Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0121723	09/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
Princeton Nassau Pediatrics-West Windsor	196 Princeton Hightstown Road, West Windsor, 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
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 Proficiency Testing (PT) results and interview with the Testing Personnel (TP), the laboratory failed to review Unacceptable result for Urine Colony Count Combination performed with the College of American Pathologists (CAP) in 2021. The finding includes: 1. The laboratory received a "Unacceptable" result 3rd event 2021 for Urine Colony Count specimen MC-8. 2. There was no documented evidence that Unacceptable PT result was reviewed. 5. The TP confirmed on 9/29/22 at 10:33 am that the laboratory did not review Unacceptable PT result. .
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), and interview with the Testing Personnel (TP), the laboratory failed to follow all procedures written for "Chart Audits" from 3/11/16 to the date of the survey. The findings include: 1. There was no documented evidence the below mentioned procedure was followed: a. "Every six months 6 random charts are selected to check for agreement between test ordered and test results reported, agreement between test records and those on reports,

	consistency of results to patient information, the effectiveness of our critical value protocol.". 2. The TP confirmed on 9/29/22 at 10:30 am that the laboratory did not follow the PM.
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 1/8/21 to the date of the survey. The finding includes: 1. There was no record of Bacitracin QC in the QC log after 12/15/20 expiration date: 1/8/21. 2. The TP confirmed on 9/29/22 at 10:50 am that the laboratory did not perform QC on Bacitracin disc as stated above.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of the Temperature Logs (TL) and interview with the Testing Personnel (TP), the laboratory did not document corrective action taken when the Incubator Temperature (RT) was out of range in December 2021. The findings include: 1. A review of the TL revealed that IT was outside the established range: a. 12/27/21 and 12/31/21. 2. There was no documented evidence of corrective action taken. 3. The TP confirmed on 9/29/22 at 11:00 am the laboratory did not document corrective action.
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: a) Based on surveyor review of the Test Report (TR) and interview with the Testing Personnel (TP), the laboratory failed to report Covid 19 testing accurately on the date of survey. The finding includes: 1. The laboratory performed non Food and Drug Administration (FDA) cleared tests and there was no statement stating "This test has not been FDA cleared or approved; The test has been authorized by FDA under an Emergency Use Authorization (EUA)". 2. The TP confirmed on 9/29/22 at 11:20 am that COVID 19 tests were not reported accurately. b) Based on surveyor review of the Test Report (TR) and interview with the TP, the laboratory failed to ensure that the interpretation of COVID 19 test was on the TR on the date of survey. The finding includes: 1. The TR failed to include interpretation of COVID 19 results as found in the Manufacturers Package Insert (MPI). 2. The MPI stated "Negative results do not rule out COVID 19 and should not be used as the sole basis for treatment or patient management decisions." 3. The TP confirmed on 9/29/22 at 11:20 am that COVID 19 tests were not reported accurately.