Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 31D0122641	**(X3) Date Survey Completed** 07/11/2023
Name of Provider or Supplier Neal Gittleman Md	**Street Address, City, State** 450 East Kennedy Boulevard, Lakewood, NJ	
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**
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: A) Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to have the work records for all of the College of American Pathologists (CAP) PT events for Throat Culture in the calendar years of 2023, 2022 and 2021. The findings include: 1. There were no work records for Throat Culture CAP PT events D1-A-2023, D1-C-2022, D1-B-2022, D1-C-2021 and D1-B-2021. 2. The TP #6 listed on the CMS form 209 confirmed on 7/11 /23 at 10:35 AM work records were not available for review. B) Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to have the Attestation Statements (AS) for all of the College of American Pathologists (CAP) PT events for Throat Culture in the calendar years of 2023, 2022 and 2021. The findings include: 1. There were no AS for Throat Culture CAP PT events D1-A-2023, D1-C-2022, D1-B-2022, D1-C-2021 and D1-B-2021. 2. The TP #6 listed on the CMS form 209 confirmed on 7/11/23 at 10:35 AM AS were not available for review.

D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on interviews with Testing Personnel (TP) and the Laboratory Director (LD, and the laboratory's requirements for a New Jersey State Clinical Laboratory License (NJCLL) under New Jersey Statutes Annotated: N.J.S.A. 45:9-42.28. License; necessity; categories, the laboratory failed to maintain a NJCLL for the calendar year of 2023. The LD and TP#6 as listed on the CMS 209 form confirmed the laboratory failed to have a NJCLL license for 2023.
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 review of the Quality Control (QC) Records and interview with the Testing Personnel (TP), the laboratory failed to retain Certificates of Analysis (COA) for Uricult culture media from 9/2/21 to the 3/8/23. The findings include: 1. The COA for Uricult media lot numbers 1901936, 1903819, 1904388, 1906155, 1906677, 1911142, 1909888, 1913262 were not retained. 2. The TP #6 as listed on the CMS 209 form confirmed on 7/11/23 at 10:00 am that COA for Uricult media were not retained.
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 surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP) the laboratory failed to follow its policies and procedures for assessing the competency of Testing Personnel (TP) who perform Bacteriology testing from 5/11/21 to the date of survey. The findings include: 1. The laboratory failed to use all the required elements applicable to Bacteriology for assessing the competency of TP. The laboratory did not use: a. #4 assessment of test performance through proficiency testing, blind sampling or previously analyzed specimens. 2. 9 out of 9 TP did not have the above listed element on their CA for Bacteriology for the calendar years 2021, 2022 and 2023 2. The TP #6 as listed on the CMS 209 form confirmed on 7/11/23 at 10:30am the laboratory failed to follow the CA procedures.

D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Test Reports (TR) for Throat Culture, and interview with the Testing Personnel (TP), the laboratory failed to have a Reference Range (RR) on Throat Culture TR on the date of survey. The findings include: 1. A review of the TR revealed the RR is missing on 5 out of 5 TR for Throat Culture. 2. The TP #6 as listed on the CMS 209 form confirmed on 7/11/23 at 12:00 pm the RR is missing on Throat Culture TR.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that PT samples were tested for Throat Culture from the College of American Pathologists (CAP) event D1-A-2022. The TP #6 as listed on the CMS 209 form confirmed on 7/11/23 at 10:45 am that the LD did not ensure PT samples for CAP event D1-A-2022 for Throat culture were tested.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor review of th Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to establish a Quality Assurance (QA) program for verifying manually entered results into the Electronic Media Record (EMR) from 5/11/21 to the date of survey. The TP#6 as stated on CMS-209 form confirmed on 7/11/23 at 11:45 AM that a QA program was not established.