Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2161490	09/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
Jonathan N Lazare Urology Pc	1729 East 12th Street, 5th Floor, Brooklyn, 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
D5032	CYTOLOGY CFR(s): 493.1221 If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on surveyor's review of laboratory policies and procedures, laboratory records and confirmed in an interview with the pathologist/laboratory director, the laboratory failed to establish, reassess and document a workload limit for the laboratory director /technical supervisor (refer to D5631, D5633, D5637, D5639, D5645 and D5647). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results in the subspecialty of Cytology.
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's review of the twice year verification records for histology, cytology and an interview with the pathologist/laboratory director/technical supervisor, the laboratory failed to verify the accuracy for the Fluorescence In Situ Hybridization (FISH) images from January 1, 2020 through September 3, 2021. FINDINGS: The pathologist/laboratory director/technical supervisor confirmed on September 3, 2021 at approximately 10:30 AM that the laboratory failed to verify the

	accuracy for the urine FISH images from January 1, 2020 through September 3, 2021. a. Approximately 5 patients were tested and reported for FISH.
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 surveyor's review of the laboratory's Quality Assessment (QA) policy, lack of QA review records for the calendar year 2020 and an interview with the pathologist /laboratory director/technical supervisor, the laboratory failed to follow their established QA policy for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems. FINDINGS: 1. The pathologist /laboratory director/technical supervisor confirmed on September 3, 2021 at approximately 10:15 AM, that the laboratory failed to follow their established QA policy for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems. 2. The laboratory's QA policy requires an annual review of all phases of laboratory's histology and cytology testing. a. the laboratory failed to perform and document the QA review for the calendar year 2020. 3. The laboratory failed to identify and take corrective action for the following issues: a. The pathologist failed to document the cytology workload from January 1, 2020 through September 3, 2021. b. failure to reassess the workload every six months c. perform and document twice year verification for accuracy for the FISH images
D5631	CYTOLOGY CFR(s): 493.1274(c)(6) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(6) An evaluation of the case reviews of each individual examining slides against the laboratory's overall statistical values, documentation of any discrepancies, including reasons for the deviation, and, if appropriate, corrective actions taken. This STANDARD is not met as evidenced by: Based on surveyor's review of cytology procedures, QA laboratory records and an interview with the pathologist/laboratory director/technical supervisor, the laboratory failed to establish and follow procedure to include: an evaluation of the cases review by the individual against the laboratory's overall statistical values, documentation of any discrepancies, including reasons for the deviation, and, if appropriate, the corrective actions taken FINDINGS: The pathologist/laboratory director/technical supervisor, confirmed on September 3, 2021 at approximately 10:00 AM , that the laboratory failed to establish and follow a procedure to include: an evaluation of the cases review by the individual against the laboratory's overall statistical values, documentation of any discrepancies, including reasons for the deviation, and, if appropriate, the corrective actions taken.

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 laboratory procedure manual, and an interview with the pathologist/laboratory director/technical supervisor, the laboratory director, acting as the technical supervisor failed to to establish and follow a written procedure for the workload limits.
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 the laboratory's cytology procedure manual,lack of laboratory records and an interview with the pathologist/laboratory director/technical supervisor, the laboratory failed to established written policies and procedures to ensure that workload limits would be reassessed at least every 6 months and adjusted when necessary for the pathologist who performs the primary screening of non-gynecologic cytology slides. FINDINGS: The pathologist/laboratory director /technical supervisor, confirmed on September 3, 2021 at approximately 1 1:00 AM, that the laboratory failed to established written policies and procedures to ensure that workload limits would be reassessed at least every 6 months and adjusted when necessary for the pathologist who performs the primary screening of non-gynecologic cytology slides.
D5639	CYTOLOGY CFR(s): 493.1274(d)(2)(i) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the Following: (d)(2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target. In addition-- (d)(2)(i) The maximum number of 100 slides is examined in no less than an 8-hour workday; This STANDARD is not met as evidenced by: Based on surveyor's review of the cytology procedure manual and an interview with the pathologist/laboratory director/technical supervisor, the laboratory failed to establish written policies and procedures to ensure that the maximum number of slides examined in a 24-hour period does not exceed 100 slides regardless of the site or location. FINDINGS: The pathologist/laboratory director/technical supervisor

	confirmed on September 3, 2021 at approximately 9:30 AM, that the laboratory failed to establish written policies and procedures that ensure the maximum number of slides examined in a 24-hour period does not exceed 100 slides regardless of the site or location.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. This STANDARD is not met as evidenced by: Based on surveyor's review of the Cytology procedure manual, lack of workload records and an interview the pathologist/laboratory director/technical supervisor, the pathologist failed to record the number of hours spent examining the cytology slides from January 1, 2020 through September 3, 2021. FINDINGS: 1. The pathologist /laboratory director/technical supervisor confirmed on September 3, 2021 at approximately 11:30 AM, the surveyor's findings that the pathologist, as the primary reader, failed to record the total number of slides examined in a 24-hour period and the number of hours spent examining slides from January 1, 2020 through September 3, 2021. 2. The pathologist stated, "that the number of slides screened and the hours screened, were not documented for this location."
D5647	CYTOLOGY CFR(s): 493.1274(d)(4) (d) Workload limits.The laboratory must establish and follow written policies and procedures that ensure the following: (d)(4) Records are available to document the workload limit for each individual. This STANDARD is not met as evidenced by: Based on surveyor's review of Cytology policies and procedures, laboratory records and confirmed in a interview with the pathologist/laboratory director/technical supervisor, at the time of this survey, the laboratory failed to establish written policies and procedures to ensure that records are maintained and available to document the workload for the individual who performs primary screening of non-gynecologic cytology slides
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and

	493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on surveyor's review of laboratory policies and procedures, laboratory records and confirmed in an interview with the pathologist/laboratory director/technical supervisor, the laboratory director/technical supervisor failed to be responsible for the overall operation and administration of the laboratory, to include assuring compliance with the applicable regulations and ensuring that all the duties of the laboratory director were performed. Refer to D5217, D5291, D5631, D5633, D5637, D5639, D5645 and D5647
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's review of laboratory policies and procedures, QC and QA laboratory records and confirmed in an interview with the pathologist/laboratory director/technical supervisor, the laboratory director/technical supervisor failed to ensure that quality assessment (QA) programs were established to assure the quality of laboratory services and identify failures in quality as they occur. Refer to D5291