| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 16D0387805 | 04/27/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Community Health Care, Inc | 500 West River Drive, Davenport, 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 |
|---|---|
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Clinical Laboratory Improvement Amendments (CLIA) Application (Form CMS-116), review of quality control (QC) records for 2017-2018, lack of Individualized Quality Control Plan (IQCP) records, and confirmed by laboratory personnel identifier #8 (refer to Laboratory Personnel Report) at approximately 5:00 pm on 04/27/2018, the laboratory failed to perform a positive and negative control each day of patient testing for the OSOM infectious mononucleosis test system from February 2017- March 2018. The findings include: 1. Review of the CLIA Application revealed that the laboratory listed the OSOM infectious mononucleosis test system in the waived testing section. 2. A discussion with personnel identifier #8 revealed that the laboratory uses serum and plasma samples for patient testing. 3. The OSOM infectious mononucleosis package insert states, "CLIA Complexity: non-waived for serum and plasma." 4. The laboratory performed a positive and negative control for each new lot and shipment of infectious mononucleosis test kits. 5. Laboratory personnel identifier #8 indicated that the laboratory intended to follow manufacturer's instructions for performing QC. 6. At the time of the survey, the laboratory did not have an IQCP for the OSOM infectious mononucleosis test system. |