Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 28D0047765	**(X3) Date Survey Completed** 08/15/2024
Name of Provider or Supplier Chi Health Plainview Laboratory	**Street Address, City, State** 704 North 3rd Street, Plainview, 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**
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 Validation of the Analytical Measurement Range (AMR) Procedure, review of AMR verification documentation performed on the Siemens Dimension ExL, and interview with the technical consultant on 8/15/2024 12:26 PM, the laboratory failed to perform one out of three AMR verification every six months on chloride, potassium, and sodium, and failed to perform three out of three AMR verification every six months on triglycerides from 7/11/2023 - 8/15/2024. Findings

	are: 1. Based on review of the laboratory's Validation of the Analytical Measurement Range (AMR) Procedure, "ExL assays listed below must have six-month AMR verification: Chloride, Potassium, Sodium, Trig". 2. Review of chloride, potassium, and sodium AMR verification records revealed AMR verification was performed on 7 /11/2023 and 6/12/2024. 3. Interview with the technical consultant confirmed the laboratory did not perform one out of three AMR verification on chloride, potassium, and sodium. 4. Review of AMR verification records revealed no triglycerides AMR verification was performed from 7/11/2023 - 8/15/2024. 5. Interview with the technical consultant confirmed the laboratory did not perform three out of three AMR verification on triglycerides.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of new instrumentation records, review of competency records, and interview with the technical consultant on 8/15/2024 at 10:40 AM, the laboratory failed to perform competency on two out of two testing personnel prior to reporting patient test results using the new moderate complexity BioRad ToxSee system detection of drugs of abuse. The findings include: 1. Review of new instrumentation records revealed the new moderate complexity BioRad ToxSee system detection of drugs of abuse was put into use on 8/8/2023. 2. Review of competency records from 2023 and 2024 revealed no competency performed on the BioRad ToxSee system detection of drugs of abuse on two out of two testing personnel. 3. Interview with the technical consultant confirmed no competency was performed on the BioRad ToxSee system detection of drugs prior to reporting patient test results.