Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0652268	08/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Northwest Medical Center	705 N College St, Albany, MO	

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: Based on review of manufacturer's instructions, documentation of freezer temperatures, observation of quality control (QC) material stored in the freezer and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for storage of control material for 2 of 44 testing days. Findings: 1. Review of the manufacturer's instructions for Bio-Rad liquid unassayed Multiqual control showed controls must be stored at minus 20 degrees Celsius (C) to minus 70 degrees C. 2. Review of the laboratory's temperature chart showed a defined acceptable range of minus 20 degrees C to minus 30 degrees C. On July 9, 2019 and August 3, 2019 the laboratory failed to meet the manufacturer's required minus 20 to minus 70 degree C range. 3. Observation of the laboratory freezer showed 17 boxes of Bio-Rad Multiqual unassayed controls currently in use in the laboratory. 4. Interview with the laboratory manager on August 13, 2019 at 3:00 PM confirmed the laboratory failed to properly monitor the freezer and store QC materials and supplies per manufacturer's instructions.
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 review of the calibration records for the Siemens Dimension chemistry analyzer for the analytes of sodium, potassium, and chloride, and on interview with the laboratory manager which confirmed the laboratory failed to perform at least a three point calibration(a minimal, mid-point, and maximum) verification every six months. Findings: 1. Review calibration records for 2017, 2018 and to date for the Siemens Dimension chemistry analyzer for the analytes: sodium, potassium, and chloride, revealed the laboratory failed to perform a calibration including, at least, a minimal, midpoint, and maximum value for each analyte, every six months. 2. Interview with the laboratory manager on August 13, 2019 at 3:00 PM confirmed the laboratory failed to perform at least a 3 point calibration of the electrolytes on the Siemens Dimension analyzer every six months.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of hematology staining for WBC manual differentials and interview with the laboratory manager the laboratory failed to check staining material each day of use. Findings: 1. Observation of hematology stain showed the laboratory failed to document stain used for manual white blood cell (WBC) differentials on each day of use. 2. Interview with the laboratory manager on August 13, 2019 at 3:00 PM confirmed the laboratory failed to check the staining material on each day of use.
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 review of blood gas controls and interview with the laboratory manager the laboratory failed to perform one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values for one of thirteen days. Findings: 1. Review of i-Stat controls and patient testing showed a patient was resulted on August 9, 2019 and no controls were documented. 2. Interview with the laboratory manager on August 13, 2019 at 3:00 PM confirmed the laboratory failed to perform one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on August 9, 2019.
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 review of chemistry instrument patient printouts and final test reports generated by the laboratory information system (LIS) August 12, 2019 and interview with testing personnel #1, the laboratory failed to ensure the electronic system in place accurately transmitted test results from the point of data entry to final test report destination. Findings: 1. Review of instrument printout for patient (C) printed on August 12, 2019 showed the chemistry instrument obtained an invalid BUN result of 11 mg/dl flagged as "abnl (abnormal) assay" 2. Review of the final report showed the invalid BUN result for patient (C) interfaced with the LIS and reported on August 12, 2019. No documentation was available to show the laboratory repeated the BUN test to obtain and report a valid result. 3. Interview with testing personnel #1 on August 13, 2019 at 10:30 AM confirmed the laboratory failed to have a system in place to detect instrument results flagged as "abnl assay" transmitted to the LIS.
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 coagulation records and two of two selected test reports for August 2019 and interview with the technical supervisor, the laboratory failed to ensure pertinent reference intervals (normal values) as determined by the laboratory were available for patient prothrombin time testing. Findings: 1. Review of coagulation records showed the laboratory established patient prothrombin time normal values of 9.1-12.1 seconds for recombiplastin lot # N0587977 in use since April 2019. 2. Review of patient prothrombin time normal values included on two test report from August 12, 2019 and generated by the laboratory information system (LIS) revealed normal values of 9.7-12.5 seconds. 3. Interview on August 13, 2019 at 11:00 AM, the technical supervisor confirmed the laboratory failed to update normal values for prothrombin time testing in the LIS.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the blood bank quality control (QC) program, QC records for May, June, July 2019, patient blood bank testing and transfusion records for May 2019 and interview with testing personnel # 8, the laboratory director failed to maintain the blood bank QC program. Findings: 1. The blood bank QC program states," Blood bank reagents used for ABO grouping, Rh typing, antibody detection and compatibility determinations must be tested for potency and specificity each day of use, preferably before use, but at least concurrently with first daily (patient) use. Quality control records must fall within stated limits as stated in the QC procedure. All reactions must be documented in the Quality Control Log." 2. Review of QC records for May, June and July 2019 revealed the laboratory did not document blood bank QC on May 14, 2019. Patient records revealed the laboratory performed ABO grouping, Rh typing, antibody detection and compatibility testing for Patient (A) on May 14, 2019. Transfusion records showed Patient (A) received two units of packed red blood cells on May 14, 2019. 3. Interview on August 13, 2019 at 10:00 AM with testing personnel confirmed the laboratory failed to document blood bank QC before or concurrent with patient testing on May 14, 2019. Interview confirmed the QC program did not identify/detect the failure May 14, 2019. Based on review of the chemistry QC program, QC and patient records for August 2019 and interview with the technical supervisor, the laboratory director failed to maintain the chemistry QC program. Findings: 1. The chemistry QC program states, " Two levels of control are run daily, if patient tests are ordered. QC results will be transmitted to the LIS (labortory information system) and stored in designated files. LIS will flag outliers and maintains action log." 2. Review of serum QC1 records generated by the LIS revealed the laboratory obtained three consecutive flagged results for Lipase testing on August 10, 2019. The QC records showed the laboratory obtained a flagged outlier result of 236 at 03:31 AM, obtained a flagged outlier result of 239 U/L at 3:49 AM and obtained a flagged outlier result of 239 U/L at 3:59 AM. The laboratory defined acceptable lipase limts of 216 -232 U/L for serum QC1. The laboratory did not obtain serum QC results within defined limits of acceptablility on August 10, 2019. Review of patient records revealed the laboratory tested and reported one patient lipase result

	on August 10, 2019. 3. Review of QC records for August 11, 2019 revealed the laboratory did not perform two levels of lipase QC Review of patient records revealed the laboratory tested and reported four patient lipase results on August 11, 2019. 4. Review of QC records for August 12, 2019 revealed the laboratory did not perform two levels of lipase QC. Review of patient records revealed the laboratory tested and reported one patient lipase result on August 12, 2019. 5. Interview with the technical supervisor on August 13, 2019 at 10:45 AM confirmed the QC program did not identify/detect the QC failures August, 10, 11 and 12, 2019.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the blood bank quality assessment (QA) program, QC records for 2019 and interview with testing personnel # 8, the laboratory director failed to ensure the written blood bank QA program was maintained and followed. Findings: 1. The blood bank QA program states," QC is performed daily when patient testing is performed. QC results are recorded in the Blood Bank QC logbook. QC results are reviewed monthly by supervisor." 2. Review of QC records revealed the laboratory did not document daily blood bank QC before or concurrent with patient testing on May 14, 2019. (Refer to #D6093) 3. The laboratory did not have documentation to show the supervisor reviewed monthly blood bank QC during 2019. 4. Interview with the technical supervisor on August 13, 2019 at 11:00 AM confirmed the QA program was not maintained and followed to idetify/detect failures in blood bank quality.