen Collection, Handling, and Reporting

- ▶ ****REVISED**** 07/28/2015
- ▶ GEN.40125 Handling of Referred Specimens Phase II
- ▶ For specimens **sent** to referral laboratories, the referring laboratory properly follows all requisition, collection and handling specifications of the referral laboratory.
 - ▶ NOTE: Pre-analytic variables must be closely controlled to maintain specimen integrity. These include specimen temperature, transport time.
- ▶ Evidence of Compliance:
 - ▶ ✓ Written procedure for submission of specimens to referral laboratories, consistent with thereferral laboratory collection and handling requirements

Specimen Collection, Handling, and Reporting

- ▶ But we don't use referral labs....
 - ▶ PGS/PGD
 - ▶ Andrology testing
 - ▶ SCSA / SDFA
 - ▶ Sperm /Hamster Egg Penetration Assay

Specimen Collection And Labeling

- ▶ ****REVISED**** 08/17/2016
- ▶ GEN.40490 Patient Identification Phase II
- ▶ The individual collecting the specimen positively identifies the patient before collecting a specimen and labels the specimen in the presence of the patient.
 - ▶ NOTE: Personnel must confirm the patient's identity by checking at least two identifiers before collecting a specimen. For example, an outpatient's name and birth date may be used. The patient's identity should be verified by asking the patient to identify him- or herself, when it is practical to do so. For example, verbal verification is not necessary if obtaining the services of a translator would delay specimen collection. The intent of this requirement is to ensure a written, consistently followed system for correct patient and specimen identification at the point of collection.
- ▶ Evidence of Compliance:
 - ▶ ✓ Written collection procedure, including criteria for patient identification

Specimen Collection And Labeling

- ▶ ****REVISED**** 08/17/2016
- ▶ GEN.40491 Primary Specimen Container Labeling Phase II
- ▶ 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
 - ▶ Examples of acceptable identifiers include but are not limited to: patient name, date of birth, medical records number, social security number, requisition number, accession number, unique random number.
 - ▶ Identifiers may be in a machine readable format, such as a barcode.

Specimen Collection And Labeling

- ▶ ****REVISED**** 07/28/2015
- ▶ GEN.40492 Specimen Label Correction Phase II
- ▶ The laboratory has a written policy regarding correction of information on specimen labels.
 - ▶ NOTE: If laboratory personnel become aware of a potential error in patient identification or other information (e.g. initials of individual collecting the specimen, date/time of collection) on a specimen label, best practice is to recollect the specimen. However, there may be circumstances when recollection is not possible or practical.
 - ▶ The laboratory should define the circumstances under which correction of the information on specimen labels is permitted. A record of all such corrections should be maintained. The laboratory should investigate errors in specimen labeling, and develop corrective action as appropriate, including education of personnel who label the specimens.
- ▶ Evidence of Compliance:
 - ▶ ✓ Records of corrections to specimen labels and corrective action

Specimen Collection and Labelling

- ▶ GEN.40505 Specimen Collection Feedback Phase I
- ▶ There is a mechanism to provide feedback to the collectors of specimens on issues relating to specimen quality and labeling.
 - ▶ NOTE: The accuracy of an analytic result depends upon the initial quality of the specimen. Proper collection techniques are essential.

Specimen Collection and Labeling

- ▶ GEN.40508 Phlebotomy Adverse Reaction Phase II
- ▶ The laboratory has procedures to care for patients who experience adverse reactions from phlebotomy.
 - ▶ NOTE: Minor adverse reactions include hematomas, abrasions, nausea, and fainting. Serious injuries include vomiting, nerve damage, seizures and injuries.
 - ▶ Training of phlebotomists should emphasize injury prevention. Serious reactions must be recorded in an incident log.
- ▶ Evidence of Compliance:
 - ▶ ✓ Written instructions to phlebotomists AND
 - ▶ ✓ Training records

Specimen Transport And Tracking

- ▶ This section applies to laboratories that send specimens to referral or other laboratories for testing, whether or not the specimen collection is performed by the laboratory staff. It also applies to referral laboratories that receive specimens from other laboratories or remote locations outside of the facility for testing.
- ▶ While transportation of clinical specimens may not be the responsibility of personnel under the control of the laboratory director, issues of tracking and specimen quality must be addressed to ensure quality laboratory results.

Specimen Transport And Tracking

- ▶ GEN.40511 Specimen Tracking/Labeling Phase II
- ▶ All specimens are properly packaged and labeled to indicate the general nature of the materials transported.
- ▶ Evidence of Compliance:
- ▶ ✓ Written procedure defining criteria for packaging and labeling

Specimen Transport And Tracking

- ▶ GEN.40512 Infectious Material Packing/Shipping Phase II
- ▶ The laboratory packages and ships infectious material in accordance with applicable federal, state and local regulations.
 - ▶ Evidence of Compliance:
 - ▶ ✓ Written procedures for packaging and shipping that comply with regulations
- ▶ **REVISED** 07/28/2015
- ▶ GEN.40515 Transport Personnel Training Phase II
- ▶ Transport personnel are trained in appropriate safety and packaging procedures suitable to specimen type and distances transported, including training for personnel involved in packaging and shipping infectious substances. It is the laboratory's responsibility to determine whether specimens that are to be shipped are subject to the regulations, or are exempt.

Requisitions And Specimen Receipt/Handling/Processing

- ▶ GEN.40700 Requisitions Phase II
- ▶ All specimens are accompanied by an adequate requisition.
 - ▶ NOTE: In computerized settings, there may not be a paper requisition that is physically attached to the specimen container.
- ▶ GEN.40725 Requisition Data Entry Phase II
- ▶ Test requisition data elements are entered accurately into the laboratory information or record system.
 - ▶ NOTE: Data elements include patient demographic data; the name and location of the individual or entity ordering the test, as well as other elements needed for the final report (see GEN.41096).
 - ▶ The laboratory must have an ongoing mechanism to ensure the accuracy of manual entries. For test orders crossing an interface to the LIS, requirements for interface integrity apply.

Requisitions And Specimen Receipt/Handling/Processing

- ▶ ****REVISED**** 07/28/2015
- ▶ GEN.40750 Requisition Elements Phase II
- ▶ The paper or electronic requisition includes all of the following elements, **as applicable**.
 - ▶ 1. Adequate patient identification information (e.g., name, registration number and location, or a unique confidential specimen code if an alternative audit trail exists)
 - ▶ 2. Patient sex
 - ▶ 3. Patient date of birth or age
 - ▶ 4. Name and address (**if different than the receiving laboratory**) of the physician, legally authorized person ordering the test, or name and address of the laboratory referring the specimen
 - ▶ 5. Tests requested
 - ▶ 6. Last menstrual period (for gynecologic specimens)
 - ▶ 7. Date of specimen collection, and if appropriate, time of collection
 - ▶ 8. Source of specimen, when appropriate
 - ▶ 9. Clinical information, when appropriate
- ▶ The patient's chart or medical record may be used as the test requisition or authorization.

Requisitions And Specimen Receipt/Handling/Processing

- ▶ GEN.40825 Specimen ID Phase II
- ▶ There is a system to positively identify all patient specimens, specimen types, and aliquots at all times.
- ▶ NOTE: Each specimen container must identify the patient uniquely. This may be text-based, numeric, bar-coded, etc. The form of this system is entirely at the discretion of each laboratory, so long as all primary collection containers and their aliquots have a unique label which one can audit back to full particulars of patient identification, collection date, specimen type, etc.
- ▶ Practical considerations of container size may limit the extent of such details. There must be an appropriate, consistently applied accessioning system.

Requisitions And Specimen Receipt/Handling/Processing

- ▶ GEN.40900 Specimen Date Received Phase II
 - ▶ The date (and time, if appropriate) that the specimen was received by the laboratory is recorded.

- ▶ GEN.40930 Authorized Requestor Phase I
 - ▶ The laboratory has a mechanism to ensure that specimens are analyzed only at the request of an authorized person.
 - ▶ NOTE: The laboratory must perform tests only at the written or electronic request of an authorized person. In some US states and other countries, individuals may order some laboratory tests without a physician's referral (direct-to-consumer testing).
 - ▶ Evidence of Compliance:
 - ▶ ✓ Written policy requiring test orders by authorized persons, if applicable in the jurisdiction in which the laboratory is located

Requisitions And Specimen Receipt/Handling/Processing

- ▶ GEN.40932 Verbal Test Authorization Phase II
- ▶ For laboratories subject to US regulations, the laboratory solicits written or electronic authorization for verbal orders within 30 days.
 - ▶ NOTE: The laboratory must retain the written authorization or record of efforts made to obtain a written authorization.
 - ▶ Evidence of Compliance:
 - ▶ ✓ Records of follow-up to obtain written order

Requisitions And Specimen Receipt/Handling/Processing

- ▶ GEN.40935 Test Order Read Back Phase II
- ▶ The laboratory has a policy that personnel receiving verbal or phone orders read back the entire order to verify accuracy of transcription.
- ▶ GEN.40938 Unclear Test Order Phase I
- ▶ The laboratory has a policy on confirmation of test orders that may be unclear (e.g. orders using non-standard or non-specific terms).

Requisitions And Specimen Receipt/Handling/Processing

- ▶ ****REVISED**** 07/28/2015
- ▶ GEN.40942 Specimen Container Analytic Interference Phase II
- ▶ The laboratory director or designee evaluates significant changes to specimen containers to ensure that they do not contribute to analytic interference in the assays to be performed and approves them for use.
 - ▶ Collection containers, blood tubes

Requisitions And Specimen Receipt/Handling/Processing

- ▶ GEN.41017 Centrifuge Operating Speeds Phase II
- ▶ The operating speeds of centrifuge are checked at least annually as needed for the intended use, and this is done in a safe manner.
 - ▶ NOTE: For centrifuges having a safety mechanism preventing the opening of the lid while in operation, the checks of rpm should be performed only by an authorized service representative of the manufacturer or an appropriately trained clinical engineer.
- ▶ Evidence of Compliance:
 - ▶ ✓ Records of verification of operating speeds at least annually

Requisitions And Specimen Receipt/Handling/Processing

- ▶ ****REVISED**** 08/17/2016
- ▶ GEN.41042 Refrigerator/Freezer Temperatures Phase II
- ▶ Refrigerator/freezer temperatures are checked and recorded daily using a calibrated thermometer.
 - ▶ NOTE: This checklist requirement applies to refrigerators/freezers containing reagents or patient/ client specimens.
 - ▶ “Daily” means every day (7 days per week, 52 weeks per year).
 - ▶ The laboratory must define the acceptable temperature ranges for these units. If temperature(s) are found to be outside of the acceptable range, the laboratory must record appropriate corrective action, which may include evaluation of contents for adverse effects.

Results Reporting And Referral Of Testing

- ▶ ****REVISED**** 07/28/2015
- ▶ GEN.41303 Patient Confidentiality Phase II
- ▶ The laboratory ensures that internal and external storage and transfer of data maintains patient confidentiality and security.
 - ▶ NOTE: Written procedures must address patient confidentiality during transfer of data to external referral laboratories or other service providers. This must include cloud based computing (e.g. for storage of confidential data), as appropriate
 - ▶ The laboratory must audit compliance with the procedures at least annually.
- ▶ Evidence of Compliance:
 - ▶ ✓ Records of patient privacy audit for compliance with the Health Insurance Portability and Accountability Act (HIPAA)

Results Reporting And Referral Of Testing

- ▶ ****REVISED**** 07/28/2015
- ▶ GEN.41096 Report Elements Phase II
- ▶ The paper or electronic report includes the following elements.
 - ▶ 1. Name and address of testing laboratory (see note below)
 - ▶ 2. Patient name and identification number, or unique patient identifier
 - ▶ 3. Name of physician of record, or legally authorized person ordering test, as appropriate
 - ▶ 4. Date of specimen collection, and if appropriate, time of collection
 - ▶ 5. Date of release of report (if not on the report, this information should be readily accessible)
 - ▶ 6. Time of release of report, if applicable (if not on the report, this information should be readily accessible)
 - ▶ 7. Specimen source, when applicable
 - ▶ 8. Test result(s) (and units of measurement, when applicable)
 - ▶ 9. Reference intervals, as applicable
 - ▶ 10. Conditions of specimen that may limit adequacy of testing

Results Reporting And Referral Of Testing

- ▶ GEN.41067 Content/Format Report Review Phase I
- ▶ An individual meeting CAP laboratory director qualifications reviews and approves the content and format of paper and electronic patient reports at least every two years.
- ▶ GEN.41300 Report Retention and Retrieval Phase II
- ▶ Copies or files of reports are legible and retained by the laboratory in a manner that permits prompt retrieval of the information.

Results Reporting And Referral Of Testing

- ▶ ****REVISED**** 07/28/2015
- ▶ GEN.41304 Patient Data Accessibility Phase II
- ▶ There is a written policy to ensure that patient data are accessible in a timely manner only to those individuals who are authorized to review test results.
- ▶ NOTE: Only those healthcare personnel authorized to review a patient's test results should have access to those results. Laboratories subject to US regulations must provide final test results to the patient or the patient's personal representative upon request. For completed tests, these results must generally be provided no later than 30 days after such a request.
- ▶ Under the HIPAA Privacy Rule, only the patient or a personal representative, defined as an individual who has authority under applicable law to make health care decisions for the patient, can be given access to a patient's personal health data. Laboratories must take reasonable steps to verify the identity of the patient and the authority of a personal representative to have access to an individual's protected health information. The Rule also allows for the release of test reports to authorized persons responsible for using the test reports and to the laboratory that initially requested the test, if applicable.

Results Reporting And Referral Of Testing

- ▶ ****REVISED**** 08/17/2016
- ▶ GEN.41306 Analyst Tracking ID Phase II
- ▶ There is a system whereby the identity of the analyst performing or completing the test and the date of the test can always be established.
 - ▶ NOTE: If results are released using autoverification, the system must be capable of identifying those test results that have been autoverified. In addition, the laboratory should be able to identify the technologist responsible for the instrument producing the result, such as through daily bench assignment charts, instrument set-up logs, or electronic audit trail

Results Reporting And Referral Of Testing

- ▶ GEN.41307 Report Errors Phase II
- ▶ When errors are detected in patient test reports, the laboratory promptly notifies responsible clinical personnel or referring laboratory as applicable and issues a corrected report.
 - ▶ NOTE: Notification should include the department of health or other legal entity as required by local regulations.
- ▶ Evidence of Compliance:
 - ▶ ✓ Records of report error notification and corrected report

Results Reporting And Referral Of Testing

- ▶ ****REVISED**** 08/17/2016
- ▶ GEN.41310 Corrected Report Phase II
- ▶ All corrected reports of previously reported, incorrect patient results are identified as corrected, and both the corrected and original data are clearly identified as such.
- ▶ NOTE: As clinical decisions or actions may have been based on the previous report, it is important to replicate previous information (test results, interpretations, reference intervals) for comparison with the corrected information. The previous information and the corrected information must be identified as such, and the original data must be present in the corrected report (for paper reports), or linked electronically or logically to the corrected information (in electronic reports).
- ▶ Displays in an electronic medical record (EMR) downstream from the laboratory should include the original report as well as the corrected report. The report elements listed in GEN.41096 should be included in the EMR.
- ▶ The correction should add explanatory language if an explanation would be helpful to the user. For example, a comment about transport or sample storage conditions uncovered post-analysis can help frame an original, invalid result.

Results Reporting And Referral Of Testing

- ▶ GEN.41312 Multiple Corrections Phase II
- ▶ When there are multiple sequential corrections of a single test result, all corrections are referenced in sequential order on subsequent reports.
- ▶ GEN.41345 Turnaround Time Phase II
- ▶ The laboratory has defined turnaround times (i.e. the interval between specimen receipt by laboratory personnel and results reporting) for each of its tests, and it has a policy for notifying the requester when testing is delayed.
 - ▶ Evidence of Compliance:
 - ▶ ✓ Written policy defining test reporting turnaround time and process for communication of delays in turnaround time

Results Reporting And Referral Of Testing

- ▶ ****REVISED**** 08/17/2016
- ▶ GEN.41350 Referral Laboratory Selection Phase II
- ▶ The laboratory has a written procedure for the selection and evaluation of laboratories to which it refers specimens or materials for testing.
- ▶ NOTE:
 - ▶ 1. The laboratory director, in consultation with the institutional medical staff or physician clients (where appropriate), is responsible for selecting referral laboratories
 - ▶ 2. Selection of referral laboratories must be based primarily upon the quality of performance of such laboratories
 - ▶ 3. Specimens or materials for testing include intermediate processing such as histologic and cytologic processing, preliminary analysis such as flow cytometry, and the use of distributive testing in next-generation sequencing. It also includes the referral of images or data files to an off-site location for interpretation.

Results Reporting And Referral Of Testing

- ▶ 4. For laboratories subject to US regulations: for tests in disciplines covered by CLIA, specimens and materials for testing must be referred only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS; this includes off-site locations where images or data files are frequently referred for review and interpretation. Laboratories that are part of the Department of Defense* must meet the referral policies of the Clinical Laboratory Improvement Program (CLIP). With respect to patients on research protocols, whose tests are referred to a research laboratory: if those test results are used for patient management decisions, the research laboratory must be CLIA-certified, or meet equivalent requirements as determined by CMS.
- ▶ 5. For disciplines not covered by CLIA, laboratories subject to US regulations must refer specimens to a laboratory accredited by CAP or a CAP accepted organization.
- ▶ 6. For non-US laboratories, whenever possible, specimens and materials for testing should be referred to a laboratory accredited by CAP; accredited to an established international standard from a recognized organization; or certified by an appropriate government agency. The inspector may need to exercise judgment with respect to determining if a referral laboratory is acceptable.
- ▶ 7. It is the responsibility of the laboratory director or designee to monitor the turnaround time and quality of test results received from referral laboratories

Results Reporting And Referral Of Testing

- ▶ GEN.41430 Referral Laboratory Report Retention Phase II
- ▶ For samples referred to another laboratory, the original or an exact copy of the testing laboratory's report is retained by the referring laboratory.
 - ▶ NOTE: The report may be retained on paper or in electronic format. Exceptions to this requirement may be made under special circumstances or for special categories, such as drugs of abuse or employee drug testing. The laboratory director may make these exceptions.
 - ▶ Evidence of Compliance:
 - ▶ ✓ Retained original referral laboratory reports OR direct access to referral laboratory reports via electronic transmission from the referral laboratory

Results Reporting And Referral Of Testing

- ▶ GEN.41440 Referral Laboratory Results Reporting Phase II
- ▶ The essential elements of referred test results are reported by the referring laboratory as received from the referral laboratory, without alterations that could affect clinical interpretation.
 - ▶ NOTE: If the laboratory transcribes results from the referral laboratory report, the test result(s), interpretation, and information directly related to the interpretation must be copied as reported by the referral laboratory. This does not mandate that the referring laboratory report every word nor retain the exact format of the referral laboratory report. There is no requirement to fully replicate the complete content of the referral laboratory report beyond the results and interpretation.
 - ▶ Suggestions for follow-up testing may, for example, be omitted at the discretion of the laboratory director.
 - ▶ Evidence of Compliance:
 - ▶ ✓ Patient results from the referral laboratory consistent with laboratory-issued patient reports

Quality Of Water And Glassware Washing

- ▶ GEN.41500 Defined Water Types Phase II
 - ▶ The laboratory defines the specific type of water required for each of its testing procedures and water quality is tested at least annually.
 - ▶ NOTE: The laboratory should define the type of water necessary for each of its procedures, and should have an adequate supply of same. The laboratory must determine the level of testing necessary for other grades of water in use.

- ▶ GEN.41770 Glassware Cleaning Phase II
 - ▶ There are written procedures for handling and cleaning glassware, including methods for testing for detergent removal.
 - ▶ NOTE: Special instructions for micropipettes, cuvetts, acid washing, etc. must be included.

Laboratory Computer Services

- ▶ The requirements in this section do NOT apply to the following:
- ▶ 1. Desktop calculators
- ▶ 2. Small programmable technical computers
- ▶ 3. Purchased services such as the Quality Assurance Service or Laboratory Management Index Service of the College of American Pathologists
- ▶ 4. Micro computers used solely for word processing, spreadsheets, or similar single user functions
- ▶ 5. Dedicated microprocessors or workstations that are an integral part of an analytic instrument

Laboratory Computer Services

- ▶ GEN.42195 Remote LIS Phase II
- ▶ If components of the LIS are located at a facility other than the one under this CAP accreditation number, there is evidence that the remote facility complies with CAP requirements for host LIS functions.

Laboratory Computer Services

- ▶ GEN.42750 Computer Facility Maintenance Phase I
- ▶ The computer facility and equipment are clean, well-maintained and adequately ventilated with appropriate environmental control.
- ▶ NOTE: The computer facilities should be clean, well maintained and in a location that is environmentally controlled, as required by the most restrictive vendor specifications.

- ▶ GEN.42800 LIS Fire Equipment Phase II
- ▶ Fire-fighting equipment (extinguishers) is appropriate for electrical components available.

- ▶ GEN.42900 LIS Power Phase II
- ▶ The computer system is adequately protected against electrical power interruptions and
- ▶ surges.

Laboratory Computer Services

- ▶ GEN.43022 LIS Testing Phase II
- ▶ There are records that programs are adequately tested for proper functioning when first installed and after any modifications, and that the laboratory director or designee has approved the use of all new programs and modifications.
 - ▶ NOTE: Computer programs must be checked for proper performance when first installed and after any changes or modifications. Any changes or modifications to the system must be recorded, and the laboratory director or designee must approve all changes, additions and deletions in programs, the test library, and major computer functions before they are released.
 - ▶ Records must be retained for at least two years beyond the service life of the system.

Laboratory Computer Services

- ▶ ****REVISED**** 07/28/2015
- ▶ GEN.43033 Custom LIS Phase I
- ▶ Customized software, and modifications to that software, are appropriately documented and records allow for tracking to identify persons that have added or modified that software.

- ▶ ****NEW**** 07/28/2015
- ▶ GEN.43040 LIS Policy and Procedure Approval Phase II
- ▶ The laboratory director or designee reviews and approves all new LIS policies and procedures, as well as substantial changes to existing documents before implementation.

Laboratory Computer Services

- ▶ ****REVISED**** 07/28/2015
- ▶ GEN.43055 Computer System Training Phase II
- ▶ There are records for training of all users of the computer system initially, after system modification, and after installation of a new system.
- ▶ GEN.43066 Computer Malfunction Notification Phase II
- ▶ There is a written procedure with instructions for contacting a responsible person (e.g. Computer System Manager) in case of computer malfunction.

Laboratory Computer Services

- ▶ GEN.43150 Access Patient Data Phase II
- ▶ There are explicit written policies that specify who may use the computer system to enter or access patient data, change results, change billing or alter programs.
- ▶ NOTE: Policies must define those who may only access patient data and users who are authorized to enter patient results, change results, change billing, or alter computer tables or programs. If data in other computer systems can be accessed through the LIS (e.g. pharmacy or medical records), policies must prevent unauthorized access to the data through the LIS.

Laboratory Computer Services

- ▶ GEN.43200 Computer Access Codes Phase II
- ▶ Computer access codes (security codes, user codes) are in place to confine individuals' access to those functions they are authorized to use, and the security of access codes is maintained (e.g. inactivated when employees leave, not posted on terminals).
- ▶ GEN.43262 Unauthorized Software Installation Phase I
- ▶ There are written policies and procedures that govern installation of software on any computer used by the laboratory.

Laboratory Computer Services

- ▶ ****REVISED**** 07/28/2015
- ▶ GEN.43325 Public Network Security Phase II
- ▶ If the facility uses a public network, such as the Internet as a data exchange medium, there are network security measures in place to ensure confidentiality of patient data.
 - ▶ Evidence of Compliance:
 - ▶ ✓ Written policy defining mechanism for data protection

Laboratory Computer Services

- ▶ GEN.43450 Calculated Patient Data Verification Phase II
- ▶ Calculated values reported with patient results are reviewed every two years or when a system change is made that may affect the calculations.
 - ▶ NOTE: This checklist requirement applies only to calculations based on formulas modifiable by the user.
- ▶ Evidence of Compliance:
 - ▶ ✓ Records of validation of calculated test results

Laboratory Computer Services

- ▶ GEN.43750 Specimen Quality Comment Phase II
- ▶ The system provides for comments on specimen quality that might compromise the accuracy of analytic results (e.g. hemolyzed, lipemic).
 - ▶ Evidence of Compliance:
 - ▶ ✓ Patient reports

Laboratory Computer Services

- ▶ GEN.43800 Data Input ID Phase II
- ▶ There is an adequate system to identify all individuals who have entered and/or modified patient data or control files.
- ▶ NOTE: When individual tests from a single test order (e.g. multiple tests with same accession number) are performed by separate individuals and the test result is entered into the LIS, the system must provide an audit trail to record each person involved.
 - ▶ For example, a single accession number having orders for electrolytes and a lipid panel may have testing done by two or more individuals. The laboratory should be able to identify the responsible personnel who performed each test and posted the data. This includes sequential corrections made to a single test result.
 - ▶ If autoverification is used, then the audit trail should reflect that the result was verified automatically at a given time.

Laboratory Computer Services

- ▶ GEN.43825 Result Verification Phase II
- ▶ Manual and automated result entries are verified before final acceptance and reporting by the computer.
- ▶ NOTE: Data entered into the computer system either manually or by automated methods must be reviewed by an authorized individual who verifies the accuracy of the input data before final acceptance and reporting by the computer.
 - ▶ An example of best practices for this step is checking the result against the reportable range and critical results for the test.

Laboratory Computer Services

- ▶ GEN.43837 Downtime Result Reporting Phase II
- ▶ There are written procedures to ensure reporting of patient results in a prompt and useful fashion during partial or complete downtime and recovery of the system.

