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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>10D0270905       | <b>(X3) Date Survey Completed</b><br><br>11/08/2018 |
| <b>Name of Provider or Supplier</b><br><br>Quantum Health Diagnostics  | <b>Street Address, City, State</b><br><br>4724 N Davis Hwy 2nd Fl, Pensacola, FL |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
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| <b>D0000</b>              | A recertification survey was conducted on November 8, 2018. Quantum Health Diagnostics clinical laboratory had two deficiencies found at the time of the visit.  |
| <b>D5209</b>              | <p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b><br/>CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on record review and interview with testing person # A, it was determined that the laboratory failed to perform competency assessments on 2 out of 2 clinical consultants reviewed to ensure performance and reporting of tests accurately. Findings included: Based on review of testing persons # D and E personnel records revealed no competency assessments for 2 years from November 2016 through November 2018 . During interview on 11/8/18 at 01:00 PM, testing person # A confirmed that the lab failed to implement policies that will show competency evaluations for clinical consultants and competency assessments were not done.</p> |
| <b>D5413</b>              | <p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b><br/>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>  |

This STANDARD is not met as evidenced by:

Based on record review and interview, it was determined that the laboratory did not monitor the two waterbaths # 1 and #2 temperature requirements to assure performance of tests accurately 23 days of February and July for the year 2017 and 23 days of June, July, August, and September 2018 documents reviewed. Review of the laboratory procedures indicated that the two waterbaths were required to maintain 40-50 degrees centigrade.. The temperature log for waterbath # 1 of February 2017 ( 2/1, to 2/3, 2//6 to 2/10 and 2/13 to 2/17 and September 2018 ( 9/4 to 9/7, 9/10 to 9/14,) were not recorded. Waterbath # 2 of July 2017 ( 7/19 to 7/21 , 7/24 to 7/26, 9/5 to 9/8 ) and June through August 2018 ( 6/4 to 6/8, 7/18 to 7/20, 7/23, 7/25, 8/1, 8/8 , 8/15, 8 /22 ) were not performed. Interview on 11/8/18 at 01:00 PM , testing person # A confirmed that the temperatures of the two waterbaths were not documented.