

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D0925425	(X3) Date Survey Completed 01/11/2023
Name of Provider or Supplier Banner Health Physicians West Llc	Street Address, City, State 1020 S Conwell, Casper, WY	
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
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 procedure manual review, lack of documentation, and staff interview, the laboratory failed to ensure the procedure manual contained all the required elements for 2 of 2 procedure manuals reviewed (Alere Triage Troponin I Test, Alere Triage D-dimer Test). The findings were: 1. Review of the Alere Triage Troponin I and the Alere Triage D-dimer procedure manuals failed to include a description of the course of action the laboratory would take if the test system became inoperable. 2. Interview with the technical consultant on 1/11/23 at 10:28 AM confirmed the laboratory's procedures were incomplete.</p>

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 lack of documentation and staff interview, the laboratory failed to verify the reportable range at least every 6 months using testing materials with values at the zero or minimal level, the mid-level, and the upper-level of the reportable range for the D-dimer and troponin I analytes for 1 of 1 year of testing (2022). The laboratory performed approximately 82 D-dimer and 30 troponin I patient tests annually using the Triage Alere analyzer. The findings were: 1. Review of the laboratory's testing validation records showed the validation for the analytes of D-dimer and troponin I was approved by the laboratory director on 8/29/21. 2. Review of the laboratory's records showed no documentation the reportable range of the analytes tested on the Alere Triage instrument had been verified in 2022. 3. Interview with the technical consultant on 1/11/23 at 10:28 AM confirmed the calibration verification studies had not been completed.