Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0382646	11/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Boone County Hospital	1015 Union Street, Boone, 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 observation during a tour of the laboratory, review of blood culture records, and confirmed by laboratory personnel identifier #9 (refer to the Laboratory Personnel Report) at approximately 4:30 pm on 11/20/2019, the laboratory failed to retain manufacturer quality control (QC) certificates for all blood culture media received from 02/15/2018 to the time of the survey on 11/20/2019. The findings include: 1. During a tour of the laboratory, personnel identifier #9 stated that the laboratory purchased a BioMerieux BacT/ALERT blood culture instrument and began patient testing on 02/15/2018. 2. At the time of the survey, the laboratory did not have manufacturer QC certificates for blood culture media received from 02/15/2018 to 11 /20/2019.
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 #9 (refer to the Laboratory Personnel Report) at approximately 4: 00 pm on 11/20/2019, the laboratory failed to verify the performance specifications of accuracy, precision, reportable range, and reference ranges for the test system, Stanbio RaPET, prior to testing and reporting patient test results. The findings include: 1. The laboratory began using the Stanbio RaPET test system in November 2018. 2. At the time of the survey, personnel identifier #9 confirmed that the laboratory did not have performance specification records for the Stanbio RaPET test system.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: A. Based on review of Osmometer 3320 records and confirmed by laboratory personnel identifier #5 (refer to the Laboratory Personnel Report) at approximately 5: 00 pm on 11/20/2019, the laboratory failed to perform and document daily maintenance for one out of one day of patient testing (07/07/2019). The findings include: 1. The laboratory's "Osmometer Check Off" log indicated that the following tasks must be done each day of patient testing: *Clean exterior *Clean chamber 2. Patient A had serum osmolality and urine osmolality testing performed on 07/07 /2019. 3. At the time of the survey, the laboratory did not have daily maintenance records for 07/07/2019. B. Based on review of Osmometer 3320 records and confirmed by laboratory personnel identifier #5 (refer to the Laboratory Personnel Report) at approximately 5:00 pm on 11/20/2019, the laboratory failed to perform and document biannual maintenance for three out of three time periods from 07/01/2018- 11/20/2019. The findings include: 1. The laboratory's "Osmometer Check Off" log indicated that the following tasks must be done biannually: *Inspect & clean vents *Perform A/D diagnostic test *Perform probe bin diagnostic test *Perform instrument calibration & sampler calibration 2. At the time of the survey, the laboratory did not have biannual maintenance records for the three time periods from 07/01/2018- 11/20 /2019.
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:

	Based on review of the Laboratory's Individualized Quality Control Plan (IQCP), review of quality control (QC) records, and confirmed by laboratory personnel identifier #14 (refer to the Laboratory Personnel Report) at approximately 3:30 pm on 11/20/2019, the laboratory failed to perform external QC as established by the laboratory for one out of one lot number (lot number E0958, expiration 11/30/2020) of fetal fibronectin (FFN) test cartridges. The findings include: 1. The laboratory's FFN IQCP stated that two levels of external QC would be performed with each new lot number and shipment of FFN cartridges. 2. The laboratory received a new lot number of cartridges, E0958 (expiration 11/30/2020), on 07/08/2019. 3. At the time of the survey, the laboratory did not have external QC records for FFN cartridge lot number E0958.
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 observation during a tour of the laboratory, lack of media quality control (QC) records, lack of an Individualized Quality Control Plan (IQCP), and confirmed by laboratory personnel identifier #9 (refer to the Laboratory Personnel Report) at approximately 4:30 pm on 11/20/2019, the laboratory failed to check each lot of blood culture media for sterility, ability to support growth, and ability to select or inhibit specific organisms or produce a biochemical response, as appropriate, from 02/15/2018 to the time of the survey on 11/20/2019. The findings include: 1. During a tour of the laboratory, personnel identifier #9 stated that the laboratory purchased a BioMerieux BacT/ALERT blood culture instrument and began patient testing on 02/15/2018. 2. Personnel identifier #9 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.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of personnel records, lack of performance specification records, and confirmed by laboratory personnel identifier #9 (refer to the Laboratory Personnel Report) at approximately 4:00 pm on 11/20/2019, the technical consultant failed to

	document training for the Stanbio RaPET test system prior to reporting patient test results for nine out of nine testing personnel (laboratory personnel identifiers #2- #9 and #13). The findings include: 1. The laboratory began using the Stanbio RaPET test system in November 2018. 2. At the time of the survey, the laboratory did not have Stanbio RaPET test system training records for testing personnel identifiers #2- #9 and #13.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory personnel records and confirmed by laboratory personnel identifier #14 (refer to the Laboratory Personnel Report) at approximately 9: 00 am on 11/20/2019, the laboratory failed to meet the testing personnel requirements by providing documentation to qualify the testing personnel who perform high complexity testing as specified in standard D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high

	school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records and confirmed by laboratory personnel identifier #14 (refer to the Laboratory Personnel Report) at approximately 9:00 am on 11/20/2019, the laboratory failed to have a diploma and/or transcripts to qualify 1 out of 13 testing personnel (personnel identifier #6, refer to the Laboratory Personnel Report) who performs high complexity testing.