Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2004180	01/13/2026
Name of Provider or Supplier	**Street Address, City, State**	
Grace Health Clinic Laboratory	3191 South Vaughn Way, Aurora, CO	

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
D0000	Based on an on-site recertification survey conducted on January 13, 2026, deficiencies were cited for Grace Health Clinic Laboratory located in Aurora, Colorado.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency test results for 2024 and 2025, and an interview with the laboratory director during the survey, the laboratory failed to perform and document any evaluation of unsatisfactory scores and the corrective action taken. Findings include: 1. A review of the API proficiency test results for the year 2024 and 2025 revealed that the laboratory did not evaluate or perform any corrective actions for unsatisfactory scores. Some of the events are HGB event 3 in 2025 (80%), RBC event 1 (80%) and event 2 (80%) in 2025, HCT event 1 in 2025 (20%), creatinine event 1 (80%) and event 2 (80%) in 2025, and Albumin event 3 in 2024 (80%). 2. An interview with the laboratory director on January 13, 2026 at 12:53 PM confirmed that the laboratory did not evaluate or perform any corrective actions for unsatisfactory scores.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of

	results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the laboratory manual of Pentra C400 analyzer and an interview with the laboratory director during the survey, the laboratory failed to include a procedure manual describing calibration and calibration verification procedure for Pentra C400 analyzer. Findings include: 1. A review of the laboratory manual for the Pentra C400 analyzer revealed that the laboratory did not have a procedure describing calibration and calibration verification procedure for Pentra C400 analyzer. 2. An interview with the laboratory director on January 13, 2026 at 12:43 PM confirmed that the laboratory failed to include a procedure manual describing calibration and calibration verification procedure for Pentra C400 analyzer.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 a review of the Pentral C400 analyzer quality control log, and an interview with the testing personel during the survey, the laboratory failed to perform and document calibration verification for Pentra C400 analyzer. Findings include: 1. A review of the Pentra C400 analyzer quality control log revealed that the laboratory performed calibration daily, however the laboratory did not perform a calibration verification every 6 months. 2. An interview with the testing personnel on January 13,

	2026 at approximately 11:40 revealed that the laboratory does not perform biannual calibration verification for Pentra C400 analyzer.