Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0686166	04/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Clarinda Regional Health Center	220 Essie Davison Drive, Clarinda, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of temperature records and confirmed by testing personnel #1 (refer to the Laboratory Personnel Report) at approximately 10:15 am on 4/22/2021, the laboratory failed to document temperatures of the respiratory therapy refrigerator for 27 out of 31 days in December 2020. The findings include: 1. The respiratory therapy department stored i-STAT testing cartridges in the respiratory therapy refrigerator. 2. The laboratory did not document the temperature of the refrigerator on the following dates: 12/2 - 12/6/2020, 12/8 - 12/23/2020, 12/25 - 12/29/20 and 12/31/20.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of Cepheid GeneXpert maintenance records and confirmed by

	laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 8:45 am on 4/22/2021, the laboratory failed to perform and document daily maintenance on the Cepheid GeneXpert instrument for four out of 31 days of patient testing in December 2020. The findings include: 1. The Cepheid GeneXpert Maintenance log stated the laboratory must daily perform the following: *clean work area *close all module doors *discard used cartridges 2. At the time of the survey, the laboratory did not document daily maintenance for the following days of patient testing: 12/13/20, 12/15/20, 12/23/20 and 12/24/20.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on lack of function check records, review of the i-STAT operator's guide and confirmed with laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 10:15 am on 04/22/2021, the laboratory failed to perform and document thermal probe function checks on the respiratory therapy i-STAT analyzer every six months for three out of three time periods from 1/1/2020 - 4/22 /2021. The findings include: 1. The i-STAT operator's guide states that a thermal probe check must be performed every six months. 2. At the time of the survey, the laboratory did not perform the thermal probe check on the respiratory therapy from 1/1 /2020 - 4/21/2021.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the MIC Panel Quality Control procedure, Individualized Quality Control Plan, and antimicrobial susceptibility testing (AST) quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 4:45 pm on 04/21/2021, the laboratory failed to perform weekly gram positive and gram negative QC for one out of five weeks in December 2020. The findings include: 1. The MIC Panel Quality Control procedure and the Individualized Quality Control Plan stated AST quality controls would be performed weekly for gram positive and gram negative panels. 2. The laboratory

	performed gram positive and gram negative AST quality controls every Wednesday. 3. At the time of the survey, the laboratory did not have gram positive and gram negative AST quality controls for the week of 12/23/2020.
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 and Annual Volume report and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 9:00 am on 04/22/2021, the laboratory failed to perform comparison testing twice annually between the Dimension EXL and the i-STAT analyzers for the analytes: sodium, potassium, chloride, bicarbonate, ionized calcium, glucose, urea nitrogen and creatinine for three out of three time periods from 1/1/2020 - 4/22/2021. The findings include: 1. The Laboratory Test List and Annual Volume report listed the laboratory as performing sodium, potassium, chloride, bicarbonate, ionized calcium, glucose, urea nitrogen and creatinine testing on both the Dimension EXL and i-STAT analyzers. 2. At the time of the survey, the laboratory did not perform comparison studies between the Dimension EXL and i-STAT analyzers for the above analytes from 1/1/2020 - 4/22/2021.
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 review of personnel records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 1:30 pm on 04 /21/21, the technical consultant failed to assess and document the competency of individuals performing moderate complexity testing at least annually for three out of three testing personnel (laboratory personnel identifiers #2, #8 and #9) in 2020.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and confirmed by the laboratory

	personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11: 00 am on 4/22/2021, the laboratory director failed to ensure that the laboratory established and maintained a quality assessment program that included the four quality systems: general laboratory, pre analytical, analytical, and post analytical.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 1:30 pm on 04 /21/2021, the technical supervisor failed to assess the competency of individuals performing high complexity testing at least semiannually during the first year the individual tests patient specimens for one out of six high complexity testing personnel. The findings include: 1. Testing personnel identifier #5 began performing patient testing on 2/3/2020. 2. At the time of the survey, the technical supervisor failed to perform a six month competency on testing personnel identifier #5.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 1:30 pm on 04 /21/2021, the technical supervisor failed to assess and document the annual competency of individuals performing high complexity for two out of two testing personnel (laboratory personnel identifiers #1 and #3) in 2020.