Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0387556	11/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Bettendorf Healthplex Lab	2140 53rd Avenue, Bettendorf, IA	

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
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 Laboratory Test List and Annual Volume form, proficiency testing records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at 10:55 am on 11/21/2023, the laboratory failed to enroll in an approved proficiency testing (PT) program for the analytes, pH, partial pressure of oxygen (PO2), and partial pressure of carbon dioxide (PCO2), for one out of one year in 2023. The findings include: 1. The laboratory began performing arterial and venous blood gas testing including the analytes, pH, PO2, and PCO2, in December 2022. 2. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not enroll in PT for the analytes, pH, PO2, and PCO2, in 2023.
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 lack of performance specification records and confirmed by Laboratory Personnel identifier #2 (refer to the Laboratory Personnel Report) at 1:30 pm on 11/21/2023, the laboratory failed to verify the performance specifications of accuracy and precision for the following test systems: Rh factor, QuickVue serum human chorionic gonadotropin (HCG) qualitative, and K-check ketone. The findings include: 1. The laboratory began using the Rh factor, QuickVue serum HCG qualitative, and K-check ketone test systems in December 2022. 2. At the time of the survey, the laboratory did not have performance specification records for the Rh factor, QuickVue serum HCG qualitative, and K-check ketone test systems.
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: A. Based on lack of Individualized Quality Control Plan (IQCP) records, review of quality control (QC) records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at 1:00 pm on 11/21/2023, the laboratory failed to perform two levels of quality control each day of patient testing for the Abbott iStat test system. The findings include: 1. The laboratory performed arterial and venous blood gas testing on two Abbott iStat test systems. 2. The laboratory performed controls with each new lot and shipment of test cartridges and monthly for the Abbott iStat test systems. 3. Laboratory personnel identifier #2 indicated that the laboratory intended to follow the manufacturer's instructions for performing QC. 4. At the time of the survey, the laboratory did not have an IQCP for the Abbott iStat test systems. B. Based on lack of Individualized Quality Control Plan (IQCP) records, review of quality control (QC) records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at 1:30 pm on 11/21/2023, the laboratory failed to perform a positive and negative control each day of patient testing for the QuickVue serum human chorionic gonadotropin (HCG) qualitative test system. The findings include: 1. The laboratory performed controls with each new lot and shipment of test kits for the QuickVue serum HCG qualitative test system. 2. Laboratory personnel identifier #2 indicated that the laboratory intended to follow the manufacturer's instructions for performing QC. 3. At the time of the survey, the laboratory did not have an IQCP for the QuickVue serum HCG qualitative test system.
D5775	COMPARISON OF TEST RESULTS

	CFR(s): 493.1281(a)(c) (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. This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List & Annual Volume form, lack of comparison activity records, observation during the survey, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at 1:00 pm on 11/21/2023, the laboratory failed to perform and document comparison activities twice annually between two out of two iStat test systems for the analytes: partial pressure of oxygen (PO2), partial pressure of carbon dioxide (PCO2), and pH, for two out of two time periods from 01/01/2023 - 11/21/2023. The findings include: 1. The Laboratory Test List & Annual Volume form listed the laboratory as performing arterial and venous blood gas testing including the analytes, PO2, PCO2, and pH, on the i-STAT test system. 2. An observation made during the survey indicated that the laboratory has two iStat test systems in use. 3. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not perform and document comparison studies between the two iStat test systems from 01/01/2023 - 11 /21/2023.