

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D1080428	(X3) Date Survey Completed 02/03/2023
Name of Provider or Supplier Chi St Vincent Medical Group Hot Springs (Pcb)	Street Address, City, State 1662 Higdon Ferry Rd,Ste 110, Hot Springs, AR	
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: Through a review of quality control documentation, review of manufacturer's package insert for Architect 2nd Generation Testosterone Controls, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to establish statistical parameters over time for Architect 2nd Generation Testosterone Controls lot# 9029455258 low, med and high. Survey findings include: A) During a review of September quality control documentation for chemistry tests performed on the Architect Immunochemistry analyzer, the surveyor observed the following 2 standard deviation (SD) ranges in use as acceptable ranges that didn't correlate with the Architect 2nd Generation Testosterone Control calculated 2 SD ranges from September 2022: Testosterone (lot # 9029455258 Low) 2 SD in use 2.18 ng/dl (calculated 2 SD 0.91 ng/dl);Testosterone (lot # 9029455258 Med) 2 SD in use 14.37 ng/dl (calculated 2 SD 5.2 ng/dl);Testosterone (lot # 9029455258 High) 2 SD in use 46.0 ng/dl (calculated 2 SD 26.83 ng/dl). B) Review of the manufacturer's package</p>

insert for Architect 2nd Generation Testosterone Controls revealed "each laboratory should establish its own concentration ranges for new control lots at each control level". C) Upon request, the laboratory could not produce documentation of calculations used to determine control ranges for the three levels of Architect 2nd Generation Testosterone Controls in use in September 2022. D) During a telephone interview employee #3 (as listed on the form CMS-209), at 11:45 a.m. on 2/3/23, stated the 2 SD ranges in use to establish the acceptable range for all three levels of Testosterone controls were the manufacturer's published 2 SD ranges instead of ranges established by the laboratory.