Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0955681	11/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Norman Indich Pediatrics	603 West County Line Road, Lakewood, 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
D2021	BACTERIOLOGY CFR(s): 493.823(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with Testing Personnel (TP), the laboratory failed to participate in PT for Urine Colony Count (UCC) from the American Proficiency Institute (API) for the 1st event of 2023 for Bacteriology. The findings include: 1. TP #2 as listed on the CMS-209 form stated due to a shortage of uricult media, an off cycle self test was performed when the media was received. 2. There was no documented evidence an off cycle self test was performed for UCC for the 1st Bacteriology event of 2023. 3. TP#2 as listed on the CMS-209 form confirmed on 11/28/23 at 11:45 am that the laboratory failed to participate in UCC PT for the 1st Bacteriology event of 2023.
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) records and interview with the Testing Personnel (TP), the laboratory failed to document evaluation of all unsatisfactory scores and corrective action taken for Hematology and Microbiology events performed with the American Proficiency Institute (API) from 8/3/21 to the date of survey. The findings include: 1. White Cell Count for the 2nd Hematology event in 2022, sample Hem-08 was graded as unacceptable. 2. Group A Strep for the 1st Microbiology event in 2022, sample THCU-2 had a graded score of 0.0. 3. There was no documented evidence for corrective action for the aforementioned PT events. 4. TP#2 as listed on the CMS-209 form confirmed on 11/28/23 at 11:00 am there was no corrective action taken for the failed analytes for the above mentioned PT events.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor observation of the Quality Control (QC) records, review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to follow Manufacturers Specifications (MS) for User QC for BD BBL Taxo A discs from 8/3/21 to the date of survey. The finding includes: 1. The MS states " One or more beta-hemolytic streptococcal species belonging to groups B, C, D and/or G may be employed to demonstrate lack of zone formation." 2. The laboratory did not have any of the above mentioned QC organisms to use as a negative control to demonstrate lack of zone formation. 3. The TP #2 as listed on the CMS-209 form confirmed on 11/28/23 at 12:30 pm that MS were not followed.
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 a lack of a Quality Assessment (QA) plan, review of the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to establish a QA program to assure the quality of laboratory services provided from 8/3/21 to the date of the survey. The TP #2 confirmed on 11/28/23 at 11:00 am that the LD failed to establish a QA program.