Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0936089	05/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Cullman Internal Medicine	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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records and an interview with Testing Personnel #1, the laboratory failed to enroll in an approved Proficiency Testing program for 2024. The findings include: Refer to D2001. .
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing

	(PT) records and an interview with Testing Personnel #1, the laboratory failed to enroll in an approved Proficiency Testing program for 2024. This was noted for four out of five specialties reviewed in 2024. The findings include: 1. A review of the API PT records revealed the laboratory failed to enroll in the 2024 API program for Event 1 for the following specialties: a. Chemistry b. Immunology c. Hematology d. Microbiology 2. During an interview at 10:35 AM on 5/3/2024, Testing Personnel #1 explained the laboratory enrolled in API's proficiency program in March of 2024, at which time Microbiology Miscellaneous Event 1 was the only event available for shipment.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the QIAstat-Dx Respiratory QC (Quality Control) records, a review of the patient test log, a review of the QIAstat-Dx IQCP (Individualized Quality Control Plan), and an interview with Testing Personnel #1, the Laboratory failed to ensure testing personnel performed the Qiagen QC every 30 days as per the IQCP. The surveyor noted one out of twelve months in 2023 when QC was not performed as required by the IQCP prior to patient testing. The findings include: 1. A review of the QIAstat-Dx Respiratory records revealed the laboratory exceeded the 30-day requirement for external controls QC, as follows: a) 9/28/2023 to 11/27/2023; 30 days over due. 2. A review of the patient test log revealed within those 30 days, three patients were performed on the following dates: a) 10/31/2023. b) 11/17/2023. c) 11 /21/2023. 3. A further review of the QIAstat-Dx Respiratory IQCP revealed on page 3, "Run external controls with positive and negative representation... once a month at a minimum." 4. During an interview on 5/3/2024, at 1:45 PM, Testing Personnel #1 confirmed October 2023 external QC was overlooked.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records, and an interview with Testing Personnel #1, the Laboratory Director

	failed to ensure the laboratory enrolled in an approved PT program for 2024. This was noted for four of five specialties in the first event of 2024. The findings include: Refer to D2001.