Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1000045	09/13/2022
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
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 review of the laboratory procedure manual, testing personnel records for 2021 and 2022, and interview with the laboratory liaison, the laboratory failed to have a procedure for assessing personnel competency that was in compliance with the regulations in subpart M. The findings include: 1) Review of the laboratory procedure manual revealed the following six criteria were not included in the procedure for assessing testing personnel competency: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. Further, the policy did not include a requirement for semi-annual competency assessment during the first year of testing, and/or re-evaluation of competency if test methodology changes. 2) Review of testing personnel records revealed the following: Testing personnel #1--six month competency assessment performed on 01/06/21 did not include direct observations, 2021 annual review performed on 07/06/21 did not include direct observations, 2022 annual competency assessment performed 07/20/22 did not include blind testing. Testing personnel #2--six month competency assessment performed on 08/18/22 did not include blind testing. Testing personnel #5--six month competency assessment performed on 07/30/22 did not include blind testing. Testing personnel #6--six month competency assessment performed on 08/25/22 did not include blind testing. Testing

	personnel #7--six month competency assessment performed on 08/22/21 did not include direct observations; annual competency performed on 02/26/22 did not include direct observation or blind testing. Testing personnel #8--annual competency assessment performed on 02/04/22 did not include blind testing. Testing personnel #9--annual competency assessment performed on 07/13/22 did not include blind testing and did not include direct observations. 3) Interview on 09/13/22 at 3:00 p.m. with the laboratory liaison confirmed the testing personnel competency procedure was not in compliance with the requirements at subpart M as required by the Centers for Medicare and Medicaid Services (CMS) when it did not define the procedures used for assessing competency to include the six required criteria, did not include requirements for interim competency during the first year of testing and did not require re-evaluation of competency if test methodology changes.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: CITATION NUMBER ONE: Based on observation of the laboratory, review of manufacturers' operators manuals, document request and interview with the lead testing person, the laboratory failed to monitor humidity in the area where the Sysmex pocH-100i complete blood count (CBC) instrument and Alere Triage chemistry instrument was located in 2020, 2021, and 2022. The findings include: 1. Observation of the laboratory on 09/13/22 at 8 am revealed the Sysmex pocH-100i (serial number F3100) in use for patient testing for CBC and the Alere Triage chemistry instrument (serial number 00076232WW) in use for performing cardiac testing to include Troponin I, Myoglobin, and CK-MB. 2. Review of the manufacturers operators manuals revealed the operating humidity range for the pocH-100i CBC instrument was 30-85%, and the humidity range for the Alere Triage chemistry instrument was 10-85%. 3. Document request on 09/13/22 at 8:15 am to the lead testing person for humidity monitoring records revealed no records were available. The humidity was not monitored. 4. Interview with the lead testing person on 09/13/2022 at 3:00 pm confirmed the laboratory failed to monitor environmental conditions for humidity in the area where the pocH-100i CBC instrument and Alere Triage chemistry instrument was in operation for patient testing in 2020, 2021 and 2022. CITATION NUMBER TWO: Based on observation of the laboratory, review of the manufacturer control package insert, observation of the employee break area, and interview with the lead testing person, the laboratory failed to follow manufacturer instructions for storage of chemistry controls in 2022. The findings include: 1. Observation of the laboratory on 09/13/22 at 8 am revealed the Alere Triage chemistry instrument in use for performing patient cardiac testing including Troponin I, Myoglobin, and CK-MB. 2. Review of the manufacturer control package insert revealed the following: Controls are to be stored frozen at -20 degrees Celsius or lower in a non-defrosting freezer. Do not store near the freezer door. The reagents should be handled as though they are capable of transmitting disease. 3. Observation on 09/13/22 at 1 pm of the employee

	break area revealed the freezer where the controls for the Alere Triage chemistry instrument were stored. The controls were stored in the door of the freezer; the freezer was not non-defrosting, and there was storage of frozen foods. 4. Interview on 09/13 /22 at 3 pm with the lead testing person confirmed the laboratory failed to follow the manufacturer instructions for storage of controls for the Alere Triage chemistry instrument when it stored controls in a manner that was inconsistent with manufacturer requirements.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) 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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation of the laboratory, document request, and staff interview, the laboratory failed to verify the accuracy of its' temperature recording devices in 2020, 2021, and 2022. The findings include: 1. Observation of the laboratory on 09/13/22 at 8 am revealed devices used for monitoring refrigerator and room temperatures that were not certified. The devices were used in areas where the complete blood count instrument and chemistry instrument were operated as well as the refrigerator where the complete blood count controls were stored. 2. Request for documentation of verification of accuracy of the temperature recording devices on 09/13/22 at 10:30 am revealed no records were available. 3. Interview with the lead testing person on 09/13 /22 at 3:00 pm confirmed the laboratory did not verify the accuracy of its' temperature recording devices in 2020, 2021, and 2022.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's calibration records for the Sysmex pocH-100i complete blood count (CBC) instrument, the manufacturer calibrator package insert, the manufacturer operators manual, the laboratory failed to follow the manufacturer

	instructions for recalibration of the Sysmex pocH-100i CBC instrument in April 2022 (one of three reviewed). The findings include: 1. Review of the laboratory's calibration records for the pocH-100i CBC instrument revealed calibration performed on 04/21/22. Parameters for the white blood cell were outside the acceptable range (range = 7.5 - 8.0, recovered mean = 7.4). Historic calibration records revealed no adjustment was made to the white blood cell parameter after calibration was performed. 2. Review of the Sysmex pocH-100i CBC calibrator package insert and the manufacturer operator's manual revealed the following statements: "An analyzer mean value outside the acceptable limits indicates the need for recalibration.." "However, before changing calibration settings, the results of internal quality control using Sysmex control material and insight external quality control data should be considered." The manufacturer operator's manual indicated to hit "Quit" to update calibration values. 3. Interview with the lab liaison on 09/13/22 confirmed the laboratory failed to follow the manufacturer's instructions for recalibration of the Sysmex pocH-100i CBC instrument in April 2022 (one of three reviewed).
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of complete blood count quality control records and interview with the laboratory liaison, the laboratory failed to have a process in place to monitor quality control data for shifts and/or trends in 2020, 2021 and 2022. The findings include: 1. Review of quality control records for the Sysmex pocH-100i revealed the laboratory uses the daily quality control printouts for monthly review of quality control data. The laboratory did not have a process in place to monitor for shifts or trends in 2020, 2021, and 2022. 2. Interview with the laboratory liaison on 09/13/22 at 3 pm confirmed the laboratory failed to have a process in place to monitor for shifts or trends in quality control data in 2020, 2021, and 2022.
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: CITATION NUMBER ONE: Based on review of testing personnel records and interview with the lab liaison, the laboratory director failed to ensure two of nine new testing personnel had documentation of highest level of education for performing moderately complex patient testing in 2022. The findings include: 1. Review of testing personnel records revealed the following: There were nine new testing personnel since the last survey. Two of the nine new testing personnel did not have documentation of the highest level of education (testing personnel numbers four and seven). Both of the testing personnel perform moderately complex testing for complete blood count and cardiac marker testing. 2. Interview with the lab liaison on 09/13/22 at 3pm confirmed the laboratory director failed to ensure two of nine testing personnel had documentation of highest level of education for performing moderately complex patient testing in 2022. CITATION NUMBER TWO Based on review of testing personnel records and interview with the laboratory liaison, the laboratory director failed to perform initial training/verification of accurate test performance for six of nine new testing personnel. The findings include: 1. Review of testing personnel records revealed the following: There were nine new testing personnel since the last survey. The nine new testing personnel perform moderately complex patient testing for complete blood count and cardiac markers (Troponin, Myoglobin and CK-MB). Initial training and verification that the testing personnel were performing the testing accurately was not performed/verified by the laboratory director for six of nine new testing personnel (testing personnel numbers two, three, four, five, seven and ten). 2. Interview with the laboratory liaison on 09/13/22 at 3 pm confirmed the laboratory director failed to perform initial training/verification of accurate test performance for six of nine new testing personnel.