Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1069404	03/04/2022
Name of Provider or Supplier	**Street Address, City, State**	
98 Point 6 Emergicenter	1540 Lake Lansing Road Suite 203, Lansing, MI	

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
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager (OM), the laboratory failed to have test requests for Covid-19 PCR, chemistry (chem lab), and /or white blood cell (WBC) count for 3 (#6, #16, #27) of 41 patient charts audited. Findings include: 1. A review of patient test requests revealed a lack of a request from an authorized person for the following testing completed: a. patient #6 - no orders for the Covid-19 PCR testing performed on 8/21/2021 b. patient #16 - no orders for the chem lab testing performed on 11/16/2021 c. patient #27 - no order for the WBC testing performed on 10/20/2021 2. An interview on 2/28/2022 at 1:46 pm, the OM confirmed the above patients did not have an order for testing from an authorized person.
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:

	. The laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to perform control procedures each day of patient testing for the chemistry i-stat chem8+ cartridge. Refer to D5445.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on lack of documentation and interview with the Office Manager (OM), the laboratory failed to perform and document the daily refrigerator temperature for 26 days (January 1-25 and February 5, 2022) of 2 years of documents reviewed. Findings include: 1. A record review of the "Refrigerator Temperature Logs" revealed lack of documentation of the refrigerator temperature being performed and documented for 26 days (January 1-25 and February 5, 2022) of 2 years of documents reviewed. 2. An interview on 2/28/2022 at 12:50 pm, the OM confirmed there was no documentation for the 26 days in January and February 2022 not recorded on the temperature log.
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 record review and interview with the Office Manager (OM), the laboratory failed to perform quality control each day of patient testing for the chemistry i-Stat (chem8+ cartridge) for 23 (March 2020 to February 2022) of 24 months in use. Findings include: 1. A record review of the quality control documents revealed the laboratory was performing the quality control on each new lot/shipment and then every 30 days with the following months missing and the approximate number of patients tested: 2020 a. March - 46 patients tested b. May - 18 patients tested c. July - 20 patients tested d. August - 20 patients tested e. September - 23 patients tested f. October - 25 patients tested g. November - 25 patients tested h. December - 7 patients tested 2021 a. May - 46 patients tested b. June - 66 patients tested c. August - 52 patients tested d. October - 32 patients tested e. November - 24 patients tested f. December - 15 patients tested 2. When queried on 2/28/2020 at 11:53 am, the OM informed the surveyor that during the transition of the chem8+ cartridge from waived testing to moderate complex testing that the old method of quality control carried forward. 3. A interview on 2/28/2022 at 11:53 am, the OM confirmed two different

	levels of external controls had not been performed each day of testing for the i-Stat and that an individualized quality control plan (IQCP) had not been implemented to decrease the number or frequency of running external controls.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager (OM), the laboratory failed to document corrective action for improper temperature of the refrigerator that stores the hematology HemoCue controls for 18 days (January 1-2, 7-8, 11, 14-27, 2022) of 2 years reviewed. Findings include: 1. A record review of the "Refrigerator Temperature Logs" revealed for 18 days (January 1-2, 7-8, 11, 14-27, 2022) of 2 years reviewed the temperature readings were below the optimal "range 2-8 degree C" and no corrective action was documented. 2. A interview on 2/28/2022 at 12:50 pm, the OM confirmed that no corrective action was documented for the refrigerator temperatures out of the stated range.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager (OM), the laboratory failed to maintain a record system that included the identity of the testing personnel on the final laboratory report for 1 (#15) of 41 patient charts audited. Findings include: 1. A record review for 1 (#15) of 41 patient charts revealed the identity of the testing personnel was not recorded on the final report generated from the laboratory information system (LIS) for the date of service. 2. A interview on 2/22/2022 at 1:46 pm, the OM confirmed the testing personnel failed to enter their initials into the LIS for the laboratory testing performed.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager (OM), the laboratory director failed to monitor the quality assessment procedure to monitor preanalytic, analytic, and postanalytic systems in the established Individualized Quality Control Plan (IQCP) for 2 (February 2021 to February 2022) of 2 years reviewed. Findings include: 1. A record review of the laboratory's established IQCP revealed a lack of quality assessment procedures to monitor, assess, review, and correct problems identified for the HemoCue White Blood Cell (WBC) count testing for 2 (February 2021 to February 2022) of 2 years reviewed. 2. An interview on 2/28/2022 at 1:16 pm, the OM confirmed the laboratory director did not monitor the quality assessment plan on a routine basis.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager (OM), the laboratory failed to ensure the white blood cell (WBC) counts were accurately entered into the laboratory information system (LIS) from the patient testing log for 2 (#23 and #29) of 12 patient charts reviewed. Findings include: 1. A record review of the manually transcribed WBC results into the LIS revealed for 2 (#23 and #29) of 12 patient charts reviewed, the WBC result was transcribed into the LIS system incorrectly as follows: a. #23 - should be 6.3 entered as 6.8 from 02/03/2021 b. #29 - should be 7.5 entered as 7.2 from 02/22/2022 2. A interview on 2/28/2022 at 1:46 pm, the OM confirmed the manually transcribed WBC results for patient #23 and #29 had an incorrect result reported out.
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 with the Office Manager (OM), the laboratory failed to ensure Testing Personnel #1 performing the duties of a Technical Consultant, met the qualification requirements at 493.1411. Findings include: 1. The laboratory failed to ensure the personnel performing the Technical Consultant duty of performing testing personnel competency assessments was qualified. 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 with the Office Manager (OM), the laboratory failed to ensure personnel performing the Technical Consultant (TC) duty of performing personnel competency assessments was qualified for 19 (Testing Personnel (TP) #2 - #20) of 20 personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's personnel competency records revealed TP #1 had performed competency assessments for the following testing personnel: a. TP#2 - 9/15/2020 and 9/17/2021 b. TP#3 - 3/23/2021 and 10/2/2021 c. TP#4 - 3/11/2021 and 10/11/2021 d. TP#5 - 4/30/2021 and 11/23/2021 e. TP#6 - 12/01/2020 and 7/05/2021 f. TP#7 - 9/20/2021 g. TP#8 - 4/10/2020 and 6/20/2021 h. TP#9 - 2/28/2021 i. TP#10 - 3/02/2020, 9/30/2020, and 10/20/2021 j. TP#11 - 12/01/2021 k. TP#12 - 10/15/2020 and 4/15/2021 l. TP#13 - 6/11/2020 and 6/27/2021 m. TP#14 - 9/17/2020 and 10/21 /2021 n. TP#15 - 11/25/2020, 7/29/2020 and 8/01/2021 o. TP#16 - 11/18/2020 and 6 /08/2021 p. TP#17 - 11/07/2021 q. TP#18 - 10/15/2021 r. TP#19 - 10/23/2020 and 7 /03/2021 s. TP#20 - 10/25/2021 2. A review of the qualifications for TP #1 revealed they did not meet the qualification requirements to perform Technical Consultant responsibilities. 3. The laboratory was provided 7 days to supply documentation and it

	was not made available. 4. An interview on 2/28/2022 at 10:47 am with OM, confirmed TP #1 did not meet the qualification requirements to be a Technical Consultant.