

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0341890	(X3) Date Survey Completed 02/06/2020
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the laboratory failed to follow the manufacturer's instructions for the incubation time of the Selective Streptococcus Agar (SSA) and Taxo A discs, utilized for throat Group A Streptococcus (strep) testing procedures. This deficient practice had the potential to affect three out of three patient throat cultures tested and reported on 12/05/2019. Findings Include: 1. Review of the BD BBL Taxo Discs for Differentiation of Group A Strep manufacturer's instructions revealed the following statements: BD BBL Taxo A discs "Test Procedure 1. ...place the Taxo A disc in the center of the inoculated area... 2. Incubate plate(s)...for 18 to 24 hours." 2. Review of the laboratory's 2018, 2019, and 2020 patient test records on the "Selective Streptococcus Agar with Bacitracin QC and Patient Log" worksheets revealed documentation when the throat cultures were plated as well as when the throat cultures were read (interpreted). 3. Review of three out of three of the laboratory's patient test records and test reports from 12/03/2019 revealed throat culture test results were not read (interpreted) and reported following the manufacturer's instructions of 18-24 hours of incubation with the use of the Taxo A disc as indicated below: Date Date Culture Culture Plated Read 12/03/19 12/05/19 12/03/19 12/05/19 12/03/19 12/05/19 4. The Laboratory Director confirmed, at 10:20 AM on 02/06/2020, that the laboratory's test records and final test reports for the Strep A throat culture tests utilizing SSA and Taxo A discs indicated</p>

that the laboratory did not follow the BD BBL Taxo Disc manufacturer's requirement of 18-24 hours of incubation and the three patient throat cultures indicated above were read (interpreted) and reported beyond 24 hours of incubation.