Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0236290	01/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Webster Memorial Hospital, Inc	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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on a tour of the laboratory, review of blood bank records, and interview with testing personnel, the laboratory failed to meet safety and requirements for transfusion services standards under Subpart J - Facility Management for Non-Waived Testing. Findings include: 1. Refer to cross-reference in D3011 2. Refer to cross-reference in D3015
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on a tour of the laboratory and interview with testing personnel, the laboratory

	failed to provide safety and personal protective equipment for testing personnel for use during laboratory activities of potential blood and/or body fluid exposure. Findings include: 1. During the tour of the laboratory at approximately 10:30AM, no equipment for protecting testing personnel from splashes was found (no face shields, goggles, or countertop shields were available). 2. During the lab tour, testing personnel were wearing uniforms and fabric lab coats. However, no fluid resistant lab coats were found. 3. Interviews with testing personnel 1 (TP1) on 1/10/19 at approximately 11:10 AM and testing personnel 2 (TP2) and the assistant manager at approximately 2:25 PM confirmed the findings.
D3015	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103 A facility that provides transfusion services must meet all of the requirements of this section and document all transfusion-related activities. This STANDARD is not met as evidenced by: Based on review of the blood bank patient and QC testing logs, the laboratory failed to document QC for blood bank testing performed on three separate occasions during the look-back period. Findings include: 1. Review of the Ortho Transfusion Service testing record from September 18, 2018 to January 3, 2019 identified that 26 patients were tested. 2. Comparison of dates of patient testing to quality control records in the Blood Bank Reagent QC Record binder identified three of the dates patient testing was performed that no QC was documented (11/4/18, 11/18/18, 12/23/18). 3. Patient testing was performed by the same testing personnel on all three dates that QC was not documented.
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 the laboratory's personnel records and interview with Testing Personnel (1) and Assistant Manager, the laboratory failed to document the assessment of employee competency. Findings: 1. The laboratory did have a system for recording personnel competency. However, the assistant manager was only able to produce competency records for one of the two employees requested; this competency was from 2017. No other records were found. 2. There was no written procedure or policy available that provided details on personnel competency assessment. 2. During interview with the assistant manager on 1/10/19 at approximately 1:10 PM, she stated that she had only been in the role of Assistant Manager since December 2018. The former Laboratory manager left her role suddenly in late September 2018. The competency records from the previous Laboratory manager were not found.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manuals, the laboratory failed to include required information in the procedures. Findings: 1. Review of the MTS QC procedure, the Antibody Detection Method-Two Cell Screen procedure, and the Sysmex D-Dimer procedure demonstrate that the laboratory is using the manufacturer's instructions, which do not include all the required elements. 2. The three procedures outlined above lack the following required elements: corrective action to take if results fail to meet the acceptability criteria; the procedure for entering /reporting results; and description of action to take if the system becomes inoperable. 3. There was no procedure found which outlined the process for referring out of blood bank specimens to Red Cross when the antibody screens were discovered. However, testing personnel were able to describe the process of referral.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manuals, the laboratory failed to maintain approved and signed procedures. Findings: 1. A review of the Blood Bank procedure manual, D-Dimer procedure, and General Laboratory Procedures manuals (volumes 1 and 2) showed no procedures signed by the current director, who started in February of 2018. 2. The procedures in volumes 1 and 2 of Laboratory Procedures manuals were last signed and dated in 2015 by the previous director. 3. During the exit interview, the current director (via telephone) said that she had signed all the documents that were given to her to sign at her last visit to the facility.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and

	test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a laboratory tour and review of the laboratory's records, the lab failed to ensure the temperatures in the laboratory were accurate. Findings: 1. Visual observation of the Panasonic refrigerator, AEGIS Scientific freezer, and room temperature thermometers in the blood bank and chemistry areas revealed that calibrated thermometers are not being used. 2. No documentation was found during the lab tour and review of records to indicate calibration had been completed for these thermometers. 3. Interview with TP1 on 1/10/19 at approximately 10:35 AM demonstrated that temperatures were recorded from the non-calibrated thermometers.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the blood bank patient and QC testing logs, the laboratory failed to document QC for blood bank testing performed on three separate occasions during the look-back period. Findings: 1. Review of the Ortho Transfusion Service testing record from September 18, 2018 to January 3, 2019 identified that 26 patients were tested. 2. Comparison of dates of patient testing to quality control records in the Blood Bank Reagent QC Record binder identified three of the dates patient testing was performed that no QC was documented (11/4/18, 11/18/18, 12/23/18). 3. Patient testing was performed by the same testing personnel on all three dates that QC was not documented.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review review, observation and interview with testing personnel, Assistant

	Laboratory Manager and Director, the laboratory director did not provide overall management and direction of the laboratory. Findings include: 1. Refer to cross reference in D6079 2. Refer to cross reference in D6084 3. Refer to cross reference in D6094 4. Refer to cross reference in D6097 5. Refer to cross reference in D6102 6. Refer to cross reference in D6103 8. Refer to cross reference in D6106 9. Refer to cross reference in D6107
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of records, and interviews with testing personnel, the laboratory director failed to assure that all technical supervisor and general supervisor duties were properly performed. Findings: Refer to cross-referenced details in D3015, D5209, D5291, D5559, D5403, D5413
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on a tour of the laboratory, observation, and interview with testing personnel (TP1) and Assistant Laboratory Manager, the laboratory director failed to ensure safety and personal protective equipment is provided for testing personnel. Findings: 1. During the tour of the laboratory at approximately 10:30AM, no equipment for protecting testing personnel were found or fluid resistant lab coats. 2. The Assistant Manager stated that she has the fluid resistant laboratory coats on order. 3. Refer to cross-reference details in D3011
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on review of the laboratory quality assessment (QA) records and and interview with the Assistant Manager, the Laboratory Director failed to ensure that quality assessment programs were maintained for the pre-analytic, analytic and post-analytic systems. Findings include: 1. Review of the QA binder demonstrated no policy or procedure on how to conduct QA activities. This finding dates back prior to October 2018, before administrative staff changes. There was no policy signed by the current or former laboratory director. 2. The laboratory did have a binder labeled "QA" with QA monitoring activity data included for pre-analytic, analytic, and post-analytic systems. However, the last quarter of 2018 until present (1/10/19) did not have any documentation of QA monitoring activities. 3. There were no functional job descriptions found to update the roles and responsibilities of the new general supervisor and technical supervisor, in regard to who is responsible for continuing the QA monitoring activities after the former Laboratory Manager vacated her position.
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on review of the blood bank patient and QC testing logs, the laboratory director failed to ensure that Blood bank test results were reported only when the quality control system was functioning properly from 9/18/18 to 1/3/19 Findings include: Refer to cross-referenced details in D3015 and D5559.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and interview with the assistant manager, the laboratory director failed to ensure the assistant manager had the appropriate training for her role. Findings: 1. Refer to cross-reference details in D5209
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and interview with Testing Personnel and Assistant Manager, the laboratory director failed to document the assessment of employee competency. Findings: 1. The laboratory did have a system for evaluating laboratory testing personnel competency. However, the assistant manager was only able to produce competency records for one of the two employees requested; this competency was from 2017. No other records were found. 2. During interview with the assistant manager on 1/10/19 at approximately 1:10 PM, she stated that she had only been in the role of Assistant Manager since approximately the beginning of December 2018. The former Laboratory Manager vacated her role suddenly at the end of Sept 2018. The competency records from the previous Laboratory manager were also not found.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and manuals, the laboratory director failed to ensure that approved procedure manuals are available to all personnel. Findings: 1. Refer to D5403 2. Refer to D5407
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and interview with the Assistant Manager, the laboratory director failed to specify the responsibilities and duties for laboratory personnel. Findings: 1. Refer to D5209 2. During interview with the Assistant Manager on 1/10/19 at approximately 1:10 PM, she stated that she was not given a functional job description or document listing her responsibilities as a manager.