Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0703662	10/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cascade Medical Center	402 Lake Cascade Pkwy, Cascade, ID	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) record reviews and an interview with the laboratory manager, the laboratory director and the testing personnel failed to sign the American Proficiency Institute (API) attestation statements for the specialty of Hematology and Chemistry since the last survey on January 20, 2016. Findings: 1. A review of API PT records from 2017 event 1 through 2018 event 2, revealed the laboratory director and the testing personnel who performed the tests, failed to sign the attestation statements for complete blood counts with cell identification, chemistry, and microscopic fungal and urine examinations. 2. An interview on October 3, 2018 at 9:35 AM, with the laboratory manager, confirmed the laboratory director and the testing personnel who performed the testing events failed to sign the attestation statements from 2017.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a record review of personnel documents and the procedure manual, and an

	interview with the laboratory manager, the laboratory failed to establish and follow written policies and procedures to evaluate the competency of testing personnel performing complete blood counts, chemistry, and microscopic examinations since the last survey on January 20, 2016. Findings: 1. A review of documents for the testing personnel competency assessments and laboratory procedures and policies manual, revealed the laboratory failed to establish in writing and document the competency evaluations for 3 out of 3 testing personnel listed on the CMS-209 Personnel Report form. 2. An interview on October 3, 2018 at 9:15 AM, with the laboratory manager, confirmed the laboratory failed to establish and follow written policies and procedures to assess the competency of testing personnel.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to have a written or electronic request for an ordered test from an authorized provider on April 24, 2018. Findings: 1. A review of a patient's laboratory records on April 24, 2018 revealed the laboratory failed to have an order from an authorized provider for a urine analysis on a patient's urine specimen prior to reporting the results. 2. An interview on October 3, 2018 at 11:15 AM, with the laboratory manager, confirmed the laboratory failed to have an order from an emergency room provider for a urine test prior to reporting the laboratory results.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to have a written procedure for the microscopic evaluations of urine sediment examinations since the last survey on January 20, 2016. Findings: 1. A review of the laboratory's procedure manual on October 3, 2018, revealed the laboratory failed to have a written procedure for the microscopic evaluation of urine sediment exams since the last survey. 2. An interview on October 3, 2018 at 10:05 AM, with the laboratory manager, confirmed the laboratory failed to have a written procedure for the microscopic evaluations of urine sediments performed by the laboratory testing personnel.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,

	storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a procedure manual review and an interview with the laboratory manager, the laboratory procedure manual failed to include quality control, calibration verification, maintenance, limitations in testing, specimen rejection, and corrective actions to take when steps in the procedures fail to meet specified requirements or when the test system becomes inoperable since the last survey on January 20, 2016. Findings: 1. A review of the procedure manual revealed the laboratory's test system procedures for chemistry and hematology failed to include all elements required for the procedure manual operating instructions since the last survey. 2. An interview on October 3, 2018 at 10:05 AM, with the laboratory manager, confirmed the laboratory's procedure manual failed to include all procedure element requirements.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a procedure manual review and an interview with the laboratory manager, the laboratory director failed to approve, sign, and date the laboratory procedure manual since the last survey on January 20, 2016. Findings: 1. A review of the procedure manual for the laboratory revealed the laboratory director failed to approve, sign, and date the procedure manual for tests performed in the laboratory. 2. An interview on October 3, 2018 at 10:05 AM, with the laboratory manager, confirmed the laboratory director failed to sign and date the procedure manual.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as

	acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to perform and document calibration verification activities at least once every 6 months, after major maintenance or parts replacement, issues with quality control, or verification of reportable range on the Horiba ABX Pentra 400 chemistry analytes since the last survey on January 20, 2016. Findings: 1. A review of calibration records for the chemistry analytes revealed the laboratory failed to perform calibration verification activities for all analytes tested on the Pentra since the last survey. 2. An interview on October 3, 2018 at 9:45 AM, with the laboratory manager, confirmed the laboratory failed to perform calibration verifications activities for the analytes tested on the Pentra.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to perform and document alarm system inspections for the blood storage refrigerator since the last survey on January 20, 2016. Findings: 1. A record review of the laboratory procedure manual revealed the laboratory failed to perform and document alarm system checks for the blood storage refrigerator semiannually as specified in the procedure manual. 2. An interview on October 3, 2018 at 11:35 AM with the laboratory manager, confirmed the laboratory failed to perform inspections of the alarm system where blood products are stored for emergency use only.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are

	reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory director failed to ensure all proficiency testing (PT) reports are reviewed by the appropriate personnel to evaluate and identify problems with proficiency testing from the time reviewed between 2017 event 1 through 2018 event 2. Findings: 1. A review of documents from the American Proficiency Institute (API) revealed the laboratory director failed to review, evaluate, and identify problems in the laboratory's performance in PT. 2. An interview on October 3, 2018 at 9:45 AM, with the laboratory manager, confirmed the laboratory director failed to review, evaluate, and identify problems that would require corrective actions in the laboratory's performance of PT.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manger, the laboratory director failed to ensure policies and procedures were established to monitor the competency of testing personnel in the laboratory throughout all phases of testing prior to testing patient specimens since the last survey on January 20, 2016. Findings: 1. A review of the procedure manual revealed the laboratory director failed to ensure policies and procedures were established to monitor the competency of testing personnel since the last survey. 2. An interview on October 3, 2018 at 12:05 PM, with the laboratory manager, confirmed the laboratory director failed to ensure policies and procedures were written and established to monitor the competency of testing personnel.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manger, the technical supervisor who is also the laboratory director, failed to ensure the quality control requirements for the specialties of hematology and chemistry are maintained

	throughout the testing process to final patient reporting since the last survey on January 20, 2016. Findings: 1. A review of quality control documents in the laboratory revealed the laboratory director failed to establish and review the quality control program to ensure all levels of quality control are maintained through testing to reporting of patient hematology and chemistry specimens. 2. An interview on October 3, 2018 at 12:15 PM, with the laboratory manager, confirmed the laboratory director failed to ensure the quality control program for the laboratory maintained acceptable levels through all phases of testing patient specimens.