Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0341890	(X3) Date Survey Completed 03/20/2018
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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the laboratory failed to document the handling, preparation, processing, examination and each step in the testing and reporting of proficiency testing (PT) results. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, did not find any mention of PT policies and procedures. 2. The Surveyor requested the laboratory's PT policy and procedure from the Laboratory Director. The Laboratory Director confirmed the laboratory did not have an established PT policy and procedure. The interview occurred on 03/20/2018 at 9:12 AM.
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 record review and an interview with the Laboratory Director, the laboratory failed to follow their written throat culture reporting procedures according to the manufacturer's instructions. Findings Include: 1. Review of the Beckon Dickinson (BD) BBL Taxo A disc manufacturer's package instructions found the following reporting instructions: "...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." 2. Review of the laboratory's "Selective Streptococcus Agar (SSA) / Throat Swab" policy and procedure found the following reporting instructions: "C. Positive result: ... Presumptive Group A Streptococcus by bacitracin. D. Negative result: ...Negative for Group A Streptococcus or Beta hemolytic streptococci not Group A by bacitracin. ... The absence of beta hemolytic colonies on the SSA plate should be reported as "No Group A Streptococcus isolated." 3. Review of 13 out of 13 of the laboratory's 2016, 2017 and 2018 throat culture test reports, provided on the date of the inspection, did not find that the laboratory reported throat culture results according to the manufacturer's and laboratory's instructions. The laboratory reported the 13 throat culture results reviewed in the following variety of ways: "threoat cx is negative" "throat cx isnegative" "throat cx is negative" 4. The Laboratory Director stated the laboratory's throat culture test reporting is a free text field in the patients' electronic medical record and confirmed the laboratory did not follow the manufacturer's or laboratory's throat culture reporting instructions. The interview occurred on 03/20 /2018 at 9:50 AM.
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 record review and an interview with the Laboratory Director, the Laboratory Director failed to ensure that a quality assessment program was established. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, did not find any mention of quality assessment policies and procedures. 2. The Surveyor requested the laboratory's quality assessment policy and procedure from the Laboratory Director. The Laboratory Director confirmed the laboratory did not have an established quality assessment policy and procedure. The interview occurred on 03/20/2018 at 9:19 AM.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the Laboratory Director failed to ensure that all remedial actions were taken and documented whenever the incubator temperatures deviated from the manufacturer's and laboratory's established temperature criteria for the incubation temperature of the Selective Streptococcal Agar (SSA) and Becton Dickinson (BD) BBL Taxo A discs utilized for the throat culture testing procedures performed. Findings Include: 1. Review of the manufacturer's package instructions for the SSA found the following statement: "Incubate the plates...at 35-37C" 2. Review of the manufacturer's package instructions for the BD BBL Taxo A discs found the following statements: "Incubate... at 35 to 37 C" 3. Review of the laboratory's 2016, 2017 and 2018 incubator temperature logs where the SSA and Taxo A discs were incubated prior to interpretation revealed documented incubator temperatures that were outside of the manufacturer's incubation requirements without indication of any corrective action as follows: Date(s) Incubator temperature 06/25/16 38 C 06/27/16 38 C 10/14/16 34 C 10 /18/16 38 C 10/20/16 38 C 12/20/16 38 C 12/29/16 38 C 01/05/17 38 C 05/20/17 38 C 05/26-07/27/17 42-44 C 10/17/17 38 C 10/31-11/16/17 42 C 01/18/18 38 C 01/19/18 38 C 01/22/18 38 C 02/10/18 38 C 02/22/18 34 C 4. The Surveyor requested the laboratory's 2016, 2017 and 2018 documented corrective action for the above listed incubation temperatures that were out of the manufacturer's instructions for incubation temperature from the Laboratory Director. The Laboratory Director confirmed that the laboratory did not document any corrective action for the out of range incubator temperatures. The interview occurred on 03/20/2018 at 10:11 AM.