

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2123289	<b>(X3) Date Survey Completed</b>  06/20/2018
<b>Name of Provider or Supplier</b>  K Wade Foster Md Pa	<b>Street Address, City, State</b>  1052 Downing Circle, Wauchula, 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>
<b>D5413</b>	<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 record review and interview with the Laboratory Manager, the laboratory failed to record the room humidity since 01/2017. Findings Included: Review of temperature records revealed a form titled "Laboratory Room Temperature/Humidity" that had the room temperatures recorded on days that testing was performed. No documentation of the room humidity was provided. During an interview on 06/20/18 at 11:52 AM the Laboratory Manager confirmed that the humidity had not been recorded since 01/2017.</p>
<b>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Manager the laboratory</p>

failed to perform preventative maintenance on the microscope for 1 out of 1 (2018) year reviewed. Findings Included: Review of the purchase order on the microscope revealed that it was purchased 01/2017. No documentation of yearly preventative maintenance for the microscope was provided. During an interview on 06/20/18 at 12:00 PM the Laboratory Manager confirmed the purchase of the microscope and confirmed that there was no documentation of preventative maintenance being performed.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on record review and interview with the Laboratory Manager, the laboratory failed to include the address of where testing was performed since 01/2017. Findings Included: Patient reports were pulled from 06/05/18 and 10/03/17. The patient reports did not contain the address of where the testing was performed. During an interview on 06/20/18 at 11:30 AM the Laboratory Manager confirmed the patient reports did not contain the address of where testing was performed.