Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D1015538	(X3) Date Survey Completed 11/14/2023
Name of Provider or Supplier Metro Pediatric Associates	**Street Address, City, State** 417 Benjamin Ln Suite # 101, Louisville, KY	

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	A recertification survey was initiated on 11/14/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
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, document review, and interview with the Laboratory Director (LD), the laboratory failed to enroll in a Centers for Medicare & Medicaid Services (CMS)-approved proficiency test (PT) program in the specialty of hematology for the regulated analyte complete blood count (CBC) since 2021. Findings included: During a laboratory tour on 11/14/2023, beginning at 2:15 PM, the surveyor observed a Sight Diagnostics OLO hematology analyzer. Review of a "CASPER Report 0096D" dated 10/17/2023, revealed no routine PT scores for the specialty of hematology for 2021, 2022, or 2023. PT records were requested from the Office Manager/Testing Personnel. In an interview on 11/14/2023 at 2:30 PM, the Laboratory Director (LD) confirmed the laboratory was not enrolled in a CMS approved PT program for the regulated CBC analyte.
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 document review and interview, the laboratory failed to establish a written quality assessment (QA) policy and procedure to monitor, assess, and correct problems, when indicated, in the general laboratory system for 3 (2021 through 2023) of 3 years reviewed. Findings included: On 11/14/2023 at 2:30 PM, a written QA policy and procedure was requested for review but was not provided. During an interview on 11/14/2023 at 2:30 PM, the Laboratory Director (LD) stated the laboratory lacked a written QA policy and procedure that encompassed the monitoring and review of proficiency testing (PT).
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: Based on direct observation, document review, and interview with the Laboratory Director (LD) the Laboratory Director failed to enroll in a Centers for Medicare & Medicaid Services (CMS) approved proficiency test (PT) program in the specialty of hematology for the regulated analyte complete blood count (CBC) since 2021. Refer to D6015
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 direct observation, document review, and interview with the Laboratory Director (LD), the Laboratory Director failed to enroll in a Centers for Medicare & Medicaid Services (CMS) approved proficiency test (PT) program in the specialty of hematology for the regulated analyte complete blood count (CBC) since 2021. Refer to D6015