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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 39D0179861 | (X3) Date Survey Completed 08/07/2025 |
| Name of Provider or Supplier Southwest Medical Center | Street Address, City, State 119 Wilson Road, Bentleyville, PA | |
| 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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| D5413 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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: Based on review of the laboratory's temperature records and interview with the Medical Technologist (MT), the laboratory failed to monitor and document to ensure the proper storage of reagents was met for 1 of 1 Quidel Ortho Vitros XT3400 (chemistry), 1 of 1 Quidel OrthoVitro ECiQ (immunology), and 1 of 1 Abbott Cell-Dyn Emerald (hematology) analyzers from 09/14/2023 to 08/07/2025. Findings Include: 1. On the date of the survey, 08/07/2024 at 1:00 pm, review of the laboratory's temperature control logs revealed the laboratory failed to monitor and document freezer (acceptable range: 0- -23 degrees Celsius) and refrigerator temperatures (acceptable ranges 2-10 degrees Celsius) on weekends and holidays to ensure the proper storage of reagents was met for 1 of 1 QuidelOrtho Vitros XT3400, 1 of 1 Quidel OrthoVitros ECiQ and 1 of 1 Abbott Cell-Dyn Emerald analyzers from 09/14/2023 to 08/07/2025). 2. The laboratory performed 127,170; microbiology, chemistry and hematology tests in 2024 (CMS 116, estimated annual volume, dated 07 /25/2025). 3. The TC confirmed the above findings on 11/13/2024 at 11:00 am.</p> |