Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 01D0671486	**(X3) Date Survey Completed** 04/26/2018
Name of Provider or Supplier Poarch Band Of Creek Indians Health Department Lab	**Street Address, City, State** 429 Buford Rolin Drive, Atmore, AL	
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	A recertification survey was performed on April 26, 2018. Poarch Band of Indians Health Department Laboratory is not in compliance with the 42 CFR Part 493, Requirments for laboratories. The CLIA Conditions at 42 CFR 493.801- Enrollment and Testing of Samples and 493.1407 Laboratory Director Responsibilities were not met. Laboratory A (LAB A) is Poarch Band of Creek Indians 01D0671486, located at 429 Buford Rolin Drive, Atmore, AL 36502. Laboratory B (Lab B) is the DW McMillan Hospital, located at 1301 Belleville Avenue, Brewton, AL 36426. Lab A, laboratory director transported the College of American Pathologists (CAP) K2-B 2017 Folate Proficiency Testing (PT) samples to Lab B to dertermine validity. Lab A engaged in inter-laboratory communication with Lab B pertaining to the results of PT samples prior to the date by which Lab A was required to report PT results to the CAP. Lab A reported their own samples results to CAP.
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 review of the Lab A, CAP PT results and interview with the laboratory director of the Lab A on April 26, 2018, the laboratory failed to test the PT samples in the same manner as patients' specimens. Findings Include: a. On November 16, 2017

	the Laboratory Director for Lab A performed testing on CAP PT samples at Lab B to confirm the validity of the CAP PT values obtained by testing personnel at Lab A. Before the CAP PT results due date of December 5, 2017. b. See Dtag 2013
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of Lab A CAP PT results and interview with the laboratory director, the laboratory failed to test PT samples in the same manner as patient specimens. Findings include: 1. A review of the laboratory PT records for the Siemens Dimension EXL Chemistry Analyzer revealed the laboratory performed Folate testing at Lab B on November 16, 2017. A copy of the Lab B, Folate test report was included with the Lab A CAP PT documents. 2. The Laboratory Director confirmed on April 26, 2018, at 10:08, in the office, Lab A did not test the PT samples in the same manner as patients.
D2011	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program. This STANDARD is not met as evidenced by: Based on surveyor record review and interview the laboratory engaged in inter-laboratory communications with Lab B before the test results were reported to the CAP. Findings include: 1. Lab A is certified to perform Folate testing and is enrolled in CAP Ligand Assay PT program. On November 16, 2017 the Laboratory Director revealed she transported the remaining PT sample to Lab B and performed Folate testing. A copy of the Lab B report was included in the PT documents. 2. Lab A reported the original PT results to the CAP PT Program on November 17, 2017, before the CAP PT result December 5, 2017 due date. 3. The Laboratory Director confirmed on April 26,2018 at 10:08 AM in the office, that she performed Folate testing at Lab B.
D2013	TESTING OF PROFICIENCY TESTING SAMPLES

	CFR(s): 493.801(b)(4) The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason. This STANDARD is not met as evidenced by: Based on review of the laboratory's CAP PT records for November 15, 2017 event B and interview with the laboratory director on April 26, 2018, the laboratory failed to perform proficiency testing samples in accordance to CMS regulations 493.1804(c), and the laboratory's PT policy. Findings include: 1. The laboratory subscribes to the Ligand Assay, CAP K2-B proficiency testing program for Chemistry. The due date for the CAP PT results was December 5, 2018. 2. The Laboratory director voluntarily revealed that the CAP PT Event 2, Ligand Assay samples: were tested by the Lab A laboratory staff on November 15, 2017. The results for CAP K2-B 2017 - Folate K2-04, K2-05, K2-06, recorded by the laboratory's testing personnel, were low and the laboratory director did not feel comfortable that the results were correct. The Laboratory Director took the CAP K2-04, K2-05, K2-06 samples to Lab B (where the laboratory director also worked) and reran the samples on November 16, 2017. 3. The original CAP PT results obtained by the Lab A on November 15, 2017 were then submitted to the CAP PT program for evaluation on November 17, 2017. 4. The laboratory PT records reflect the name of Lab B, and values obtained for the samples tested, as well as the evaluation of the sample results between the Lab A and Lab B. 5. The laboratory director openly revealed that the split testing samples for IFOB for 02-08-2017, and 10-27-2017 were performed in the same manner as the Folate PT testing. 6. The laboratory's PT policy states; a. "PT results are not discussed between inter-laboratory personnel or with personnel at the PCI laboratory." b. "PT samples (or portions) are not sent to any other laboratory for analysis." 7. The laboratory director affirmed by interview on April 26, 2018 at approximately 10:08 am, that confirmatory testing of PT samples CAP K2-B 2017 (K2-04, K2-05, K2-06) had been performed at an alternate hospital laboratory.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units

	of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu and package inserts on April 26, 2018, the laboratory failed to include pertinent test units of measurement or interpretation, or both. Findings include: 1. The laboratory performs TPSA testing with Siemens reagents on the Dimension EXL. 2. the laboratory failed include the identity of the PSA assay used." The laboratory test reports do not include the assay method used, or the disclaimer required by the manufacturer. 3. This deficient documentation was affirmed by interview by the laboratory director on April 26, 2018 at approximately 3: 00 pm. 4. The laboratory reports performing approximately 133 patient specimens annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: The Laboratory Director failed to ensure Lab A did not transport or perform PT testing at Lab B for validity testing prior to the CAP PT result December 5, 2017 due date.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observation of PT records and interview, the laboratory director failed to ensure that the proficiency testing samples are tested as required under Subpart H of this part; Findings Include: 1. Observation of PT records for the Siemens Dimension EXL Folate Testing on samples was performed at a different location on November 16, 2017. The CAP due date for samples to be returned was December 5, 2017. 2. The Laboratory Director performed Folate testing at Lab B to validate the sample results performed at Lab A. A Laboratory is not permitted to send PT sample(s) to another lab until after the due date has expired. 3. Interview on April 26, 2018 at 10:08AM with Laboratory director confirmed that samples were tested at Lab B.

D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on interview and review of the PCI laboratory Proficiency Testing records, the laboratory director failed to ensure that the proficiency testing samples are tested as required under Subpart H of this part; Findings Include: 1. Observation of the laboratory reports documented the PT samples run on November 15, 2017 by Lab A and on November 16, 2017 at Lab B. The laboratory director was documented as testing personnel at Lab B. 2 Interview on April 26, 2018 at 10:08AM in the office, confirmed the laboratory director performed Folate testing at Lab B.