Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0670905	08/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Princeton-Windsor Pediatrics Pa	88 Princeton-Hightstown Rd, Princeton Junction, NJ	

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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to retain copies of all PT records for Throat Culture (TC) testing performed with the College of American Pathologists (CAP) in the calendar year 2018 and event A and B of 2019. The findings include: 1. The laboratory did not retain records as follows: a. D1-B 2018 - result evaluation sent from CAP b. D1-C 2018 - attestation statement and result evaluation sent from CAP c. D1 -A 2019 result evaluation sent from CAP d. D1-B 2019 - attestation statement and result evaluation sent from CAP 2. The TP #1 listed on CMS form 209 confirmed on 8/6/19 at 1:00 pm that PT records were not retained.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to evaluate results when the laboratory received an unacceptable score in PT for Throat Culture performed with the College of American Pathologists (CAP) in 2018. The finding includes: 1. There was no review or evaluation documented when the laboratory received an

	unsatisfactory score of 0 for D1-B 2018 event. 2. The TP #1 listed on CMS form 209 confirmed on 8/6/19 at 1:20 pm that the laboratory did not perform and document an evaluation of unacceptable PT performance.
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 surveyor review of the Procedure Manual (PM), observation of streaked plates and interview with the Testing Personnel (TP), the laboratory failed to follow the PM for plating throat culture specimens from 8/1/17 to the date of the survey. The findings include: 1. The PM stated to use one plate for each patient but the laboratory streaked four patients per plate. 2. At the time of the survey a plate was observed in the incubator divided into four sections. 3. TP #1 listed on CMS form 209 stated the laboratory plated four patients on a single plate. 4. The TP #1 listed on CMS form 209 confirmed on 8/6/19 at 1:20 pm that the laboratory did not follow the PM.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) 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 surveyor review of the Manufacturer's Package Insert (MPI), the Procedure Manual (PM), observation of the incubator, and interview with the Testing Personnel (TP), the laboratory failed to follow the manufacturer's instruction for incubating throat culture plates from 8/1/17 to the date of survey. The findings include: 1. The laboratory did not follow the MPI for bacitracin discs as stated below: a. MPI stated to incubate the sample between 33-37 Celsius (C) but the incubator temperature log revealed the acceptable temperature was 34-38 (C). b. The MPI stated to read the discs between 18 and 24 hours but the laboratory read and resulted patients between 24 and 48 hours. 2. The TP #1 listed on CMS form 209 confirmed on 8/6/19 at 1:10 pm that the laboratory did not follow the MPI.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must

	document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to check each lot number and shipment of Bacitracin Discs for positive and negative reactivity from 8/1/17 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 8/6/19 at 2:10 pm that QC was not performed.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Reports (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure that the Test Report Date (TRD) was indicated on the FR from 8/1/17 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 8/6/19 at 2:20 pm that the TRD was not on the FR.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that all PT results received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action for Throat Culture testing performed with the College of American Pathologists (CAP) in the calendar years 2018 and events A and B in 2019. The TP #1 listed on CMS form 209 confirmed on 8/6/19 at 1:30 pm that the CAP PT results were not reviewed.
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 surveyor observation of a lack of a Quality Assurance (QA) plan and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a QA plan from 8/1/17 to the date of the survey. The TP #1 listed on CMS form 209 confirmed 8/6/19 at 2:15 pm that a QA plan had not been established.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on surveyor review of Personnel Files and interview with the Testing Personnel (TP), the Laboratory Director failed to have education documented for two out of two TP from 8/1/17 to the date of the survey. TP #1 listed on CMS form 209 confirmed on 8/6/19 at 2:10 pm that education records were not available.