

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D2056586	<b>(X3) Date Survey Completed</b>  04/06/2023
<b>Name of Provider or Supplier</b>  Muscatine Fire Department	<b>Street Address, City, State</b>  312 East Fifth Street Ste 2, Muscatine, 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>CONTROL PROCEDURES 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 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 approximately 11:40 am on 04/06/2023, the laboratory failed to perform two levels of QC each day of patient testing for the analytes: creatine kinase isoenzyme (CK-MB), myoglobin, and troponin from 01/01/2023- 04/06/2023. The findings include: 1. The laboratory performed QC with each new lot and shipment of cardiac test cartridges and monthly. 2. Laboratory personnel identifier #2 indicated that the laboratory intended to follow manufacturer's instructions for performing QC. 3. At the time of the survey, the laboratory did not have an IQCP for the cardiac test kits (CK-MB, myoglobin, and troponin). This is a repeat deficiency.</p>