

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0968213	(X3) Date Survey Completed 02/15/2024
Name of Provider or Supplier Associated Specialists Inc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A routine recertification survey was conducted at Associated Specialists Inc. on February 15, 2024, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendments (CLIA) regulations under 42 CFR 493. Specific deficiencies cited are explained below.
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of written policies and procedures (P&P), analyzer verification records, and interview the laboratory failed to update the (10) reference ranges for 16</p>

of 16 analytes tested in Hematology to reflect the DxH 520 performance specifications. Findings: 1. Review of verification records for the DxH 520 Hematology analyzer, which was put into use on 6/23/22, identified reference ranges for the 16 analytes as established during the verification of performance specifications. 2. Review of P&P identified the reference ranges for the Act Diff 2 Hematology analyzer, which was taken out of use on 6/23/22. Updated reference ranges for the DxH 520 Hematology analyzer could not be located. 3. An interview with testing personnel. 2/15/24 at 11:15 AM, confirmed the reference range P&P for Hematology had not been updated to reflect the reference ranges verified for the DxH 520 analyzer. 4. An exit interview with the technical consultant and testing personnel, 2/15/24 at 12:00 PM, confirmed the findings.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

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 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 written policies and procedures (P&P), lack of documentation, and interview, the laboratory failed to establish the (b)(2) calibration verification acceptable limits for the 27 analytes tested on the Cobas e411 and ABX Pentra 400 analyzers in Chemistry. Findings: 1. Review of P&P identified "Calibration /Calibration Verification" procedure stating "each laboratory and its director should establish its own acceptance criteria for calibration verification. When acceptable performance is met, the calibration has been verified. If calibration verification is found to be unacceptable, the instrument must be recalibrated and all corrective action must be documented." 2. No acceptance criteria for the calibration verification of the 27 analytes on the Cobas e411 and ABX Pentra 400 Chemistry analyzers could be located. 3. An interview with the technical consultant and testing personnel, 2/15/24 at 10:30 AM, confirmed that no specific acceptability criteria for the calibration verification of the 27 analytes in Chemistry could be located. 4. An exit interview with the technical consultant and testing personnel, 2/15/24 at 12:00 PM, confirmed the findings.