

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0675421	(X3) Date Survey Completed 05/23/2023
Name of Provider or Supplier Jay D Geller Md Pc	Street Address, City, State 310 Route 24 East, Chester, 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
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on survey review of the Procedure Manual (PM), Biannual Assessment Documentation (BAD) and interview with the Testing Personnel (TP) the laboratory failed to verify the accuracy of Histopathology testing from 4/13/21 to the date of survey. The findings include; 1) The credentials of the reviewing physician were on available at the time of survey. 2) There was no documented evidence that the referring physician reviewed the BAD. 3) There was no documented evidence that the reviewing physician examined the referred slides. 4) The TP confirmed on 5/23/23 at 1:30 pm that the laboratory failed to verify the accuracy of Histopathology testing.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Testing</p>

	<p>Personnel (TP), the laboratory failed to establish a detailed procedure for Biannual Assessment (BA) from 4/13/21 to the date of survey. The TP confirmed on 5/23/23 at 1:15 pm that the laboratory did not have a detailed BA procedure.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), and interview with the Office Manager (OM), the laboratory failed to have a procedure for Tissue processing performed on the Tissue-Tek VIP tissue processor, Hematoxylin-Eosin (HE) staining and Periodic acid-Schiff staining performed on the Varistain Gemini ES auto stainer from 4/13/21 to the date of survey. The TP confirmed on 5/23/23 at 1:30 pm that the laboratory did not have the aforementioned procedure in the PM.</p>
<p>D5407</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP) , the laboratory failed to have an approved, signed and dated PM by the Laboratory Director 4/13/21 to the date of the survey. The TP confirmed on 5/23/23 at 1:30 pm a PM signed by the LD was not available. Note: This was previously cited.</p>
<p>D5413</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of Temperature Logs (TL) and interview with the Testing Personnel (TP), the laboratory failed to monitor and document Room temperature and humidity, where the Technical Component (TC) and Professional Component (CP) for Histopathology tests were performed from 4/13/23 to the date of survey. This findings include: 1) The TC and PC were performed in separate rooms. 2) There was no TL for</p>

the TC and PC areas. 3) The TP confirmed on 5/23/23 at 1:35 pm that the aforementioned TL's were not maintained.

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:

Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory did not establish a maintenance protocol for the Olympus CX41 microscope, Tissue-Tek VIP tissue processor, and Varistain Gemini ES auto stainer, from 4/13/23 to the date of survey. The TP confirmed on 5/23/23 at 1:30 pm the laboratory did not have a maintenance procedure for the aforementioned laboratory equipment.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP) , the Laboratory Director (LD) failed to establish a Competency Assessment (CA) procedure with all the required elements for Testing Personnel from 4/13/21 to the date of survey. The LD confirmed on 10/12/22 at 1:00 pm that a CA procedure was not established.