Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	28D2104924	03/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Cancer Partners Of Nebraska - Pine Lake Location	3901 Pine Lake Road, Suite 111, Lincoln, NE	

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
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 surveyor review of procedure manual (Refer to D5401), review of calibration verification data (Refer to D5401), and lack of comparison of results (Refer to D5775) the laboratory failed to monitor and evaluate the overall quality of testing.
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 surveyor review of Cobas Integra 400 Linearity and Calibration Verification Procedure, review of quality control monitoring logs from September 2022 - March 2023, review of calibration verification data, and interview with the technical supervisor the laboratory failed to follow its own procedure pertaining to calibration

	verification. 1. Based on review of the laboratory's Cobas Integra 400 Linearity and Calibration Verification Procedure, the laboratory should "perform and document calibration verification procedures" when "there is major preventative maintenance or replacement of critical parts that may influence test performance." 2. Review of the laboratory's quality control monitoring logs for Cobas Integra 400 from September 2022 - March 2023, revealed the laboratory changed the electrode on 9/20/2022, 10/21/2022, 11/21/2022, 12/20/2022, 1/12/2023, 2/17/2023, and 3/6/2023. 3. Review of calibration verification data revealed calibration was performed on 2/28/2022 and 8/30/2022. 4. Interview with the technical supervisor on 3/23/2023 at 10:45 AM confirmed the laboratory did not follow their procedure indicating calibration verification is performed when "there is major preventative maintenance or replacement of critical parts that may influence test performance."
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 surveyor review of Cobas Integra 400 Linearity and Calibration Verification Procedure, review of quality control monitoring logs from September 2022 - March 2023, review of calibration verification data, and interview with the technical supervisor the laboratory failed to perform calibration verification after major preventative maintenance or replacement of critical parts that may influence test performance. 1. Based on review of the laboratory's Cobas Integra 400 Linearity and Calibration Verification Procedure, the laboratory should "perform and document calibration verification procedures" when "there is major preventative maintenance or replacement of critical parts that may influence test performance." 2. Review of the laboratory's quality control monitoring logs for Cobas Integra 400 from September 2022 - March 2023, revealed the laboratory changed the electrode on 9/20/2022, 10/21/2022, 11/21/2022, 12/20/2022, 1/12/2023, 2/17/2023, and 3/6/2023. 3. Review of calibration verification data revealed calibration was performed on 2/28/2022 and 8/30/2022. 4. Interview with the technical supervisor on 3/23/2023 at 10:45 AM confirmed the laboratory did not perform calibration verification after the laboratory changed the

	electrode on 9/20/2022, 10/21/2022, 11/21/2022, 12/20/2022, 1/12/2023, 2/17/2023, and 3/6/2023.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's list of tests performed, lack of documentation, and interview with the technical supervisor the laboratory failed to have a system that twice annually evaluated the relationship between test results using different methodologies for white blood cell (WBC) differentials for 2021 and 2022. Findings are: 1. Review of the laboratory's list of tests performed revealed the laboratory was performing WBC differentials by automated instrument and by manual method. 2. No documentation could be presented at the time of survey to demonstrate the laboratory evaluated the relationship between these different methodologies. 3. Interview with the general supervisor on 3/23/2023 at 10:20 AM confirmed patient testing was being performed using both methods, but no semi annual evaluations had been documented for 2021 and 2022 comparing these two methodologies.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of competency assessments and interview with the technical supervisor the technical supervisor failed to fulfill the technical supervisor responsibilities. Refer to D6128.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's list of tests performed, CMS-209 form, competency evaluations for 2021 and 2022, and an interview with the technical supervisor, the laboratory failed to evaluate and document performance on high

	complexity manual white blood cell (WBC) differential on six out of six testing personal. Findings are: 1. The laboratory's list of tests performed indicate the laboratory performs high complexity manual WBC differentials, with an annual volume of twenty five. 2. The CMS-209 form completed by the laboratory revealed six high complexity testing personnel. 3. Review of 2021 and 2022 competency evaluations revealed the technical supervisor did not have documentation of competency on high complexity manual WBC differential for the six testing personnel. 4. Interview with the technical supervisor on 3/23/2023 at 10:15 AM, confirmed competency evaluations on high complexity manual WBC differential for the six testing personnel was not performed.