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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>51D1093164            | <b>(X3) Date Survey Completed</b><br>05/10/2023 |
| <b>Name of Provider or Supplier</b><br>Hahn Medical Practices Inc  | <b>Street Address, City, State</b><br>215 South Louisiana Avenue, Martinsburg, WV |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |   |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
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| <b>D0000</b>              | An announced, on site, routine recertification survey was conducted for Hahn Medical Practices Inc. on May 10, 2023, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.   |
| <b>D5413</b>              | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br/>CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of records, a tour of the laboratory, and interview the laboratory failed to (a) define the acceptable room temperature and humidity range criteria to monitor the testing environment for 3 of 3 months in 2023 and (b) record room temperature and humidity from a NIST certified thermometer/hydrometer. Findings:<br/>1. Review of the temperature and humidity logs for January, February, and March 2023, revealed no established range for the acceptability of the room temperatures and humidity listed. 2. A tour of the laboratory, 5/10/23 at approximately 9:15 AM, identified the thermometer/hydrometer used to record room temperature and humidity had an expired NIST calibration (SN 192554890 expiration 10/10/2021). 3. An interview with the laboratory manager, 5/10/23 at approximately 9:20 AM, confirmed the thermometer/hydrometer had an expired calibration and the laboratory had not established acceptable ranges for room temperature and humidity.</p> |