

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0236290	(X3) Date Survey Completed 02/09/2022
Name of Provider or Supplier Webster Memorial Hospital, Inc	Street Address, City, State 125 Diana Drive, Webster Springs, 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	An announced, on site, routine recertification survey was conducted at Webster Memorial Hospital Inc on February 8 and 9, 2022, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory failed to (5) document and maintain the examination and interpretation of all proficiency testing (PT) results and the attestation statements signed by the laboratory director (LD) for 2021. Findings: 1. Review of American Proficiency Testing (API) PT records for 2021 revealed a lack of documentation for the interpretation of all specimen results for ABO/RH, Compatibility, and Crossmatch in 3 of 3 Immunohematology events. 2. Review of API PT records for 2021 identified no LD signature on the attestation statements for 5 of 17 PT events: 3rd event Chemistry Core, 3rd event Microbiology, 2nd event Chemistry Miscellaneous, 3rd event</p>

	<p>Hematology, 3rd event Immunohematology/Immunology. 3. An interview with the general supervisor and the technical consultant, on 2/8/22 at approximately 10:20 AM, confirmed the findings.</p>
D2081	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to submit results for the American Proficiency Institute (API) proficiency testing (PT) 2021 3rd Immunology event before the deadline. Findings: 1. Review of API records identified an unsatisfactory score of 0% for analyte #0215 Infectious Mono and HIV. 2. An interview with the technical consultant, on 2/8/22 at approximately 11:30 AM, confirmed the results were not submitted before the API deadline for grading.</p>
D2159	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to submit the results of American Proficiency Institute (API) Immunohematology 2021 3rd proficiency testing (PT) event before the deadline. Findings: 1. Review of API records identified an unsatisfactory score of 0% for the analyte #0860 ABO/RH. 2. Review of API records revealed a documented self-evaluation of results by the laboratory. 3. An interview with the general supervisor, on 2/8/22 at approximately 11:20 AM, confirmed the results were not submitted for the event before the deadline.</p>
D2169	<p>UNEXPECTED ANTIBODY DETECTION CFR(s): 493.861(c)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to submit the American Proficiency Institute (API) proficiency testing (PT) results for the 2021 3rd Immunohematology event before the deadline. Findings: 1. Review of API records identified an unsatisfactory score of 0% for analyte #0855 Antibody Detection. 2. Review of API records revealed a documented self-evaluation of results by the laboratory. 3. An interview with the general supervisor, 2/8/22 at approximately 11:20 AM, confirmed the results had not been submitted to API before the deadline.</p>

<p>D2178</p>	<p>COMPATIBILITY TESTING CFR(s): 493.863(c)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to submit the American Proficiency Institute (API) proficiency testing (PT) results for the 2021 3rd Immunohematology event before the deadline. Findings: 1. Review of API records identified an unsatisfactory score of 0% for analyte #0895 Compatibility Testing. 2. Review of API records revealed a documented self-evaluation of results by the laboratory. 3. An interview with the general supervisor, 2/8/22 at approximately 11:20 AM, confirmed the results had not been submitted to API before the deadline.</p>
<p>D5209</p>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of policies and procedures (P&P), record review, lack of documentation, and interview the laboratory failed to perform and document the annual competency for 1 of 7 laboratory testing personnel (TP) for 2020 and 2021. Findings: 1. Review of P&P identified a process for documenting the competency of laboratory testing personnel. 2. Review of personnel records identified a lack of documentation for the annual competency of TP1 for 2020 and 2021. 3. An interview with the general supervisor, 2/8/22 at approximately 10:00 AM, confirmed the findings.</p>
<p>D5403</p>	<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</p>

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.

This STANDARD is not met as evidenced by:

Based on review of policies and procedures (P&P), record review, lack of documentation, and interview the laboratory failed to (1) specify the criteria for referral of an abnormal hematology specimen and (6) provide the reportable ranges for all 28 analytes in Chemistry, Endocrinology, and Toxicology ran on the Vitros 5.1, Vitros 350, and Vitros Eci analyzers. Findings: 1. Review of P&P for Hematology revealed no written criteria to specify referral (manual differential or pathologist review) of an abnormal hematology specimen from the automated differential testing performed in the laboratory on the Sysmex XN-450 and BC Act T Diff analyzers. 2. Review of P&P for Chemistry, Endocrinology, and Toxicology revealed no specified reportable ranges for the 28 analytes tested in the laboratory. Review of the initial validations of the Vitros analyzers (5.1, 350, and Eci) identified data points to establish reportable ranges for the analytes. 3. An interview with the technical consultant and general supervisor, 2/9/22 at approximately 9:45 AM, confirmed the lack of a written P&P for hematology referral and reportable ranges in chemistry.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on record review, lack of documentation, and interview the laboratory failed to (c) document the comparison of results between the Vitros 5.1 and Vitros 350 chemistry analyzers for 2020 and 2021 twice a year. Findings: 1. Review of Chemistry records revealed no documentation of the comparison of results for the analytes tested on both the Vitros 5.1 and Vitros 350 in 2020 and 2021. 2. An interview with the general supervisor and technical consultant, 2/9/22 at approximately 11:00 AM, confirmed the findings.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of policies and procedures (P&P), blood bank transfusion records, and interview the laboratory failed to (a) establish a process to monitor, assess, and correct problems identified in transfusion medicine. Specifically: 1) Ensuring all blood bank documentation is accurate and complete for transfusions of blood and

blood products 2) Ensuring the retention of blood and blood product transfusion records 3) Ensuring the established P&P for documenting visual inspections of blood products during storage and before issuance are performed and documented Findings:

1. Review of 2020 and 2021 blood bank emergency release records identified the following documentation and retention issues with 2 of the 3 reviewed: i) 4 units listed on the emergency release form, 1 of the 4 unit transfusion forms had no time unit was issued ii) 2 units listed on the emergency release form, no unit transfusion forms could be located for the 2 units
2. Record review of 4 random blood product transfusions from the Blood Product Transfusion logs identified incorrect or lack of documentation for 3 of the 4 reviewed: i) Two units of red cells transfused. One unit had a different unit number in the computer than was documented on the transfusion log and unit transfusion form ii) Two units of red cells transfused. No patient transfusion record card could be located for the patient and no unit transfusion form could be located for the 2 units iii) One unit of red cells transfused. Patient transfusion record card had no documentation of unit number for the transfused unit of red blood cells
3. Review of P&P identified "Donor Blood Inspection" which states "Pre-issue inspections must be recorded in the logbook when signing out unit and daily in the maintenance log". No documentation of daily inspection of blood products could be located.
4. An interview with the general supervisor, 2/9/22 at approximately 1:30 PM, confirmed the findings.