Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0689141	03/03/2022
Name of Provider or Supplier	**Street Address, City, State**	
Bethany Children's Health Center	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 03/03/2022. The findings were reviewed with technical consultant #2 and the laboratory informatics coordinator at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with technical consultant #2, the laboratory failed to have a written technical consultant competency policy based on the position responsibilities as listed in Subpart M for one of two technical consultants. Findings include: (1) On 03/03/2022, the surveyor reviewed the competency assessment policy. It did not include guidance for assessing the competency of the technical consultant; (2) The surveyor then reviewed personnel records for competency assessments performed during 2021. There was no evidence of competencies performed for the technical consultant based on their job responsibilities; (3) The surveyor asked technical consultant #2 if a written policy to evaluate the technical consultant based on job responsibilities was available. Technical consultant #2 stated on 03/03/2022 at 12:08 pm a policy had not been written and the above competency had not been performed.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the

	current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of policies and interview with technical consultant #2, the laboratory failed to ensure policies had been approved, signed, and dated by the laboratory director before use. Findings include: (1) On 03/03/2022 at 01:00 pm, technical consultant #2 stated the following to the surveyor: (a) pH, pO2, pO2, Sodium, Potassium, Chloride, CO2, Ionized Calcium, BUN, Glucose, Creatinine, Hemoglobin, and Hematocrit testing were performed using the EPOC analyzer; (b) IQCP's (Individualized Quality Control Plan) had been developed for the above test system. (2) The surveyor reviewed the IQCP's for the EPOC analyzer and identified the QCP (Quality Control Plan) for the test systems had not been approved, signed, and dated by the laboratory director; (3) The surveyor reviewed the records with technical consultant #2 who stated on 03/03/2022 at 01:53 pm, the QCP for the above test system had not been approved, signed, and dated by the laboratory director.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the laboratory failed to provide evidence the verification data had been evaluated prior to implementing one of one new test system. Findings include: (1) On 03/03/2022 at 01:00 pm, technical consultant #2 stated the following to the surveyor: (a) The laboratory began using the EPOC analyzer to perform pH, pO2, pO2, Sodium, Potassium, Chloride, CO2, Ionized Calcium, BUN, Glucose, Creatinine, Hemoglobin, and Hematocrit on 05/24/2021. (2) The surveyor reviewed the performance specification records for the test system. There was no evidence the data had been reviewed and evaluated by the laboratory; (3) The surveyor reviewed the records with technical consultant #2. Technical consultant #2 stated on 03/03/2022 at 01:40 pm, the data had not been signed and dated as approved. (NOTE: The interpretive guidelines at 493.1253(b)(1) state, "The laboratory is responsible for verifying the performance specifications of each nonwaived unmodified FDA-cleared or approved test system that it introduces, prior to reporting patient test results." In addition, the interpretive guidelines state, "Prior to introducing a test for routine patient testing, the laboratory must review and evaluate the verification data.")