

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 51D0968213	<b>(X3) Date Survey Completed</b> 01/05/2022
<b>Name of Provider or Supplier</b> Associated Specialists Inc	<b>Street Address, City, State</b> 527 Medical Park Drive, Suite 204, Bridgeport, WV	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced, on site, recertification survey was conducted at Associated Specialists Inc on January 5, 2022, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendments (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
<b>D5469</b>	<p><b>CONTROL PROCEDURES</b> 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 record review and interview the laboratory failed to (ii) verify the manufacturer stated values for new lots of assayed quality control (QC) material for all 7 of 7 analytes tested on the Roche Cobas e411 analyzer in 2021. Findings: 1. Review of 2021 QC records revealed no documentation for the verification of manufacturer stated value ranges for new lots of QC material for the following analytes: TSH, Vitamin D, Vitamin B12, FT4, PSA, Folate, and Ferritin. 2. An interview with the technical consultant and testing personnel 1, on 1/5/22 at</p>

approximately 12:00 PM, confirmed that no verification of new lot QC ranges for the 7 analytes on the Roche analyzer were being performed.