CRITICAL ACCESS HOSPITALS

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. See also Survey and Cert Letter 05-42. 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					
The provision of laboratory services that exceed the requirements for basic laboratory services is an optional requirement. The CAH must maintain or have available laboratory services, either directly or through arrangement, whenever its patients need those services. The CAH may maintain laboratory services at the CAH or may make laboratory services, except for the required basic services, available through contractual agreements.					
Does the CAH provide on-site basic laboratory services essential to the immediate diagnosis and treatment of the patient which include: a. chemical examination of urine by stick or tablet method or both (including urine ketones)? b. hemoglobin or hematocrit? c. blood glucose? d. examination of stool specimens for occult blood? e. pregnancy tests? f. primary culturing for transmittal to a certified laboratory? C-0282 COP §485.635(b)(2)	❑ ❑ ❑ ❑ ❑ ❑	❑ ❑ ❑ ❑ ❑ ❑	❑ ❑ ❑ ❑ ❑ ❑		
Does the CAH have a CLIA certificate or waiver to perform all the tests performed onsite? C-0282 COP §485.635(b)(2)	❑	❑	❑		
Does the CAH have an agreement or arrangement with an outside laboratory to perform laboratory services not provided on-site? C-0288 COP §485.635(c)(1) and (2)	❑	❑	❑		
Does the outside laboratory have a current CLIA certificate or waiver for all tests performed? C-0288 COP §485.635(c)(1) and (2)	❑	❑	❑		
Does the CAH have policies and procedures for additional or specialized laboratory services provided under arrangement or agreement that list which laboratory services and the collection, preservation, transportation, receipt, and reporting of tissue specimen results? C-0288 COP §485.635(c)(1) and (2)	❑	❑	❑		
Can the laboratory assure, either on the premises or by contract with a reference laboratory,	❑	❑	❑		

LABORATORY SERVICES

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prompt performance of adequate examinations in the fields of hematology, clinical chemistry, urinalysis, microbiology, immunology, anatomic pathology, cytology and immunochemotology? 19 CSR 30-20.098(1)					
Are emergency laboratory services available 24/7? C-0282 COP §485.635(b)(2)	❑	❑	❑		
Does the lab annually report an antibiogram the DHSS by July 1? 19 CSR 20-20.020	❑	❑	❑		
Is the medical 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)	❑	❑	❑		
If the medical director, is not a pathologist, is a pathologist retained as an on-site, part-time consultant? 19 CSR 30-20.098(2)	❑	❑	❑		
If the pathologist is a part-time consultant, is: a. a written report of the consultant's evaluation and recommendations submitted after each visit? b. consultation provided at least monthly? 19 CSR 30-20.098(2)	❑ ❑	❑ ❑	❑ ❑		
Is the FT or PT pathologist actively involved in educational programs, medical staff functions, the laboratory QA program, and committees that review tissue, infection control and blood usage? 19 CSR 30-20.098(3)	❑	❑	❑		
Is the pathology and medical laboratory services integrated with other hospital services? 19 CSR 30-20.098(3)	❑	❑	❑		
Are there sufficient qualified laboratory technologists and competent support staff to perform the tests required? 19 CSR 30-20.098(4)	❑	❑	❑		
Are laboratory personnel provided with continuing education opportunities? 19 CSR 30-20.098(4)	❑	❑	❑		
Are all inpatient laboratory tests and specimen examinations performed only on the order of a	❑	❑	❑		

LABORATORY SERVICES

Self-Assessment Questions	YES	NO	N/A	Date/Initials	Comments
medical staff member or other personnel authorized in the medical staff bylaws? 19 CSR 30-20.098(5)					
Are all outpatient tests performed only on written order of a medical staff or other personnel authorized 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 order, the tests required and the date? 19 CSR 30-20.098(5)	❑	❑	❑		
Are all orders for pathological examinations, including surgical specimens, accompanied by pertinent clinical information? 19 CSR 30-20.098(5)	❑	❑	❑		
Does the lab maintain complete written or electronic instructions for specimen collection, processing, storage, testing and reporting of results? 19 CSR 30-20.098(6)	❑	❑	❑		
Do the instructions at a minimum: a. follow the manufacturer's recommendations? b. provide a step-by-step description of the testing procedure? c. include reagent use and storage? d. include control and calibration procedures? e. contain pertinent literature references? 19 CSR 30-20.098(6)	❑ ❑ ❑ ❑ ❑	❑ ❑ ❑ ❑ ❑	❑ ❑ ❑ ❑ ❑		
Are all dated lab reports recorded in the patient's medical record? 19 CSR 30-20.098(7)	❑	❑	❑		
Are retrievable records maintained for at least two years of: a. copies of all laboratory tests and examinations and original reports from reference laboratories? b. quality control results? c. proficiency and validation testing? 19 CSR 30-20.098(7), (9), (10)	❑ ❑ ❑	❑ ❑ ❑	❑ ❑ ❑		
Are dated reports of all laboratory/referring laboratories examinations of outpatients promptly sent to the individual/facility ordering the test? 19 CSR 30-20.098(7)	❑	❑	❑		

LABORATORY SERVICES

Self-Assessment Questions	YES	NO	N/A	Date / Initials	Comments
Do the laboratory instruments and equipment have: a. periodic evaluations following manufacturer's recommendations 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 per hospital's record retention policy? 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 laboratory successfully participate in all available proficiency testing programs for all anatomical and clinical specialties for which the laboratory tests? 19 CSR 30-20.098(10)	❑	❑	❑		
Does the hospital laboratory do validation testing twice per year for all laboratory tests without a proficiency testing program? 19 CSR 30-20.098(10)	❑	❑	❑		
Are specimens, except for teeth and foreign objects and specimens that have been previously determined to be exempt, removed during a surgical, diagnostic or other procedure submitted for pathological examination along with pertinent clinical information? 19 CSR 30-20.098(11)	❑	❑	❑		
Note: Specimens exempted from pathologic examination are those for which examination does not add to the diagnosis, treatment or prognosis.					
Are exempted specimens and those specimens requiring only a gross description and diagnosis determined by the medical staff in consultation with the pathologist and documented in writing? 19 CSR 30-20.098(11)	❑	❑	❑		
For specimens not submitted for pathological exam, is a report of the removal present in the medical record?	❑	❑	❑		

LABORATORY SERVICES

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19 CSR 30-20.098(11)					
Are autopsy services available to meet the needs of the hospital? 19 CSR 30-20.098(12)	❑	❑	❑		
Is the pathologist or the physician who performs/supervises all autopsies qualified in anatomical pathology? 19 CSR 30-20.098(12)	❑	❑	❑		
Are all microscopic interpretations made by a pathologist qualified in anatomical pathology? 19 CSR 30-20.098(12)	❑	❑	❑		
Does the hospital provide safety equipment for laboratory employees including, but not limited to, personal protective equipment? 19 CSR 30-20.098(14)	❑	❑	❑		
Are flammable, combustible or hazardous materials that are considered to be a severe hazard protected in accordance with the Safety Standards for Laboratories in Health Related Institutions 1980? 19 CSR 30-20.098(15)	❑	❑	❑		
Does the hospital provide reports to the department as required by 19 CSR 10-33.050 and section 192.131, RSMo? 19 CSR 30-20.098(16)	❑	❑	❑		
Blood Transfusion and Blood Banking Services					
Is there an established procedure for obtaining a supply of blood and blood components? 19 CSR 30-20.098(13)	❑	❑	❑		
Are facilities provided to ensure the safe keeping and administration of blood and blood products? 19 CSR 30-20.098(13)	❑	❑	❑		
Is positive patient identification using two unique identifiers required for blood collection and administration? 19 CSR 30-20.098(13)	❑	❑	❑		
Are procurement, safekeeping and transfusion of blood and blood products needed for emergencies available directly or through arrangement on a 24-hours a day basis? C-0205 COP §485.618(c)(1)	❑	❑	❑		

CRITICAL ACCESS HOSPITALS

LABORATORY SERVICES					
Self-Assessment Questions	**YES**	**NO**	**N/A**	**Date/Initials**	**Comments**
Note: CAHs are not required to store blood and blood products on site. CAHs must at a minimum demonstrate that it has an effective system in place of making blood products available to emergency patients 24 hours a day.					
If blood banking services are provided under an arrangement, is the arrangement approved by the medical staff and CAH administration? C-0206 COP §485.618(c)(2)	❑	❑	❑		
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 temperature? 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 facility is collecting blood for transfusion, is it registered with the FDA? C-0205 COP §485.618(c)(1)	❑	❑	❑		
If your facility performs blood type and compatibility testing, does it have a CLIA certificate and have all the necessary equipment and reagents? C-0205 COP §485.618(c)(1)	❑	❑	❑		
If your facility is storing blood, does it meet the requirements of 42 CFR Part 493, subpart K and under the control and supervision of a pathologist or other qualified physician? C-0206 COP §485.618(c)(2)	❑	❑	❑		

Key Resources and Links

- 19 CSR 30-20.098
- 19 CSR 10-33.050
- COP §485.618
- COP §485.635
- 192.131, RSMo