Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1071166	11/26/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ambulatory And Occupational Medicine Clinic	2302 Madison Street, 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
D0000	During a recertification survey performed on 11/26/2024, the laboratory was found out of compliance with the following conditions: 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the Department of Health and Human Services Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), laboratory procedures, laboratory personnel records, final patient test reports, and staff interviews, the laboratory failed to follow its policy for testing personnel (TP) training and competency for five of five TP that performed complete blood count (CBC), creatine kinase myocardial band (CK-MB), Troponin, and Myoglobin patient testing in 2024. This was cited on the previous survey conducted on 10/16/2023, and compliance was not maintained. The findings include: 1. Observation of the laboratory on 11/26/2024 at 9:15 am revealed a Sysmex pocH-100i (serial number G4769) instrument used for patient CBC testing and the Triage MeterPro (serial number 00074960) used for CK-MB, Troponin, and Myoglobin patient testing. 2. A review of Form CMS-209 revealed five TP who performed CBC, CK-MB, Troponin, and Myoglobin patient testing. The form listed the Laboratory Director as the Technical Consultant. 3. A review of the laboratory policy titled "Laboratory Quality Assessment & Improvement Plan" section "E" titled "Personnel" revealed: "Initial training with evaluation, a 6 (six) month evaluation, and an annual evaluation yearly thereafter will be conducted with the Laboratory Director and/or Technical Consultant reviewing the performance of each employee working in

the laboratory to ensure employee competency". The following elements would be evaluated: (1) Direct observation of routine patient test performance, (2) Monitoring the recording and reporting of test results, (3) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records, (4) Direct observation of the performance of instrument maintenance and function checks, (5) Assessment of test performance through previously analyzed specimens, internal blind testing, or external proficiency testing samples, and (6) Evaluation of problem solving skills. 4. A review of the laboratory personnel records revealed the following: TP One (hired 03/22/2024): The laboratory director did not sign or date the training forms for the Sysmex pocH-100i or the Triage Meter. The laboratory director did not sign or date the form titled "Review of Competency for Moderately Complexity Testing" for the initial competency assessment, and the level of competency was not documented for either the Sysmex pocH-100i or the Triage Meter. On the survey date (11/26/2024), a six-month competency assessment for the Sysmex pocH-100i or the Triage Meter that was due 09 /22/2024 was not available. TP Two (hired 09/03/2024): The laboratory director did not sign or date the training forms for the Sysmex pocH-100i or the Triage Meter. The laboratory director did not sign or date the form titled "Review of Competency for Moderately Complexity Testing" for the initial competency assessment, and the level of competency was not documented for either the Sysmex pocH-100i or the Triage Meter. For the Sysmex pocH-100i, The sections on Routine patient test performance (Direct Observation) and Performance of instrument maintenance and function checks (Direct Observation) were incomplete. The sections on Monitoring the recording and reporting of test results, Assessment of Test Performance, and Evaluation of problem-solving skills were not addressed. For the Triage Meter, The sections on Routine patient test performance (Direct Observation), Monitoring the recording and reporting of test results, and Performance of instrument maintenance and function checks (Direct Observation) were incomplete. The sections on Review of intermediate test results and Assessment of test performance were not addressed. TP three (hired 08/14 /2024): The laboratory director did not sign or date the training forms for the Sysmex pocH-100i or the Triage Meter. The laboratory director did not sign or date the form titled "Review of Competency for Moderately Complexity Testing" for the initial competency assessment, and the level of competency was not documented for either the Sysmex pocH-100i or the Triage Meter. For the Sysmex pocH-100i, Performance of instrument maintenance and function checks (Direct Observation) was incomplete. For the Triage Meter, The sections on Routine patient test performance (Direct Observation) and Performance of instrument maintenance and function checks (Direct Observation) sections were incomplete. The sections on Review of intermediate test results, Performance of instrument maintenance and function checks (Direct Observation), and Assessment of test performance were not addressed. TP four (hired 10/07/2024) The laboratory director did not sign or date the training forms for the Sysmex pocH-100i or the Triage Meter. The forms had incomplete sections. The laboratory director did not sign or date the form titled "Review of Competency for Moderately Complexity Testing" for the initial competency assessment, and the level of competency was not documented for either the Sysmex pocH-100i or the Triage Meter. For the Sysmex pocH-100i, The sections on Review of intermediate test results, Performance of instrument maintenance and function checks (Direct Observation), and Evaluating problem-solving skills were incomplete. The sections on the Performance of instrument maintenance and function checks (Direct Observation) and Assessment of test performance were not addressed. For the Triage Meter, Assessment of test performance was not completed. Routine patient test performance (Direct Observation), Monitoring the recording and reporting of test results, review of intermediate test results, and performance of instrument maintenance and function

	checks (Direct Observation) sections were incomplete. TP five (hired 06/05/2024) The laboratory director did not sign or date the training forms for the Sysmex pocH-100i or the Triage Meter. The forms had incomplete sections. The laboratory director did not sign or date the form titled "Review of Competency for Moderately Complexity Testing" for the initial competency assessment, and the level of competency was not documented for either the Sysmex pocH-100i or the Triage Meter. For the Sysmex pocH-100i, The Monitoring, recording, and reporting of test results, Review of intermediate test results, Performance of instrument maintenance and function checks, Assessment of test performance, and Evaluation of problem-solving skills were not addressed. For the Triage Meter, The sections on Routine patient test performance, Review of intermediate test results, Performance of instrument maintenance, and function checks were incomplete. The sections on Monitoring the recording and reporting of test results and Assessment of test performance were not addressed. 5. A review of final patient test reports revealed the following: Patient 109596215 CBC reported 10/10/2024 performed by TP two Patient 89500038 CBC reported 10/14/2024 performed by TP three and TP five Patient 50167 CBC reported 10/26/2024 performed by TP three Patient 82888 CBC reported 11/12 /2024 performed by TP four 6. An interview with the Director of Operations and TP one on 11/26/2024 at 1:00 pm confirmed the survey findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of the Department of Health and Human Services Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), laboratory job descriptions, personnel records, and staff interviews, the laboratory director failed to provide overall management and direction of the laboratory. (Refer to D6029)
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the Department of Health and Human Services Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), laboratory job descriptions, personnel records, and staff interviews, the laboratory director failed to ensure five of five TP had

	documented training and competency before performing CBC, CK-MB, Troponin, and Myoglobin patient testing in 2024. This was cited at the previous survey (10/16 /2023), and compliance was not maintained. (Refer to D5209) The findings include: 1. Observation of the laboratory on 11/26/2024 at 9:15 am revealed a Sysmex pocH-100i (Serial GG4769) instrument used for patient CBC testing and the Triage MeterPro (Serial 00074960) used for CK-MB, Troponin, and Myoglobin patient testing. 2. A review of Form CMS-209 revealed five TP who performed CBC, Troponin, CK-MB, and Myoglobin patient testing. The Laboratory Director fulfilled the Technical Consultant position. 3. A review of the policy titled "Laboratory Director Responsibilities" revealed that the laboratory director was responsible for monitoring the laboratory personnel who performed patient test procedures. 4. A review of the laboratory personnel records revealed the following: The laboratory director failed to document training (ten of ten reviewed) for the five TP that performed moderately complex testing. The laboratory director failed to document initial competency (five of five reviewed) for the five TP that performed moderately complex testing. The laboratory director failed to perform the six-month competency evaluation for TP one, which was due in September 2024. 5. During an interview with the Director of Operations and TP one on 11/26/2024 at 1:00 p.m., TP one stated that training was provided by personnel no longer employed at the laboratory. This confirmed the survey findings.