Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D2298413	10/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Clinton County Ems	1501 S Jackson Street, Frankfort, IN	

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
D0000	A initial survey was completed on 10-7-2024. The following condition level deficiencies existed: Condition Not Met:: 1. 42 CFR 493.1250 Analytical Systems 2. 42 CFR 493.1409 Technical Consultant- Moderate Complexity 3. 42.CFR 493.1421 Laboratory Testing Personnel
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on lack of documentation, record review and interview the laboratory failed to meet the following analytic system requirements: the laboratory's policy and procedure manual failed to include daily testing of control material and calibration verification procedures for four of four instruments (Abbott I-Stat 1- serial numbers 436917,436920,436992,and 437278) and twelve of twelve analytes (sodium (Na), potassium (K), chloride (Cl), total carbon dioxide (TCO2), ionized calcium (iCa), blood urea nitrogen (BUN), creatinine (Crea), hematocrit (HCT), hemoglobin (Hgb), potential of hydrogen (pH),Glucose(g) and partial pressure of carbon dioxide (PCO2)) tested (Refer to D5403); the laboratory failed to perform two control materials of different concentrations at least once daily for four of four patients (Pt#1-Pt#2) tested (refer to D5447); the laboratory failed to test one sample of control material each 8 hours of testing using a combination of control materials the include both low and high values on each day of testing for three of four patients (Pt#1, PT#2, and Pt#4) tested receiving blood gas testing (pH, pO2, and pCO2) (Refer to D5537); and the

	laboratory failed to have a written policy or procedure for an ongoing mechanism to monitor, assess, and correct problems in the analytic system from 9-10-2024, when patient testing started, to 10-7-2024, the date of the survey (Refer to 5791).
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 on lack of documentation, record review and interview, the laboratory's policy and procedure manual failed to include daily testing of control material and calibration verification procedures for four of four instruments (Abbott I-Stat 1- serial numbers 436917,436920,436992,and 437278) and fourteen of fourteen analytes (sodium (Na), potassium (K), chloride (Cl), total carbon dioxide (TCO2), ionized calcium (iCa), blood urea nitrogen (BUN), creatinine (Crea), hematocrit (HCT), hemoglobin (Hgb), potential of hydrogen (pH), Glucose (glu), oxygen partial pressure of oxygyn (PO2), and partial pressure of carbon dioxide (PCO2)) tested on four of four patients (Pt#1-Pt#4) reviewed. Findings include: 1. Review of the Clinical Laboratory Improvement Amendments (CLIA) application for Certification FORM CMS 116, signed by the laboratory director on 10-7-2024, the laboratory was performing the following moderate complex tests using the I-Stat 1: Na, K, Cl, TCO2, iCa, BUN, Crea, HCT, Hgb, pH, glu, PO2, and PCO2. 2. Upon request for policies and procedures for the laboratory on 10-7/2024 at 12:30pm, SP-01 (Testing personnel) provided the procedure," I-Stat-1", with no approval by the laboratory director. The procedure had no requirements for external quality control material or calibration verification. 3. In the interview on 10-7- at 12:30 pm, SP-01 (testing personnel) confirmed the internal simulator testing was the daily control for patient testing and no external quality control was performed. In interview with SP-01 on 10-7-2024 at 11:52 am SP-01 provided validation studies approved by Abbott diagnostics for the I-Stat-1 devices signed by the laboratory director on 9-11-2024. 4. Medical record review indicated four patients were tested using the I-Stat 1. Patients Date Test Results Pt#1 9-10-2024 pH=7.492 PC02=33.9 mmHg P02=56 mmHg TC02=27mmol /L Na=137 mmol/L K= 4.6 mmol/L iC=1.17 mmol/L Glu= 84 mg/dL Hct= 33 %PCV Hgb= 11.2 g/dL Pt#2 9-11-2024 pH= 7.351 PCO2= 35.2 mmHg PO2= 28 mmHg TCO2= 21 mmol/L Na= 140 mmol/L K= 3.1 mmol/L iCa= 1.52 mmol/L Glu= 138 mg

	/dL Hct= 37 %PCV Hgb= 12.6 g/dL Pt#3 9-11-2024 Na= 139 mmol/L K=3.6 mmol/L Cl= 108 mmol/L iCa= 1.17 mmol/L TCO2= 18 mmol/L Glu= 98 mg/dL BUN= 8 mg /dL Crea= 0.6 mg/dL Hct= 42 %PCV Hgb= 14.3 g/dL Pt#4 9-18-2024 pH= 7.097 PCO2= 59.6 mmHg PO2= 72 mmHg TCO2= 20 mmol/L Na= 141 mmol/L K= 4.2 mmol/L iCa= 1.24 mmol/L Glu= 129 mg/dL Hct= 33 %PCV Hgb= 11.2 g/dL 5. Annual test volume for routine chemistry and hematology is 8,000
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on interview and record review, the laboratory failed to include two control materials of different concentrations at least once daily for four of four patients (Pt#1-Pt#4) tested. Findings Include: 1.Medical record review indicated four patients were tested using the I-Stat 1 without performing external quality control: Patients Date Test Results Pt#1 9-10-2024 Na=137 mmol/L K= 4.6 mmol/L iC=1.17 mmol/L Glu= 84 mg/dL Hct= 33 %PCV Hgb= 11.2 g/dL Pt#2 9-11-2024 Na= 140 mmol/L K= 3.1 mmol/L iCa= 1.52 mmol/L Glu= 138 mg/dL Hct= 37 %PCV Hgb= 12.6 g/dL Pt#3 9-11-2024 Na= 139 mmol/L K=3.6 mmol/L Cl= 108 mmol/L iCa= 1.17 mmol/L Glu= 98 mg/dL BUN= 8 mg/dL Crea= 0.6 mg/dL Hct= 42 %PCV Hgb= 14.3 g/dL Pt#4 9-18-2024 Na= 141 mmol/L K= 4.2 mmol/L iCa= 1.24 mmol/L Glu= 129 mg/dL Hct= 33 %PCV Hgb= 11.2 g/dL 2. In an interview on 10-7-23 at 12:11pm, SP-01 (testing personnel) confirmed the laboratory had not performed external quality control since the I stat validation completed on 6-21-2024. Last documented liquid quality control was run on 6-21-2024 3. Annual test volume for routine chemistry and hematology is 8,000
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on interview and record review, the laboratory failed to test one sample of control material each 8 hours of testing using a combination of control materials the include both low and high values on each day of testing for four of four patients (Pt#1-Pt#4) tested receiving blood gas testing (pH, pO2, pCO2, and TCO2). Findings Include: 1.Medical record review indicated four patients were tested using the I-Stat 1 without performing external quality control: Patients Date Test Results Pt#1 9-10-2024 pH=7.492 PC02=33.9 mmHg P02=56 mmHg TC02=27mmol/L Pt#2 9-11-2024 pH= 7.351 PCO2= 35.2 mmHg PO2= 28 mmHg TCO2= 21 mmol/L Pt#3 9-11-2024 TCO2= 18 mmol/L Pt#4 9-18-2024 pH= 7.097 PCO2= 59.6 mmHg PO2= 72 mmHg

	TCO2= 20 mmol/L 2. In an interview on 10-7-23 at 12:11pm, SP-01 (testing personnel) confirmed the laboratory had not performed external quality control since the I stat validation completed on 6-21-2024. Last documented liquid quality control was run on 6-21-2024 3. Annual test volume for routine chemistry is 7,000
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on lack of documentation, record review and interview, the laboratory failed to have a written policy or procedure for an ongoing mechanism to monitor, assess, and correct problems in the analytic system from 9-10-2024, when patient testing started, to 10-7/2024, the date of the survey. Findings Include: 1. Review of the Clinical Laboratory Improvement Amendments (CLIA) application for Certification FORM CMS 116, signed by the laboratory director on 10-7-2024, the laboratory was performing the following moderate complex tests using the I-Stat 1: Na, K, Cl, TCO2, iCa, BUN, Crea, HCT, Hgb, pH, Glucose and PCO2. 2. Medical record review indicated four patients were tested using the I-Stat 1. Patients Date Test Results Pt#1 9-10-2024 pH=7.492 PC02=33.9 mmHg P02=56 mmHg TC02=27mmol/L Na=137 mmol/L K= 4.6 mmol/L iC=1.17 mmol/L Glu= 84 mg/dL Hct= 33 %PCV Hgb= 11.2 g/dL Pt#2 9-11-2024 pH= 7.351 PCO2= 35.2 mmHg PO2= 28 mmHg TCO2= 21 mmol/L Na= 140 mmol/L K= 3.1 mmol/L iCa= 1.52 mmol/L Glu= 138 mg/dL Hct= 37 %PCV Hgb= 12.6 g/dL Pt#3 9-11-2024 Na= 139 mmol/L K=3.6 mmol/L Cl= 108 mmol/L iCa= 1.17 mmol/L TCO2= 18 mmol/L Glu= 98 mg/dL BUN= 8 mg/dL Crea= 0.6 mg/dL Hct= 42 %PCV Hgb= 14.3 g/dL Pt#4 9-18-2024 pH= 7.097 PCO2= 59.6 mmHg PO2= 72 mmHg TCO2= 20 mmol/L Na= 141 mmol/L K= 4.2 mmol/L iCa= 1.24 mmol/L Glu= 129 mg/dL Hct= 33 %PCV Hgb= 11.2 g/dL 3. Upon request for policies and procedures for the laboratory on 10-7-2024 at 11:52 am, SP-01 provided the procedure," I-Stat-1", with no approval by the laboratory director. The procedure did not require any ongoing monitoring or assessing of laboratory or how to correct problems in the analytic system. 4. In an interview on 10-7-24 at 12:30 pm, SP-01 confirmed the laboratory did not have a program in place to monitor, assess and correct problems in the laboratory. 5. Annual test volume for routine chemistry and hematology is 8,000
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure one of one personnel (SP-2) listed on the "Laboratory Personnel Report (CLIA)" CMS FORM 209 as a Technical Consultant was qualified to fulfill the position as technical

	consultant to oversee moderate complex testing from 9-10-2024, when patient testing started, to 10-7-2024, the date of the survey (Refer to D6035).
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) 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; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed ensure one of one personnel (SP-2) listed on the "Laboratory Personnel Report (CLIA)" CMS FORM 209 as a Technical Consultant was qualified to fulfill the position as technical consultant to oversee moderate complex testing from 9-10-2024, when patient testing started, to 10-7-2024, the date of the survey. Findings include: 1. The "Laboratory Personnel Report (CLIA) CMS FORM 209", signed by the laboratory director (SP-2) on 10-7-24, indicated SP-2 was the Technical Consultant for Routine Chemistry and Hematology. 2. Personnel file review for SP-2 confirmed they had an Indiana license as a physician, but there was no documentation of at least 1 year laboratory experience or training in nonwaived testing for Routine Chemistry and Hematology. 3. Medical record review indicated four patients were tested using the iStat 1. Patients Date Test Results Pt#1 9-10-2024 pH=7.492 PC02=33.9 mmHg P02=56 mmHg TC02=27mmol/L Na=137 mmol/L K= 4.6 mmol/L iC=1.17 mmol/L Glu= 84 mg/dL

	Hct= 33 %PCV Hgb= 11.2 g/dL Pt#2 9-11-2024 pH= 7.351 PCO2= 35.2 mmHg PO2= 28 mmHg TCO2= 21 mmol/L Na= 140 mmol/L K= 3.1 mmol/L iCa= 1.52 mmol/L Glu= 138 mg/dL Hct= 37 %PCV Hgb= 12.6 g/dL Pt#3 9-11-2024 Na= 139 mmol/L K=3.6 mmol/L Cl= 108 mmol/L iCa= 1.17 mmol/L TCO2= 18 mmol/L Glu= 98 mg/dL BUN= 8 mg/dL Crea= 0.6 mg/dL Hct= 42 %PCV Hgb= 14.3 g/dL Pt#4 9-18-2024 pH= 7.097 PCO2= 59.6 mmHg PO2= 72 mmHg TCO2= 20 mmol/L Na= 141 mmol/L K= 4.2 mmol/L iCa= 1.24 mmol/L Glu= 129 mg/dL Hct= 33 %PCV Hgb= 11.2 g/dL 4. In an interview on 10-7-2024 at 1:45 pm, SP-01(testing personnel) confirmed SP-2 did not have 1 year experience or training in nonwaived testing for Routine Chemistry and Hematology. 5. Annual test volume for routine chemistry and hematology is 8,000
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure two of two testing personnel (SP-03 and SP-08) met the qualifications including received training on the Abbot I-Stat 1 prior to performing testing on four of four patients (Pt-1 to Pt-4) from 9-10-2024, when patient testing started, to 10-7-2024, the date of the survey (Refer to D6066).
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on lack of documentation, record review and interview, the laboratory failed to perform and document training for two of eleven testing personnel (Sp-03, SP-08) prior to performing moderate complexity testing using the Abbott I-Stat 1 on four of four patients (Pt-1 to Pt-4) from 9-10-2024, when patient testing started, to 10-7-2024, the date of the survey. Findings Include: 1. Personnel file review indicated SP-01, SP-03 to SP-12 did not have documentation of training on Abbot I-Stat 1. 2. In an interview on 10-7-23 at 1:13 pm, SP-01 confirmed personnel never received training prior to analyzing patient testing. 3. Upon request for policies and procedures for the laboratory on 10-7/2024 at 11:52 am, SP-01 (testing personnel) provided the procedure ," I-Stat-1", with no approval by the laboratory director. The procedure did not require documentation of training or personnel competency. 4. Review of patient records indicated the following patients reviewed had testing performed using the Abbot I-Stat 1: Patients Date Test Results Pt#1 9-10-2024 pH=7.492 PC02=33.9 mmHg P02=56 mmHg TC02=27mmol/L Na=137 mmol/L K= 4.6 mmol/L iC=1.17 mmol/L Glu= 84 mg/dL Hct= 33 %PCV Hgb= 11.2 g/dL Testing Person: SP-08 Pt#2 9-11-2024 pH= 7.351 PCO2= 35.2 mmHg PO2= 28 mmHg TCO2= 21 mmol/L Na= 140 mmol/L K= 3.1 mmol/L iCa= 1.52 mmol/L Glu= 138 mg/dL Hct= 37 %PCV Hgb= 12.6 g/dL Testing Person: SP-08 Pt#3 9-11-2024 Na= 139 mmol/L K=3.6 mmol

	/L Cl= 108 mmol/L iCa= 1.17 mmol/L TCO2= 18 mmol/L Glu= 98 mg/dL BUN= 8 mg/dL Crea= 0.6 mg/dL Hct= 42 %PCV Hgb= 14.3 g/dL Testing Person: SP-03 Pt#4 9-18-2024 pH= 7.097 PCO2= 59.6 mmHg PO2= 72 mmHg TCO2= 20 mmol/L Na= 141 mmol/L K= 4.2 mmol/L iCa= 1.24 mmol/L Glu= 129 mg/dL Hct= 33 %PCV Hgb= 11.2 g/dL Testing Person: SP-03 5. Annual test volume for routine chemistry and hematology is 8,000