

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0707433	(X3) Date Survey Completed 12/03/2019
Name of Provider or Supplier Wvu Medicine Thomas Hosp Ob & Gyn Ii	Street Address, City, State 4607 Maccorkle Avenue Sw Suite 301, South Charleston, WV	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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: Based on review of laboratory personnel files, written policies and procedures, and an interview with Testing Personnel 1 (TP1), the laboratory failed to assess the annual competency of laboratory personnel for 2018 and 2019. Findings: 1. The written laboratory policy/procedure states " Personnel must be evaluated by the Technical Consultant at least semi-annually during the first year of employment. Thereafter, testing personnel are evaluated yearly." 2. No documentation of an annual employee competency for TP1 could be located for 2018 and 2019. 3. An interview with TP1, on 12/3/19 at approximately 1:00 PM, confirmed the findings.</p>
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>

This STANDARD is not met as evidenced by:

Based on a tour of the laboratory and an interview with Testing Personnel 1 (TP1), the laboratory failed to accurately monitor the condition (2) temperature essential for proper test system operation. Findings: 1. A tour of the laboratory identified the use of the BD Affirm III test system. The manufacturer instructions state "When performing this test the temperature of the testing environment must be 22 to 28 degrees Celsius." 2. A tour of the laboratory identified the use of a NIST calibrated thermometer to monitor the environmental temperature but no documentation of that monitoring could be located. 3. An interview with TP1, on 12/3/19 at approximately 2:00 PM, confirmed the findings. TP1 stated that she did not know she needed to document the daily room temperature of the lab, but that the thermometers had alarms to notify when temperatures were out of range.