Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>44D0923891 | (X3) Date Survey Completed<br>08/21/2023 |
|---|---|---|
| **Name of Provider or Supplier**<br>Cookeville Medical Center, Pllc | **Street Address, City, State**<br>225 North Willow Ave Ste 3, Cookeville, TN | |

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 |
|---|---|
| **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 observation of the laboratory, review of manufacturers' operator's manuals, lack of records, and staff interview, the laboratory failed to monitor humidity in the area where the Medonic M Series Complete Blood Count (CBC) and Horiba ABX Pentra 400 chemistry instruments were in use for patient testing in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on 08/21/23 at 8:30 am revealed the following: - The Medonic M Series (SN: 46110) analyzer in use for performing patient CBC testing. - The Horiba ABX Pentra 400 (SN: 212P4-3201) analyzer in use for performing routine chemistry patient testing. - No device for monitoring of humidity was present in the testing area. 2. Review of the manufacturers' operator's manuals revealed the following humidity requirements: - Medonic M Series = Less than 85% relative humidity - Horiba ABX Pentra 400 = 20 - 85% relative humidity, without condensation 3. There were no records for humidity monitoring available for surveyor review. 4. Interview with laboratory manager on 08 /21/23 at 2:00 pm confirmed the laboratory did not monitor the humidity in the area where the Medonic M Series CBC instrument and the Horiba ABX Pentra 400 chemistry instrument were in use for patient testing in 2021, 2022, and 2023. |
| **D5415** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT |

CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of the manufacturer control package inserts, and staff interview, the laboratory failed to label control vials used for performing quality control (QC) on the Medonic M Series and Horiba ABX Pentra 400 analyzers with corrected expiration date. The findings include: 1. Observation of the laboratory on 8/21/23 at 8:30 am revealed the following: - Medonic M Series complete blood count (CBC) instrument (SN: 46110) and Horiba ABX Pentra 400 (SN: 212P4-3201) chemistry instrument in use for patient testing. - Three levels of opened Boule Con-Diff controls (Lot: 22306) in use for CBC QC and were not labeled with an open date or corrected expiration date. - Reconstituted ABX Pentra N MultiControl (Lot: 21053) and ABX Pentra P MultiControl (Lot: 21052) in use for chemistry QC and were not labeled with an open date or corrected expiration date. 2. Review of the manufacturer control package inserts revealed the following: - Opened vials of Boule Con-Diff Controls are stable for 14 days stored at 2 - 10 degrees Celsius (C). - ABX Pentra MultiControl stability after reconstitution is 12 hours at 15-25 degrees C, 5 days at 2-8 degrees C, and 28 days at -15 to -25 degrees C. 3. Interview with the laboratory manager on 8/21/23 at 2:00 pm confirmed the laboratory failed to label controls used to monitor CBC and Chemistry patient testing with corrected expiration date for five of five control vials observed on the date of the survey (8/21/23).