

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0686166	<b>(X3) Date Survey Completed</b>  02/10/2023
<b>Name of Provider or Supplier</b>  Clarinda Regional Health Center	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5445</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plans (IQCP) and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 02/10/2023, the laboratory failed to include a quality assessment plan as part of the IQCP for the following test systems: Alere Combo serum qualitative human chorionic gonadotropin (HCG), Abbott iStat, Cepheid GenXpert, Medtox Scan Profile V, and Alere Triage Meter.</p>
<b>D5783</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p>

This STANDARD is not met as evidenced by:  
Based on review of chemistry quality control (QC) records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 02/10/2023, the laboratory failed to take and document corrective action when chemistry QC fell outside the laboratory's established criteria for acceptability for one out of 31 days of patient testing in July 2022. The findings include: 1. The laboratory performs chemistry testing on the Siemens Dimension EXL instrument. 2. Review of chemistry QC records revealed a result of 0.4 mg/L with "lo" and "assay range" flags on the level 1 c-reactive protein (CRP) QC for 07/23/2022. 3. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not have documented corrective action for level 1 CRP QC on 07/23/2022.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on review of the Clinical Laboratory Improvement Amendment (CLIA) application (Form CMS-116), patient test reports, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 02/10/2023, the laboratory failed to indicate the correct address of the testing facility for 11 out of 11 patient test reports reviewed from July 2022. the findings include: 1. The CLIA application listed the address of the facility as 220 Essie Davison Drive, Clarinda, IA 51632. 2. The 11 patient test reports reviewed recorded the address of the testing facility as PO Box 217, Clarinda, IA 51632. 3. At the time of the survey, personnel identifier #2 confirmed that the patient test reports had the incorrect address listed for the testing facility.