Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0385663	(X3) Date Survey Completed 02/16/2022
Name of Provider or Supplier Stewart Memorial Community Hospital	**Street Address, City, State** 1301 West Main Street, Lake 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of coagulation reagent study records, direct observation, and confirmed by personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 11:10 am on 02/16/2022, the laboratory failed to retain records used to establish the normal patient mean for one out of one lot number of thromboplastin reagent (lot 549763, expiration 11/28/2022). The findings include: 1. The laboratory established a normal patient mean of 10.8 seconds for thromboplastin lot 549763 (expiration 11/28/2022) in November 2021. 2. The coagulation reagent study records for lot 549763 (expiration 11/28/2022) did not include the patient test results and records used to establish the normal patient mean. 3. Observation of the thromboplastin reagent in the laboratory's refrigerator confirmed current use of lot 549763 (expiration 11/28/2022). 4. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not retain the patient test results and records used to establish the normal patient mean for thromboplastin lot 549763 (expiration 11/28 /2022).
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)

	(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on lack of performance specification records and confirmed by Laboratory Personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 3: 25 pm on 02/16/2022, the laboratory failed to verify the performance specifications of accuracy and precision for the Alere QuikDiff Complete Clostridium difficile antigen /toxin test system. The findings include: 1. The laboratory began using the Alere QuikDiff Complete Clostridium difficile antigen/toxin test system in May 2020. 2. At the time of the survey, the laboratory did not have performance specification records for this test system.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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. This STANDARD is not met as evidenced by: A. 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 3:30 pm on 02/16/2022, the laboratory failed to perform a positive and negative control each day of patient testing for the following test systems: ActimProm rupture of membranes (ROM), Alere QuikDiff Complete clostridium difficile, Alere Determine human immunodeficiency virus (HIV) 1/2 antibody/antigen, and Quidel Solana (Streptococcus A and SARS CoV-2). The findings include: 1. The laboratory performed controls with each new lot and shipment of tests for the following test systems: ActimProm ROM, Alere QuikDiff Complete clostridium difficile, and Alere Determine HIV 1/2 antibody/antigen. 2. The laboratory performed controls with each new lot and shipment of tests and monthly for the Quidel Solana (Streptococcus A and SARS CoV-2) test system. 3. Laboratory personnel identifier #2 indicated that the laboratory intended to follow manufacturer's instructions for performing QC. 4. At the time of the survey, the laboratory did not have an IQCP for the ActimProm ROM, Alere QuikDiff Complete clostridium difficile, Alere Determine HIV 1/2 antibody /antigen, and Quidel Solana test systems. B. 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 3:00 pm on 02/16/2022, the laboratory failed to perform two levels of QC each day of patient testing for the Opti CCA-TS2 test system. The findings include: 1. The laboratory performed QC with each new lot and shipment of 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 Opti CCA-TS2 test system. C. Based on review of the laboratory's Individualized Quality Control Plan (IQCP) and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 3:30 pm on 02/16/2022, the laboratory failed to include a risk assessment as part of the IQCP for the BioFire FilmArray (gastrointestinal and respiratory panels) test system.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Test List and Annual Volume form, lack of media quality control (QC) records, lack of an Individualized Quality Control Plan (IQCP), and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 3:30 pm on 02/16/2022, the laboratory failed to check each lot of Cary Blair transport media for sterility, ability to support growth, and ability to select or inhibit specific organisms or produce a biochemical response, as appropriate, from the last survey on 12/12/2019 to the time of the survey on 02/16/2022. The findings include: 1. Review of the Test List and Annual Volume form indicated that the laboratory uses the BioFire FilmArray test system to perform gastrointestinal (GI) panel testing. 2. The laboratory's BioFire GI Panel Testing procedure indicated that stool specimens must be placed in Cary Blair transport media prior to testing. 3. Personnel identifier #2 indicated that the laboratory intended to retain the manufacturer's QC certificates and not perform additional QC. 3. At the time of the survey, the laboratory did not retain the manufacturer's QC certificates and did not have an IQCP.
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 #2 (refer to the Laboratory Personnel Report) at approximately 8:20 am on 02/16/2022, the technical supervisor failed to assess and document the competency of individuals performing high complexity testing at least annually for three out of 11 testing personnel and three out of three years from 2019- 2021. The findings include: 1. Review of personnel records indicated that personnel identifier #7 did not have a

	competency evaluation completed in 2019. 2. Review of personnel records indicated that personnel identifiers #6, #7, and #12 did not have competency evaluations completed in 2020. 3. Review of personnel records indicated that personnel identifiers #7 and #12 did not have competency evaluations completed in 2021. 4. At the time of the survey, personnel identifier #2 confirmed that competency evaluations were not completed for personnel identifiers #6, #7, and #12 for the years listed above.