Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1074396	03/03/2026
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Place Of Union City Llc	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
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 laboratory observation, a review of the laboratory's procedure manual, and staff interview, the laboratory policy for testing personnel competency assessment was not in compliance with Subpart M of the Clinical Laboratory Improvement Amendments (CLIA) regulatons when it did not include a requirement for semi-annual competency during the first year of patient testing, did not include a requirement for reassessment of competency if test methods change, and failed to include the six criteria defined in Subpart M of the CLIA regulations. The findings include: 1. Laboratory observation on 03/03/26 at 9:15 a.m. revealed the Sysmex XN-L 330 instrument used for performing patient testing for Complete Blood Count (CBC) and CBC with automated White Blood Cell differential (CBC w/Diff). 2. A review of the laboratory policy titled "General Lab Quality Assessment Plan" revealed that the policy for testing personnel competency assessment did not include a requirement for semi-annual competency during the first year of testing or a requirement for reassessment of competency when test methodology changes. The six criteria defined in Subpart M were not included in the policy (direct observation of patient testing, monitoring the recording and reporting of test results, record review (quality control, maintenance records, proficiency testing records), direct observation of instrument maintenance and function checks, assessment of test performance using previously analyzed test specimens, internal blind testing samples, or external proficiency testing samples, evaluation of problem solving skills). 3. The sole testing person confirmed the survey findings during interview on 03/03/26 at 1:00 p.m.

D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of patient test results, a review of the laboratory's CBC w/Diff quality control records and a lack of documentation, a review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), and staff interview, the laboratory did not have a procedure in place to monitor for shifts or trends in CBC w/Diff quality control (QC) data in 2024 or 2025, with approximately 1,027 patient tests reported annually. The findings include: 1. Laboratory observation on 03/03/26 at 9:15 a.m. revealed the Sysmex XN-L 330 instrument used for performing patient testing for CBC w/Diff. 2. A review of laboratory records revealed patient testing performed on 09/18/24 for patient sample identification number (ID) 3857 for CBC, on 10/13/25 for patient ID 2920 for CBC, patient ID 7135 on 01/05/26 for CBC, and patient ID 8729 on 03/03 /26 for CBC w/Diff. 3. A review of the laboratory's CBC w/Diff quality control records for the selected dates revealed no documented review of the laboratory's cumulative daily quality control data to monitor for shifts or trends. 4. A review of the Form CMS-116 revealed that the laboratory reported approximately 1,027 analytes annually from the Sysmex XN-L 330 hematology instrument. 5. The sole testing person stated during an interview on 03/03/26 at 1:00 p.m. that the laboratory used the Sysmex Interlaboratory Quality Assessment Program (IQAP) peer review comparison for review of quality control and did not have a process in place for review of the laboratory's daily cumulative quality control. This confirmed the survey findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the manufacturer's operator's manual, a review of the laboratory procedure manual, a review of laboratory records, a review of

	the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), and staff interviews, the laboratory policy for performance of quality control (QC) for the Sysmex XN-L CBC w/Diff instrument was not consistent with the manufacturer's requirements, resulting in performance of patient testing after maintenance and reagent changes were performed, without first performing quality control in 2024 and 2025, with approximately 1,027 patient tests reported annually. The findings include: 1. Laboratory observation on 03/03/26 at 9: 15 a.m. revealed the Sysmex XN-L 330 CBC w/Diff instrument used for patient testing. During observation, the sole testing person was asked about the quality control protocol and whether quality control was performed after changing reagents or performing maintenance. She stated that it was not. She stated that weekly cleaning was performed after startup and quality control, and that quality control was not performed again after the task was completed. She further stated that reagent changes occurred randomly when prompted, and that QC was not routinely performed after reagent changes. 2. A review of the Sysmex XN-L 330 Basic Operation manual revealed the following regarding the performance of quality control: "QC is performed at the following times. Before sample analysis After replacement /replenishment of reagents After instrument maintenance When there is a concern about the accuracy of analysis values" 3. A review of the laboratory procedure for the Sysmex XN-L 330 revealed that the procedure did not include a requirement for performance of quality control before patients, after replacement/replenishment of reagent, after instrument maintenance, or if patient results are questioned. 4. A review of laboratory records revealed the following: Weekly routine cleaning was performed on 03/02/26 at 8:21 a.m. QC was not performed after the cleaning maintenance task was performed. One patient was reported on 03/02/26 at 9:05 a.m. (after maintenance but before QC was performed the next day (03/03/26) for patient ID 13356. 5. A review of the Form CMS-116 revealed that the laboratory reported approximately 1,027 analytes annually from the Sysmex XN-L 330 hematology instrument. 6. The sole testing person confirmed that the laboratory did not have control procedures for the Sysmex XN-L 330 CBC w/Diff instrument that were consistent with the manufacturer's requirements during interview on 03/03/26 at 1:00 p.m.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on laboratory observation, review of laboratory records, a review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), and staff interview, the laboratory failed to review the background counts for the Sysmex XN-L 330 CBC w/Diff instrument from the date of the last survey on 06/17/24 to the date of the survey on 03/03/26 with approximately 1,027 patient tests reported annually. The findings include: 1. Laboratory observation on 03 /03/26 at 9:15 a.m. revealed the Sysmex XN-L 330 CBC w/Diff instrument used for patient testing. 2. A review of laboratory records revealed no documented review of the background counts from the date of the last survey to the current survey date. 3. A review of the Form CMS-116 revealed that the laboratory reported approximately

	1,027 analytes annually from the Sysmex XN-L 330 hematology instrument. 4. The sole testing person confirmed the survey findings during an interview on 03/03/26 at 1 p.m.