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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 33D2262322 | (X3) Date Survey Completed 07/11/2023 |
| Name of Provider or Supplier Gold Coast Pediatrics | Street Address, City, State 18 Railroad Ave, Glen Head, NY | |
| 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>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: Based on direct observation and the lack of temperature and relative humidity records, the laboratory failed to follow the Horiba Micros 60 manufacturer's temperature and humidity requirements from July 21, 2022, through the survey date. FINDINGS: 1. The Horiba Micros 60 hematology analyzer required temperatures of 16 - 34C (61 - 93F) and relative humidity of 80%; also, temperatures up to 31C (88F) and decreasing linearity humidity to 40C (104F). 2. The relative humidity and temperature were not monitored and documented from July 21, 2022, through the survey date. 3. Confirmed the findings by interview with laboratory director on July 11, 2023, at approximately 11:30 A.M.</p> |