

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0904046	(X3) Date Survey Completed 09/10/2024
Name of Provider or Supplier Gel Laboratories Llc	Street Address, City, State 2040 Savage Road, Charleston, SC	
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	An announced CLIA Recertification survey was conducted on 9/10/2024. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific standard deficiencies cited as follows:
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory records and an interview with the technical supervisor (TS) #3, the laboratory failed to perform calibration at least once every 6</p>

months for the performance of two high-complexity tests, Strontium and Tritium for two of two years reviewed. a. The form CMS-116 filled out by the laboratory at the time of the survey listed the following two high-complexity tests: Strontium and Tritium. b. The laboratory's procedure "GL-RAD-I-015 - Operating Instructions for WPC 9550 Gross Alpha/Beta Counter" states under 14.0 Instruction calibration, standardization, and performance Part 14.1: The calibration will be reestablished and /or reevaluated on a twelve-month frequency. c. A review of the laboratory's Strontium-90 Urine calibration instrument data printout revealed that the calibration was performed on 8/18/2022 and 8/15/2023. d. A review of the laboratory's Tritium Urine calibration instrument data printout revealed that the calibration was performed on 7/1/2022, 10/15/2022, and 8/1/2023. e. Laboratory technical supervisor #3 confirmed the findings on 9/10/2024 around 11:00 AM.