Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2008689	01/30/2020
Name of Provider or Supplier	**Street Address, City, State**	
General Physician Pc	520 Delaware Avenue, Buffalo, 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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on the lack of written laboratory procedure manual and an interview with the office manager, the laboratory failed to to establish and follow written procedures to ensure patient identification, labeling, testing and reporting of results. FINDINGS: The office manager confirmed on January 30, 2020 at approximately 1:30 PM, that the laboratory failed to establish and follow written procedures for patient identification and specimen integrity from collection through reporting test results for the Provider Performed Microscopy Procedures (PPMP) potassium hydroxide (KOH) and wet mounts.
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, the laboratory failed to establish a written procedure for competency assessment for the providers performing PPMP testing. FINDINGS: The office

	manager confirmed on January 30, 2020 at approximately 1:35 PM, that the laboratory failed to establish and follow written procedures for competency assessment based on specific skills for KOH and wet mounts; proficiency in using a microscope; ability to detect and identify elements present in a specimen; ability to differentiate significant elements from debris or artifacts and understanding that PPM specimens are labile.
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, the laboratory failed to verify the accuracy for KOH and wet mounts.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on on lack of Quality Assessment policy and confirmed at survey with the office manager, 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.
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 lack of written standard operating procedures (SOP) and confirmed at survey with the office manager, the laboratory failed to establish written policies /procedures for the KOH and wet mount tests.
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 lack of the laboratory's SOP and confirmed at survey with the office manager, the laboratory failed to establish written procedures for: 1. Requirements for patient preparation; specimen collection, labeling, processing. 2. Microscopic examination for KOH and wet mounts 3. Corrective action for inadequate slides. 4. Step-by-step procedure, for KOH and wet mounts and interpretation of results. 5. Policy and procedure for unacceptable specimens such as inadequate requisition information and mislabeled/unlabeled specimens.