

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0236290	(X3) Date Survey Completed 03/11/2026
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	A routine recertification survey was conducted at Vandalia Health Webster Memorial Hospital on March 10 and 11, 2026, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the CLIA regulations under 42 CFR 493, Requirements for Laboratories. Noncompliance was found and cited below.
D2173	<p>COMPATIBILITY TESTING CFR(s): 493.863(a)</p> <p>(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of CASPER 155D report, American Proficiency Institute (API) proficiency testing (PT) evaluation reports, interview with the general supervisor (GS), and exit interview with the laboratory director, the laboratory failed to attain the required 100% for satisfactory performance in compatibility testing (analyte # 0895) for one of three consecutive testing events in 2025. Findings: 1. Review of CASPER 155D report identified an unsatisfactory performance of 80% for #0895 compatibility testing in the 2025 API PT event 3. 2. Review of Immunoematology API PT evaluation reports for 2025 event 3 verified the unsatisfactory performance of #0895 compatibility testing. The laboratory reported the incorrect result of Compatible for specimen SER-11. API expected the laboratory to report the result for SER-11 as Incompatible, resulting in a score of 80%. 3. During an interview, 3/10/26 at approximately 10:45 AM, the GS stated the review and corrective action for the compatibility testing score of 80% identified the TP (TP1) who performed the unacceptable testing and provided reeducation. 4. During a video conference call exit interview, 3/11/26 at approximately 2:30 PM, the state surveyor confirmed 80% in the API 3rd event of 2025 for compatibility testing with the laboratory director.</p>

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:

Based on review of written policies and procedures, laboratory testing personnel (TP) competency assessment files, lack of documentation, interview with the general supervisor (GS), and exit interview with the laboratory director (LD), the laboratory failed to document direct observations for 7 of 7 TP competency assessments performed in 2025 as required by the laboratory's competency assessment policy. Findings: 1. Review of "Competency Assessment Policy" identified a process for assessing TP competency on an initial, six month, and annual basis, including the following: a. direct observation of routine patient testing b. monitoring, recording, and reporting of test results c. review of intermediate results/worksheets, QC, PT, and preventive maintenance d. direct observation of performance of instrument maintenance function checks and calibration e. test performance, which may include PT, internal blind samples, or testing previously analyzed samples f. problem-solving skills 2. Review of 2025 competency assessments revealed 7 of 7 TP had no documented direct observation of (a) routine patient testing and (d) performance of maintenance/function checks and calibrations (if applicable) for all moderate and high complexity test specialties and methods. 3. During an interview, 3/10/26 at 9:54 AM, the GS stated all 7 TP competency assessments for 2025 lacked a direct observation for all moderate and high complexity testing methods. 4. During a video conference call exit interview with the LD, 3/11/26 at 2:30 PM, the state surveyor confirmed the findings.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(14)

(e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

This STANDARD is not met as evidenced by:

Based on review of 74 laboratory policies and procedures in the document management software PolicyStat, lack of current laboratory director (LD) approval, interview with the general supervisor (GS), and exit interview with the current LD, the LD failed to ensure 33 of the 74 policies and procedures required for all testing processes in the laboratory were signed, dated, and approved for use after taking over directorship of laboratory in November 2025 thru date of survey. Findings: 1. Review of the PolicyStat document management system, 3/10/26 at 1:00 PM, identified 33 policies and procedures having no current LD approval for use in the laboratory: 12 for chemistry testing (17502758, 18497822, 17971880, 18825813, 18497831, 17900596, 17502599, 18055985, 18497809, 17900597, 18055995, 17502563), 15 for immunohematology testing (17502759, 16500414, 16500385, 14755346, 16500412, 17996782, 17900593, 14755344, 14095563, 16500413, 15044963, 14165152, 14087377, 16500388, 15104167), and 6 for general laboratory systems (16500392, 15394825, 13522496, 18791864, 17502611, 16500393). 2. During an interview, 3/10/26 at 1:15 PM, the GS verified the current LD had not approved the 33 policies in

PolicyStat for chemistry, immunohematology, and general laboratory systems. 3.
During a video conference call exit interview, 3/11/26 at 2:30 PM, the state surveyor confirmed the lack of approval for the 33 policies with the current LD from start of laboratory directorship in November 2025 thru date of survey.