

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2160375	(X3) Date Survey Completed 09/04/2019
Name of Provider or Supplier Schwarz And Ammirati Medical Associates	Street Address, City, State 450 Waverly Avenue, Patchogue, NY	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the pathology laboratory's procedure manual and interview with the laboratory director and the laboratory supervisor/testing person, the laboratory failed to have a complete and accurate written procedure manual to include the following procedures: 1. A written procedure for transportation of patients' specimens solely from the physician office at 205 East 76th Street , New York NY to the laboratory in Patchogue for testing. The current procedure indicates delivery of specimens from independent physician offices, laboratories and hospitals to the laboratory in Patchogue for processing; 2. A procedure describing laboratory's</p>

	<p>turnaround time for the histopathology from sample collection to processing and to when final diagnosis is determined by the pathologist at the technical component laboratory and entered into the lab computer system; 3. Entering patient pathology results into the laboratory computer system and the procedure to be followed if the computer system is inoperable; 4. Policy for significant and unexpected findings; and, 5. Policy for in-house and preventive maintenance of all the laboratory equipment.</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 a surveyor review of temperature records and an interview with the laboratory supervisor/testing person, the laboratory failed to follow the manufacturer's and laboratory's written temperature requirement. Findings Include: It was confirmed by the laboratory supervisor/testing person on September 4, 2019 at approximately 11:30 AM that the laboratory failed to follow the laboratory's and the manufacturer's written criteria to monitor and document the humidity level where testing is performed from February 2019 and up to survey date.</p>
<p>D5601</p>	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of quality control records and an interview with the laboratory supervisor/testing person at the time of this survey, the laboratory director failed to review and document the quality control acceptability of the staining characteristics of the Hematoxylin & Eosin (H&E) stain, special stain and Immunohistochemistry (IHC) stain on each day of reading. 1. On September 4, 2019 at approximately 11:30 AM the laboratory supervisor/testing person confirm surveyor findings that the pathologists failed to review and document the quality control acceptability of the staining characteristics of the H&E stain, special stain and IHC stain on the following dates: 5/29/19, 8/7/19, 8/17/19 and 8/21/19. 2. Approximately 350 patients' histopathology slides were read and reported during above time frame.</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p>

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 reviewing randomly selected pathology test reports and confirmation by the laboratory supervisor/testing person, the laboratory failed to indicate on the pathology reports the address of the laboratory where the professional component of the histopathology is performed. Findings include: On September 4, 2019 at approximately 11:30 AM, the laboratory supervisor/testing person confirmed surveyor's findings that although the technical component laboratory moved to a new location in Patchogue in July 2019, the pathology final reports still indicate the previous laboratory's address.