Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0928464	01/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Terrence A Cronin Jr Md	1399 S Harbor City Blvd, Melbourne, 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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to dispose of chemicals per manufacturer's instructions for 2 out of 2 years reviewed (1/23/17 to 1/23/19). Findings: Review of the manufacturer's instructions on the bottle of 100% Reagent Alcohol read, "Contact a licensed professional waste disposal service to dispose of this material." Manufacturer's instructions on the bottle of Histo-Clear read, "Dispose of contents/container to an approved waste disposal plant." The laboratory's procedure titled "Disposal of Non-Toxic Reagents" read, "Due to the fact that all our reagents are non-toxic non-xylene based, all spent reagents are greatly diluted and washed down the drain with lots of water." During an interview on 1/23/19 at 2:03 PM, the Mohs Technician confirmed that the chemical reagents are disposed down the sink drain, and did not follow the manufacturer's instructions from 1/23/17 to 1/23/19.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the general laboratory system and correct problems identified. The laboratory failed to document annual competency assessment on the Mohs technician for 2017 and 2018. This is a repeat deficiency from the survey performed in 2017. Findings: 1. Cross Reference D5209. Based on record review and staff interview, the laboratory failed to document annual competency assessment on the Mohs Technician for 2017 and 2018. This is a repeat deficiency from the survey performed in 2017. 2. Cross Reference D5217. Based on record review and staff interview, the laboratory failed to verify the accuracy of the reading and interpretation of the Hematoxylin and Eosin (H&E) stain in 2018 at least twice annually.
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 staff interview, the laboratory failed to document annual competency assessment on the Mohs Technician for 2017 and 2018. This is a repeat deficiency from the survey performed in 2017. Findings: Review of the competency records showed that the laboratory failed to have documentation of annual competency assessments for one out of one Mohs technician in 2017 and 2018. During an interview on 1/23/19 at 2:33 PM, Mohs Technician stated that he did have a competency evaluation in 2017 or 2018 but could not provide evidence of this.
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 record review and staff interview, the laboratory failed to verify the accuracy of the reading and interpretation of the Hematoxylin and Eosin (H&E) stain in 2018 at least twice annually. Findings: The laboratory uses peer review to verify the accuracy of the reading and interpretation H&E stain. Review of the laboratory's records showed that peer review was performed on 12/31/18 for testing person A. The procedure titled "Proficiency Testing" read that slides will be sent twice yearly. During an interview on 1/23/19 at 3:50 PM, the Office Manager stated that peer review was sent out in late spring or early summer but was unable to provide the documentation.
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 1/23/17 to 1/23/19. Findings: Review of the laboratory's logs showed that the laboratory failed to record the room temperature and humidity of the room where testing was performed from 1 /23/17 to 1/23/19. During a interview on 1/23/19 at 1:35 PM, the Mohs Technician acknowledged that they did not record the temperature or humidity of the laboratory.