Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1074396	(X3) Date Survey Completed 06/17/2024
Name of Provider or Supplier Pediatric Place Of Union City Llc	**Street Address, City, State** 1345 Edwards St, Union City, 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 laboratory policy, American Association of Bioanalysts Medical Laboratory Evaluation (AAB/MLE) proficiency testing (PT) records, lack of records, and staff interviews, the laboratory failed to follow the Quality Assurance policy in place for PT review in 2023 (one of six events reviewed). The findings include: 1. A review of the laboratory policy titled "Quality Assurance Plan" section "II. Proficiency Testing" revealed all unacceptable, unsatisfactory, or unsuccessful proficiency testing results would be evaluated. 2. A review of the laboratory's AAB MLE PT records revealed the following for 2023 Event two: Lymphocyte % scored as unacceptable for sample number ten with no documented evaluation or corrective action. 3. An interview with testing person one on 06/17/2024 at 12:00 pm confirmed the survey findings. Word Key % - percent
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results.

	(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the laboratory procedure manual, and staff interview, the laboratory procedure for the Sysmex XN 330 complete blood count (CBC) instrument failed to include reportable ranges and panic values. The findings include: 1. Observation of the laboratory on 06/17/2024 at 9:30 am revealed the Sysmex XN 330 instrument (Serial #13393) used for CBC patient testing. 2. A review of the laboratory procedure for the Sysmex XN 330 CBC instrument revealed the procedure did not include the required elements of reportable ranges or panic values. 3. An interview on 06/17/2024 at 12:00 pm with testing person one confirmed the survey findings.
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, the manufacturer's operator's manual, lack of records, and a staff interview, the laboratory failed to monitor the temperature and humidity in the area where the Sysmex XN 330 complete blood count (CBC) instrument was used for patient testing in 2023 and 2024. The findings include: 1. Observation of the laboratory on 06/17/2024 at 9:30 am revealed the Sysmex XN 330 (Serial #13393) used for CBC patient testing. During the observation testing person one stated that the laboratory did not monitor room temperature or humidity in the testing area. 2. A review of the manufacturer operator's manual for the Sysmex XN 330 revealed the following operating conditions: Ambient temperature 15-35 degrees Celsius Relative humidity 20-85 percent 3. There was no documentation of room temperature or humidity monitoring available on the date of the survey (06/17/2024). 4. Testing person one confirmed the survey findings during an interview on 06/17 /2024 at 12:00 pm.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)

	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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Association of Bioanalysts Medical Laboratory Evaluation (AAB/MLE) proficiency testing (PT) records and a staff interview, the laboratory director failed to document the review of two PT performance evaluations (two of six) in 2023. The findings include: 1. A review of the laboratory's 2023 and 2024 AAB/MLE PT records revealed that the laboratory director did not review the performance evaluations for 2023 Events One and Two. 2. An interview on 06/17/2024 at 12:00 pm with testing person one confirmed the survey findings.