Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1078647	01/23/2020
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
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 surveyor review of the twice per year verification records and confirmed in an interview with the Laboratory Director/Technical Supervisor, the laboratory failed to verify the accuracy of interpretation of histopathology at least twice per year in calendar years 2018 and 2019 and failed to verify the accuracy of interpretation of FISH analysis at least twice per year for calendar year 2019.
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 interview with the Laboratory Director/Technical 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.
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 the pathology laboratory's procedure manual and interview with the Laboratory Director/Technical Supervisor, the laboratory failed to establish written procedures for: 1. A procedure describing laboratory's turnaround time for the histopathology, urine cytology and FISH from sample collection to processing and to when final diagnosis is determined by the pathologist and entered into the lab computer system; 2. Retention of FISH images. 3. Policy for retention and storage of pathology slides; 4. Entering patient pathology results into the laboratory computer system and the procedure to be followed if the computer system is inoperable; 5. Twice per year verification and remediation of any discrepant results found during the twice yearly verification of histopathology, urine cytology and FISH testing; 6. Acceptability of the staining characteristics of the Hematoxylin & Eosin (H & E) stain, special stain, Immunohistochemistry (IHC) stain, Papanicolaou (PAP) stain. PLEASE NOTE: THIS IS A RECITE DEFICIENCY FROM THE SURVEY CONDUCTED ON OCTOBER 18, 2018.
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 the review of the laboratory records, lack of a complete procedure manual and interview with the Laboratory Director/Technical Supervisor, the laboratory failed to establish written policies and procedures to ensure that a maximum workload limit was established by the Laboratory Director/Technical Supervisor for the Pathologist when performing primary screening of the non-gynecologic slides from July 1, 2018 when testing was initiated through survey date. Findings include: 1. On January 23, 2020 at approximately 10:30 AM the Laboratory Director confirmed surveyor's

	findings that the laboratory failed to establish written policies and procedures to ensure that maximum workload limits were established by the Laboratory Director /Technical Supervisor for the pathologist that performed the primary evaluation of nongynecologic cytology specimens. 2. Approximately 400 non-gynecologic cytology slides were reviewed and reported during this time frame. PLEASE NOTE: THIS IS A RECITE DEFICIENCY FROM THE SURVEY CONDUCTED ON OCTOBER 18, 2018.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor findings and interview with the Laboratory Director/Technical Supervisor, the laboratory director failed to provide overall management of the pathology laboratory. The laboratory director failed to ensure that the laboratory: 1. Maintained the plan of correction from the survey conducted on October 18, 2018; 2. QA program for histology/cytology and FISH were maintained, refer to D6094.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the Laboratory Director/Technical Supervisor, the Laboratory Director/Technical Supervisor failed to ensure that quality assessment programs were established to assure the quality of laboratory services and identify failures in quality as they occur for histopathology, urine cytology and FISH testing. Refer to: D5217, D5291, D5403, 5633