

# CRITICAL ACCESS HOSPITALS

LABORATORY SERVICES					
Self-Assessment Questions	YES	NO	N/A	Date/Initials	Comments
<p>All hospitals also must comply with applicable CoPs and interpretive guidelines for laboratories and laboratory services in <a href="#">CoPs 493.1 thru 493.1780</a> and/or the higher standards of their laboratory accrediting organization and any other optional services found in the <a href="#">Medicare State Operations Manual</a> that the hospital provides. See also <a href="#">Survey and Cert Letter 05-42</a>.</p> <p>Note: Other regulations applicable to hospital laboratories include:</p> <ul style="list-style-type: none"> <li>• <a href="#">19 CSR 20-20.080</a> Duties of Laboratories</li> <li>• <a href="#">19 CSR 20-20.091</a> Testing for Contagious or Infectious Disease</li> </ul>					
<p>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.</p>					
<p>Does the CAH provide, as direct services, basic laboratory services essential to the immediate diagnosis and treatment of the patient which include:</p> <p>a. chemical examination of urine by stick or tablet method or both (including urine ketones)?</p> <p>b. hemoglobin or hematocrit?</p> <p>c. blood glucose?</p> <p>d. examination of stool specimens for occult blood?</p> <p>e. pregnancy tests?</p> <p>f. primary culturing for transmittal to a certified laboratory?</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>Can the laboratory assure prompt performance of adequate examinations in the fields of hematology, clinical chemistry, urinalysis, microbiology, immunology, anatomic pathology, cytology and immunochemistry?</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>Are all laboratory services CLIA certified? See <a href="#">COP §493 Subpart K</a>.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>Are all contracted laboratory services provided by a CLIA-certified laboratory?</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>Are the laboratory services integrated into your hospital-wide QA/PI program?</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>Are emergency laboratory services available 24/7?</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>Does the lab annually report an antibiogram the DHSS?</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>Are these reports only from the first unique isolate from each patient?</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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Is the annual facility antibiogram sent to the DHSS by July 1 of the following year?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the director of laboratory services a pathologist? If not, is a pathologist retained as an on-site consultant?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the pathologist: a. FT, PT, or on-site consultant? b. If a consultant, is - a written report of the consultant's evaluation and recommendations submitted after each visit? - consultation provided at least monthly? c. actively involved educational programs, medical staff functions, the laboratory QA program, and committees that review tissue, infection control and blood usage? d. qualified in anatomical pathology?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are autopsy services available to meet the needs of the hospital?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the pathologist or the physician who performs/supervises all autopsies qualified in anatomical pathology?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are there sufficient qualified laboratory technologists and competent support staff to perform the tests required?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are laboratory personnel provided with continuing education opportunities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are all inpatient laboratory tests and specimen examinations performed only on the order of a medical staff member?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are all outpatient tests performed only on written	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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request?					
Do all test requests received by the laboratory clearly identify the patient, the source of the request, the tests required and the date?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are dated reports of all laboratory/referring laboratories examinations of outpatients promptly sent to the individual/facility ordering the test?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are all specimens requiring only a gross description determined by the medical staff in consultation with the pathologist and documented in writing?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are all specimens requiring both macroscopic and microscopic exams determined by the medical staff in consultation with the pathologist and documented in writing?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are all specimens submitted for pathological examination, including surgical specimens, accompanied by pertinent clinical information?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are all lab reports in the medical records department dated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are retrievable records maintained for at least two years of: a. original reports and copies of all laboratory tests and examinations? b. participation in a proficiency testing program covering all anatomical and clinical specialties for which the laboratory performs tests and in which proficiency testing is available?	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>		
Do 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	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		

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deficiencies?					
Does each section of the pathology and medical laboratory have a written quality control program to verify accuracy, measure precision and detect error?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the hospital provide safety equipment for laboratory employees including, but not limited to, gloves?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is it mandated that food, drink, tobacco or personal-care items are not allowed in the laboratory testing area?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the laboratory properly ventilated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Do hospital policies list the laboratory tests provided either directly or under arrangement by your facility?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<b>Blood Transfusion and Blood Banking Services</b>					
Is there an established procedure for obtaining a supply of blood and blood components?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
If blood banking services are provided under an arrangement, is the arrangement approved by the medical staff and CAH administration?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are blood products needed for emergencies available on a 24-hours a day basis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is an armband with a number or other unique identifying symbol used to provide positive patient identification placed on the patient before or at the time of drawing the first tube of blood to be used for transfusion preparation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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Is the refrigerator used for the routine storage of blood for transfusion:					
a. maintained at a temperature between 1 and 6 degrees Celsius?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
b. have the temperature verified by an outside recording temperature?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
d. on the power line supplied by the emergency generator?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
If your facility is collecting blood, is it registered with the FDA?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

## Helpful Hints

### Key Resources and Links

- [19 CSR 30-20.098](#)
- [COP §485.618\(c\)](#)
- [COP §485.623\(b\)\(1\)](#)
- [COP §485.623\(b\)\(5\)](#)
- [COP §485.635\(b\)\(2\)](#)
- [COP §485.635\(c\)](#)