

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2283079	(X3) Date Survey Completed 02/25/2025
Name of Provider or Supplier Calvin Strand	Street Address, City, State 207 Shearwater Court W, Jersey City, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Biannual Assessment (BA) records and interview with Laboratory Director (LD), the laboratory failed to verify the accuracy and reliability of Histopathology testing twice annually from 6/1/23 to 2/25/25. The findings include: 1. There was no documented evidence that BA was performed . 2. The LD confirmed on 2/25/25 at 10:30 am that the laboratory did not perform BA.</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 (PM) and interview with the Laboratory Director (LD), the laboratory failed to establish a detailed procedure for Biannual Assessment (BA) on from 6/1/2023 to 2/25/25. The findings include: 1. There was no BA procedure in the PM. 2. The LD confirmed on 2/25/25 at 11:15 am that the laboratory did not have a BA procedure.</p>
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(b)

(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on the lack of room temperature logs, thermometer interview with the Laboratory Director (LD) the laboratory failed to document the temperature where Histopathology testing is performed from 06/01/23 to 2/25/25. The LD confirmed on 2/25/25 at 10:30 am, the laboratory did not monitor the room temperature where Histopathology testing is performed.

D5805

TEST REPORT

CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Test Reports (TR) and interview with the Laboratory Director (LD), the laboratory failed to ensure that the TR included all the required information on the date of survey. The finding includes: 1. The TR did not have the correct name and address of where the Professional Component for Histopathology testing was performed. 2. The LD confirmed on 2/25/25 at 11:30 am that the TR failed to include all the required information.