Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1053355	11/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Marion Diagnostic Center L L C	3003 Civic Circle Blvd, Marion, IL	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, lack of documentation, and interview with the laboratory representative; the laboratory failed to ensure attestation statements were completed for six of six PT events for Chem 8+ testing on the i-STAT analyzer in 2022 and 2023. Findings Include: 1. Review of the American Proficiency Institute (API) PT records for 2022 and 2023 revealed a lack of attestation statements for six of six routine chemistry events in 2022 and 2023, including the eight regulated analytes listed below. Regulated Chem 8+ analytes: Chloride, Creatinine, Glucose, Potassium, Sodium, Urea Nitrogen (BUN), Hematocrit, and Hemoglobin 2. On survey date 11/29/2023, at 12:59 pm, an interview with the laboratory representative confirmed these findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory records, lack of documentation, and interview with the laboratory representative; the laboratory failed to have a competency policy

	/procedure in place to assess employee competency on the i-STAT analyzer used for Chem 8+ cartridges (testing Sodium, Potassium, Chloride, Glucose, Calcium, Total Carbon Dioxide, BUN, Creatinine, Hematocrit, and calculated Anion Gap and Hemoglobin) as required per 493.1235. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the lack of a competency assessment policy/procedure in place as required per 493.1235. 2. On survey date 11-29-2023, at 9:42 am, the laboratory representative confirmed the laboratory failed to have a competency policy/procedure in place to assess employee competency.
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 record review and an interview with the laboratory representative; a) the laboratory's policy/procedure for the Chem 8+ testing on the i-STAT analyzer and b) the laboratory's Quality Control Plan (QCP) failed to meet the requirements of paragraph (b)(1) through (b)(12) of section 493.1251. Findings: 1. Review of the laboratory's policy/procedure for the Chem 8+ testing on the i-STAT analyzer and the laboratory's Quality Control Plan (QCP) showed no reference to the manufacturer's instructions or the laboratory's own developed procedure for the following: a. patient preparation; specimen collection; labeling storage, preservation, transportation, processing, and referral; nor criteria for specimen acceptability and rejection. b. control procedures, including corrective action to take when control results fail to meet the laboratory's criteria for acceptability. c. reference to a calibration verification procedure, frequency, and corrective action to take when calibration verification results fail to meet the laboratory's criteria for acceptability. d. limitations in the test methodology, including interfering substances. e. reference to the laboratory's system for entering results in the patient record and reporting patient results. f. a description of the course of action to take if a test system becomes inoperable. 2. Interview with the laboratory representative at 12:59 pm on 11/29/2023 confirmed these findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)

	Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with the laboratory representative; the laboratory failed to perform calibration verifications every six months, as required per 493.1255, for i-STAT Chem 8+ testing (Sodium, Potassium, Chloride, Glucose, Calcium, Total Carbon Dioxide, BUN, Creatinine, and Hematocrit) in 2021 through 2023. Findings Include: 1. The calibration verification records for the i-STAT Chem 8+ cartridges on the i-STAT analyzer (Serial Number: 332957) identified calibration verifications were not performed since 2020. 2. Upon the tour of the facility on 11/29/2023, at 9:38 am, the laboratory representative stated calibration verification materials and an external stimulator are to be ran every six months, but they had just recently been made aware of this. 3. Review of the laboratory's "Problem / Corrective Action Log" revealed the laboratory representative had made a log entry on 11/22/2023 which stated: "i-STAT - Chem 8 - unaware that verification controls needed to be ran every 6 months....made aware of this on 11/22 /23...." 4. On a survey conducted on 11/29/2023 at 12:59 pm, the laboratory representative confirmed the above findings.
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 review of laboratory records and interview with the laboratory

	representative; the laboratory failed to include all the required components of a laboratory test report including a) the facility's address for four of eight i-STAT Chem 8+ test reports and b) the reference range for two of eight i-STAT Chem 8+ test reports reviewed, as required by 493.1291. Findings Include: 1. Upon review patient test reports, four of eight patient test reports (32681, 64618, 38795, and 35583) for Chem 8+ testing on the i-STAT analyzer found the laboratory failed to indicate the facility address on the laboratory's test report. 2. Review of two of eight patient test reports (64618 and 38795) for Chem 8+ testing on the i-STAT analyzer found the laboratory failed to indicate the Chem 8+ analytes (Sodium, Potassium, Chloride, Glucose, Calcium, Total Carbon Dioxide, BUN, Creatinine, Hematocrit, Anion Gap and Hemoglobin) reference ranges on the laboratory's test report. 3. On survey date 11-29-2023, at 12:59 pm, the laboratory representative confirmed these findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of employee competency assessments and interview with the laboratory representative; the laboratory failed to have competency assessments performed by a qualified technical consultant for two of three individuals responsible for moderate complexity Chem 8+ cartridge testing on the i-STAT analyzer at least semiannually during the first year the individuals tested patient specimens as per 493. 1413. Findings: 1. Upon record review, two of three testing personnel (TP)'s competency assessments in their first year of testing patient specimens were not performed by a qualified technical consultant. Testing Personnel: Individual performing competency: TP #2 TP #1 TP #3 TP #1 2. An interview with the laboratory representative at 9:38 am on 11/29/2023 confirmed these findings.