Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0906177	04/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Absentee Shawnee Tribal Health System -	15951 Little Axe Drive, Norman, 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 04/12,13/2021, The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the compliance officer, laboratory director, and laboratory manager during an exit conference performed at the conclusion of the survey.
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 policy and procedure manual, and interview with the laboratory manager, the laboratory failed to have complete written quality control policies and procedures. Findings include: (1) On 04/12/2021, the laboratory manager

	stated to the surveyor ESR (Erythrocyte Sedimentation Rate) testing was performed using the Sedimat 15 analyzer; (2) The surveyor reviewed the procedure titled, "ESR with Sedimat 15 Plus". Under the heading "Quality Control" the following had not been included: (a) Identity (e.g., normal, abnormal, level I,II, patient or a control); (b) Number and frequency of testing controls; (c) Control limits established (i.e., the laboratory's method for establishing quality control means and limits); (d) Criteria to determine acceptable control results; (e) Corrective action to take when control results fail to meet the laboratory's criteria for acceptability. (3) The surveyor reviewed the findings with the laboratory manager, who stated on 04/12/2021 at 1:30 pm, the procedures had not been written.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for the Ortho Vitros ECiQ analyzer. Findings include: (1) On 04/12/2021 at 09:40 am, the laboratory manager stated to the surveyor Folate, Vitamin B12, Vitamin D, TSH (Thyroid Stimulating Hormone), and Free T4 (Thyroxine) testing were performed using the Ortho Vitros ECiQ analyzer; (2) The surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirements were as follows: (a) Monthly (i) Back Up QC, Calibration, and Configuration Files (ii) Inspect the Reagent Cooler Filter (b) Every Two Months (i) Change the Vapor Adsorption Cartridge (c) Every Three Months (i) Change the Universal Wash Reservoir Filter (3) The surveyor then reviewed maintenance records from January 2020 through March 2021. The following was identified: (a) Monthly - Not documented as performed: (i) Between 03/31/2020 and 06/30/2020 (ii) Between 07/28/2020 and 10/19/2020 (b) Every Two Months - Not documented as performed: (i) After 12/17/2020 (c) Every Three Months - Not documented as performed: (i) Between 01/10/2020 and 07/28/2020 (ii) After 12/17 /2020 (4) The surveyor reviewed the records with the laboratory manager, who stated on 04/12/2021 at 3:00 pm the maintenance had not been documented as performed as indicated above.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

	This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the laboratory manager, the laboratory failed to follow their written protocol for ensuring the urine centrifuge was functioning properly. Findings include: (1) On 04/12/2021 at 10:15 am, the laboratory manager stated to the surveyor, urine sediment examinations were performed in the laboratory. The specimens were processed in the Drucker Horizon 642 VES centrifuge at a speed of 1800 rpm for 5 minutes; (2) The surveyor reviewed the policy titled "Instrument Maintenance and Repair". Under the section titled, "Centrifuge RPM Checks" it stated, "Every six months we need to make sure the Centrifuges are operating at an optimal speed and time"; (3) The surveyor reviewed the centrifuge maintenance records. The records showed the centrifuge speed and timer checks had not been performed every six months as required by policy. The checks had not been performed since 06/12/2020 (due 12/2020); (4) The surveyor reviewed the findings with the laboratory manager who stated the centrifuge speed and timer had not been checked since 06/12/2020.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to have control procedures that would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for Vitamin D testing for 2 of 2 lot numbers. Findings include: (1) On 04/12/2021 at 09:40 am, the laboratory manager stated the following to the surveyor: (a) Vitamin D testing was performed on the Ortho Vitros ECiQ analyzer; (b) Two levels of Audit Micro Controls QC (quality control) materials were performed each day of patient testing. (2) On 04/13/2021 the surveyor reviewed the package insert for the control materials which stated, "The performance range for each level, based on data by combining estimates of assay variance as determined by participating laboratories using approved FDA instruments and reagents, is provided below. Average values obtained in the laboratory should fall within the performance range although the recovery may not be identical with the mean value listed. Variation between labs will be greater than the precision for any one instrument. Accuracy and precision depend on differences in equipment, reagents, supplies, and techniques. Therefore, a lab must establish its own acceptable target values and ranges"; (3) The surveyor then reviewed QC records for 2 lot numbers of control materials used from 12/07/2020 to 03/30/2021. The review showed the laboratory was using ranges wider than the package insert guideline ranges. The following was identified for 2 of 2 lot numbers reviewed: (a) Level 1 lot #6687B1 - The package insert range was 12.4-18.6. A range of 6.1-22.10 had been used to evaluate QC results; (b) Level 2 lot #6687B2 -

	The package insert range was 56.5-84.8. A range of 42.7-98.7 had been used to evaluate QC results. (4) The surveyor reviewed the records with the laboratory manager who stated on 04/13/2021 at 10:30 am, ranges wider than the package insert guideline ranges, as indicated above, had been used to evaluate QC results.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's quality control specifications for Vitamin B12 testing for 1 of 2 lot numbers. Findings include: (1) On 04/12/2021 at 10:15 am, the laboratory manager stated the following to the surveyor: (a) Vitamin B12 testing was performed on the Ortho Vitros ECiQ analyzer; (b) Two levels of Bio-Rad Liquichek Immunoassay Plus Control QC (Quality Control) materials were performed each day of patient testing. (2) On 04/13/2021, the surveyor reviewed the manufacturer's instructions for the QC materials which stated, "The mean values and the corresponding +/-3SD ranges in the Assignment of Values Data Charts were derived from replicate analyses and are specific for this lot of product. Data from Unity Interlaboratory Program are included in the determination of some ranges. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides"; (3) The surveyor reviewed records for testing performed from 06/05/2020 through 02/28/2021. For 1 of 2 lot numbers, it was identified the laboratory had used the package insert guideline ranges instead of laboratory established ranges to determine acceptability for Vitamin B12 QC results. The package insert range had been used during the review period as follows: (a) Bio-Rad Immunoassay Premium Control (level 3 lot #85242) - The laboratory used the manufacturer's range of 371-675 pg/ml. (4) The surveyor reviewed the findings with the laboratory manager who stated on 04/13/2021 at 10:30 am, the laboratory had used the manufacturer's provided ranges for determining acceptability of the results for level 3 control, as indicated above, and did not establish their own ranges.