

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  18D1099915	<b>(X3) Date Survey Completed</b>  07/18/2019
<b>Name of Provider or Supplier</b>  Meade County Pediatrics	<b>Street Address, City, State</b>  1010 Lawrence Street, Brandenburg, KY	
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 staff interview on 07/18/2019, the laboratory failed to monitor and document room temperature, humidity, and refrigerator temperature to ensure requirements were met for the proper storage of reagents and requirements were consistent with the manufacturer's instructions for operation of the Hitachi Luminometer Allergy instrument. Findings include: 1. Review of the policy and procedure manual failed to include a policy defining the monitoring and documentation of refrigerator temperatures for proper storage of reagents. 2. Review of the policy and procedure manual failed to include a policy defining the monitoring and documentation of room temperature and humidity for the operation of the Hitachi Luminometer. 3. Review of temperature logs failed to reveal recordings of room temperature, humidity, and refrigerator temperature on 03/28/2018, 04/12/2018, 04/20/2018, and 04/25/2018. 4. Testing personnel acknowledged in an interview at 11:00 AM on 07/18/2019, the laboratory failed to have a policy in place to ensure room temperatures, humidity, and refrigerator temperatures were documented daily.</p>