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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 52D2152949 | (X3) Date Survey Completed 05/11/2021 |
| Name of Provider or Supplier Marquette University | Street Address, City, State Schroeder Health Complex Room 267a, Milwaukee, WI | |
| 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 survey review of laboratory procedures and temperatures logs and interview with the laboratory director, the laboratory did not monitor and document the humidity in the laboratory to ensure proper performance conditions for the Hologic Panther system. Findings include: 1. Review of procedure PA-01 "Operator's Guide and Maintenance for the Panther System" showed the humidity needs to be 20-85% for proper performance conditions. 2. Review of the temperature logs showed no monitoring or documentation of humidity in the laboratory. 3. Interview with the laboratory director on May 11, 2021 at 10:33 AM confirmed the laboratory did not monitor or document humidity in the laboratory to ensure proper performance conditions for the Hologic Panther system.</p> |