Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
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## Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 06D0055902	**(X3) Date Survey Completed** 03/11/2024
Name of Provider or Supplier Csu Health And Medical Center	**Street Address, City, State** 151 W Lake St, Fort Collins, CO	
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
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 and an interview with the Technical Supervisor (TS), the laboratory failed to assess the competency of and establish policies or procedures to evaluate the competency of TS, General Supervisor (GS), and Clinical Consultant (CC) roles, since the last survey on 02/14/2022. The laboratory performs approximately 83,400 tests annually. Findings include: 1. A review of the laboratory's competency records revealed that the laboratory did not have any documented evaluations of TS, GS, or CC competencies, since the last survey on 02/14/2022. 2. A review of the laboratory's manuals revealed that the laboratory did not have an approved policy or procedure to evaluate TS, GS, or CC competencies, since the last survey on 02/14/2022. 3. An interview with the TS on 03/11/2024, at 2 p.m., confirmed that the laboratory did not assess the competency of and establish an approved policy or procedure to evaluate TS, GS, or CC competencies, since the last survey on 02/14/2022.
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 review of the laboratory's procedure manuals and an interview with the Technical Supervisor (TS), the laboratory failed to include normal ranges of analytes, panic values, reporting instructions, and steps to take if test systems become inoperable, for chemistry, hematology, and microbiology test systems, since the last survey on 02/14/2022. The laboratory performs approximately 83,400 tests annually. Findings include: 1. A review of the laboratory's procedure manuals revealed that the procedures for the laboratory's chemistry, hematology, and microbiology test systems were missing sections detailing the laboratory's normal ranges of analytes, panic values, reporting instructions, and instructions to deal with test system outages, since the last survey on 02/14/2022. 2. An interview with the TS on 03/11/2024 at 2 p.m., confirmed that these sections were not present in the procedures of several different test systems, since the last survey on 02/14/2022.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on document review of the laboratory's policies and individual quality control plans (IQCPs); and interview with the Technical Supervisor (TS), the laboratory failed to follow written policy requiring an annual review of the laboratory's individual quality control plans (IQCPs) risk assessments (RA) and to evaluate quality assurance measures for all phases of testing in microbiology testing systems covered under the laboratory's IQCPs, since the last survey on 02/14/2022. The laboratory performs approximately 8,560 microbiology tests annually. Findings include: 1. A review of the laboratory's policies and IQCPs revealed that the laboratory failed to follow written policy requiring annual review of IQCP RAs, since the last survey on 02/14/2022. 2. A review of the laboratory's policies and IQCPs showed that these documents failed to evaluate quality assurance measures in all phases of testing in microbiology testing

	systems covered under the laboratory's IQCPs, since the last survey on 02/14/2022. 3. An interview with the TS on 03/11/2024, at 2 p.m., confirmed that the laboratory failed to annually review the laboratory's IQCP RAs and failed to evaluate quality assurance measures in all phases of testing in microbiology testing systems covered under the laboratory's IQCPs, since the last survey on 02/14/2022.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on a review of the laboratory's procedure manuals and an interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to ensure that an approved procedure manual for all chemistry and microbiology testing performed in the laboratory was available to laboratory staff, since the last survey on 02/14/2022. The laboratory performs approximately 49,100 chemistry and 8560 microbiology tests annually. Findings include: 1. A review of the laboratory's procedure manuals revealed that the policies for chemistry and microbiology testing performed in the laboratory had not been approved, signed, and dated by the LD, since the last survey on 02/14/2022. 2. An interview with the TS on 03/11/2024, at 2 p.m., confirmed that the chemistry and microbiology policies available to staff were not approved by the LD, nor signed and dated, since the last survey on 02/14/2022.