

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0671486	(X3) Date Survey Completed 04/21/2022
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	An off-site Revisit Federal Jurisdictional Survey was conducted on May 23, 2022, on the Poarch Band of Creek Indians Public Health Laboratory - CLIA #01D0671486 for all previous deficiencies cited April 20, 2022. All deficiencies have been corrected and no new noncompliance was found. The facility in compliance with all areas of the regulations surveyed.
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on Bacteriology procedure manual, records review, and staff interview, the laboratory failed to have a procedure and perform comparison of test results two times a year for the Throat Culture test procedure performed as a confirmation test for Group A beta-hemolytic Streptococci during the years 2020-2022. Findings include: 1. Review of the Bacteriology procedure manual did not show any Throat Culture test procedure. 2. Review of the Throat Culture records showed patient results as a confirmation test for the waived Group A beta-hemolytic Streptococci with a negative test result. 3. The Bacteriology Throat Culture records did not include any documentation of proficiency testing (PT) or comparison of test results two times a year during the years 2020, 2021, and 2022. 4. During an interview on April 21, 2022, at approximately 2:45 PM (CST) with the Laboratory Director/Technical Consultant (LD/TC) confirmed no procedure, PT or comparison of test results two times a year for the moderately complex Throat Culture test procedure during the years 2020-2022.</p>

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 observation, review of manufacturer's instructions, temperature records and staff interview, the laboratory failed to document corrective actions. The freezer temperatures were not within temperature ranges for three of four months for chemistry testing controls stored in the Xiltek Chemistry Freezer from January-April 2022. Findings include: 1. Observed on a tour of the chemistry section of the laboratory on April 20, 2022 at 11:45 AM were chemistry testing controls kept frozen in the Xiltek Chemistry Freezer in the storage room across from the laboratory director's office. 2. Review of the manufacturer's instructions for the BioRad Liquichek Specialty Immunoassay Control Levels LTA, 1, 2, and 3 (Lot #64910: Level LTA #64911L, Level 1 #64911, Level 2 #64912, Level 3 #64913 with an expiration date of 2022-11-30) that acceptable storage temperature range specified on the package insert stated: a. "Storage and Stability: This product will be stable until the expiration date when stored at -20 to -70°C." b. "Limitations: This product should not be used past the expiration date." 3. Review of the laboratory's Temperature Log for the Chemistry Freezer for the period January 1 - April 20, 2022, showed the Acceptable Temperature Ranges 0°C to -30°C with daily testing personnel written temperature entries and initials. Review of the daily temperature monitoring logs for January-April 2022 found the chemistry freezer temperatures were out of range for the storage and stability of the BioRad Liquichek Specialty Immunoassay Control Levels LTA, 1, 2, and 3. 4. There was no corrective action documented for the following 59 of 109 documented temperature dates: a. January 1-31, 2022: 30 of 31 days temperatures documented out of range for the controls i. January 1, 2022 - Temperature documented -18.4°C ii. January 2, 2022 - Temperature documented -18.4°C iii. January 3, 2022 - Temperature documented -18.8°C iv. January 4, 2022 - Temperature documented -18.9°C v. January 5, 2022 - Temperature documented -18.9°C vi. January 6, 2022 - Temperature documented -18.9°C vii. January 7, 2022 - Temperature documented -19.0°C viii. January 8, 2022 - Temperature documented -18.9°C ix. January 9, 2022 - Temperature documented -18.9°C x. January 10, 2022 - Temperature documented -19.0°C xi. January 11, 2022 - Temperature documented -18.9°C xii. January 12, 2022 - Temperature documented -18.5°C xiii. January 13, 2022 - Temperature documented -19.0°C xiv. January 14, 2022 - Temperature documented -18.9°C xv. January 15, 2022 - Temperature documented -18.4°C xvi. January 16, 2022 - Temperature documented -18.4°C xvii. January 17, 2022 - Temperature documented -18.3°C xviii. January 18, 2022 - Temperature documented -19.2°C xix. January 19, 2022 - Temperature documented -19.4°C xx. January 20, 2022 - Temperature documented -19.9°C xxi. January 21, 2022 - Temperature documented -19.8°C xxii. January 22, 2022 - Temperature documented -19.8°C xxiii. January 23, 2022 - Temperature documented -19.8°C xxiv. January 24, 2022 -

Temperature documented -19.7°C xxv. January 26, 2022 - Temperature documented -18.8°C xxvi. January 27, 2022 - Temperature documented -18.9°C xxvii. January 28, 2022 - Temperature documented -18.9°C xxviii. January 29, 2022 - Temperature documented -18.6°C xxix. January 30, 2022 - Temperature documented -18.6°C xxx. January 31, 2022 - Temperature documented -18.5°C b. February 1-28, 2022: 16 of 28 days temperatures documented out of range for the controls i. February 1, 2022 - Temperature documented -19.0°C ii. February 2, 2022 - Temperature documented -19.0°C iii. February 3, 2022 - Temperature documented -18.9°C iv. February 4, 2022 - Temperature documented -18.9°C v. February 5, 2022 - Temperature documented -19.7°C vi. February 6, 2022 - Temperature documented -19.1°C vii. February 7, 2022 - Temperature documented -19.6°C viii. February 8, 2022 - Temperature documented -19.1°C ix. February 9, 2022 - Temperature documented -19.0°C x. February 10, 2022 - Temperature documented -19.1°C xi. February 11, 2022 - Temperature documented -18.5°C xii. February 12, 2022 - Temperature documented -17.2°C xiii. February 13, 2022 - Temperature documented -17.2°C xiv. February 14, 2022 - Temperature documented -16.4°C xv. February 15, 2022 - Temperature documented -13.3°C xvi. February 16, 2022 - Temperature documented -14.4°C c. March 1-31, 2022: 4 of 30 recorded days temperatures documented out of range for the controls i. March 16, 2022 - Temperature documented -18.0°C ii. March 24, 2022 - Temperature documented -10.0°C iii. March 29, 2022 - Temperature documented -10.0°C iv. March 30, 2022 - Temperature documented -18.6°C d. April 1-20, 2022: 0 of 20 recorded days temperatures documented out of range for the controls e. Review of the Temperature Log for the Chemistry Freezer revealed no corrective action entries for the period January 1 - April 20, 2022. 5. During an interview on April 20, 2022, at approximately 9:30 AM (CST) with the Laboratory Director /Technical Consultant (LD/TC) confirmed the out of range temperatures listed above. LD/TC stated the Temperature Log for the Chemistry Freezer inaccurately portrayed the correct temperature ranges to monitor for the BioRad Liquichek Specialty Immunoassay Control Levels LTA, 1, 2, and 3, stored in the Xiltek during January - April 2022.

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 Center for Medicaid Services Form CMS-116, patient test reports and staff interview, it was determined that six of six final patient test reports from March 2020 to April 2022 failed to indicate the correct address of the laboratory where the test was performed. Findings include: 1. Review of the Center for Medicaid Services Form CMS-116 revealed the facility address of the laboratory in Section I as: 429 Buford L. Rolin Drive, Atmore, Alabama 36502. 2. A review of six of six final patient test reports from March 16, 2020, until April 1, 2022, was conducted. All six of six final patient test reports failed to indicate the current correct address of the

laboratory where the test(s) were performed. 3. The previous Health Administration address was listed at the top of each of the six final patient test reports: 5811 JackSpring Road, Atmore, Alabama 36502. The final patient test reports included: a. Complete Blood Count patient (2/10/2021) b. Erythrocyte Sedimentation Rate (5/26/2020) Accession [UID]: SO 20 794 [6020000794] c. Thyroid Stimulating Hormone (5/26/2020) Accession [UID]: CH 0526 2 [1001470002] d. Comprehensive Metabolic Panel (4/1/2022) Accession [UID]: CH 0401 27 [1020910027] e. Urinalysis/Urine Sediment Microscopic (3/16/2020) f. Abbott ID NOW COVID-19 (9/15/2021) 4. During an interview on April 21, 2022, at approximately 2:45 PM (CST) with the Laboratory Director/Technical Consultant (LD/TC) confirmed the incorrect facility address was listed at the top of the final patient test reports listed above for the period March 2020 - April 2022.