

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0681275	(X3) Date Survey Completed 10/10/2023
Name of Provider or Supplier Gordon T Connor Md	Street Address, City, State 2018 Brookwood Med Ctr Dr Pob Suite 209, Birmingham, AL	
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
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Maintenance records and interviews with Testing Personnel #1, the laboratory failed to ensure maintenance for the centrifuge was documented. This was noted from the date of the last survey, 8/20/2023, to the date of the current survey, 10/10/2023. The findings include: 1. A review of Maintenance records revealed centrifuge maintenance records dated in 2013. No current documentation of maintenance for the laboratory's centrifuge was available for review. 2. During an interview on 10/10/2023 at 11:00 AM, Testing Personnel #1 explained a Southeast Clinical Laboratories representative came annually to perform maintenance, and retained those records. After reaching out to Southeast Clinical Laboratories, Testing Personnel #1 informed the surveyor no maintenance records were available for review.</p>
D6032	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform</p>

test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on a review of Personnel records and an interview with Testing Personnel #1, the Laboratory Director failed to specify in writing the job duties and responsibilities of all laboratory personnel as listed on the Laboratory Personnel Report (CMS-209). This was noted from the date of the previous survey, August 20, 2023, to the date of the current survey, October 10, 2023. The findings include: 1. A review of the Personnel records revealed no evidence of a job description for the Laboratory Director, Testing Personnel #1, or Testing Personnel #2. 2. During an off site interview on 10/12/2023 at 9:50 AM, Testing Personnel #1 confirmed the above findings.