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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 25D2167145 | (X3) Date Survey Completed 10/11/2022 |
| Name of Provider or Supplier Mrh Medical Grp-Premier Diabetes & Medical Clinic | Street Address, City, State 2394 Mccullough Blvd, Belden, MS | |
| 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 review of laboratory temperature and humidity records since 2/25/2022 and confirmation with testing personnel (TP) and technical consultant (TC) at 2:00 p.m. on 10/11/2022, the laboratory failed to monitor and document the room humidity and temperature of the laboratory room where the Qualigen analyzer was stored and testosterone, TSH and Free T4 testing performed. Findings include: 1. Observation of the laboratory where testosterone, TSH, and Free T4 testing was performed revealed no thermometer or hygrometer to monitor the room temperature or humidity for optimal performance of the IP Fast Pack Qualigen analyzer. 2. Laboratory records (room temperature and humidity) available for review were documented from monitoring the thermometer and hygrometer in another room (where phlebotomy was performed and the refrigerator was housed). 3. IP Fast Pack Qualigen manufacturer's instructions require a room temperature of 15 - 32 degrees Celsius and a relative humidity of 10 - 80%. The instructions read "Record the temperature and humidity of the lab area on a daily basis and write values in the daily environment log." 4. Interview with the TP and the TC at 2:00 p.m. on 10/11/2022 confirmed that room temperatures and humidity results recorded on the Qualigen environment log were taken from the thermometer and hygrometer in another room rather than the</p> |

laboratory room where testosterone, TSH, and Free T4 testing was performed on the Qualigen analyzer.