Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	17D0046900	09/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Wilson Medical Center	2600 Ottawa Road, Neodesha, KS	

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
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) results and interview with the technical supervisor #1 the laboratory failed to evaluate and document any unsatisfactory PT analyte or test performance. Findings: 1. Review of blood gas PT in 2017 showed event 3 pH was 80% with no evaluation documented. 2. Review of blood gas PT in 2017 showed event 3 pO2 was 80% with no evaluation documented. 3. Interview with the technical supervisor #1 on September 21, 2018 at 11:00 AM confirmed the laboratory failed to evaluate and document 80% blood gas scores in 2017.
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 review of procedure manual, quality control records and interview the laboratory failed to meet the condition: Analytic systems. The laboratory failed to follow procedure manual for blood bank quality control (refer to D5401); failed to follow manufacturer's instructions for ISI value (refer to D5411); failed to calibrate pipettes (refer to D5429); failed to perform sodium, potassium and chloride calibration (refer to D5439); failed to perform quality control each day of testing for Mycoplasma (refer to D5449) and failed to perform blood gas control material every 8 hours of patient testing (refer to D5537)
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of procedures, blood bank quality control (QC) and interview with the technical supervisor #1 the laboratory failed to follow blood bank QC procedure. Findings: 1. Review of blood bank procedure shows "the individual performing blood bank testing on patients will perform the quality control if it has not already been performed for that day." 2. On May 5, 2018, two units of blood were cross matched and no QC was completed. 3. On August 20, 2018 two units of blood were cross matched and no QC was completed. 4. On September 19, 2018 two units of blood were cross matched and no QC was completed. 5. Interview with the technical supervisor #1 on September 21, 2018 at 11:00 AM confirmed the laboratory failed to follow blood bank QC procedure.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of prothrombin time (PT) RecombiPlasTin2G package insert for lot # N0972299, ACL Elite instrument and interview with the technical supervisor #1 the laboratory failed to follow the manufacturer's instructions for ISI value. Findings: 1. Review of the package insert for lot #N097229 defines the ISI at 1.06. 2. Review of the instrument shows the ISI is 1.03. 3. Interview with the technical supervisor #1 on September 21, 2018 at 11:00 AM confirmed the laboratory failed to follow the manufacturer's instructions for the ISI value.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)

	Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of Prothrombin time (PT) and Partial thromboplastin time (PTT) quality control (QC) and interview with technical supervisor #1 the laboratory failed to define acceptable QC ranges. Findings: 1. Placed on a piece of paper attached to the front of the instrument PT level 1 Control range 10-13 and PT level 3 control range 31.3-46.9. 2. Package insert for lot #N1073419 and N0771137 in use PT level 1 control range 9.6-12.6 and PT level 3 control range 26.6-39.8. 3. Placed on a piece of paper attached to the front of the instrument PTT level 1 control range 23.1-31.1 and level 3 control range 45.7-61.9. 4. Package insert for lot #N1073419 and N0771137 in use PTT level 1 control range 23.2-31.2 and level 3 range 48.5-65.6. 5. Interview with the technical supervisor #1 on September 21, 2018 at 11:00 AM confirmed the laboratory failed to define acceptable QC ranges for PT and PTT.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation of MLA pipettes and interview with technical supervisor #1 on September 21, 2018 at 11:30 AM confirmed the laboratory failed to calibrate two MLA pipettes in 2017 to date.
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 chemistry calibration and interview with the technical supervisor #1 on September 21, 2018 at 11:30 AM confirmed the laboratory failed to perform calibration including a minimal (or zero) value, a mid-point value and a maximum value near the upper limit on sodium, potassium and chloride every six months for 2017 to date
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Immunocard Mycoplasma test and interview with the technical supervisor #1 on September 21, 2018 at 11:30 AM confirmed the laboratory failed to perform a positive and negative control each day of patient testing
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 quality control (QC) and interview with testing personnel #3 the laboratory failed to test one sample of control material each 8 hours of patient testing using a combination of control materials that include both low and high values on each day of testing. Findings: 1. Review of blood gas patients showed since May 1, 2018 to date 75 patients were reported out. Review of blood gas QC showed controls were performed 3 times in 2018. 2. Interview with testing personnel #3 on September 21, 2018 confirmed the laboratory failed to test one sample of control material each 8 hours of patient testing using a combination of control materials that include both low and high values on each day of testing.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance

	with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of procedures, quality control program, calibration and interviews the director failed to provide overall management and direction: failed to maintain quality control program (refer to D6093); failed to ensure the establishment and maintenance of acceptable levels of analytical performance (refer to D6095) and failed to ensure that an approved procedure manual is available (D6106).
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 blood bank quality control, blood gas quality control (QC), protime QC and interview with the technical supervisor #1 and testing personnel #3 the laboratory director failed to ensure QC is maintained to assure the quality of laboratory services provided. Findings: 1. Review of blood bank procedure shows "the individual performing blood bank testing on patients will perform the quality control if it has not already been performed for that day." On May 5, 2018, two units of blood were cross matched and no QC was completed. On August 20, 2018 two units of blood were cross matched and no QC was completed. On September 19, 2018 two units of blood were cross matched and no QC was completed. 2. Blood gas QC material must be performed each 8 hours of patient testing using a combination of control materials that include both low and high values on each day of testing Review of blood gas patients showed since May 1, 2018 to date 75 patients were reported out. Review of blood gas QC showed controls were performed 3 times in 2018. 3. Prothrombin time ISI is 1.03 in ACL Elite and package insert for lot number in use N0972299 ISI is 1.06. 4. Interview with technical supervisor #1 and testing personnel #1 on September 21, 2018 at 11:30 AM confirmed the laboratory director failed to ensure QC was maintained.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on review of blood bank, Prothrombin time (PT), partial thromboplastin time (PTT), blood gas and interview with technical supervisor #1 confirmed the laboratory director failed to ensure acceptable levels of analytical performance for blood bank, PT, PTT and blood gas
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)

	The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of blood gas procedure and interview with the technical supervisor #1 on September 21, 2018 at 11:30 AM confirmed the laboratory director failed to ensure that an approved blood gas procedure manual is available to all personnel.