

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2270190	(X3) Date Survey Completed 06/12/2023
Name of Provider or Supplier My Doctors Medical Group, PLLC	Street Address, City, State 6385 Stage Rd Ste 2, Bartlett, TN	
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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of records, review of patient test reports, and staff interview, the laboratory failed to verify patient normal ranges for four of four test platforms in use (total of 44 tests) from the time patient testing began on 02/27/23 until the date of the survey on 06/12/23. The findings include: 1. Observation of the laboratory on 06/12/23 at 8:00 am revealed the following laboratory instruments in use for patient testing: Beckman Coulter DxH 560 serial # BF060257 for Complete Blood Count with automated White Blood Cell differential (CBC w /Diff). Tosoh G8 serial # 16361910 for performing glycosylated hemoglobin (HbA1C). Beckman Coulter AU480 serial #2022084955 in use for performing chemistry and immunology testing to include alkaline phosphatase, amylase, total and direct bilirubin, blood urea nitrogen, calcium, chloride, cholesterol, creatine kinase, carbon dioxide, cortisol, creatinine, c-reactive protein, gamma-glutamyl transferase, glucose, high density lipoprotein, iron, lactate dehydrogenase, lipase, magnesium, potassium, total protein, aspartate aminotransferase, alanine aminotransferase, rheumatoid factor, sodium, triglyceride, and uric acid. Beckman Coulter Access 2 serial #82894608 in use for performing general chemistry, endocrinology and immunology testing to include vitamin B12, ferritin, folate, prostate specific antigen, free triiodothyronine, free thyroxine, testosterone, thyroid stimulating hormone, and</p>

vitamin D. 2. There were no records for verification of the normal ranges in use by the laboratory. 3. Review of patient test reports revealed patient testing began on 02/28/2023 (reported on 02/28/23). 4. Interview with the laboratory supervisor on 06/12/23 at 5:00 pm revealed the following statement: The laboratory does not use the manufacturer reference interval for testing performed, but instead uses reference / normal ranges of their previous reference laboratory. The laboratory did not perform a normal range study to verify the range used was appropriate for their patient population. This confirmed the survey findings.