Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1000045	04/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ambulatory And Occupational Medicine Clinic	2320 Wilma Rudolph Blvd Suite B, Clarksville, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records and staff interview, testing personnel failed to sign one of nine PT attestation statements reviewed from 2022, 2023, and 2024. The findings include: 1. A review of proficiency testing records revealed that the testing person did not sign the attestation statement for Hematology 2022 event three. 2. The lead testing person confirmed during interview on 04/10/24 at 12:45 pm that the testing person who performed the Hematology PT for 2022 event three did not sign the PT attestation statement.
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

	This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) Casper Report 0155D (CMS 155), the laboratory's PT records, staff interview, electronic mail, and patient test reports, the laboratory failed to participate in the 2023 event two proficiency testing (PT) for Complete Blood Count (CBC) with patient testing being performed. The findings include: 1. A review of the CMS 155 revealed a score of 0% for the Hematology specialty for 2023 event two. 2. A review of the laboratory's American Proficiency Institute (API) PT evaluation report for Hematology 2023 event two revealed a score of 0% for "Failure to Participate." 3. The lead testing person stated the following during interview on 04/10/24 at 10:00 am: The laboratory had taken the instrument out of service and had stopped CBC testing due to a calibration failure. The instrument was taken out of service on 07/15/23. Neither the PT program nor the State agency was notified. 4. A review of electronic mail received from API on 04/12/24 at 7:30 a.m. revealed that the CBC PT kit was delivered to the lab on 07 /11/23 at 11:09 a.m. The event's due date was August 2, 2023. 5. A review of patient test reports revealed the laboratory tested two patients for CBC on 07/14/23 (Lab test #s 86968 and 86969) after the kit was received but before the instrument was taken out of service. This confirmed the survey findings.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of the laboratory's API PT records and staff interview, the laboratory failed to evaluate two non-graded scores for Troponin I for 2023 PT event two. The findings include: 1. A review of the laboratory's PT records revealed two non-graded scores for Troponin I for 2023 event two. The laboratory had not documented the evaluation of the non-graded scores to determine the accuracy of the results. 2. The lead testing person confirmed during interview on 04/10/24 at 12:45 p. m. that the laboratory did not evaluate the non-graded PT scores for the Troponin I analyte for 2023 event two.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on review of patient test reports and lack of documentation, the laboratory failed to have documentation of a provider order for testing performed on patient accession number (Lab Test #) 85882 (one of five patients selected for review). The findings include: 1. Review of patient number 105272558, Lab Test # 85882 revealed patient testing for Complete Blood Count, Troponin I, Myoglobin, Creatine Kinase Myocardial Band (CK-MB) testing on 03/02/23. 2. The laboratory was asked for and failed to provide an order for the patient testing performed on 03/02/23 for patient accession number (Lab Test #) 85882. 3. The lead testing person confirmed during

	interview on 04/10/24 at 12:45 p.m. that the laboratory did not have documentation of a provider order for accession number 85882 for testing performed on 03/02/23.