

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0656919	(X3) Date Survey Completed 11/14/2018
Name of Provider or Supplier Wallowa Memorial Hospital Lab	Street Address, City, State 601 Medical Parkway, Enterprise, OR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of records and discussion with Testing Personnel (TP), the laboratory failed to document quality assessment activities. Findings include: 1. No documentation of an ABO discrepancy event on 10/19/2018 could be produced by the person currently designated as the Technical Supervisor (TS) when it was requested. 2. The current Blood Bank policy / procedure for ABO typing for Wallowa Memorial hospital lab does not address ways to resolve ABO discrepancies encountered on the bench.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of procedures submitted for review and discussion with staff, the laboratory failed to establish a Quality Assurance (QA) policy / procedure (SOP).</p>

Findings include: 1. The procedure submitted as the laboratory's QA SOP is not the laboratory's but rather an administrative policy for Wallowa County Health Care District titled Quality Improvement. 2. The aforementioned SOP does not address laboratory specific events or activities for monitoring.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on phone interviews with allegations of lack of oversight in the overall operation of the laboratory and review of documents submitted by laboratory staff, reveals the laboratory director failed to assure the duties and responsibilities of the positions for technical supervisor (TS) and the general supervisor (GS) are fulfilled and performed by qualified personnel to ensure effective direction over the operation of the laboratory. Findings include: 1. The updated CMS 209 form signed and dated by the laboratory director (LD) on 11/05/2018 was used to review the qualifications of the current technical personnel in the laboratory. 2. The laboratory director (LD) is listed as the TS for blood bank and microbiology. Phone interview and follow up written communication with testing personnel reveal limited availability of technical supervision by LD/TS for blood bank and microbiology. The LD/TS does not provide an amount of time in the laboratory sufficient to supervise the technical performance of the staff in microbiology and blood bank. It was stated that the LD comes to laboratory once a month. 3. Further discussion with staff and subsequent documentation submitted for review revealed the LD/TS failed to provide technical consult ensuring effective overall operation in blood bank during the shifts with minimal staffing. A blood bank issue that occurred on 10/19/2018 at 0445 was shared with hospital administrative staff and not addressed by LD. The hospital administrative staff was notified at the end of the shift regarding the blood bank concerns prior to the weekend. The testing personnel has been tasked by the administrative staff to come up with solutions and recommendations for "identifying some gaps in the blood bank process" for the next time they meet. The staff has requested additional training and have also requested assurance that there is readily available technical consultation in stressful urgent events that have not been addressed by the LD. 4. Review of the qualification of the outside consultant designated as the technical supervisor (TS) for chemistry, hematology and immunology and as the general supervisor (GS) for the laboratory listed on the CMS 209 form does not qualify as TS and does not fulfill the GS responsibilities. 5. The laboratory director failed to ensure the designated TS had at least four (4) years of laboratory experience in the specialties of hematology, chemistry and immunology. Review of the submitted resume by the designated TS indicates two (2) years work experience in hematology, chemistry, microbiology and blood bank specialties within a large hospital laboratory

in Spokane, Washington. 6. The designated TS/GS does not provide an amount of time in the laboratory sufficient to supervise the technical performance of the staff in chemistry, hematology and immunology. Currently, the designated TS/GS comes to the laboratory for two (2) days per month. 7. The interview with laboratory staff and record review reveals the testing personnel are tasked by the GS to sign off each others training records and competency assessments, which none of them are qualified to do. .

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on document review and discussion with laboratory staff, the laboratory director (LD) failed to provide a written quality assessment program that ensures continuous improvement of the laboratory's performance and services through ongoing monitoring of all facets of laboratory's technical and non-technical functions that identifies, evaluates and resolves problems. Findings include: 1. The designated technical supervisor submitted the administrative policy for Wallowa County Health Care District titled Quality Improvement in response to the State Agency request for review of a copy of the Wallowa Memorial Hospital Lab policy for quality assessment. 2. Discussion with laboratory staff reveal there is no quality assessment of the general laboratory system that includes assessing practices/issues related to having readily available technical oversight during testing events by phone or on site supervision, discussion with technical supervisor regarding request for additional training in highly technical specialties and assessing competency and ensuring all testing personnel are provided with ongoing training when needed or requested.

D6100

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(10)

The laboratory director must ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under 493.1489(b)(4).

This STANDARD is not met as evidenced by:

Based on discussion with staff and the individual currently designated as the General Supervisor (GS), the Laboratory Director (LD) failed to ensure that there is adequate on site supervision and support for testing personnel (TP) by the GS. Findings include: 1. The GS is only present on site two (2) days per month. 2. Staff members have described frustration with the lack of supervisory / technical support for high complexity testing both verbally and in writing.

D6101

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(11)

The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate

consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart.

This STANDARD is not met as evidenced by:

Based on review of educational records and discussion with staff, the Laboratory Director (LD) failed to ensure qualified staffing and competency assessment of laboratory testing personnel (TP). Findings include: 1. The LD failed to follow the written Laboratory Procedure (SOP) titled "Competency Testing" for Competency Assessment, specified in subpart 3.2 "Initial Competency", page 4 which states "The laboratory director must ensure that the individuals performing competency assessments are qualified through education and experience to meet the defined regulatory requirements associated with the complexity of the testing". 2. The LD failed to insure the current person designated as the Technical Supervisor (TS) for Hematology, Chemistry and Immunology was qualified to act in this position with a minimum of four (4) years of experience in each specialty. 3. The LD failed to ensure the laboratory has a qualified individual to act as a General Supervisor (GS) and be available on site on a routine basis to support and oversee patient testing by TP.

D6108

LABORATORY TECHNICAL SUPERVISOR

CFR(s): 493.1447

The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of educational records of the currently designated Technical Supervisor (TS) for Hematology, Chemistry and Immunology and discussion with same, this individual does not qualify to act as the TS. Findings include: 1. The designated individual does not have four (4) years of experience in each of the specialties of Hematology, Chemistry and Immunology. 2. Review of additional employment history reveal the designated TS had extensive hands on experience in the specialty cytogenetics, from December 2001 to 2008 and as a Tissue Recovery Specialist from Sept 2008 through June 2012 at the same hospital. Unfortunately, this laboratory experience is not needed for Wallowa Memorial Hospital Laboratory.

D6151

GENERAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1463(b)(3)(4)

(3) The director or technical supervisor may delegate to the general supervisor the responsibility for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel.

This STANDARD is not met as evidenced by:

Based on phone interviews and record review, it is revealed that the individual designated as both the technical supervisor (TS) and general supervisor (GS) failed to fulfill the responsibilities of day-to-day onsite supervision or oversight of the laboratory operation and personnel performing tests and reporting test results. Findings include: 1. The phone interview and submitted written concerns of the laboratory staff indicated that the GS did not fulfill responsibilities of providing

orientation , training and creating competency assessments for newly hired testing personnel. Instead, the laboratory staff were tasked to train and write competency assessment for newly hired testing personnel.