

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D1019516	(X3) Date Survey Completed 05/22/2024
Name of Provider or Supplier Internal Medicine & Pediatric Clinic Of New Albany	Street Address, City, State 118 Fairfield Dr, New Albany, MS	
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	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory proficiency records and interview with the technical consultant (TC), testing personnel (TP) #1 and TP #2 as listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory failed to verify the accuracy of the drugs of abuse (DOA) testing at least twice annually for two of two verifications of accuracy. Findings Include: 1. Review of the proficiency records from 2023 and 2024, revealed the DOA panel had not been verified as accurate for the year 2023. Two of two verifications of accuracy had not been performed for the DOA panel. The drugs of abuse (DOA) panel include the following: Amphetamines, Benzodiazapine, Opiates, Methadone, Barbiturates, Cocaine, THC (Tetrahydrocannabinol), PCP (Phencyclidine), and Oxycodone 2. During an interview with the TC, TP #1, and TP #2 (by phone) on 5/22/2024 at 4:00 pm, confirmed the accuracy had not been verified on the drugs of abuse panel performed on the Vitros 5600 chemistry analyzer.</p>
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</p>

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 the Ortho 5600 chemistry analyzer records including quality control, maintenance and calibration records and confirmation with the technical consultant (TC) and testing personnel (TP)#2 as listed on the CMS 209 personnel form, the laboratory failed to document as performed, the calibration verification on the Ortho 5600 chemistry analyzer every 6 months for Vitamin D, Vitamin B12, TIBC, LDL. Two of two calibration verifications were not performed during the timeframe reviewed. Findings include: 1. Calibration verification is required every 6 months on any assay which is calibrated with less than 3 levels of calibration material. These 4 tests mentioned only have 2 calibrators provided by the manufacturer to use during calibration. 2. Review of calibration records since installation of the Ortho 5600 chemistry analyzer in 3/2023 through the day of survey, revealed the laboratory failed to perform calibration verification every 6 months on Vit D, Vit B12, TIBC and LDL. 3. The TC and TP#2 (by phone) confirmed in an interview on 5/22/2024 at 1:00 p.m. that the calibration verification was not performed at the appropriate timeframe or frequency during the period of 3/2023 through 5/22/2024. Two of two calibration verifications required were not performed and exceeded the 6-month timeframe required by the manufacturer.