


SPECIMEN COLLECTION, DATA HANDLING, AND REPORTING



Specimen collection, data handling, and results reporting are critical. Specific instructions for the proper collection and handling of specimens must be made available to laboratory personnel and to anyone collecting patient test materials that are sent to the laboratory.

Inspector Instructions:

	<ul style="list-style-type: none"> Follow a patient specimen beginning with test ordering through patient identification, phlebotomy/collection, labeling, transport, receipt and processing, delivery to test area, analysis, result review, and reporting. Determine if practice matches related policies and procedures.
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COLLECTION MANUAL AND OTHER DOCUMENTATION

Inspector Instructions:

	<ul style="list-style-type: none"> Sampling of specimen collection policies and procedures Reference laboratories policies and procedures
	<ul style="list-style-type: none"> Specimen collection manuals (available)

GEN.40016 Collection Manual Biennial Review Phase II

There is documentation of at least biennial review of the specimen collection/handling procedure manual by the current laboratory director or designee.

****REVISED** 07/11/2011**

GEN.40032 New Specimen Collection Procedure Review Phase II

The director reviews and approves all substantial changes to the specimen collection/handling procedure manual before implementation.

NOTE: Current practice must match policy and procedure documents.

GEN.40050 Distribution of Manuals Phase II

The specimen collection manual is distributed to all specimen-collecting areas within the hospital (nursing stations, operating room, emergency room, out-patient

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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.

REFERENCES

- 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Oct 1):1034 [42CFR493.1242(d)]

****REVISED****

07/11/2011

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**

NOTE: Because of the importance of clinical information in the practice of surgical pathology and cytopathology, requisitions for such specimens should include pertinent clinical data, as well as pre-operative and/or post-operative diagnosis. Instructions should be documented for all applicable tissue and cytologic specimens, including biopsies, resections, PAP tests, sputum washings, brushings, body fluids, fine needle aspirations, etc. These instructions must be included in the procedure or user manuals at all sites where specimens are collected (e.g. nursing stations, clinics, physicians' offices). Instructions must include proper fixation of slides and tissue specimens. A variety of tests in clinical pathology also require specific clinical information (e.g. maternal AFP screening, TDM peak and trough measurements, antibiotic therapy, etc.) or special instructions for collection, preservation, and storage (e.g. timed or 24-hour urine specimens).

REFERENCES

- 1) Nakhleh RE, et al. Necessity of clinical information in surgical pathology. A College of American Pathologists Q-Probes study of 771 475 surgical pathology cases from 341 institutions. *Arch Pathol Lab Med*. 1999;123:615-619
- 2) Burton JL, Stephenson TJ. Are clinicians failing to supply adequate information when requesting a histopathological investigation? *J Clin Pathol*. 2001;54:806-808
- 3) Department of Health and Human Services, Centers for Medicare & Medicaid Services. *Fed Register*. 2003(Jan 24):3706 [42CFR493.1251(b)(1)]
- 4) Clinical and Laboratory Standards Institute (CLSI). *Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline—Third Edition*. CLSI document GP15-A3 (ISBN 1-56238-679-4). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2008.
- 5) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Oct 1):1034 [42CFR493.1242(a)]

GEN.40125 Referral Laboratory Specimen Handling

Phase II

For specimens sent to reference laboratories, the referring laboratory properly follows all requisition, collection and handling specifications of the reference laboratory.

NOTE: Pre-analytic variables must be closely controlled to maintain specimen integrity. These include specimen temperature, transport time, and the interval before separation of blood cells from serum/plasma. For coagulation tests, important considerations include

proper filling of the collection tube, the use of waste tubes, and, if blood must be drawn through an indwelling line, flushing of the line. For surgical pathology and cytopathology, specimens must be preserved by proper fixation or refrigeration. Twenty-four-hour urine specimens may require special preservatives for specific tests. Also, it may be necessary to collect specific patient information required by the testing laboratory (e.g. menstrual history for cytopathology, gestational age for prenatal neural tube defect screening, preoperative diagnosis for surgical pathology, bleeding history for specialized coagulation assays, etc.).

Evidence of Compliance:

- ✓ Written procedure for submission of specimens to referral laboratories, consistent with the referral laboratory collection and handling requirements





REFERENCES

- 1) Valenstein P, Meier F. Outpatient order accuracy. A College of American Pathologists Q-Probes study of requisition order entry accuracy in 660 institutions. *Arch Pathol Lab Med.* 1999;123:1145-1150
- 2) Narayanan S. The preanalytic phase. An important component of laboratory medicine. *Am J Clin Pathol.* 2000;113:429-452
- 3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Oct 1):1034 [42CFR493.1242(a)]

SPECIMEN COLLECTION

Accurate and precise laboratory data depends on properly performed phlebotomy to obtain a high quality specimen.

Inspector Instructions:

	<ul style="list-style-type: none"> • Specimen collection (patient identification, specimen labeling, correction of labeling, and adverse event) policies and procedures • Sampling of phlebotomy training records • Paternity/forensic collection policies and procedures
	<ul style="list-style-type: none"> • Sampling of phlebotomy supplies (expiration date, storage) • Specimen collection at one or more sites within the institution.
	<ul style="list-style-type: none"> • How is feedback related to specimen quality provided to the phlebotomist?
	<ul style="list-style-type: none"> • If specimen collection errors are a recurring problem, further evaluate the laboratory's investigation of how the errors occurred and the corrective actions that were implemented

GEN.40460 Phlebotomy Supplies

Phase I

Phlebotomy supplies such as blood collection tubes are used within their expiration

date and stored per manufacturer's instructions.

GEN.40470 Specimen Collection Training

Phase II

There is documentation that all personnel performing patient blood collection have been trained in collection techniques and in the proper selection and use of equipment/supplies.

NOTE: This includes phlebotomists at remote sites that are owned and operated by the laboratory.

REFERENCES

- 1) Galena HJ. Complications occurring from diagnostic venipuncture. *J Fam Pract.* 1992;34:582-584
- 2) Piton JD, Forstater AT. Recurrent asystole associated with vasovagal reaction during venipuncture. *J Emerg Med.* 1993;11:723-727
- 3) Becan-McBride K, et al. Phlebotomy. Collection, professionalism, and QA. Chicago, IL: ASCP Press, 1993
- 4) Strand CL, et al. Effect of iodophor versus iodine skin preparation on blood culture contamination rate. *JAMA.* 1993;269:1004-1006
- 5) Spitalnic SJ, et al. The significance of changing needles when inoculating blood cultures; a meta-analysis. *Clin Infect Dis.* 1995;21:1103-1106
- 6) Strasinger SK, di Lorenzo MA. Phlebotomy workbook for the multiskilled healthcare professional. Philadelphia: FA Davis, 1996
- 7) So You're Going to Collect a Blood Specimen. An Introduction to Phlebotomy. 12th edition. Northfield, IL: College of American Pathologists, 2007
- 8) Gibb AP, et al. Reduction in blood culture contamination rate by feedback to phlebotomists. *Arch Pathol Lab Med.* 1997;121:50-507
- 9) Klosinski DD. Collecting specimens from the elderly patient. *Lab Med.* 1997;28:518-522
- 10) Brigden ML, et al. Prothrombin time determination: the lack of need for a discard tube and 24-hour stability. *Am J Clin Pathol.* 1997;108:422-426
- 11) CLSI. *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard - Sixth Edition.* CLSI Document H3-A6 (ISBN 1-56238-650-6). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, USA, 2007
- 12) Larsson BA, et al. Venipuncture is more effective and less painful than heel lancing for blood tests in neonates. *Pediatrics.* 1998;101:882-886
- 13) Berns SD, Matchett JL. Effect of phlebotomy technique on serum bicarbonate values. *Acad Emerg Med.* 1998;5(1):40-44
- 14) Adcock DM, et al. Minimum specimen volume requirements for routine coagulation testing. Dependence on citrate concentration. *Am J Clin Pathol.* 1998;109:595-599
- 15) Reneke J, et al. Prolonged prothrombin time and activated partial thromboplastin time due to underfilled specimen tubes with 109 mmol/l (3.2%) citrate anticoagulant. *Am J Clin Pathol.* 1998;109:754-757
- 16) Phelan S. Phlebotomy: review guide. Chicago, IL: ASCP Press, 1998
- 17) Dale JC. Preanalytic variables in laboratory testing. *Lab Med.* 1998;29:540-545
- 18) Dale JC, et al. Accidental needlesticks in the phlebotomy service of the department of laboratory medicine and pathology at Mayo Clinic Rochester. *Mayo Clin Proc.* 1998;73:611-615
- 19) Pruett S. Needle-stick safety for phlebotomists. *Lab Med.* 1998;29:754-760
- 20) Dale JC, Hamrick HJ. Neonatal bilirubin testing practices. Reports from 312 laboratories enrolled in the College of American Pathologists Excel proficiency testing program. *Arch Pathol Lab Med.* 2000;124:1425-1428
- 21) Burns ER, Yoshikawa N. Hemolysis in serum samples drawn by emergency department personnel versus laboratory phlebotomists. *Lab Med.* 2002;33:378-380

GEN.40490 Patient Identification

Phase II

The individual collecting the specimen positively identifies the patient before collecting a specimen.

NOTE: Personnel must confirm the patient's identity by checking at least two identifiers before collecting a specimen. For example, an inpatient's wristband may be checked for name and unique hospital number; an outpatient's name and birth date may be used. The patient's room number may not be used as an identifier. The patient's identity should be verified by asking the patient to identify him- or herself, when it is practical to do so. The identifying label must be attached to the specimen container(s) at the time of collection, and not deferred until a later time. The intent of this requirement is to ensure a documented, consistently followed system for correct patient sample identification at the point of collection.*

**For example, verbal verification is not necessary if obtaining the services of a translator would delay specimen collection.*

Evidence of Compliance:

- ✓ Written collection procedure defining criteria for patient identification

REFERENCES

- 1) Garza D, Becan-McBride K. Phlebotomy handbook, 2nd ed. Norwalk, CT: Appleton & Lange, 1989
- 2) Renner SW, et al. Wristband identification error reporting in 712 hospitals. A College of American Pathologists' Q-Probes study of quality issues in transfusion practice. *Arch Pathol Lab Med.* 1993;117:573-577
- 3) So You're Going to Collect a Blood Specimen. An Introduction to Phlebotomy. 12th edition. Northfield, IL: College of American Pathologists, 2007
- 4) Dale JC, Renner SW. Wristband errors in small hospitals. A College of American Pathologists' Q-Probes study of quality issues in patient identification. *Lab Med.* 1997;28:203-207
- 5) CLSI. *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard - Sixth Edition.* CLSI Document H3-A6 (ISBN 1-56238-650-6). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, USA, 2007
- 6) Howanitz PJ, et al. Continuous wristband monitoring over 2 years decreases identification errors. A College of American Pathologists Q-Tracks study. *Arch Pathol Lab Med.* 2002;126:809-815

****REVISED****

07/11/2011

GEN.40491 Specimen Labeling

Phase II

Primary specimen containers are labeled by at least 2 identifiers.

NOTE: All primary specimen containers must be labeled with 2 identifiers at the time of collection. Submitted slides may be labeled with a single identifier, but two identifiers are preferred. 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.

The 'primary' specimen container is the innermost container received by the laboratory that actually holds the specimen.

In the outpatient setting, obtaining uniform compliance with this requirement may be difficult for the laboratory. In this setting, the laboratory should 1) Provide a list of acceptable identifiers to its clients; 2) Communicate with its clients regarding the importance of this requirement; and 3) Have a procedure for following up with clients when inadequately labeled specimens are received. Communication and follow-up may be through written memoranda, phone calls, visits by client service personnel, or other means of transport disclosure.

Evidence of Compliance:

- ✓ Written collection procedure defining criteria for labeling of primary specimen containers

REFERENCES

- 1) Clinical and Laboratory Standards Institute (CLSI). *Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard—Sixth Edition.* CLSI document H01-A6 (ISBN 1-56238-740-5). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2010
- 2) So You're Going to Collect a Blood Specimen. An Introduction to Phlebotomy, 12th edition. Northfield, IL: College of American Pathologists, 2007
- 3) CLSI. *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard - Sixth Edition.* CLSI Document H3-A6 (ISBN 1-56238-650-6). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, USA, 2007
- 4) CLSI. *Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard--Second Edition.* CLSI document AUTO2-A2 (ISBN 1-56238-589-5). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2005
- 5) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Oct 1):1034 [42CFR493.1242(a)]

GEN.40492 Specimen Label Correction

Phase I

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

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other information (e.g. phlebotomist initials, 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 (e.g. for specimens that are impossible or difficult to recollect, such as cerebrospinal fluid, etc.). 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/preventive action as appropriate, including education of personnel who collect specimens.

Evidence of Compliance:

- ✓ Records of corrections to specimen labels and corrective action

NOTE TO INSPECTOR: The following requirement applies to laboratories that do not perform compatibility testing in-house, and for whom no Transfusion Medicine checklist is used.

****REVISED** 07/31/2012**

GEN.40493 Compatibility Specimen Labeling

Phase II

All blood samples used for compatibility testing are labeled at the time of specimen collection in the presence of the patient with:

- 1. Patient's first and last name**
- 2. Unique identification number**
- 3. Date of collection**
- 4. A method to identify the phlebotomist**

NOTE: Blood specimens collected for compatibility testing must be positively and completely identified and labeled before leaving the patient. Acceptable practices for positive identification of patient and blood specimen labels must be defined in the procedure manual and may include visual inspection and/or an electronic system to read the identifying information contained in bar codes or radio-frequency identification (RFID) microchips or the patient's wristband. Acceptable practices for generating specimen labels must be defined in the procedure manual and may include electronic devices utilizing information encoded in bar codes or RFID microchips. There must be a dependable method to identify the phlebotomist who collected the blood sample, such as initials or another identifier on the tube, or an electronic record.

Evidence of Compliance:

- ✓ Written procedure defining labeling requirements of specimens for compatibility testing **AND**
- ✓ Written procedure defining system identifying the phlebotomist collecting compatibility testing specimens

REFERENCES

- 1) Wenz B, et al. Practical methods to improve transfusion safety by using novel blood unit and patient identification systems. *Am J Clin Pathol.* 1997;107(suppl 1):S12-S16
- 2) Dale JC, Renner SW. Wristband errors in small hospitals. A College of American Pathologists' Q-Probes study of quality issues in patient identification. *Lab Med.* 1997;28:203-207
- 3) Sandler SG, Langeberg A, Carty K, Dohnalek LJ. Bar codes and radio-frequency technologies can increase safety and efficiency of blood transfusions. *LabMedicine* 2006;37:436-439
- 4) Sandler SG, Langeberg A, DeBandi L, Gibble J, Wilson C, Feldman CL. Radio-frequency identification technology can standardize and document blood collections and transfusions. *Transfusion* 2007;47:763-70

GEN.40497 Paternity/Forensic Data

Phase II

If the laboratory collects specimens for paternity/forensic identity testing, the following data are obtained:

- 1. Place and date of specimen collection**

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2. **Identity of person collecting the specimen**
3. **Photograph, or photocopy of a picture identification card for each individual tested**
4. **Signed record of information (including name, race, relationship) for each individual tested**
5. **Date of birth of child**
6. **Synopsis of case history/investigation, sample source**
7. **Documentation of informed consent**

NOTE: If the laboratory uses prepackaged kits for specimen collection, any additional instructions that accompany the kit must be followed.

REFERENCES

- 1) Standards for Parentage testing laboratories. American Association of Blood Banks. Standards for parentage testing laboratories. Bethesda, MD: 2003:5.2.4

GEN.40498 Specimen Labeling - Paternity/Forensic ID Phase II

For paternity/forensic identity testing, the information about each individual and the accuracy of the sample label is verified by that individual or the legal guardian.

Evidence of Compliance:

- ✓ Records of information and label verification by patient or legal guardian

GEN.40505 Phlebotomist Feedback Phase I

There is a mechanism to provide feedback to the collector of the specimen on issues relating to specimen quality.

NOTE: The accuracy of an analytic result depends upon the initial quality of the specimen. Proper phlebotomy technique are essential.

Evidence of Compliance:

- ✓ Written policy defining methods for providing feedback to phlebotomists **AND**
- ✓ Records of phlebotomy issues communication such as staff meeting minutes **OR** records of employee counseling

GEN.40508 Phlebotomy Adverse Reaction Phase I

The laboratory has procedures to care for patients who experience adverse reactions from phlebotomy.

NOTE: Adverse reactions include fainting, seizures and injuries. Immediate assistance should be available.