Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D1062383	02/28/2019
Name of Provider or Supplier	**Street Address, City, State**	
Northwest Medical Plaza At Sugar Creek	1102 Nw Lowes Ave Suite 2, Bentonville, AR	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Through observation, lack of documentation and interview it was determined the laboratory failed to monitor room temperature in one of two rooms in which supplies with storage temperature requirement were stored. Findings follow: A. In a tour of the laboratory on 2/28/19 at approximately 11:00 AM, one box of Sofia Strep A test kit lot # 704843 with an expiration date of 2020-09-30 storage temperature requuirement of 15 degrees C. to 30 degrees C. and three boxes of Para-Pak C&S transport media lot # 24850K, expiration date 2020-02 and storage temperature requirement of 2 degrees C. to 30 degrees C. were observed stored in a nursing station area separate from the laboratory . C. Upon request, the laboratory was unable to provide records of room temperature in the nursing station area. D. In an interview on 2/28/19 at approximately 11:15 AM, the Laboratory Manager, identified on a separate personnel identification record, stated that the laboratory did not monitor the room temperature in the nursing station area identified above.
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: Through review of quality control results, the data log for the Medonic hematology analyzer, patient result reports, lack of documentation, and interview it was determined that the laboratory failed to document quality control results prior to reporting moderately complex Complete Blood Cell (CBC) assays on two of twenty-one days of testing in November 2018. Findings follow: A. Review of quality control reports for November 2018 revealed that no quality control results were reported for CBC assays on November 4, 2018 or November 23, 2018. B. Review of the Medonic hematology analyzer data log listing revealed that CBC assays were performed and reported on a patient identified as number 1 on the "patient identification list I" on November 4, 2018 and on a patient identified as number 2 on the "patient identification list I" on November 23, 2018 and no quality control results were included on both days . C .Review of patient reports revealed that CBC assays were performed and reported on a patient identified as number 1 on the "patient identification list I" on November 4, 2018 and on a patient identified as number 2 on the "patient identification list I" on November 23, 2018 . D. Upon request, the laboratory could not produce quality control results for CBC assays on November 4, 2018 or November 23, 2018 E. In an interview on 11/28/19 at approximately 11:15 AM, the laboratory manager, identified on the separate laboratory employee identification record, confirmed that quality control results were not documented for CBC assays on November 4, 2018 and November 23, 2018.
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: Through a review of the form CMS-209, review of authorizations to test, a review of competency assessments for 2017 and 2018, lack of documentation and interview with laboratory staff, it was determined the technical consultant failed to evaluate the competency of one of three testing personnel. Survey findings follow: A. The CMS-209 form completed for the survey reveals three testing personnel employed by the laboratory. B. Review of authorizations to test reveal that the testing personnel, identified as number four on the CMS 209 form, was authorized by the laboratory director to perform testing on April 2017. C. Review of competency evaluations for 2017 and 2018 revealed that competency evaluations were not present for the testing personnel identified as number four on the CMS 209 form. D. Upon request, the laboratory was not able to produce competency evaluations for the testing personnel identified as number four on the CMS 209 form. E. In an interview on 2/28/29 at approximately 11:15 AM the laboratory manager, identified on a separate personnel

	identification record, confirmed that competency evaluations were not available for the testing personnel identified as number four on the CMS 209 form.