Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0520354	02/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Physicians Immediate Care Pocatello	495 Yellowstone Ave, Pocatello, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on proficiency testing (PT) record review from the Wisconsin State Laboratory of Hygiene (WSLH) and an interview with the laboratory supervisor, the laboratory failed to enroll in PT for microbiology throat cultures performed on patient specimens since the last survey on March 30, 2017. Findings: 1. A PT record review from the WSLH revealed the laboratory failed to enroll in PT for the specialty of Microbiology. 2. The laboratory performs approximately 1500 throat cultures per year. 3. An interview on February 13, 2018 at 9:05 AM, with the laboratory supervisor, confirmed the laboratory was not enrolled in a CMS-approved PT program for the specialty of Microbiology.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on the Beckman Coulter prostate-specific antigen (PSA) reagent manufacturer's instructions and an interview with the laboratory supervisor, the laboratory failed to follow the Beckman Coulter Access II instructions to include the test method for PSA on the patient's test reports since the last survey on March 30, 2017. Findings: 1. A review the of Beckman Coulter Access II instruction sheet for PSA reagent revealed the laboratory failed to report the identity of the PSA assay to the physicians for patient PSA test results. 2. An interview on February 13, 2019 at 11:40 AM, with the laboratory supervisor, confirmed the identity of the PSA assay was not included on patient test reports.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory supervisor, the laboratory failed to perform and document calibration procedures at least once every 6 months as required by the manufacturer for the Medonic M hematology analyzer since March 30, 2017 and October 11, 2018. Findings: 1. A record review of calibration reports for 2017 through 2018, for the Medonic analyzer, revealed the laboratory failed to perform and document calibration procedures at least once every 6 months as recommended by the manufacturer during 2017. 2. The laboratory performs approximately 2000 hematology tests per year. 3. A review of the hematology procedure revealed the written procedure failed to include the criteria for calibration. 4. An interview on February 13, 2019 at 11:30 AM, with the laboratory supervisor, confirmed the laboratory failed to perform and document calibration procedures in 2017.
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 a record review and an interview with the laboratory manager, the laboratory failed to conduct a Risk Assessment (RA) and establish the Quality Assurance Plan (QAP) for the Individualized Quality Control Plan (IQCP) for throat cultures since the last survey on March 30, 2017. Findings: 1. A review of the IQCP for throat cultures performed on Healthlink Strep Select agar (SSA) revealed the laboratory failed to establish the RA and the QAP. 2. The laboratory performs approximately 1500 throat cultures per year. 3. An interview on February 13, 2018 at 10:35 AM, with the laboratory supervisor, confirmed the laboratory failed to include the RA and QAP in the IQCP.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on an observation, a quality control records review, and an interview with the laboratory supervisor, the laboratory failed to meet the Bio-Rad Liquid Assayed Multiqual Level 1 and 3 quality control acceptability requirements for sodium before reporting patient chemistry results in January 2019. Findings: 1. An observation on February 13, 2019 at 9:30 AM, revealed a Beckman Coulter AU chemistry analyzer and Bio-Rad Multiqual quality control materials. 2. A review of the Bio-Rad Liquid Assayed Multiqual Level 1 manufacturer assay sheet for lot #45771 and quality control data from the Beckman Coulter AU revealed the laboratory failed to meet the sodium acceptability (range 107-117 mEq/L) requirements for 4 out of 22 days of patient testing in January 2019. 3. A review of the Bio-Rad Liquid Assayed Multiqual Level 3 manufacturer assay sheet for lot #45773 and quality control data from the Beckman Coulter AU revealed the laboratory failed to meet the sodium acceptability (range 150-1617 mEq/L) requirements for 18 out of 22 days of patient testing in January 2019. 4. The laboratory reported 153 patient sodium results between 01/01 /2019 and 01/31/2019. 5. An interview on February 13, 2019 at 12:15 PM, with the laboratory supervisor, confirmed the quality control values for sodium did not meet Bio-Rad's acceptability range.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) record review from the Wisconsin State

	Laboratory of Hygiene (WSLH) and an interview with the laboratory supervisor, the laboratory director failed to enroll in PT for the specialty of microbiology since the last survey on March 30, 2017. Findings: 1. A PT record review from the WSLH revealed the laboratory failed to enroll in PT for the specialty of Microbiology. 2. The laboratory performs approximately 1500 throat cultures per year. 3. An interview on February 13, 2018 at 9:05 AM, with the laboratory supervisor, confirmed the laboratory was not enrolled in a CMS-approved PT program for the specialty of Microbiology.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a records review and an interview with the laboratory supervisor, the laboratory director failed to ensure the quality assessment program for the laboratory was established and monitored to ensure the quality of laboratory tests since the last survey on March 30, 2017. Findings: 1. A record review revealed the laboratory director failed to establish and write polices or procedures for a system to monitor, assess, and correct problems in the preanalytic, general laboratory system, analytic, and post-analytic processes in the laboratory. 2. A review of the quality control records for the microbiology media revealed the laboratory failed to meet the CLIA quality control requirements or write an Individualized Quality Control Plan. Refer to D5445.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on personnel records and an interview with the laboratory supervisor, the laboratory technical consultant failed to ensure 5 out of 20 testing personnel were trained to perform complete blood counts (CBCs) and microbiology throat cultures since the last survey on March 30, 2017. Findings: 1. A review of testing personnel training documents revealed the laboratory failed to identify and assure 5 out of 20 newly hired testing personnel were trained to performed CBCs and read microbiology throat cultures. 2. An interview on February 13, 2019 at 9:55 AM, with the laboratory supervisor, confirmed the laboratory could not show how the new testing personnel were trained.