

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0903784	(X3) Date Survey Completed 05/21/2019
Name of Provider or Supplier Advanced Diagnostic Imaging Pc	Street Address, City, State 3939 Central Pike 1st Floor, Hermitage, TN	
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
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> <p>This STANDARD is not met as evidenced by: Based on lack of records available for review and interview with the lead testing person the laboratory failed to monitor and document the room temperature and humidity of the laboratory in 2017, 18 and 19. The findings include: 1. There were no room temperature and humidity records available for review between July 26, 2017 through May 21, 2019. 2. Interview with the lead testing person on May 21, 2019 at 11:45 am confirmed the laboratory failed to monitor and document the room temperature and humidity of the laboratory between July 26, 2017 through May 21, 2019.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of employee personnel records and interview with the lead testing person, the laboratory's technical consultant failed to document the six required criteria for assessing personnel competency in 2017. The findings include: 1) Review of employee personnel records revealed missing documentation for 3 out of 6 testing persons (#1, 3 and 6) for the six required criteria of competency assessment that include: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and, assessment of problem solving skills in 2017. 2) An interview with the lead testing person on May 21, 2019 at 11:30 am confirmed 3 of 6 testing personnel (#1, 3 and 6) were not evaluated using the six criteria for competency assessment required by Centers for Medicare and Medicaid (CMS) in 2017.