

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0936089	(X3) Date Survey Completed 05/13/2026
Name of Provider or Supplier Cullman Internal Medicine	Street Address, City, State 1890 Alabama Hwy 157 Suite 300, Cullman, 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
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Beckman Coulter DxI Immunoassay analyzer quality control (QC) records, the patient results log, and an interview with the Technical Consultant (TC), the laboratory failed to ensure at least two levels of QC were acceptable prior to analyzing patient specimens and reporting the results. This was noted two days out of 1 month reviewed in 2024. The findings include: 1. A review of the QC records for the DxI Immunoassay analyzer revealed the QC for the following dates and analytes were unacceptable due to expired calibration: a) 10/29/2024; Folate and Free Triiodothyronine (FT3), b) 10/30/24; Folate and Testosterone. 2. A further review of the patient log revealed the following patients were affected; a) 10/29/24; 55 Folate and 11 FT3, b) 10/30/24; 21 Folate and 1 Testosterone. 3. During an interview on 5/13 /2026 at 11:15 AM, the TC confirmed the above findings.</p>