

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0384378	(X3) Date Survey Completed 11/18/2020
Name of Provider or Supplier Loring Hospital	Street Address, City, State 211 Highland Avenue, Sac City, 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review the BioFire FilmArray Gastrointestinal (GI) Panel Instructions for Use, BioFire Individual Quality Control Plan (IQCP), quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 10:40 am on 11/18/2020, the laboratory failed to follow manufacturer's instructions for performing positive and negative controls on the GI panel for three out of four months from 8/1/2020 - 11/18/2020. The findings include: 1. The BioFire FilmArray GI Panel Instructions for Use state, "Good laboratory practice recommends running external positive and negative controls regularly." 2. The laboratory's BioFire IQCP plan states that external QC will be performed monthly and with each new lot and/or shipment of GI panels. 3. The GI panel tests for 22 pathogens. 4. The laboratory used either level 1 or level 2 of ZeptoMetrix QC monthly and with each new lot number and/or shipment of GI panels. ZeptoMetrix control 1 is positive for half of the pathogens and negative for half the pathogens on the GI panel. ZeptoMetrix control 2 is positive and negative for the opposite half of pathogens on the GI panel. Example, control 1 is positive for Clostridium difficile and control 2 is negative for Clostridium difficile. 5. The laboratory performed either control 1 or 2 (not both) on the following dates: *8/21/2020 GI panel lot number 166419; Control 2 *10/22/2020 GI panel lot number 20702; Control 1 *11/5/2020 GI panel lot number 304820; Control 2 6. At the time of the survey, the laboratory did not have records documenting positive and negative controls for all 22 pathogens on the GI panel on 8 /21/2020, 10/22/2020, and 11/5/2020.</p>