

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0689141	(X3) Date Survey Completed 11/05/2019
Name of Provider or Supplier Bethany Children's Health Center	Street Address, City, State 6800 Nw 39th Expressway, Bethany, 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 11/05/19. The laboratory was found out of compliance with the following CLIA regulation: 493.801: D2000: Condition: Enrollment and Testing of Samples The findings were reviewed with the laboratory informatics coordinator at the conclusion of the survey.
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory informatics coordinator, the laboratory failed to enroll in a proficiency testing program for each regulated analyte listed in Subpart I in the specialties and subspecialties for which it seeks certification. Findings include: (1) At the beginning of the survey, the laboratory informatics coordinator stated to the surveyor the laboratory used the Abbott i-STAT 1 analyzer to test the analytes Sodium, Potassium, Chloride Carbon Dioxide, Ionized Calcium, Glucose, BUN (Blood Urea Nitrogen), Creatinine, Hematocrit, and Hemoglobin on capillary, venous, and arterial samples using the Chem8+ cartridge (The testing is moderate complexity when capillary and arterial samples are analyzed); (2) The surveyor reviewed proficiency testing records from 2018 to the date of the survey in 2019. The surveyor identified the laboratory failed to enroll in and perform proficiency testing for the analytes BUN, Chloride, and</p>

Creatinine in 6 of the 6 proficiency testing events in 2018 through the date of the survey in 2019 (Events: AAFP-PT 2018-A, AAFP-PT 2018-B, AAFP-PT 2018-C, AAFP-PT 2019-A, AAFP-PT 2019-B, and AAFP-PT 2019-C); (3) The surveyor then reviewed the records with the laboratory informatics coordinator and asked if the laboratory had enrolled in an another proficiency testing program for the analytes BUN, Chloride, and Creatinine during the review period. The laboratory informatics coordinator stated the laboratory had not enrolled and participated in any other proficiency testing programs; (4) The surveyor and the laboratory informatics coordinator reviewed the 2018 and 2019 proficiency testing enrollment forms and determined the laboratory failed to enroll and participate in a proficiency testing module that included the analytes BUN, Chloride, and Creatinine during 2018 through the date of the survey in 2019.