

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D1021465	(X3) Date Survey Completed 06/11/2018
Name of Provider or Supplier First You Medical Center Pllc - Bedford Office	Street Address, City, State 18 Alexander Avenue Unit One, Bedford, KY	
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and record review, it was determined the Technical Consultant failed to perform quality assurance from June 21, 2016 through June 3, 2018. Findings include: Record review revealed there was no documented evidence of Quality Assurance performed from June 21, 2016 through June 3, 2018. The staff acknowledged in an interview on 6/11/2018 at 10:00 AM, that from June 21, 2016 through June 3, 2018, there was no system in place to document Quality Assurance on a quarterly basis.</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: Based on staff interview and record review on 6/11/2018, it was determined the Technical Consultant failed to perform and document annual competency using the six (6) mandated competency assessment requirements for testing personal. Competency assessment was performed using zero (0) of six (6) methods of</p>

assessment for three (3) out of three (3) employees from June 21, 2016 to June 3, 2018. Findings include: Record review on 06/11/18, revealed there was no documented evidence the competency assessments for three (3) employees reviewed included the following: direct observation of routine patient test performance; direct observation of performance of instrument maintenance function checks and calibration; monitoring the recording and reporting of test results; review of worksheets; review of quality control records; review of proficiency test results; review of maintenance records; and assessment of testing external proficiency testing samples and problem solving skills. Interview with staff on 6/11/2018 at 9:35 AM, revealed the facility failed to have a system in place to ensure competency was performed using all six (6) mandated competency assessment requirements from June 21, 2016 through June 3, 2018.