| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 51D0236290 | 02/28/2024 |
| **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 |
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| **D0000** | A routine recertification survey was conducted at Webster Memorial Hospital, Inc., on February 27 and February 28, 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** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of policies and procedures (P&P) and interview the laboratory failed to establish a P&P for (4) the verification of performance specifications for new lots |

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| | of reagents and (13) the method for issuing a corrected report when erroneous results are released. Findings: 1. Review of P&P revealed no established process for the verification of performance specifications for new lots of Innovin and Actin reagents used on the Sysmex CA-660 coagulation analyzer before being placed into use for patient testing. 2. Review of P&P revealed no established process to promptly notify the authorized test requestor of erroneous results, the issuance of a corrected patient report, and the retention of both the original and corrected reports. 3. An exit interview with the laboratory director and laboratory supervisor, 2/28/24 at 4:00 PM, confirmed the lack of established P&P for verifying new lots of reagents and issuing corrected reports. |
| **D5425** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(3)<br><br>The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, lack of documentation, and interview the laboratory failed to document the verification of performance specifications for one of one new lot of Actin APTT reagent on the Sysmex CA-660 coagulation analyzer in 2024. Findings: 1. Review of quality control (QC) records (January and February 2024) for coagulation testing identified a new lot (562716A expiry 6/28/24) of Actin reagent put into use 1/4/24 on the Sysmex CA-660 analyzer for APTT testing. 2. January 2024 QC records included a note that stated "only Level 3 QC ran 25 times." No other documentation for the verification of the new lot of Actin reagent could be located. 3. An interview with the laboratory supervisor, 2/27/24 at 10:15 AM, confirmed the lack of documentation for the verification of lot 562716A Actin reagent. 4. An exit interview with the laboratory director and laboratory supervisor, 2/28/24 at 4:00 PM, confirmed the findings. |
| **D5555** | IMMUNOHEMATOLOGY<br>CFR(s): 493.1271(c)(f)<br><br>(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on policies and procedures (P&P), record review, lack of documentation, and interview the laboratory failed to (c)(2) document inspections of the audible alarm system for the refrigerator and freezer used to store blood products in 2023. Findings: 1. Review of P&P identified "Blood Bank Refrigerator Alarm Check" that stated an alarm check is performed quarterly to ensure proper activation of the alarm by testing the upper and lower temperature limits. 2. Review of temperature record logs of the refrigerator used to store packed red blood cells (PRBC) and the freezer used to store fresh frozen plasma (FFP) for all of 2023 revealed no documentation on the record |

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| | wheels to indicate the upper and lower limits of the temperature ranges were exceeded and the audible alarm activated. 3. No documentation of the quarterly audible alarm checks for the refrigerator or the freezer could be located for 2023. 4. An interview with the general supervisor, 2/28/24 at 1:00 PM, confirmed the lack of audible alarm checks for the refrigerator and freezer used to store blood products in 2023. 5. An exit interview with the laboratory director and general supervisor, 2/28/24 at 4:00 PM, confirmed the findings. |
| **D5781** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(1)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of policies and procedures (P&P), record review, lack of documentation, and interview the laboratory failed to document the corrective actions taken when complete blood count (CBC) and automated differential parameters were flagged as outside the operating specifications for 7 of 36 patient results obtained from the Sysmex XN-450 hematology analyzer in January 2024. Findings: 1. Review of P&P identified "CBC Auto Diff W/ Reflex" that states the laboratory "will reflex abnormal specimens for a manual differential of the peripheral blood smear to the reference laboratory based on the established parameters below", which included parameters for the CBC (MCV, hematocrit, hemoglobin, platelet count, white blood cell count) and automated differential (>10% immature granulocytes, >6.0 absolute lymphocytes, blast indication, atypical lymphocyte indication, reactive lymphocyte indication, nucleated red blood cell indication). 2. Review of 36 hematology test records from January 2024 identified 4 abnormal patient results were released with flagged automated differential parameters. a. One of the 4 abnormal patient results reviewed had an atypical lymphocyte indication. b. 3 of the 4 abnormal patient results reviewed had a blast/abnormal lymphocyte indication. c. No documentation of the performance of a reflexed manual differential could be located. 3. Review of the same 36 hematology test records (January 2024) identified 3 abnormal patient results released with a flagged platelet parameter in the CBC. a. 3 of the 3 patient results had a thrombocytopenia flag for the CBC parameter. b. No documentation of corrective action taken for the 3 CBC flagged platelet parameters could be located. 4. An interview with the laboratory supervisor, 2/28/24 at 2:15, confirmed the lack of corrective action taken and documented for the 7 abnormal hematology specimens. 5. An exit interview with the laboratory director and laboratory supervisor, 2/28/24 at 4:00 PM, confirmed the findings. |