Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0882284	03/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Murray Hill Urology, Pc	120 East 34 Street, New York, 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
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on surveyor's direct observation of the work area in the laboratory and confirmed in an interview with the laboratory director and technical consultant/testing person, the laboratory failed to have adequate workbench space and floor space. FINDINGS: The laboratory director, technical consultant/testing person confirmed on March 12, 2019 at approximately 1:30 PM, that the laboratory itself was not maintained to ensure the space was adequate for conducting all phases of testing. a. the laboratory failed to have clean workbenches; papers, manuals, testing material boxes, etc. were stacked on all open spaces b. the DPC Immunlite 2000 and Horiba Pentra 400 analyzers were covered with stacked paper and test materials c. the reagents for the Horiba Pentra 400 were on the floor and in front of refrigerator next to the analyzer d. manuals, binders and boxes stacked on top of both refrigerators not within the 23 inch space required for fire safety
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's procedure manual, Bio-rad Unity Peer

	Review reports for 2017 & 2018 in the Laboratory Information System (LIS), QC file for the Siemens DPC Immunlite 2000 and ABX Horiba Pentra 400 and an interview with the technical consultant/testing person, the laboratory failed to retain chemistry, endocrinology and general immunology quality control (QC) records and QC & calibration control Bio-rad assay sheets from January 2, 2017 through March 12, 2019. FINDINGS: 1. The current technical consultant/testing person confirmed on March 12, 2019 at approximately 1:30 PM the surveyor's findings that the laboratory failed to retain chemistry, endocrinology and general immunology QC records and QC & calibration control Bio-rad assay sheets from January 2, 2017 through March 12, 2019. The following number of patient samples were tested and results reported for these specialties during the above time-period: a. approximately 2000 patient samples for both chemistry and endocrinology b. approximately 1000 patient samples for general immunology 2. The current technical consultant/testing person stated, "that he only keeps a current lot of QC raw data in the LIS LABDAQ software system and deletes the QC data after he enters the results to Bio-rad Unity QC Peer Review program" 3. Surveyor could not determine if the QC raw data entered into the Bio-rad system was accurate due to the lack of documentation. a. surveyor was unable to confirm that the manufacturer's established QC package insert ranges matched the current lot numbers of QC material. 4. The laboratory's LIS using LABDAQ software was down during this survey and the records were not available for review of the current lot of controls for the Immunlite 2000 and Horiba Pentra 400.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: **AMENDED DEFICIENCY STATEMENT** Based on surveyor review the American Proficiency Institute (API) Proficiency Testing (PT) records on-line in the LABDAQ system, observed College of Pathologist (CAP) PT report and interview with the technical consultant/testing person, the laboratory failed to retain API & CAP PT records and documentation to include signed attestation forms, instrument printouts and a signed PT summary reports for the 3rd event of 2017, all three events in 2018 and 1st event of 2019. FINDINGS: The technical consultant/testing person confirmed on March 12, 2019 at approximately 1:30 PM the surveyor's findings that the laboratory failed to retain API & CAP PT records and documentation to include signed attestation forms, test results & instrument printouts and a signed PT summary reports for the 3rd event of 2017, all three events in 2018 and 1st event of 2019.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on the surveyor's review of API PT summary reports on-line and an interview with the technical consultant/testing person, the laboratory failed to evaluate 3rd event of 2017, all three events in 2018 and 1st event of 2019 PT summary reports; perform and document remedial action for the PT scores of less than 100%.

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 API PT records, laboratory test requisition records and confirmed in an interview with the technical consultant/testing person, the laboratory failed to verify twice annually the accuracy of test results for Androstenedione, Calcitonin, Thyroid Binding Globulin tests for 2018. Approximately 100 patients samples were tested and reported for the above tests in 2018.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on the surveyor's review of API PT summary reports on-line and an interview with the technical consultant/testing person, the laboratory failed to evaluate the 2nd & 3rd events of 2017, all three events in 2018 and 1st event of 2019 PT summary reports; perform and document remedial action for the PT scores of less than 100% and for the following analytes: 2017 second event: Chloride = 80% Total Iron = 80% Total LDH = 80% Chemistry 97% Thyroid Stimulating hormone (TSH) = 80% Thyroxine = 80% Endocrinology = 94% 2017 third event: Chloride = 40% Total cholesterol = 80% Creatinine = 80% BUN = 80% Chemistry = 94% Thyroxine = 40% Endocrinology = 91% 2018 first event: Endocrinology = 93% Alpha Feto-Protein (AFP) =80% General Immunology = 80% Albumin = 80% Total Iron = 80% Uric Acid = 0% Chemistry =93% Thyroxine = 80% Endocrinology = 97% 2018 third event: Chemistry = 99% Sodium = 80% 2019 first event: General Immunology = 80% AFP = 80% Chemistry = 96% Sodium = 20% Endocrinology = 97% Cortisol = 80%
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) policies and procedures and confirmed in an interview with the technical consultant/testing person, at the time of this survey, the laboratory failed to follow their established QA policy and perform a QA review for the 2017 and 2018 calendar years.
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's review of laboratory records and findings and an interview with the pathologist/laboratory director, the laboratory director failed to fulfill his responsibilities and provide overall management of the laboratory. Refer to D6091and D6094.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's available records, lack of laboratory documentation and confirmed in an interview with the technical consultant/testing person, the laboratory director failed to ensure that the API & CAP PT reports were evaluated and reviewed with the appropriate staff for the 2nd & 3rd events of 2017, all three events in 2018 and 1st event of 2019. Refer to: D3037, D5211, D5217 and D5221.
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 a surveyor review of the QA program and confirmed in an interview with the technical consultant/testing person at the time of the survey, the laboratory director failed to ensure that the laboratory's QA program was maintained as part of the laboratory's overall quality systems program. Refer to: D3001, D3031, D3037 and D5291