Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D1096966	04/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Physicians Immediate Care Center	134 W Chubbuck Rd, Chubbuck, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory supervisor, the laboratory failed to test the Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) samples for complete blood counts (CBCs) by the same personnel who perform patient testing since the last survey on April 11, 2016. Findings: 1. A WSLH PT record review revealed the laboratory failed to rotate and test the CBC PT samples by the same testing personnel who perform patient testing since the last survey. 2. An interview on April 9, 2018 at 10:30 AM, with the laboratory supervisor, confirmed the laboratory failed to test the CBC proficiency samples from WSLH by personnel who routinely test patient CBCs since the last survey.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test

	system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory supervisor, the laboratory director failed to sign the attestation statements from the Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) program, and the laboratory failed to retain complete blood count (CBC) test results from the Medonic analyzer since the last survey on April 11, 2016. Findings: 1. A WSLH PT document review revealed the laboratory director failed to sign the attestation statements for the Hematology and Urinalysis events since the last survey. 2. A WSLH PT document review revealed the laboratory failed to retain CBC PT test results printed from the Medonic analyzer since the last survey. 3. An interview on April 9, 2018, at 10:30 AM, with the laboratory supervisor, confirmed the laboratory director failed to sign the attestation statements from WSLH, and the laboratory failed to retain the CBC PT sample test results since the last survey.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and an interview with the laboratory supervisor, the laboratory failed to document the evaluation of unsatisfactory PT results for the wet mount test from the Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) program 2017 event 1. Findings: 1. A review of PT results from WSLH 2017 event 1, revealed the laboratory failed to document the evaluation and corrective action for the unsatisfactory wet mount test performed by the laboratory provider. 2. An interview on April 9, 2018 at 10:35 AM, with the laboratory supervisor, confirmed the laboratory failed to document the evaluation and corrective action for the failed KOH test performed on the WSLH 2017 event 1.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory supervisor, the laboratory failed to document corrective actions when the temperature was out of range for the refrigerator where quality control material for complete blood counts

	(CBCs) are stored for February 2018. Findings: 1. A record review of temperature recording logs during February 2018, revealed the laboratory failed to document the corrective actions for 19 out of 28 days when the temperature of the refrigerator used to store CBC quality control material was out of range. 2. An interview on April 9, 2018, at 12:15 PM, with the laboratory supervisor, confirmed the laboratory failed to document corrective actions when the temperature was out of range for the refrigerator used to store CBC controls during February 2018.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record reviews, the laboratory failed to have a qualified technical consultant perform the responsibilities for the position since the last survey on April 11, 2016. Refer to D6035. Findings: 1. A record review of the CMS-209 Personnel Report form revealed the laboratory supervisor was listed as technical consultant but failed to qualify for the position. 2. A review of competency assessments revealed the laboratory failed to have a qualified technical consultant perform the competency assessments for the 16 testing personnel listed on CMS-209 Personnel Report form since the last survey.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for

	"laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory supervisor, the laboratory supervisor who was acting as the laboratory technical consultant failed to qualify for the position based on the education requirements for technical consultant since the last survey on April 11, 2016. Findings: 1. A review of personnel documents for the laboratory supervisor revealed the education failed to meet the technical consultant requirements. 2. An interview on April 9, 2018 at 11:00 AM, with the laboratory supervisor, revealed the education requirement was not met for the technical consultant position.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a record review of personnel documents and an interview with the laboratory supervisor, the laboratory failed to follow the laboratory policy to evaluate and document the competency at least semiannually for a new employee during the first year of patient testing on the Medonic complete blood count (CBC) analyzer used to test complete blood counts since the last survey on April 11, 2016. Findings: 1. A record review of personnel documents revealed 1 out of 16 testing personnel listed on the CMS-209 Personnel Report form, failed to have a competency assessment performed at least semiannually during the first year of patient testing. 2. An interview on April 9, 2018, at 10:15 AM, with the laboratory supervisor, confirmed the laboratory failed to perform competency at least semiannually on 1 testing personnel.