Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2044741	10/20/2023
Name of Provider or Supplier	**Street Address, City, State**	
Hope Centre For Advancement, Llc	701 Morreene Road, Durham, NC	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of 2021, 2022 and 2023 American Proficiency Institute (API) proficiency testing (PT) records and interview with laboratory director (LD) and testing personnel (TP) 10/20/23, the LD and TP failed to sign attestation statements for 4 of 6 PT events reviewed. Findings: Review of 2021, 2022 and 2023 API PT records revealed the LD and TP failed to sign attestation statements for the following 4 PT events: 2021 API - Chem Misc - 2nd event 2022 API - Chem Misc - 1st event 2022 API - Chem Misc - 2nd event 2023 API - Chem Misc - 1st event Interview with LD and TP at approximately 10:30 a.m. confirmed attestation statements were not signed by the LD and TP for 4 of 6 PT events reviewed.
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 2021, 2022, and 2023 calibration records, review of 2021, 2022 and 2023 calibration verification records and interview with LD and TP 10/20/23, the laboratory failed to perform calibration verifications for the creatinine (CREA) and potential hydrogen (PH) testing at least every 6 months from April of 2021 to October of 2023, a period of approximately 29 months. Findings: Review of 2021, 2022 and 2023 calibration records for CREA and PH testing revealed the laboratory performs calibrations using 2 levels of calibrators. Review of 2021, 2022, 2023 calibration verification records for the CREA and PH testing revealed the laboratory performed calibration verifications using 3 levels of calibrators in April of 2021 and October of 2023. The laboratory failed to perform calibration verifications in October of 2021, April of 2022, October of 2022 and April of 2023. Interview with LD and TP at approximately 11:30 a.m. confirmed the laboratory failed to perform calibration verifications for the CREA and PH testing every 6 months from April of 2021 to October of 2023.
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 laboratory policy, review of 2021, 2022 and 2023 quality assessment (QA) records and interview with LD and TP 10/20/23, the LD failed to ensure the laboratory's QA program was maintained. Findings: Review of laboratory policy "QUALITY ASSURANCE MONITORING SCHEDULE" revealed quarterly tasks to be performed for the laboratories quality assessment, for example: "March - 1st Quarter - QC, maintenance/action log reviews. Safety QA audit. Expired reagent Audit. Check CLIA license expiration for docs." Review of 2021, 2022 and 2023 QA records revealed the laboratory had completed quarterly tasks for the 1st quarter of 2022 and the 3rd quarter of 2023. The laboratory failed to complete the quarterly tasks for 2nd, 3rd and 4th quarters of 2022. The laboratory also failed to complete the quarterly tasks for the 1st and 2nd quarter of 2023. Interview with LD and TP at approximately 11:00 a.m. confirmed the LD failed to ensure the laboratory's QA program was maintained.
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 review of 2020. 2021, 2022 and 2023 TP competency records and interview with LD 10/20/23, the technical supervisor (LD) failed to access the competency of TP #1 since November of 2020, a period of approximately 34 months in which the competency of TP #1 was not accessed. Findings: Review of TP #1 competency records revealed a competency assessment was performed in November of 2020. There was no documentation of a competency assessment for TP #1 in 2021, 2022 or 2023. Interview with LD (technical supervisor) at approximately 11:15 a.m. confirmed competency assessments for TP #1 were not performed in 2021, 2022 or 2023.