Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 01D0964738	**(X3) Date Survey Completed** 08/13/2024
Name of Provider or Supplier Winfield Neurology Family Medicine	**Street Address, City, State** 125 Bob Lawrence Drive, Winfield, AL	
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 a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Technical Consultant, the Laboratory Director failed to sign the PT attestation statements. This was noted for two of seven events reviewed in 2024. The findings include: 1. A review of the API PT records revealed no signature by the Laboratory Director (or qualified designee) on attestation statements for the following surveys: a) 2024 Chemistry 1st Event. b) 2024 Chemistry 2nd Event. 2. During an interview on 8/13/24, at 10:22 AM, the Technical Consultant confirmed the above findings.
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 a review of calibration verification (C-V) records, the Free Thyroxine (FT4) C-V policy and procedure, and an interview with the Technical Consultant, the laboratory failed to ensure C-V was performed and documented on the Qualigen FastPack analyzer for FT4 for the second half of 2023 (one of three 2023-2024 C-V's missed). The findings include: 1. A review of the FT4 C-V records for the Qualigen FastPack analyzer revealed C-V documentation on 5/8/23 and then a year later on 5/16 /24. There was no evidence of a C-V performed and documented the second half of 2023. 2. A further review of the FT4 Calibration Verification Records revealed, "Complete the system method verification every 6 months..." 3. During an interview on 8/13/24 at 3:52 PM, the Technical Consultant confirmed the above findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b) (1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the freezer temperature records, the Lysis Buffer Strip reagent box, and an interview with the Technical Consultant (TC), the Laboratory failed to document corrective actions when freezer temperatures were outside the manufacturers' storage parameters for items therein. The surveyor noted 19 of 19 months reviewed in 2023 through 2024 that the freezer temperatures were higher than the manufacturers' acceptable ranges. The findings include: 1. A review of freezer temperature records revealed freezer temperatures were above the manufacturers' storage parameters with no evidence of documentation of corrective action for the following months: a) 2023: January through December. b) 2024: January through July. 2. A further review of the Lysis Buffer Strip reagent box revealed manufacturers' required temperature range of -15 degrees Celsius to -25 degrees Celsius. The ranges documented were 2 degrees Celsius to 15 degrees Celsius. 3. During the exit interview on 8/13/24, at 4:18 PM, the TC confirmed the above findings.