

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0873163	(X3) Date Survey Completed 05/17/2022
Name of Provider or Supplier Knoxville Center For Reproductive Health	Street Address, City, State 1547 W Clinch Avenue, Knoxville, 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
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> <p>===== Based on review of employee personnel records for 2020 and 2021 and interview with the laboratory manager, the laboratory's technical consultant failed to document the six required criteria for assessing personnel competency for three of three testing personnel (TP). The findings include: 1) Review of three of three employee personnel records for 2020 and 2021 failed to include documentation of the six required criteria of competency 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. 2) An interview with the laboratory manager on May 17, 2022 at approximately 2:15 p.m. confirmed three of three testing personnel evaluated during 2020 and 2021 were not evaluated using the six criteria for competency required by Centers for Medicare and Medicaid (CMS).</p> <p>=====</p>