Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1074396	04/11/2022
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
D0000	The laboratory was found not to be in compliance with the following CLIA conditions: D2000: 493.801 Condition: Enrollment and testing samples D5200: 493.1230 Condition: General laboratory systems D5400: 493.1250 Condition: Analytic system D6000: 493.1403 Condition: Laboratories performing moderate complexity testing, laboratory director The laboratory's failure to be in compliance with these regulations was found to pose IMMEDIATE JEOPARDY to patients served by the laboratory.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on observation of the laboratory, lack of documentation, review of patient test records, interview with testing personnel and an email, the laboratory failed to enroll in proficiency testing (PT) for the Complete Blood Count (CBC) analytes in 2021 and 2022, with 124 patients reported since testing began on 03.15.2021. The findings include: 1. Observation of the laboratory on 04.11.2022 at 9:45 am revealed a Sysmex XN-330 in use for complete blood count (CBC) patient testing. 2. Request for PT records on 04.11.2022 at 11:10am revealed no PT records were available. The sole testing person stated the laboratory was not enrolled in PT for the CBC analytes. 3. Review of patient test reports revealed CBC testing began on 03.15.2021 (patient

	#2640) until the date of the survey (04.11.2022). 4. Interview with the sole testing person on 04.11.2022 at 11:50 am confirmed the laboratory was not enrolled in PT for the CBC analytes in 2021 and 2022 with patient testing performed. 5. Email communication from the sole testing person received on 04.12.2022 revealed the laboratory performed 124 patient CBCs since testing began on 03.15.2021-04.11.2022.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: The laboratory failed to establish testing personnel competency assessment policies (Refer to D5209) and failed to establish a general laboratory systems quality assessment policy in 2021. (Refer to D5291)
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 personnel records, lack of documentation, interview with testing personnel and an email, the laboratory failed to establish written policies and procedures to assess employee competency in 2021 and 2022 for performance of complete blood count (CBC), with 124 patients reported since testing began on 03.15.2021. The findings include: 1. Review of personnel records revealed no documentation of competency for the sole testing person. 2. The testing personnel competency policies and procedures were requested from the sole testing person on 04.11.2022 at 11:15 am. The sole testing person stated the laboratory did not have policies or procedures for assessing testing personnel competency. 3. Interview with the sole testing person on 04.11.2022 at 11:50 am confirmed the laboratory did not have established policies and procedures for assessing testing personnel competency. 4. Email communication from the sole testing person received on 04.12.2022 revealed the laboratory reported 124 patient CBCs since testing began on 03.15.2021-04.11.2022.
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 observation of the laboratory, lack of documentation, interview with testing personnel and an email, the laboratory failed to establish general quality assessment (QA) policies and procedures in 2021 and 2022 for monitoring of moderately complex complete blood count (CBC), with 124 patients reported since testing began on 03.15.2021. The findings include: 1. Observation of the laboratory on 04.11.2022 at 9: 45 am revealed a Sysmex XN-330 in use for patient testing for CBC. 2. Request for QA policies and procedures from the sole testing person on 04.11.2022 at 11:15 am revealed the laboratory had no general QA policies or procedures. 3. Interview with the sole testing person on 04.11.2022 at 11:50 am confirmed the laboratory did not have any general QA policies or procedures. 4. Email communication from the sole testing person received on 04.12.2022 revealed the laboratory performed 124 patient CBCs since testing began on 03.15.2021 until the date of the survey on 04.11.2022.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of documentation, interview with testing personnel and an email, the laboratory failed to establish preanalytic quality assessment (QA) policies and procedures for the complete blood count (CBC) performed on the Sysmex XN-330 in 2021 and 2022, with 124 patients reported since testing began on 03.15.2021. The findings include: 1. Observation of the laboratory on 04.11.2022 at 9:45 am revealed a Sysmex XN-330 in use for CBC for patient testing. 2. Request for QA policies and procedures for the Sysmex XN-330 CBC instrument from the sole testing person on 04.11.2022 at 11:20 am revealed no procedures were available. 3. Interview with the sole testing person on 04.11.2022 at 11:50 am confirmed the laboratory failed to establish preanalytic QA policies and procedures for use of the Sysmex XN-330 in 2021 and 2022. 4. Email communication from the sole testing person received on 04.12.2022 revealed the laboratory reported 124 patient CBCs since testing began on 03.15.2021 until the date of the survey on 04.11.2022.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by:

	The laboratory failed to have a written procedural manual (Refer to D5401), failed to have a quality control plan (Refer to D5441), and failed to have a written analytic quality assessment plan (Refer to D5791).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of documentation, interview with testing personnel and an email, the laboratory failed to have a written procedure manual for the Sysmex XN-330 complete blood count (CBC) instrument in 2021 and 2022, with 124 patients reported since testing began on 03.15.2021. 1. Observation of the laboratory on 04.11.2022 at 9:45 am revealed a Sysmex XN-330 in use for CBC for patient testing. 2. Request for CBC procedure manual from the sole testing person on 04.11.2022 at 11:20 am revealed no written procedures were available. 3. Interview with the sole testing person on 04.11.2022 at 11:50 am confirmed the laboratory failed to have a written procedure manual for use of the Sysmex XN-330 CBC instrument. 4. Email communication from the sole testing person received on 04.12.2022 revealed the laboratory reported 124 patient CBCs since testing began on 03.15.2021.
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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of documentation, interview with testing personnel and an email, the laboratory failed to establish a quality control plan for the complete blood count (CBC) performed on the Sysmex XN-330 in 2021 and 2022, with 124 patients reported since testing began on 03.15.2021. The findings include: 1. Observation of the laboratory on 04.11.2022 at 9:45 am revealed a Sysmex XN-330 in use for CBC for patient testing. 2. Request for the quality control plan for the Sysmex XN-330 CBC instrument from the sole testing person on 04.11.2022 at 11:20 am revealed no procedures were available. 3. Interview with the sole testing person on 04.11.2022 at 11:50 am confirmed the laboratory failed to establish QC policies or procedures for use of the Sysmex XN-330 in 2021 and 2022. 4. Email communication from the sole testing person received on 04.12.2022 revealed the laboratory reported

	124 patient CBCs since testing began on 03.15.2021 until the date of the survey 04.11.2022.
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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of documentation, interview with testing personnel and an email, the laboratory failed to establish analytic quality assessment (QA) policies and procedures for the complete blood count (CBC) performed on the Sysmex XN-330 in 2021 and 2022, with 124 patients reported since testing began on 03.15.2021. The findings include: 1. Observation of the laboratory on 04.11.2022 at 9: 45 am revealed a Sysmex XN-330 in use for CBC for patient testing. 2. Request for QA policies and procedures for the Sysmex XN-330 CBC instrument from the sole testing person on 04.11.2022 at 11:20 am revealed no procedures were available. 3. Interview with the sole testing person on 04.11.2022 at 11:50 am confirmed the laboratory failed to establish QA policies and procedures for use of the Sysmex XN-330 in 2021 and 2022. 4. Email communication from the sole testing person received on 04.12.2022 revealed the laboratory reported 124 patient CBCs since testing began on 03.15.2021 until the date of the survey on 04.11.2022.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of documentation, interview with testing personnel and an email, the laboratory failed to establish postanalytic quality assessment (QA) policies and procedures for the complete blood count (CBC) performed on the Sysmex XN-330 in 2021 and 2022, with 124 patients reported since testing began on 03.15.2021. The findings include: 1. Observation of the laboratory on 04.11.2022 at 9:45 am revealed a Sysmex XN-330 in use for CBC for patient testing. 2. Request for QA policies and procedures for the Sysmex XN-330 CBC instrument from the sole testing person on 04.11.2022 at 11:20 am revealed no procedures were available. 3. Interview with the sole testing person on 04.11.2022 at 11:50 am confirmed the laboratory failed to establish postanalytic QA policies and procedures for use of the Sysmex XN-330 in 2021 and 2022. 4. Email communication from the sole testing person received on 04.12.2022 revealed the laboratory reported 124 patient CBCs since testing began on 03.15.2021 until the date of the survey on 04.11.2022.
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: The laboratory director failed to ensure the laboratory was enrolled in proficiency testing (Refer to D6015), failed to establish a quality control plan (Refer to D6020), failed to establish a quality assessment plan (D6021), and failed to establish policies for employee competency (Refer to D6030).
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of documentation, and interview with testing personnel, the laboratory director failed to ensure the laboratory was enrolled in proficiency testing (PT) for the complete blood count (CBC) analytes in 2021 and 2022, with 124 patients reported since testing began on 03.15.2021. The findings include: 1. Observation of the laboratory on 04.11.2022 at 9:45 am revealed a Sysmex XN-330 in use for complete blood count (CBC) for patient testing. 2. Request for PT records from the sole testing person on 04.11.2022 at 11:10am revealed no proficiency testing records were available. The sole testing person stated the laboratory was not enrolled in PT for the CBC analytes. 3. Interview with the sole testing person on 04.11.2022 at 11:50 am confirmed the laboratory director failed to ensure the laboratory was enrolled in PT for the CBC analytes in 2021 and 2022. (Refer to D2000)
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of documentation and interview with testing personnel, the laboratory director failed to establish a quality control plan for the complete blood count (CBC) performed on the Sysmex XN-330 in 2021 and 2022. The findings include: 1. Observation of the laboratory on 04.11.2022 at 9:45 am

	revealed a Sysmex XN-330 in use for CBC for patient testing. 2. Request for the quality control plan for the Sysmex XN-330 CBC instrument from the sole testing person on 04.11.2022 at 11:20 am revealed no quality control procedures were available. 3. Interview with the sole testing person on 04.11.2022 at 11:50 am confirmed the laboratory director failed to establish a quality control plan for the Sysmex XN-330 in 2021. (Refer to 5441)
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of documentation and interview with testing personnel, the laboratory director failed to ensure the establishment of a quality assessment (QA) program in 2021 and 2022. The findings include: 1. Observation of the laboratory on 04.11.2022 at 9:45 am revealed a Sysmex XN-330 in use for CBC for patient testing. 2. Request for the QA procedure for the Sysmex XN-330 CBC instrument from the sole testing person on 04.11.2022 at 11:20 am revealed no QA policies or procedures were available. 3. Interview with the sole testing person on 04.11.2022 at 11:50 am confirmed the laboratory director failed to ensure the laboratory had established a QA policy for use of the Sysmex XN-330 in 2021 and 2022. (Refer to D5391, D5791 and D5891)
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on lack of documentation and interview with testing personnel, the laboratory director failed to ensure policies and procedures were established to assess testing personnel competency in 2021 and 2022 for the performance of complete blood count (CBC), with 124 patients reported since testing began on 03.15.2021. The findings include: 1. Request for the personnel competency assessment policy from the sole testing person on 04.11.2022 at 11:15 am revealed the laboratory did not have competency assessment policies or procedures. 2. Interview with the sole testing

	person on 04.11.2022 at 11:50 am confirmed the laboratory director failed to ensure established procedures for testing personnel competency. (Refer to D5209)