Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0669872	02/13/2020
Name of Provider or Supplier	**Street Address, City, State**	
Sapulpa Indian Health Center	1125 E Cleveland, Sapulpa, OK	

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
D0000	The recertification survey was performed on 02/12/20 and 02/13/20. The findings were reviewed with the technical consultant and testing person #1 at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1409; D6033: Technical Consultant
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 review of records and interview with the technical consultant and testing person #1, the laboratory director failed to sign a proficiency testing attestation statement for 1 of 23 events. Findings include: (1) At the beginning of the survey, the surveyor reviewed 2018 and 2019 proficiency testing records and identified the following for 1 of 23 events: (a) First 2019 Chemistry Miscellaneous Event - The attestation statement had not been signed by the laboratory director. (2) The surveyor reviewed the findings with the technical consultant and testing person #1. Both stated the attestation statements had not been signed by the laboratory director.
D3031	RETENTION REQUIREMENTS

	CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant and testing person #1, the laboratory failed to maintain analytic test records for at least 2 years. Findings include: (1) At the beginning of the survey, the technical consultant and testing person #1 stated to the surveyor CBC (Complete Blood Count) testing was performed using the Cell-Dyn Ruby analyzer; (2) On the second day of the survey, the surveyor requested patient records, which contained morphologic flags (i.e., BAND, VAR LYM, RBC MORPH), from testing person #1. This was requested in order to determine if CBC morphologic flags obtained from testing on the analyzer had been verified according to the manufacturer's instructions and laboratory policy. Testing person #1 explained to the surveyor since patient information was transferred to their LIS (laboratory information system), the instrument printouts were not maintained; (3) While searching in the analyzer's memory, the technical consultant and testing person #1 stated to the surveyor patient data could not be retrieved prior to 09/18/18. Therefore, the surveyor could not determine if morphology flags, obtained from patient testing prior to 09/18/18 had been verified; (4) The surveyor explained to the technical consultant and testing person #1 that records of patient testing (instrument printouts) must be maintained for at least 2 years.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that 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 review of records and interview with the technical consultant and testing person #1, the laboratory director failed to ensure proficiency testing reports were reviewed. Findings include: (1) On the first day of the survey, the surveyor reviewed 2018 and 2019 proficiency testing records. The Performance Evaluations for 2 of 23 events not been signed and dated as reviewed by the laboratory director: (a) Second 2018 Chemistry Miscellaneous Event (b) First 2019 Chemistry Core Event (2) The surveyor reviewed the records with the technical consultant and testing person #1. Both stated the Performance Evaluations, as indicated above had not been signed and dated as reviewed by the laboratory director;
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 a review of records and interview with the technical consultant and testing person #1, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035.
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 review of records and interview with the technical consultant and testing person #1, the technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Findings include: COMPETENCY EVALUATIONS (1) On the first day of the survey, the

	surveyor reviewed personnel records for 2 persons performing moderate complexity testing. The records indicated the six month evaluations for 1 of 2 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #2 - The 02/06/19 evaluation had been performed by testing person #1 (this person had earned an associate degree in science). (2) The surveyor explained to the technical consultant and testing person #1 that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service). PROFICIENCY TESTING ATTESTION FORMS (1) The surveyor reviewed 2018 and 2019 proficiency testing records. The attestation statements for 19 of 23 had been signed by an individual who did not meet the minimal educational qualifications of a technical consultant or designee. The attestation statements had been signed by testing person #1 (this person had earned an associate degree in science): (a) First 2018 Chemistry Core Event (b) Third 2018 Chemistry Core Event (c) Second 2018 Chemistry Miscellaneous Event (d) First 2018 Hematology Event (e) Second 2018 Hematology Event (f) Third 2018 Hematology Event (g) First 2018 Immunology Event (h) Second 2018 Immunology Event (i) Third 2018 Immunology Event (j) Third 2018 Microbiology Event (k) First 2019 Chemistry Core Event (l) Second 2019 Chemistry Core Event (m) Third 2019 Chemistry Core Event (n) First 2019 Hematology Event (o) Second 2019 Hematology Event (p) First 2019 Immunology Event (q) Second 2019 Immunology Event (r) First 2019 Microbiology Event (s) Third 2019 Microbiology Event (2) The surveyor reviewed the records with the technical consultant and testing person #1. Both stated the attestation statements, as indicated above, had been signed and dated by an individual who did not meet the regulatory qualification requirements of a technical consultant or designee. PROFICIENCY TESTING PERFORMANCE EVALUATIONS (1) The surveyor reviewed 2018 and 2019 proficiency testing records. The Performance Evaluations for 3 of 23 events had been signed by an individual who did not meet the regulatory qualification requirements of a technical consultant or designee. The Performance Evaluations had been signed by testing person #1 (this person had earned an associate degree in science): (a) First 2018 Hematology Event (b) First 2018 Immunology Event (c) Second 2018 Immunology Event (2) The surveyor reviewed the records with the technical consultant and testing person #1. Both stated the Performance Evaluations, as indicated above, had been signed and dated by an individual who did not meet the regulatory qualification requirements of a technical consultant or designee.