Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2122981	05/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
James Highsmith Md Llc	1809 Collier Parkway, Lutz, FL	

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	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of scabies peer review records and interview with the Lab Assistant, the laboratory failed to verify the accuracy of the scabies test results at least every 6 months.. Findings included: During review of scabies peer review records, it was found that the laboratory last performed the scabies peer review June 2017. During an interview on 05/30/18 at 10:15 AM, the Laboratory Assistant confirmed the scabies peer review had only been performed once (June 2017) since the initial survey which was conducted on 02/03/17.
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 review of the laboratory's Histology procedure manual and quality control records, and interview with the Laboratory Assistant, the laboratory failed to have a written quality control procedure for the hematoxylin and eosin (H & E)stain. Findings included: During the review of the Histology procedure manual it was noticed that the procedure manual did not include a H & E stain quality control procedure. During the record review of the Histology Moh's Daily Quality Control Slide Log, it was found that the Daily Control Slide Log did not indicate the acceptability criteria for the H & E stain. During an interview on 05/30/18 at 10:45 AM, the Laboratory Assistant confirmed that the laboratory did not have in writing the criteria for acceptability of the H & E quality control.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and interview with the Laboratory Assistant, the laboratory failed to have the procedure manual signed by the Laboratory Director. Findings included: During review of the laboratory procedure manual, it was discovered that the manual had not been signed by the Laboratory Director. During an interview on 05/30/18 at 10:30 AM, the Laboratory Assistant stated the procedure manual had been revised within the last 3 to 6 months but the Laboratory Director had not signed the revised procedure.
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 of the laboratory's temperature logs and procedure manual and interview with the Laboratory Assistant, the laboratory failed to document room temperature and air humidity. Findings included: During the instrument manual review, the instrument manual stated that for operation of the Leica Cryostat the room temperature must not exceed 35 degrees and the air humidity must not exceed 60%.

	During record review of the laboratory's logs, it was found that the laboratory was not documenting room temperature and air humidity. During an interview on 05/30/2018 at 9:45 AM, the Laboratory Assistant confirmed the laboratory was not documenting room temperature or air humidity but the laboratory did have a thermometer for the room that also measured humidity.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 observation, record review of the laboratory's reagent log, Potassium Hydroxide (KOH) Case Log and the Mohs Log, and interview with the Laboratory Assistant, the laboratory failed to remove expired reagents (potassium hydroxide (KOH) and Gill 2 Hematoxylin) from testing procedures. Findings included: During the tour of the laboratory on 05/30/18 at 9:40 AM, it was observed that the KOH (Lot number 1618011) had an expiration of 06/28/17 and the Gill 2 Hematoxylin (Lot number 049045) had an expiration of 03/18. During record review it was found the laboratory's reagent log stated the Gill 2 Hematoxylin Lot number 049045 expired on 03/18, record review of the KOH case log revealed that 11 patients were tested from 06/30/17 to 05/18/18 with the expired KOH, and record review of the Mohs log showed 4 patients were tested from 04/20/18 to 05/11/2018 with the expired Gill 2 Hematoxylin reagent. During an interview on 05/30/18 at 09:50 AM, the Laboratory Assistant confirmed the expired KOH reagent and the Gill 2 Hematoxylin were expired and had been used for patient testing.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, record review of laboratory's logs and interview with the Laboratory Assistant, the Laboratory Director failed to follow and document the laboratory's procedure for annual meetings for quality assurance. Findings included: During review of the laboratory's procedure manual, it was noticed that the procedure manual stated that at least annually the Laboratory Manager and the Laboratory Director would meet to address any concerns with the laboratory and any employee would be invited to the meeting. During record review, it was found there was no documentation of the annual meeting for quality assurance. During an interview on 05/30/2018 at 11:00 AM, the Laboratory Assistant confirmed that the annual meetings for quality assurance had not been conducted and documented.