Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0694853	03/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
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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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish a written policy to assess the training and competency of testing personnel using the six competency assessment criteria, and failed to retain the competency performed on the Mohs technician for 2018. Findings: Review of the laboratory's procedure "Quality Assurance Program" in the section personnel noted "The histologist is evaluated annually for the performance of of her technical skills." The following six competency assessment criteria are the minimal regulatory requirements for assessment of competency for all personnel performing laboratory testing: 1. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; 2. Monitoring the recording and reporting of test results; 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; 4. Direct observations of performance of instrument maintenance and function checks; 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples 6. Assessment of problem solving skills. Competency assessment, which includes the six competency assessment criteria, must be performed for testing personnel for each test that the individual is approved by the laboratory director to perform. Review of the "Employee Evaluation" form for 2019 showed that the Mohs Lab Technician was evaluated for punctuality, attitude, adherence to duties, cleanliness, and ability to perform lab duties. No evaluation for 2018 was available for review. During an interview on 3/11/19 at 2:22 PM, the Mohs Technician stated that she was unable to find her 2018 employee

	evaluation. During an interview on 3/11/19 at 3:45 PM, the Laboratory Director acknowledge the six competency assessment criteria were missing.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory's procedure manual failed to include complete step by step instructions for performing proficiency testing. Findings: Review of the procedure on proficiency testing showed that the procedure failed to include what the laboratory would do if there was a difference in the diagnosis between initial doctor and doctor reviewing the proficiency testing, and what would be done if the patient's report needed to be amended. During an interview on 3/11/19 at 3:50 PM, the Laboratory Director acknowledged the procedure did not include the steps the laboratory would take if there was a difference between the doctor's diagnosis, and what would be done if the patient's report needed to be amended.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (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. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to record the temperature and humidity of the room where testing was performed from 3/11/17 to 3/11/19. Findings: The manual for the Leica CM1530S cryostat noted that the room

	temperature of the laboratory should have a "room temperature maximum 35 degrees C." The manual also noted that the relative humidity of the laboratory should be a "relative humidity, maximum 60%." A review of the laboratory's logs showed that the laboratory failed to record the temperature and humidity of the room where testing was performed. On 3/11/19 at 2:15 PM, the Mohs Technician stated that they did not record the room temperature or the humidity of the laboratory.