Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0123149	03/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Bruce L Warshauer Md	2424 Bridge Avenue, Pt Pleasant, 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
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on surveyor review of the Biannual Assessment (BA) records, lack of Procedure Manual (PM) and Quality Control (QC) records, instrument maintenance and interview with the Laboratory Director (LD) via telephone the laboratory failed to ensure that quality systems for the preanalytic and analytic phase of Histopathology testing was monitored from 4/27/18 to the date of survey. 1. The laboratory referred the technical component of Histopathology to a non- CLIA certified laboratory. Cross Refer to D5315 2. The laboratory failed to perform maintenance on the microscope used for Histopathology. Cross Refer to D5433 3. The laboratory failed to document all control procedures performed. Cross Refer D5601 4. The laboratory failed to retain Histopathology slides Cross Refer to D5603
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 Biannual Assessment (BA) records and interview with the Laboratory Director (LD), the laboratory failed to verify the accuracy of Histopathology testing twice annually in the calendar years 2019 and 2020. The LD

	via telephone confirmed on 3/16/21 at 10:30 am that the laboratory did not verify the accuracy of the Histopathology testing twice annually. * Note- this is a repeat deficiency. This was cited at the last survey (4/27/18)
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 lack of a Procedure Manual and interview with the Laboratory Director (LD), the laboratory failed to establish a written procedure for Biannual Assessment (BA) from 4/27/18 to the date of survey. The LD via telephone confirmed on 3/16/21 at 10:35 am that a BA procedure was not established. * Note- this is a repeat deficiency. This was cited at the last survey (4/27/2018)
D5315	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(c) The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS. This STANDARD is not met as evidenced by: Based on lack of Histopathology records and interview with the Laboratory Director (LD), the laboratory referred the technical portion of Histopathology testing to a non-CLIA-certified laboratory from 4/27/18 to the date of survey. The LD via telephone confirmed on 3/16/21 at 10:42 am that testing was referred to a non-CLIA-certified laboratory. .
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: a) Based on lack of a Procedure Manual (PM), observation of the maintenance sticker on the microscope, lack of a maintenance log, and interview with the Laboratory Director (LD), the laboratory did not perform and document maintenance on the microscope, from October 2020 to the date of the survey. The LD via telephone confirmed on 3/16/21 at 11:15 am the laboratory did not perform and document maintenance on the microscope. b) Based on lack of a PM and interview with the LD,

	the laboratory did not establish a maintenance protocol for the microscope from 4/27 /18 to the date of the survey. The LD via telephone confirmed on 3/26/21 at 10:16 am the laboratory did not have a maintenance protocol.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on the surveyor review of the lack of Quality Control (QC) record and interview with the Laboratory director (LD), the laboratory failed to prepare and record the QC procedures on each day of Histopathology testing from 4/27/18 to the date of survey. The LD via telephone confirmed on 3/16/21 at 10:30 am that QC was not recorded on each day of patient testing.
D5603	HISTOPATHOLOGY CFR(s): 493.1273(b)(f) (b) The laboratory must retain stained slides, specimen blocks, and tissue remnants as specified in 493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under 493.1449(b), (l), or (m). (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on surveyor review of Histopathology and interview with the Laboratory Director (LD), the laboratory failed to retain Histology Slides (HS) from April 2018 to the date of the survey The LD confirmed on 3/16/21 at 10:15 am that HS were not retained.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on the lack of a Procedure Manual and interview with the Laboratory Director (LD) the laboratory failed to have a Corrective Action Procedure (CAP) to ensure accurate and reliable patient results from 4/27/18 to the date of the survey. The findings include: 1. There were no CAP available in the event Histopathology slides: a. Arrived broken b. Did not correspond with diagnosis c. Were improperly labeled d.

	Did not agree with previous diagnosis by another Pathologist 2. The LD via telephone confirmed at 10:20 am that the laboratory did not have a CAP.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on the lack of an Accession Logs (AL) and interview with the Laboratory Director (LD), the laboratory failed to maintain an accurate information or record system that includes the time of specimen receipt into the laboratory from 4/27/18 to the date of the survey. The LD via telephone confirmed on 3/16/21 at 10:40 am that the laboratory failed to have a accurate record system that included the time of specimen receipt into the laboratory.
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 review of the laboratory records, lack of Procedure Manual, Quality Control (QC), Maintenance and Biannual Assessment (BA) records and interview with the Laboratory Director (LD) via telephone, the LD failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily for Histopathology tests and in compliance with the CLIA regulations from 4/27/18 to the date of the survey 1. The LD failed to ensure that Biannual Assessment performed was completed, reviewed and evaluated. Cross Refer to D5217 2. The LD failed to establish a QC program to assure the quality of laboratory services provided and to identify failures as they occur. Cross Refer to D6093 3. The LD failed to ensure the laboratory established an accurate QA program. Cross Refer to D6094. 4. The LD failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Cross Refer to D6106. .
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 lack of a Procedure Manual and interview with the Laboratory Director (LD), the LD failed to establish a Quality Control (QC) program to assure the quality of laboratory services provided and to identify failures as they occur from 4/27/18 to the date of the survey. The LD via telephone confirmed on 3/16/21 at 10:20 am that a QC program was not established.
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 the lack of laboratory procedures and interview with the Laboratory Director (LD), the LD failed to ensure a Quality Assurance (QA) program was established to assure quality of laboratory services provided from 4/27/18 to the date of the survey. The LD via telephone confirmed on 3/16/21 at 10:25 am the LD did not establish a QA program.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on lack of a Procedure Manual (PM) and interview with the Laboratory Director (LD), the LD failed to have an approved PM for the professional component of Histopathology testing from 4/27/18 to the date of the survey. The LD, via telephone confirmed on 3/16/21 at 10:10 am that the LD did not ensure an approved PM was available.