

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0689141	(X3) Date Survey Completed 01/24/2018
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 findings were reviewed with the lab informatics coordinator at the conclusion of the survey.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the lab informatics coordinator, the laboratory failed to demonstrate the performance specification of precision for replacement analyzers. Findings include: (1) At the beginning of the survey, the lab informatics coordinator stated to the surveyors that two Abbott iSTAT 1 analyzers (serial number 352495 and serial number 350775), were used to perform the following: (a) pH, pCO₂, pO₂ testing using the G3+cartridge (b) Sodium, Potassium Chloride, Ionized Calcium, CO₂, Glucose, BUN (Blood Urea Nitrogen), Creatinine, Hematocrit testing using the Chem 8+ cartridge and capillary specimens (classifying this test as a non-waived test system). (2) Later during the survey, the lab informatics coordinator stated the following to the surveyors: (a) Abbott iSTAT 1 analyzer serial number 350775 was put into use on 10/06/16; (b) Abbott iSTAT 1 analyzer serial number 352495 was put into use on 11/03/16. (3) The surveyors reviewed the validation records for the analyzers. There was no documentation precision had been</p>

demonstrated for each cartridge type and analyzer; (4) The surveyors reviewed the records with the lab informatics coordinator who stated the precision had not been demonstrated.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (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 lab informatics coordinator, the laboratory failed to ensure the IQCP included the required components. Findings include: (1) At the beginning of the survey, the lab informatics coordinator stated to the surveyors two iSTAT 1 analyzers were used to perform the following testing: (a) Blood Gas (pH, pCO₂, pO₂) testing using the G3+ cartridge; (b) Sodium, Potassium, Chloride, CO₂, Ionized Calcium, Glucose, BUN (Blood Urea Nitrogen), Creatinine, Hemoglobin, and Hematocrit testing using capillary specimens (classifying this a non-waived test) and the Chem 8+ cartridge. (2) The lab informatics coordinator stated to the surveyors IQCP's (Individualized Quality Control Plan) had been developed for the test systems and each cartridge type; (3) Surveyor #1 reviewed the IQCP's for the test systems and identified a Quality Assessment (QA) plan had not been included in the IQCP's (they consisted of Risk Assessments and Quality Control Plans only); (4) The surveyors reviewed the records with the lab informatics coordinator who agreed QA plans had not been included in the IQCP's.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the lab informatics coordinator, the technical consultant failed to evaluate testing persons performing moderate complexity testing at least annually. Findings include: (1) During the survey, surveyor #1 reviewed personnel records for 7 persons who performed testing in 2016 and 2017. For 1 of the 7 persons (testing person #2), there was no evidence an annual evaluation had been performed in 2017; (2) The surveyors reviewed the findings with the lab informatics coordinator who stated the annual evaluation had not been performed in 2017 for the testing person.