

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1058391	(X3) Date Survey Completed 01/09/2025
Name of Provider or Supplier Margaret Ravits & Associates	Street Address, City, State 721 Summit Avenue, Hackensack, 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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of the laboratory reagents, refrigerator and interview with the Medical Assistant (MA), the laboratory failed to ensure protection from biohazardous materials from 11/16/24 to 1/9/25. The findings include: 1. Mart-1 reagents used in Histopathology testing were observed to be stored in the refrigerator where food and drinks were also stored. 2. The MA confirmed on 1/9/25 at 12:15 pm that the laboratory did not ensure protection from biohazardous material.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering</p>

substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM), and interview with the Medical Assistant (MA) the laboratory failed to have a complete procedure for Histopathology tests in the PM from 4/5/23 to 1/9/25 . The finding includes: 1. The procedure for the BioSB Mart-1 states "heat slides for 3 min on slide warmer." 2. The procedure does not state at what temperature the slides must be heated to and what an acceptable range is. 3. The MA confirmed on 1/9/25 at 1:00 pm that the PM did not have a complete procedure.

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 surveyor review of the BioSB Mart-1 package insert, lack of refrigerator temperature logs and interview with the Medical Assistant (MA) the laboratory failed to document the temperature where Mart-1 reagents used in Histopathology testing were stored from 4/25/23 to 1/9/25. The findings include: 1. The BioSB Mart-1 package insert states the reagents must be stored at 2-8C. 2. There were no documented temperature logs for the refrigerator where the reagents were stored. 3. The MA confirmed on 1/9/25 at 1:10 pm, the laboratory did not monitor the refrigerator temperature where the reagents were stored.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on surveyor observation of Tissue Marking Dyes and Reagents and interview with the Medical Assistant (MA), the laboratory used and failed to discard expired Tissue Marking Dye (TMD) used for Histopathology testing from 12/17/24 to 1/9/25. The findings include: 1. One Black TMD Lot# 160078 was observed to be expired on

10/31/24. 2. The Black TMD had an opened date of 12/17/24. 3. Eighteen patients tests results were reported using the expired black TMD. 4. The MA confirmed on 1/9 /25 at 12:35 pm, the laboratory used and failed to discard expired TMD for Histopathology testing.