Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0047368	05/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Morton County Hospital	445 Hilltop, Elkhart, KS	

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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on lack of documents and interview, the laboratory failed to have and follow policies and procedures to monitor, assess, and when indicated correct problems identified in general laboratory system. Findings: 1. No Quality Assurance (QA) plan or procedure was made available at the time of survey. 2. Interview with the general supervisor (GS) 5/20/21 at 10:15 a.m. confirmed, the laboratory failed to have and follow policies and procedures to monitor, assess, and when indicated correct problems identified in general laboratory system.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or

	control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based upon a review of the laboratory procedure, instrument test menu, patient test report and interview, the laboratory failed to define by written procedure: correct analytes performed and reported, correct criteria for specimen acceptability and rejection, correct limitations of the procedure, correct analyte reportable range, refernce ranges for all reported analytes and test calculations for the ABL 80 Flex Co-Ox analyzer. Findings: 1.Review of the procedure "ABL 80 Flex Co-Ox" found the following analytes listed as measured by the ABL 80 Co-Ox that were not found as part of the analyzer's test menu: CCa++ CK-, cNa+, cCl-, and cGlu. 2. Review of the patient test report found 2 reported analytes not listed in this procedure: HCO3 and Base Excess (BE). 2. Procedure section "Type" referred to the use of specimen anticoagulants and perservatives that would affect sodium (cNa+), calcium (cCa++) and glucose (cGlu) results when these analytes were not tested. 3. Procedure section "Limitations of the Procedure" referred to impact on test results not provided by this analyzer: chloride (CCl-), sodium (cNa+), and calcium (cCa++). 4. Analytes Reportable Range (ARR) section lists the ARRs for analytes not reported by this analyzer and failed to include the verified ARR for the analytes tested. The unverified manufacturer's ARRs were listed. No ARR was provide for total hemoglobin, CO hemoglobin, Met hemoglobin, HCO3. 5. Procedure section "Calculations" the calculated analytes and the calcuation formulas were not provided. 6. Procedure section "Reporting Format" referred to reporting analytes not tested by this analyzer. 7. Procedure section "Analytes Units Critical Values" listed critical values criteria for analytes not tested by this analyzer. 8. Procedure section "Reference Ranges" listed analytes not tested by this analyzer and did not have reference ranges for O2 saturation, total hemoglobin, CO hemoglobin, Met hemoglobin, HCO3 and BE. Units of measure were only provided for the reported analytes pCO2 and pO2. 9. Interview with the General Supervisor 5/20/21 at 2:35 p.m. confirmed, the laboratory failed to define by written procedure: correct analytes performed, correct criteria for specimen acceptability and rejection, correct limitations of the procedure, correct analyte reportable range, reference ranges for all reported analytes and test calculations for the ABL 80 Flex Co-Ox analyzer.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

	This STANDARD is not met as evidenced by: Based on the review of the Arterial Blood Gas (ABG) report in the electronic medical record (EMR), procedure manual and interview, the laboratory failed to have a test report that included the units of measurement for pCO2, pO2, total hemoglobin, O2 hemoglobin, CO hemoglobin, Met hemoglobin, O2 saturation, and HCO3. Findings: 1. Review of a patient test result from the EMR showed no units of measurement for pCO2, pO2, total hemoglobin, O2 hemoglobin, CO hemoglobin, Met hemoglobin, O2 saturation, and HCO3. 2. The procedure "ABL 80 Flex Co-Ox" listed units of measurment as mmHg for pCO2 and pO2. 3. The GS stated the EMR patient report was a nurse's note and not built as a lab test as the reason that no units of measurement were included. 4. Interview with the GS on 5/20/21 on 2:35 p.m confirmed, the laboratory failed to have a test report that included the units of measurement for pCO2, pO2, total hemoglobin, O2 hemoglobin, CO hemoglobin, Met hemoglobin, O2 saturation, and HCO3.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of patient reports, reference ranges in the laboratory procedure manual and interview, the laboratory failed to ensure the test report included normal ranges as determined by the laboratory. Findings: 1. Review of the patient reports from the EMR revealed 10 of 10 analytes for arterial blood gas did not include reference ranges. 2. Review of the procedure manual found that the patient report contains results for two analytes not listed in the procedure manual as reported values: HCO3, and Base Excess (BE). 3. Interview with the GS 5/20/21 at 2:35 p.m. confirmed, the laboratory failed to ensure the test report included normal ranges as determined by the laboratory.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on the review of the job description policy, validation documentation of the ABL 80 analyzer, patient test results and interview, the laboratory director failed to ensure that the ABL 80 test system provided quality laboratory services prior to use in patient testing. Findings: 1. Review of the policy "Job Description 2020" revealed

	under laboratory director (LD) job description #5: Ensure selection of quality test systems relevant to: a) Accuracy b) Precision c) Verification d) Method Selection 2. Item #5 was not listed as a delegated duty and remained the responsiblity of the LD. 3. Review of the ABL 80 analyzer test verification documentation found it was signed only by Technical Supervisor #2 with the designation below the signature as Medical Director. 4. Review of the patient test logs found 10 patients reports released from 4/1 /21 to 5/20/21. 5. Interview with the GS on 5/20/21 at 2:35 p.m. confirmed, the laboratory director failed to ensure that the ABL 80 test system provided quality laboratory services prior to use in patient testing.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on the review of the procedure for the ABL 80 Flex Co-Ox and interview, the laboratory director failed to ensure an approved procedure for the ABL 80 Flex Co-Ox was signed by the laboratory director before used for patient testing. 1. Review of the procedure "ABL 80 Flex Co-Ox" found that it had been signed by the CEO, Board Member and Respiratory Therapy Director, but not by the laboratory director. 2. Interview with the GS on 5/20/21 at 2:35 p.m. confirmed, the laboratory director failed to ensure an approved procedure for the ABL 80 Flex Co-Ox was signed by the laboratory director before used for patient testing.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Review of CMS 209 personnel form, CMS116 test lists, job description policy and staff interview revealed that the laboratory director failed to specify, in writing, the duties and responsibilities of the technical consultant. 1. Review of the CMS 209 revealed the GS also served as the technical consultant (TC). 2. Review of the CMS 116 test lists found moderate complexity testing was performed in microbiology, diagnostic immunology, chemistry and hematology. 3. Review of the laboratory

	policy "Job Decription 2020" found no entry for the qualifications and responsibilities of the Technical Consultant. 4. Interview with the GS on 5/20/21 at 11:45 a.m. confirmed, the laboratory director failed to specify, in writing, the duties and responsibilities of the technical consultant.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on the review of 2021 ABL 80 Flex Co-Ox training records, test report records, and interview, the technical consultant failed to ensure 4 of 4 moderate complexity testing personnel received appropriate training for the ABL 80 Flex Co-Ox instrument prior to performing patient testing. Findings: 1. Training documentation in the use of the ABL 80 Flex Co-Ox system for blood gas pO2, pCO2, HCO3, pH, SaO2, CO Hb, and Met Hb for 4 of 4 moderate complexity testing personnel had no technical consultant signature. 2. Test report records revealed 10 patient reports since 4/1/21. 3. Interview with the GS on 5/20/21 at 2:35 p.m.confirmed, the technical consultant failed to ensure 4 of 4 moderate complexity testing personnel received appropriate training for the ABL 80 Flex Co-Ox instrument prior to performing patient testing.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: The Technical Supervisor (TS) of immunohematology failed to provide supervision in accordance with 493.1451. See D6117, D6118, D6119 and D6123.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of 5/16/19 to 3/16/21 quality control logs and interview, the TS for immunohematology failed to ensure analytical performance was maintained at acceptable levels. Findings: 1. No documentation of review by the TS for immunohematology of quality control logs were available for 5/16/19 to 3/16/21. All

	available documentation showed review with dates of 5/15/19 or earlier. Review documentation resumed dated as 3/17/21 2. Interview with GS on 5/20/21 at 10:30 a. m. confirmed, the TS for immunohematology failed to ensure analytical performance was maintained at acceptable levels.
D6118	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5) The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on review of 10/24/19 to 3/16/21 patient testing logs and interview, the TS for immunohematology failed to ensure remedial actions were taken whenever testing deviated from established performance. Findings: 1. No documentation of review by the TS for immunohematology of patient testing logs were available for the time period of 10/24/19 to 3/16/21. All available documentation showed review with dates of 10/23/19 or earlier. Review documentation resumed dated as 3/17/21 2. Interview with GS on 5/20/21 at 10:30 a.m. confirmed, the TS for immunohematology failed to ensure remedial actions were taken whenever testing deviated from established performance.
D6119	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(6) The technical supervisor is responsible for ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly. This STANDARD is not met as evidenced by: Based on review of 10/24/19 to 3/16/21 patient testing logs and interview, the TS for immunohematology failed to ensure that patient results are not reported until all corrective actions are taken. Findings: 1. No documentation of review by the TS for immunohematology of patient testing logs were available for the time period of 10/24 /19 to 3/16/21. All available documentation showed review with dates of 10/23/19 or earlier. Review documentation resumed dated as 3/17/21. 2. Interview with GS on 5/20 /21 at 10:30 a.m. confirmed, the TS for immunohematology failed to ensure that patient results are not reported until all corrective actions are taken.
D6123	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of 4/2/19 to 5/20/21 patient testing logs and interview, the TS for immunohematology failed to review intermediate test results for the 2020 competency

	evaluation for 3 of 3 high complexity test personnel performing immunohematology patient testing. Findings: 1. No documentation of review by the TS for immunohematology of patient testing logs were available for the time period of 10/24 /19 to 3/16/21. All available documentation showed review with dates of 10/23/19 or earlier. Review documentation resumed dated as 3/17/21. 2. Interview with GS on 5/20 /21 at 10:30 a.m. confirmed, the TS for immunohematology failed to review intermediate test results for the 2020 competency evaluation for 3 of 3 high complexity test personnel performing immunohematology patient testing.