Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0158843	03/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
Nshoa	118 North Country Road, Port Jefferson, NY	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on lack of competency assessment written procedure and an interview with the office manager and the laboratory supervisor, the laboratory failed to establish a written procedure for competency assessment for the providers performing PPMP testing. FINDINGS: The laboratory supervisor and the office manager confirmed on March 4, 2020 at approximately 10:00 AM, that the laboratory failed to establish and follow written procedures for competency assessment based on specific skills for KOH, Wet Mounts and Fern test.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on the lack of twice yearly verification and confirmed at survey with the office manager and the laboratory supervisor, the laboratory failed to verify the accuracy for KOH, Wet Mounts and Fern tests at least twice per year.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b)

	The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory's records and interview with the office manager and the laboratory supervisor, the laboratory failed to establish a written policy/procedures for: 1. Requirements for patient preparation; specimen collection, labeling, processing. 2. Corrective action for inadequate slides. 3. Step-by-step procedure, for microscopic examination of KOH, Wet Mounts, Fern test and interpretation of results. 4. Twice per year verification and remediation of any discrepant results found during the twice yearly verification of KOH, Wet Mount and Fern test.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on a lack of Quality Assessment (QA) records and confirmed at survey with the office manager and the laboratory supervisor, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems.