Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1078647	10/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
A Kim Medical Pc	2500 Nesconset Hwy Bldg 21a Ste 76, Stony Brook, 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
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 records and interview with the laboratory director /technical supervisor, the laboratory failed to establish a comprehensive policy /procedure manual to include a written policy for retention and storage of histopathology and cytology slides and records.
D5633	CYTOLOGY CFR(s): 493.1274(d)(1)

	(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening. This STANDARD is not met as evidenced by: Based on surveyor's review of the pathology procedure manual, laboratory records and confirmed in an interview with the laboratory director, the laboratory failed to establish written policies and procedures to ensure that the pathologist/technical supervisor, established maximum workload limit for the pathologist when performing primary screening of the non-gynecologic slides from July 1, 2018 when testing was initiated through survey date. Approximately 400 non-gynecologic cytology slides were reviewed and reported during this time frame.
D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. This STANDARD is not met as evidenced by: Based on surveyor's review of written procedures, laboratory records and an interview with the laboratory director, the laboratory failed to establish and follow written policies and procedures to ensure that the workload limits were reassessed at least every six months for the pathologist who performs a primary screening, to determine if workload adjustment is needed.