Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0964738	04/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Winfield Neurology Family Medicine	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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of QuantStudio Real-Time PCR System procedures, API (American Proficiency Institute) proficiency testing (PT) records, lack of Split Testing records, and interviews with the Testing Personnel #1 and #2, the laboratory failed to verify accuracy for the Respiratory Panel, Urinary Tract Infection Panel, and Wound /Infection Panel on the QuantStudio Real-Time PCR System (a non-regulated high-complexity test) since starting patient testing in December 2019. The findings include: 1. A review of the Med 360 Laboratory Protocol Determination of Respiratory Pathogens using Real-Time Reverse Transcriptase Quantitative Polymerase Chain Reaction (RT-QPCR) and Med 360 Laboratory Protocol Determination of Urinary Tract Infection Pathogens using Real-Time Reverse Transcriptase Quantitative Polymerase Chain Reaction (RT-QPCR) revealed in 12.0 Proficiency Testing "12.1 Enrollment...Further, PT will be performed by Split Sampling of Pathogen with a certified laboratory two times per calendar year for all analytes." 2. A review of the API proficiency testing records revealed that PT was not performed on the QuantStudio Real-Time PCR System for Respiratory, Urinary Tract Infection, and Wound/Infection Pathogens. 3. A review of the Split Testing Records for QuantStudio Real-Time PCR System revealed instrument printouts from Winfield Neurology Family Medicine (3-11-2020) were split testing was performed with Assurance Laboratory. However, there was no evaluation to determine accuracy of the Split Testing Performed. A second split testing for 2020 was not observed by the surveyor. 4. During an interview on 04/08/2021 at 1:52 PM, Testing Personnel #1 and #2

	confirmed they sent their results to Assurance Laboratory for Split Testing but did not receive an evaluation back for the Laboratory Director and laboratory to review results for accuracy.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a review of QuantStudio Real-Time PCR System procedures, pipettes and centrifuge calibration records, and interviews with the Testing Personnel #1 and #2, the laboratory failed to perform maintenance for pipettes and centrifuges as established in the procedure for the Respiratory Panel and Urinary Tract Infection Panel on the QuantStudio Real-Time PCR System since starting patient testing in December 2019. The findings include: 1. A review of the Med 360 Laboratory Protocol Determination of Respiratory Pathogens using Real-Time Reverse Transcriptase Quantitative Polymerase Chain Reaction (RT-QPCR) and Med 360 Laboratory Protocol Determination of Urinary Tract Infection Pathogens using Real-Time Reverse Transcriptase Quantitative Polymerase Chain Reaction (RT-QPCR) revealed in 13.0 Maintenance "13.1 Pipettes All pipettes in the laboratory are calibrated prior to initial use (by the manufacturer) and every 6 months thereafter..." 2. A review of the Med 360 Laboratory Protocol Determination of Urinary Tract Infection Pathogens using Real-Time Reverse Transcriptase Quantitative Polymerase Chain Reaction (RT-QPCR) revealed in 13.0 Maintenance "13.3 Centrifuges All centrifuges (plate and microcentrifuge) in use in the laboratory are calibrated prior to initial use (by the manufacturer) and every year thereafter." 3. A review of pipette calibration records revealed the calibration was performed 10/09/2019 and 11/11 /2020. A review of centrifuge calibration revealed the laboratory did not have records for the two previous and new centrifuges used for the QuantStudio Real-Time PCR System. 4. During an interview on 04/08/2021 at 2:00 PM, Testing Personnel #1 and #2 confirmed the pipette calibration was not performed every six months. 5. During an interview on 04/08/2021 at 2:00 PM, Testing Personnel #1 confirmed the current centrifuges (two) are new and was not sure if the calibrations were retained from the manufacturer.
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 the procedure manual and an interview with Testing Personnel #2, the laboratory failed to perform calibrations verifications at least every six months as per CLIA regulations and laboratory's procedures for the QuantStudio Real-Time PCR System. The findings include: 1. A review of the Med 360 Laboratory Protocol Determination of Respiratory Pathogens using Real-Time Reverse Transcriptase Quantitative Polymerase Chain Reaction (RT-QPCR) and Med 360 Laboratory Protocol Determination of Urinary Tract Infection Pathogens using Real-Time Reverse Transcriptase Quantitative Polymerase Chain Reaction (RT-QPCR) revealed in 8.3 Qualitative Cut-Off "...The qualitative cutoff will be re-established every six months." 2. During an interview at 1:40 PM on 04/08/2021, Testing Personnel #2 confirmed the laboratory currently uses the cutoff values confirmed during initial validation (12/09/2019) and did not re-establish the cut-off values every six months since validation.
D6127	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with Testing Personnel #2, the Technical Supervisor failed to evaluate and document the performance of the individual performing QuantStudio Real-Time PCR System at least semiannually during the first year of patient testing. This was noted on one of one personnel records for QuantStudio Real-Time PCR System reviewed by the surveyor. The finding include: 1. A review of the personnel records revealed Testing Personnel # 2 semiannual evaluation was not performed for QuantStudio Real-Time PCR System. Testing Personnel #2 initial training was documented on 10/07/2019. 2. During an interview conducted on 04/08/2021 at 03:00 PM, Testing Personnel #2 confirmed the semiannual evaluation was not performed for QuantStudio Real-Time PCR System.
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 a review of the personnel records and an interview with the Testing Personnel #2, the Technical Supervisor failed to evaluate and document the performance of the individual performing QuantStudio Real-Time PCR System at least annually after the first year of patient testing. This was noted on one of one personnel records for QuantStudio Real-Time PCR System reviewed by the surveyor. The finding include: 1. A review of the personnel records revealed Testing Personnel # 2 annual evaluation was not performed for QuantStudio Real-Time PCR System. Testing Personnel #2 initial training was documented 10/07/2019. 2. During an interview conducted on 04/08/2021 at 03:00 PM, Testing Personnel #2 confirmed the annual evaluation was not performed for QuantStudio Real-Time PCR System.