

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0667729	(X3) Date Survey Completed 11/21/2019
Name of Provider or Supplier Pediatric Place Inc	Street Address, City, State 3690 Orange Place #100, Beachwood, 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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Director and the Office Manager (OM), the laboratory failed to document the evaluation of proficiency testing (PT) results obtained for four out of four of failed results using Wisconsin State Laboratory Hygiene (WSLH) Group A Strep (Streptococcus) Culture proficiency testing (PT) events in 2018 and 2019. All patient Group A Strep Culture testing performed in 2018 and 2019 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's 2018 and 2019 WSLH Group A Strep Culture PT records did not find any indication of PT result evaluations for four out of four failed PT samples. 2. Further review of the laboratory's 2018 and 2019 WSLH Group A Strep Culture PT records revealed the first PT event of 2018 and the first, second and third PT events of 2019 were all scored at 80% by WSLH with no evaluation documentation by the laboratory for the failed samples as indicated below. Year Testing Event Sample Number 2018 first ST-01 2019 first ST-04 2019 second ST-10 2019 third ST-14 3. The Inspector requested the laboratory's 2018 and 2019 WSLH Group A Strep Culture failed PT result evaluation documentation for the indicated sample numbers above from the Laboratory Director and OM. The Laboratory Director and OM confirmed the laboratory did not document the failed PT result evaluations, as required, and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 11/21/2019 at 11:05 AM.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</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.

This STANDARD is not met as evidenced by:

Based on record review and interviews with the Laboratory Director and the Office Manager (OM), the laboratory failed to follow the manufacturer's result reporting instructions for the BD (Becton Dickinson) BBL Taxo Discs for Differentiation of Group A Streptococci (Strep). This deficient practice had the potential to affect all patient throat cultures tested and reported in 2018 and 2019. Findings Include: 1. Review of the BD BBL Taxo Discs for Differentiation of Group A Strep manufacturer's instructions revealed the following result reporting instructions: "Results A zone of inhibition is formed around the Taxo disc if the organism is a group A streptococcus. It is recommended that any zone of inhibition, regardless of diameter, be reported as 'beta-hemolytic Streptococcus, presumptively group A by bacitracin.' No zone of inhibition (growth up to the edge of the disc) is reported as 'beta-hemolytic Streptococcus, presumptively not group A by bacitracin.'" "Limitations of the Procedure The Taxo A disc test is presumptive, and a positive result should be followed with more specific physiological and/or serological tests." 2. Review of the laboratory's policies and procedures, provided on the date of the inspection, did not find any mention of result reporting instructions. 3. Review of four out of four of the laboratory's 2019 patient test records and final test reports found strep A culture results documented and reported as "neg"/"negative" or "pos"/"positive". neg; negative pos; positive 4. The Laboratory Director and the OM confirmed that the laboratory did not follow the manufacturer's result reporting instructions and reported the strep A culture results as "neg"/"negative" or "pos"/"positive" in the test records and on the final test reports respectively. The interviews occurred on 11/21/2019 at 10:45 AM.