LABORATORY SERVICES

Self-Assessment Questions	YES	NO	N/A	Date/Initials	Comments
All hospitals also must comply with applicable CoPs and interpretive guidelines for laboratories and laboratory services in CoPs 493.1 thru 493.1780 and/or the higher standards of their laboratory accrediting organization and any other optional services found in the Medicare State Operations Manual that the hospital provides. **Note:** Other regulations applicable to hospital laboratories include: • 19 CSR 20-20.080 Duties of Laboratories • 19 CSR 20-20.091 Testing for Contagious or Infectious Disease					
Does the hospital maintain or have available adequate laboratory services to meet the needs of its patients at each location of the hospital? A-0576 COP §482.27	❑	❑	❑		
Can the laboratory provide either on the premises or by contract, prompt performance or adequate examinations in the fields of hematology, clinical chemistry, urinalysis, microbiology, immunology, anatomic pathology, cytology and immunochematology? 19 CSR 30-20.098 (1)	❑	❑	❑		
Are all laboratory services CLIA certified? See SOM, Appendix C. A-0582 COP §482.27(a)	❑	❑	❑		
Are all contracted laboratory services provided by a CLIA-certified laboratory? A-0582 COP §482.27(a)	❑	❑	❑		
Can you demonstrate that laboratory services are integrated into your hospital-wide QAPI program? A-0576 COP §482.27	❑	❑	❑		
Are onsite emergency laboratory services available 24/7 at each campus? A-0583 COP §482.27(a)(1)	❑	❑	❑		
If the hospital has off-campus locations, does the medical staff determine which, if any, lab services must be immediately available to meet the emergency laboratory needs of the patients who are likely to seek care at that location? A-0583 COP §482.27(a)(1)	❑	❑	❑		
Are these off-campus laboratory services available during the hours of operation of that location? A-0583 COP §482.27(a)(1)	❑	❑	❑		

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Self-Assessment Questions	YES	NO	N/A	Date/Initials	Comments
Does your hospital have policies, protocols and/or procedures that address: a. collection, preservation, transportation, processing, examination, storage, recording and reporting of tissues and other specimens? b. testing procedures, reagent use and storage, controls, calibration and pertinent literature references? c. obtaining blood and blood components? d. a look-back policy and plan related to the notification and documentation of potentially HIV or HCV-infectious blood or blood-products given to patients or another facility? 19 CSR 30-20.098(6) A-0583 COP §482.27(a)(3)	❑ ❑ ❑ ❑	❑ ❑ ❑ ❑	❑ ❑ ❑ ❑		
If the laboratory performs culture and sensitivity testing, is an annual facility antibiogram sent to the DHSS by July 1 of the following year? 19 CSR 30-20.098(16)	❑	❑	❑		
Is a current and accurate written description of routine and STAT laboratory services provided by the hospital readily available to the medical staff? A-0584 COP §482.27(a)(2)	❑	❑	❑		
Is the director of the pathology and medical laboratory services a qualified physician who is a member of the medical staff and appointed by the governing body? 19 CSR 30-20.098 (2)	❑	❑	❑		
Is there a full-time, part-time or consultant pathologist? 19 CSR 30-20.098 (2)	❑	❑	❑		
Is the full-time, part-time or consultant pathologist qualified in anatomical pathology and actively involved educational programs, medical staff functions, the laboratory QA program, and committees that review tissue, infection control and blood usage? 19 CSR 30-20.098 (2)	❑	❑	❑		
If a consultant pathologist is used, is consultation provided at least monthly and a written report of the consultant's evaluation and recommendations submitted after each visit?	❑	❑	❑		

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If autopsy services are available in your hospital, is the pathologist or the physician who performs/supervises all autopsies qualified in anatomical pathology? 19 CSR 30-20.098 (12)	❑	❑	❑		
Are there sufficient qualified laboratory technologists and competent support staff to perform the tests required? 19 CSR 30-20.098 (4)	❑	❑	❑		
Have the laboratory technologists in your hospital graduated from a medical technology program approved by a nationally recognized body, or have documented equivalent education, training and experience? 19 CSR 30-20.098 (4)	❑	❑	❑		
Are laboratory personnel provided with continuing education opportunities? 19 CSR 30-20.098 (4)	❑	❑	❑		
Are all laboratory (inpatient and outpatient) tests and specimen examinations performed only on the order of a medical staff member or authorized personnel as stated in the medical staff bylaws? 19 CSR 30-20.098 (5)	❑	❑	❑		
Do all test requests received by the laboratory clearly identify the patient, the source of the request, the tests required and the date? 19 CSR 30-20.098 (5)	❑	❑	❑		
Are all data reports part of the patient's medical report and retained for two years? 19 CSR 30-20.098 (7)	❑	❑	❑		
Are all test reports on outpatients from referring laboratories sent promptly to the individual or ordering facility? 19 CSR 30-20.098 (7)	❑	❑	❑		
Are all specimens requiring only a gross description determined by the medical staff in consultation with the pathologist and documented in writing? 19 CSR 30-20.098 (11)	❑	❑	❑		
Are all specimens requiring both macroscopic and microscopic exams determined by the medical staff in consultation with the pathologist and	❑	❑	❑		

LABORATORY SERVICES

Self-Assessment Questions	YES	NO	N/A	Date/Initials	Comments
documented in writing? A-0586 COP §482.27(a)(4)					
Are tissue exemptions (those which examination does not add to the diagnosis, treatment or prognosis) determined by the medical staff in consultation with the pathologist and documented in writing? 19 CSR 30-20.098 (11)	❑	❑	❑		
Can you demonstrate that all specimens submitted for pathological examination, including surgical specimens, are accompanied by pertinent clinical information? 19 CSR 30-20.098 (11)	❑	❑	❑		
Upon review of a random selection of medical records, would all lab reports show documentation of being dated and timed? 19 CSR 30-20.098 (5)	❑	❑	❑		
Are records maintained for at least two years of participation in a proficiency testing program? Does the proficiency testing program cover all anatomical and clinical specialties for which the laboratory performs tests and in which proficiency testing is available? 19 CSR 30-20.098 (10)	❑	❑	❑		
Can you demonstrate that the laboratory instruments and equipment have: a. periodic evaluations to ensure they properly function at all times? b. temperatures recorded daily for all temperature-controlled instruments? c. updated records showing the date of inspection, calibration, performance evaluation and action taken to correct deficiencies? 19 CSR 30-20.098 (8)	❑ ❑ ❑	❑ ❑ ❑	❑ ❑ ❑		
Does each section of the pathology and medical laboratory have a written quality control program to verify accuracy, measure precision and detect error? 19 CSR 30-20.098 (9)	❑	❑	❑		
Does the hospital provide safety equipment for laboratory employees including, but not limited to, appropriate personal protective equipment?	❑	❑	❑		

LABORATORY SERVICES

Self-Assessment Questions	YES	NO	N/A	Date/Initials	Comments
19 CSR 30-20.098 (14)					
Upon observation would you be able to demonstrate that food, drink, tobacco or personal-care items are not allowed in the laboratory testing area?	❑	❑	❑		
For blood and blood products, is positive identification with two unique patient identifiers always used? 19 CSR 30-20.098 (13)	❑	❑	❑		
Is the refrigerator used for the routine storage of blood for transfusion: a. maintained at a temperature between 1 and 6 degrees Celsius? b. have the temperature verified by an outside recording thermometer? c. constantly monitored by an audible alarm visibly located in an area that is staffed at all times, either battery-operated or one that is on a circuit different from the one supplying the refrigerator? d. on the power line supplied by the emergency generator? 19 CSR 30-20.098 (13)	❑ ❑ ❑ ❑	❑ ❑ ❑ ❑	❑ ❑ ❑ ❑		
If your hospital regularly uses the services of an outside blood collecting establishment (BCE), does your hospital ensure that it: a. meets all regulations and requirements of the FDA as well as other accrediting bodies? b. has a written agreement with the hospital for notification expectations approved by an appropriate representative? c. has policies that govern the procurement, transfer and availability of blood and blood products? d. has policies requiring the BCE to notify the hospital within 3 days after the BCE supplied blood and blood components collected from an infectious donor, whenever records are available, as set forth at 21 CFR 610.48(b)(3)? e. has policies that require the blood bank to notify hospitals within 3 calendar days of any supply of blood and blood products collected from a donor that are negative at the time of donation but tests reactive for evidence of HIV or HCV infection on a later donation or who is determined to be at increased risk for	❑ ❑ ❑ ❑ ❑	❑ ❑ ❑ ❑ ❑	❑ ❑ ❑ ❑ ❑		

LABORATORY SERVICES

Self-Assessment Questions	YES	NO	N/A	Date/Initials	Comments
transmitting HIV or HCV infections? f. has policies that require the blood bank to notify hospitals within 45 days of results of supplemental test for HIV or HCV or other follow-up testing required by FDA? A-0592 COP §482.27(b)(3)(i)(ii)(iii)	❑	❑	❑		
Has the hospital developed and effectively implemented a look-back plan and procedures in the event of notification of potentially HIV or HCV-infected blood and blood components by the blood collecting establishment (either internal or under agreement) which includes: a. policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for the confidentiality of medical records and other patient information? b. details of the actions that the hospital must take immediately? c. actions that the hospital must take when confirmatory test results are not received from the blood bank within 30 days? d. how and where are the follow-up confirmatory test results documented? e. the determination of the disposition of the blood or blood component and quarantine all blood and blood components from previous donations in inventory? f. if follow-up testing by BCE is negative, the release from quarantine? g. if follow-up testing is indeterminate, the disposal or relabeling of prior collections of blood or blood components held in quarantine as set forth in 21 CFR 610.46(b)(2), 610.47(b)(2), and 610.48(c)(2). h. if follow-up testing by BCE is positive, the disposal of the blood and blood components and notification of transfusion recipients? A-0592COP §482.27(b)(3)(4)	❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑	❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑	❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑		
Does the hospital have policies and procedures					

LABORATORY SERVICES

Self-Assessment Questions	YES	NO	N/A	Date/Initials	Comments
outlining actions that must be taken if the hospital has administered potentially HIV or HCV infectious blood or blood components (either directly through its own blood collecting establishment or under an agreement from donors tested after 2/20/08) or released such blood or blood components to another entity or appropriate individual which include:					
a. making reasonable attempts within 12 weeks to notify the patient, or to notify the attending physician who ordered the blood or blood component and ask the physician to notify the patient, or other individual as permitted that potentially HIV or HCV infectious blood or blood components were transfused to the patient and that there may be a need for HIV or HCV testing and counseling?	❑	❑	❑		
b. making reasonable attempts for at least 12 weeks if unable to locate patient or physician?	❑	❑	❑		
c. if the physician is unavailable or declines to make the notification, making reasonable attempts to give this notification to the patient, legal guardian or relative?	❑	❑	❑		
d. documenting in the patient's medical record the notification or attempts to give the required notification?	❑	❑	❑		
COP §482.27(b)(6-7)					
Note: If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. For possible HIV infectious transfusion recipients that are deceased, the physician or hospital must inform the deceased patient's legal representative or relative. If the patient is a minor, the parents or legal guardian must be notified. COP §482.27(b)(10)					
Does the notification given to the patient include:					
a. a basic explanation of the need for HIV or HCV testing and counseling?	❑	❑	❑		
b. enough oral or written information so that the transfused patient can make an informed decision about whether to obtain HIV or HCV testing and counseling?	❑	❑	❑		
c. a list of programs or places where the person can obtain HIV or HCV testing and counseling, including any requirements or restrictions the program may impose?	❑	❑	❑		
Is all documentation related to notification made	❑	❑	❑		

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Self-Assessment Questions	YES	NO	N/A	Date/Initials	Comments
a part of the patient's medical record? A-0592 COP §482.27(b)(8)(i)(ii)(iii)					
Is it ensured that documents related to notification that become part of the patient's medical record are subject to the normal safeguards for access, information release, patient consent and other precautions for confidential information? A-0592 COP §482.27(b)(9)	❑	❑	❑		
Does your hospital provide for the safe and sanitary disposal of blood and blood components not suitable for use or distribution, in accordance with 21 CFR 606.40?	❑	❑	❑		
Does your hospital maintain adequate records of the source and disposition of all units of blood and blood components for at least 10 years after the date of disposition? A-0592 COP §482.27(b)(5)(i)	❑	❑	❑		
Does the hospital have a fully funded plan to transfer these records to another hospital or other entity if such hospital ceases operation for any reason? A-0592 COP §482.27(b)(5)(ii)	❑	❑	❑		

Helpful Hints

Key Resources and Links

- SOM, Appendix C
- 19 CSR 30-20.098
- 19 CSR 20-20.080
- 19 CSR 20-20.091
- 21 CFR 606.40
- 21 CFR 610.48(b)(3)
- COP 482.27
- CoPs 493.1 thru 493.1780