Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2115392	05/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Javier Alonso Md Pa	475 Biltmore Way Ste 308, Coral Gables, 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
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on observation and interview with the office manager, laboratory failed to provide adequate testing space for histopathology staining technician and Dermatologist-MOHS and PATHOLOGY. The findings include: During laboratory tour on May 30, 2018 at 10:15AM, surveyor observed microscope for MOHS slide reading on very small slide storage table across the cryostat, leaving no adequate testing space for staining technician and dermatologist-MOHS and PATHOLOGY. During an interview on May 30, 2018 at 12:30 PM, office manager confirmed that microscope for MOHS slide reading was on very small slide storage table across the cryostat, leaving no adequate testing space for staining technician and dermatologist-MOHS and PATHOLOGY.
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 observation, record review and interview with office manager, laboratory failed to check and monitor room temperature and humidity from December 2016 to May 30, 2018 for the subspecialty of histopathology. The findings include: On 5/30 /18 at 10:30PM, surveyor did not observe humidity check/ room temperature monitoring device in the laboratory. Instrument maintenance records from December 2016 to May 30, 2018 did not show records of humidity and room temperature check for the subspecialty of histopathology. During an interview on 5/30/18, at 12:30 PM, office manager confirmed that the laboratory did not have the monitoring device for the room temperature and humidity and there were no records from December 2016 to May 30, 2018 for the subspecialty of histopathology laboratory.
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 and interview with office manager, the histopathology subspecialty laboratory had expired reagents in use. The findings include: Observation on May 30, 2018 at 10:00 AM revealed; 1) Red dye - lot# 5272, expiration date; 2017 /03. 2) Green dye - lot# 5355, expiration date; 2017/06. 3) Blue dye - lot# 5320, expiration date; 2017/05. 4) Yellow dye- lot # 5313; expiration date; 2017/05. 5) Black dye- lot# 5315, 2017/05. During an interview on May 30, 2018 at 12:30 PM, office manager confirmed that the reagents 1to 5 had expired and they were in use.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and interview with the office manager, laboratory failed to perform and record Airfilteronix- air filter-fume hood maintenance from December 2016 to May 30, 2018 for the subspecialty of histopathology. The findings include: On 5/30/18 at 10:45 AM, instrument maintenance records from December 2016 to May 30, 2018 showed no documentation of Airfilteronix- air filter- fume hood maintenance for the subspecialty of histopathology. & Manufacturer's instructions for Airfilteronix- air filter- fume hood was not available at the time of survey. During an interview on 5/30/18, at 12:30 PM, the office manager confirmed that; 1) the laboratory did not perform any maintenance for Airfilteronix- air filter - fume hood from December 2016 to May 30, 2018 for the subspecialty of histopathology. 2) Manufacturer's instructions for Airfilteronix- air filter- fume hood was not available at the time of survey.
D5805	TEST REPORT CFR(s): 493.1291(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 record review (from 12/16 to 5/30/18) and interview with office manager, histopathology subspecialty laboratory failed to: 1- Have the facility address for the DERM VISIT, DERMATOPATHOLOGY REPORT and the MOHS OPERATIVE NOTES. 2- Provide the PATIENT MEDICAL INTAKE FORM and SURGICAL CONSENT FORM that had the same facility address as the address of the physical location of the laboratory surveyed. The findings include: On May 30, 2018, during the patient reports -record review, surveyor observed that: A- DERM VISIT and DERMATOPATHOLOGY REPORT did not include the address of the laboratory. During an interview on 5/30/18, at 12:30 PM, office manager confirmed that DERM VISIT and DERMATOPATHOLOGY REPORT did not include the address of the laboratory. B- (I) PATIENT MEDICAL INTAKE FORM and SURGICAL CONSENT FORM did not have the address same as the physical location of the laboratory surveyed. (II) MOHS OPERATIVE NOTES did not include the address of the laboratory. The laboratory had provided: (a) PATIENT MEDICAL INTAKE FORM, (b) SURGICAL CONSENT FORM, and (c) MOHS OPERATIVE NOTES Via e-mail and so, there was no interview with the office manager.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory manager, technical supervisor failed to assess the competency of dermatologist-MOHS and PATHOLOGY, from December 2016 to May 30, 2018 that included the competency assessment for the job duties and responsibilities as dermatologist MOHS and PATHOLOGY. The findings include: Competency record review (12/2016-5/2018) on May 30, 2018 at 11:15AM for Dermatologist-MOHS and PATHOLOGY revealed that: 1- Yearly evaluation questionnaire form dated 1/2018 was the same for both, the histology staining technician and the Dermatologist-MOHS and PATHOLOGY for histopathology subspecialty laboratory. 2- It did not include the competency evaluation for Dermatologist-MOHS and PATHOLOGY for histopathology subspecialty laboratory based on the job duties and responsibilities as Dermatologist-MOHS and PATHOLOGY. During an interview on May 30, 2018 at 12:30 PM, office manager confirmed that: I- competency assessment for Dermatologist-MOHS and

	PATHOLOGY for histopathology subspecialty laboratory was on the evaluation form that had same evaluation questionnaire as histology staining technician. II- It did not include the competency evaluation for Dermatologist-MOHS and PATHOLOGY for histopathology subspecialty laboratory based on the job duties and responsibilities as Dermatologist-MOHS and PATHOLOGY. III- Technical supervisor failed to assess the competency of dermatologist-MOHS and PATHOLOGY, from December 2016 to May 30, 2018 that included the competency assessment for the job duties and responsibilities as dermatologist MOHS and PATHOLOGY.