| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br><br>51D0236838 | (X3) Date Survey Completed<br><br>10/22/2019 |
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| **Name of Provider or Supplier**<br><br>Manchin Clinic | **Street Address, City, State**<br><br>100 Main Street, Farmington, 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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| **D2087** | ROUTINE CHEMISTRY<br>CFR(s): 493.841(a)<br><br>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory American Proficiency Institute (API) proficiency testing (PT) records and an interview with Technical Consultant 1 (TC1), the laboratory failed to attain a score of at least 80 percent for the analyte Total Bilirubin in the 3rd Chemistry Core 2019 testing event. Findings: 1. A review of API PT records identified an unsatisfactory performance of 40 percent for the analyte Total Bilirubin in the Chemistry Core 2019 3rd testing event. 2. An interview with TC1, on 10/22/19 at approximately 11:15 AM, confirmed the findings. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a tour of the laboratory and an interview with Testing Personnel 1 (TP1), the laboratory failed to accurately monitor the conditions (2) temperature and (3) |

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| | humidity essential for proper storage of reagents and test system operation. Findings: 1. The room temperature and humidity of the laboratory were being monitored and documented from a thermometer that had an expired NIST calibration. The certificate of calibration for the NIST certified Thomas 9337T07 thermometer expired 10/18. 2. The room temperature reagents and supplies were located in a separate storage area from the lab. This storage area was not being monitored and documented for temperature and humidity conditions. 3. An interview with TP1, on 10/22/19 at approximately 11:38 AM, confirmed the findings. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of laboratory Quality Control (QC) records, calibration records, and an interview with Testing Personnel 1 (TP1), the laboratory failed to perform and document calibration verification for the Sodium, Potassium, and Chloride analytes in chemistry testing. Findings: 1. A review of calibration records for 2018 and 2019 established that no calibration verification of Sodium, Potassium, and Chloride analytes had been performed and documented on the Vitros 350 chemistry analyzer. The calibration of Sodium, Potassium, and Chloride analytes utilizes only two levels of calibration materials. 2. A review of QC records identified the laboratory ran 2 levels of Quality Control materials once each day of testing on the Vitros 350 chemistry analyzer. 3. An interview with TP1, on 10/22/19 at approximately 11:30 AM, confirmed that the laboratory had not performed or documented calibration verification for the Sodium, Potassium, and Chloride analyte testing on the Vitros 350. |