Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 36D0341890	**(X3) Date Survey Completed** 05/14/2024
Name of Provider or Supplier James P D'Apolito Md Pediatrics Inc	**Street Address, City, State** 4316 Belmont Avenue, Youngstown, OH	
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**
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 record review and an interview with the Office Manager (OM), the laboratory failed to enroll with a proficiency testing (PT) provider for the Group A Streptococcus (Strep) throat culture (cx) tests performed in the subspecialty of Bacteriology. This deficient practice had the potential to affect 93 out of 93 patient Group A Strep throat cx tests performed in this laboratory from 01/02/2024 through 05/14/2024. Findings Include: 1. Review of the laboratory's "Throat Culture Quality Control" policy and procedure, approved by the Laboratory Director on 04/10/2018 and provided on the date of the inspection, found the following statements: "Every Quarter We have enrolled in a quality control program through the C.A.P...to test our proficiency with throat cultures... When office receives our C.A.P. kit; it is immediately refigerated. The kit is opened and checked for due date...we perform testing on the "unknowns" according to the enclosed instructions... ....cultures are performed just as we would on a patient." CAP; College of American Pathologists 2. Review of the laboratory's CAP PT documentation provided on the date of the inspection did not find any PT records for 2024. 3. The Inspector requested the laboratory's 2024 PT documentation from the OM. The OM was unable to locate any PT documentation for 2024 at the time of the inspection on 05/14/2024 at 9:50 AM

	and later confirmed via electronic mail (email) on 05/14/2024 at 10:33 AM "I called CAP and we unfortunately did not enroll in proficiency testing for 2024."
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on record review and an interview with the Office Manager (OM), the Laboratory Director failed to ensure that patient Group A Streptococcus (Strep) throat culture (cx) test results were only reported when the incubator temperatures were monitored and documented according to the manufacturer's specifications and laboratory's policy and procedure. This deficient practice had the potential to affect nine out of nine patient Group A Strep throat cx test results performed on three days of patient testing when the incubator temperatures were out of the acceptable range between 12/14/2023 through 01/25/2024. Findings Include: 1. Review of the laboratory's Form CMS-209, signed by the Laboratory Director on 05/14/2024, found the Laboratory Director was listed as the sole testing personnel. 2. Review of the "BD BBL Taxo A Discs for Differentiation of Group A Streptococci" manufacturer's package insert revealed the following instructions: "2. Incubate plate(s) in ambient air (or in an atmosphere enriched with 5 to 10% CO2) at 35 to 37 C for 18 to 24 hours." 3. Review of the laboratory's "Selective Streptococcus Agar (SSA)/Throat Swab" policy and procedure, approved by the Laboratory Director on 02/11/2016 and provided on the date of the inspection found the following statement: "8. Invert the plate and place it in the incubator at 35C +/- 2 in CO2 for 18 - 24 hours." 4. Review of the laboratory's "CLIA Management Sheet" revealed a chart with the columns labeled and documentation indicated as follows on days of patient Group A Strep throat cx testing: Date Time Incubator Temp 12/14/23 8:41 40 01/18/24 8:30 34 01/25/24 3:02 34 5. Further review of the laboratory's "CLIA Management Sheet" found the following statement: "Incubator temps must stay between 35-37 degrees Fahrenheit... revised 1/20" 6. Review of the laboratory's Selective Streptococcus Agar with Bacitracin QC and Patient Log" worksheet found the following patient Group A Strep throat cx testing conducted on days when the incubator temperatures were out of the acceptable limits. Patient Date Date CX Plated Read Result #1 12/14/23 12/15/23 negative #2 12/14/23 12/15/23 negative #3 12/14/23 12/15/23 negative #4 12/14/23 12 /15/23 negative #5 01/18/24 01/19/24 negative #6 01/18/24 01/19/24 negative #7 01 /25/24 01/26/24 negative #8 01/25/24 01/26/24 negative #9 01/25/24 01/26/24 negative 7. Review of the laboratory's "Throat Culture Quality Assessment" policy and procedure, approved by the Laboratory Director via signature and date on 04/10 /2018 and provided on the date of the inspection, found two (2) patient throat cx cases were reviewed each quarter in 2022, 2023 and the first quarter in 2024 per the laboratory's protocol with no incubator temperature errors identified for corrective action to be implemented. 8. The OM confirmed the incubator temperatures identified above were not within the required range, no corrective action was documented and the laboratory continued to perform patient Group A Strep throat cx testing. The interview occurred on 05/14/2024 at 8:38 AM. C ; degrees Celsius