

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0706289	<b>(X3) Date Survey Completed</b>  08/03/2023
<b>Name of Provider or Supplier</b>  Kilby Correctional Facility	<b>Street Address, City, State</b>  12201 Wares Ferry Road, Mount Meigs, AL	
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>D5291</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> 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 reviews of personnel records and an interview with the Laboratory Director/ Technical Consultant, the laboratory failed to implement a mechanism and procedures to assess five of the six minimal competency assessment criteria required for moderate complexity testing. This was noted for one of one testing personnel since before the previous survey on 3/11/2021. The findings include: 1. A review of the electronic quality assurance records revealed the Laboratory Director/ Technical Consultant documented the competency assessments for the testing personnel by using the proficiency testing scores in 2021-2023. All scores were 100%, so the Director deemed the Testing Personnel #1 competent. 2. During an interview with the Laboratory Director on 8/3/2023 at 10:45 AM, the surveyor reviewed the six competency assessment criteria required for moderate complexity testing, as follows: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples. f) Assessment of problem solving skills. 3. As the interview continued on 8/3 /2023 at approximately 10:50 AM, the surveyor explained the current system failed to include assessments for five of the six minimal competency assessment criteria. The</p>

Laboratory Director confirmed he had no other means for assessing competency, and had not realized there were other requirements. SURVEYOR ID# 32558 and 46292  
Licensure and Certification Surveyors