| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 10D1092470 | 04/03/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| My Pediatrics | 20646 Wilderness Lake Blvd, Land O Lakes, FL | |

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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| **D2122** | HEMATOLOGY<br>CFR(s): 493.851(b)<br><br>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on American Proficiency Institute (API ) proficiency testing record review for the last two of two years (2016 Hematology 1st, 2nd, and 3rd Event -2017 Hematology 1st, 2nd and 3rd Event) and interview with the Laboratory Director, the laboratory failed to achieve an 80% proficiency testing score for White Blood Differential, Granulocytes, and Lymphocytes plus Monocytes for the 2017 Hematology 2nd Event. Findings included: During API record review (2016 Hematology 1st, 2nd, and 3rd Event and 2017 Hematology 1st, 2nd, and 3rd Event ) it was found that the laboratory obtained a 0% proficiency testing score for White Blood Differential, Granulocytes, and Lymphocytes Plus Monocytes for the 2017 Hematology 2nd Event. No corrective documentation was present. During an interview at 12:00 PM on 04/03/18, the Laboratory Director stated the Testing Personnel had entered the whole number result instead of the percentage result. The Laboratory Director also stated they had reviewed the proficiency testing results with staff but did not implement and document corrective action. |
| **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. |

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| | (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 record review of the temperature log, procedure manual, Hematology analyzer operational manual, package insert for the quality controls, and interview with the Laboratory Director, the laboratory failed follow manufacturer's instructions for environmental requirements for the Hematology analyzer and the quality controls for the respiratory panel (testing started the last week of December of 2017). Findings included: The review of the Hematology analyzer operational manual revealed that the Room Temperature should be 20-32 degrees Celsius and the Relative Humidity should be below 80%. The review of the Daily Logs and Temperature Logs revealed that the laboratory was not documenting Room Temperature or Humidity. During review of the package insert for the quality controls for the respiratory panel, it disclosed that the quality controls should be stored at -20 degree Celsius. During the review of the Freezer Temperature logs (starting with the last week of December 2017), the coldest temperature was documented as 11.5 degree Celsius. During an interview on 04/03/18 at 12:00 PM, the Laboratory Director stated they did not know the hematology instrument had specific environmental conditions and the new waived respiratory panel controls also had specific environmental conditions. |