Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0316234	01/29/2024
Name of Provider or Supplier	**Street Address, City, State**	
Jonathan D Allred Md Pc	234 W Central Ave, Jamestown, 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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual and staff interview, the laboratory failed to establish a written policy or procedure defining the quality activities used to monitor, assess, and correct problems in the laboratory's testing systems. The findings include: 1. A review of the laboratory procedure manual revealed no approved policy or procedure defining the laboratory's quality assessment activities for the surveyor to review on the survey date (01/29/2024). 2. Interview with the Laboratory Director on 01/29/24 at 1:00 p.m. confirmed the laboratory did not have written quality assessment policies or procedures.
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: Based on observation of the laboratory, review of the instrument instructions for use, lack of records, and staff interview, the laboratory failed to monitor temperature and humidity in the area where the Beckman Coulter DxH 520 hematology instrument was used to perform complete blood count (CBC) patient testing in 2022, 2023, and 2024. The findings include: 1. Observation of the laboratory on 01/29/24 at 8:15 a.m. revealed a Beckman Coulter DXH-520 hematology instrument (SN: BF020093) in use for performing patient CBC testing. No device for monitoring ambient temperature and humidity was observed in the laboratory area. 2. A review of the Beckman Coulter DxH 520 instructions for use manual revealed the following statements: -"The instrument configured with DxH 520 consumables meets performance specifications when operated at a temperature of +18 to 32C (64.4 to 89.6F). If the average room temperature changes more than 10F (or 6C) from the temperature at which the instrument CBC was calibrated, verify the calibration and recalibrate, if necessary, to ensure optimum performance." -"The instrument meets performance claims when operated at a maximum 80% relative humidity." 3. A review of the laboatory environmental records for 2022, 2023, and 2024 revealed the laboratory did not document room temperature or humidity. 4. In an interview on 01/29/24 at 12:30 p.m., the lead testing person confirmed the laboratory did not monitor room temperature or humidity in the area where the Beckman Coulter DxH 520 hematology instrument was being used to perform CBC patient testing in 2022, 2023, and 2024.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's policy, quality control (QC) records, procedure analysis report, and staff interview, the laboratory failed to ensure Complete Blood Count (CBC) QC was within acceptable limits prior to reporting eighteen patient CBC results on 08/29/2023. The findings include: 1. Observation of the laboratory on 01/29/24 at 8:15 a.m. revealed a Beckman Coulter DXH-520 hematology instrument (SN: BF020093) in use for performing patient CBC testing. 2. A review of the laboratory's policy titled "Quality Control" revealed the following: - "Patient testing results will not be reported until all levels of control are within range." 3. A review of quality control records from 08/29/23 revealed the following unacceptable DxH 500 Series QC results: - Normal Level (Lot: 362315112) flagged the WBC, LY, NE, LY#, NE#, RBC, HBG, HCT, and PLT analytes out of range. - Abnormal High Level (Lot: 372315113) flagged the RBC, HGB, and HCT analytes out of range. 4. A review of the procedure analysis report for CBC testing revealed eighteen patient CBC samples were reported by the laboratory on 08/29/23. 5. In an interview on 01/29/24 at 11:30 a.m., the lead testing person confirmed two of three levels of CBC QC were not within acceptable limits before reporting patient results on 08/29/23. Key: WBC = White Blood Cell count, LY= Lymphocyte count, NE= Neutrophil count, LY# = Absolute lymphocyte count, NE# = Absolute neutrophil count, RBC= Red Blood Cell count, HGB= Hemoglobin, HCT= Hematocrit, PLT= Platelet count.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CMS-209) and Clinical Laboratory Improvement Amendments Application for Certification (CMS-116), competency assessment records, and staff interviews, the laboratory failed to document all six required criteria for assessing personnel competency for one of two testing personnel (TP) performing complete blood count (CBC) testing in 2022 and 2023. The findings include: 1. A review of the CMS-209 and CMS-116 provided by the laboratory on 01/29/2024 revealed two testing personnel performing CBC patient testing. 2. A review of competency assessment records for TP-2 revealed the following: - Assessment completed on 02/10 /23 failed to include documentation of (1) review of preliminary test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records; (2) direct observation of the performance of instrument maintenance and function checks; (3) assessment of test performance through testing previous specimens, blind test samples, or external proficiency testing samples. - Assessment completed on 07/14/22 failed to include documentation of (1) review of preliminary test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records; (2) direct observation of the performance of instrument maintenance and function checks; (3) assessment of test performance through testing previous specimens, blind test samples, or external proficiency testing samples; (4) assessment of problem-solving skills. 3. Interview with the Laboratory Director and lead testing person on 01/29/24 at 1:00 p.m. confirmed the laboratory failed to document all six required criteria for assessing personnel competency for TP-2 performing CBC patient testing in 2022 and 2023.