

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0670151	(X3) Date Survey Completed 09/21/2023
Name of Provider or Supplier Mid-South Internal Medicine Specialist Pc	Street Address, City, State 7550 Wolf River Blvd Suite 102, Germantown, 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
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's QC records, review of patient records, and interview with the laboratory lead, the laboratory failed to ensure new QC lots without established ranges were tested concurrently with previous QC lots for the Free Triiodothyronine (FT3) analyte, with use of the new lots beginning on 09/13/23 until the date of the survey on 09/21/23, with 68 patients reported during the period. The findings include: 1. Review of the laboratory's QC records for the Ortho Vitros 5600 revealed the following: a. The current QC lot numbers in use for the Biorad Immunoassay Control were 85351, 85352 and 85353. b. The laboratory started using the new lots on 09/13/23. c. The manufacturer package insert did not have QC ranges for the FT3 analyte. d. There was no overlap testing of the new QC lot in parallel with the old lot of QC. 2. Review of patient records revealed the laboratory had reported 68 patients since 09/13/23 when the laboratory began using the new QC lot without any established ranges for the FT3 analyte. 3. Interview with the laboratory lead on 09/21</p>

/23 at 2 pm revealed the following: The laboratory switched to new lots for the Biorad Immunoassay Plus QC material on 09/13/23. The manufacturer communicated to the laboratory that no ranges existed for the FT3 analyte. The laboratory discarded all the old lot of QC and did not run the new QC lot in parallel with the old lot while establishing the targets for the new control. The laboratory used the QC ranges from the previous lot number for ranges for the FT3 analyte. This confirmed the survey findings.