Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2080708	07/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Integrated Dermatology Of Tidewater-Norfolk	885 Kempsville Road - Suite 309, Norfolk, VA	

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
D0000	An announced CLIA recertification survey was conducted at Integrated Dermatology of Tidewater on July 25, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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 a review of policies, temperature logs, patient logs, and interview, the laboratory failed to document the cryostat equipment temperature on three (3) dates of patient testing in the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's policy manual revealed a "Thermometer and Temperature" policy that stated: "record the cryostat temperature and lab area for each day of operation". 2. Review of the laboratory's Cryostat Temperature charts from August 2016 to the date of the survey on July 25, 2018, revealed that the laboratory failed to document temperatures on: 2/20/17, 8/19/18, and 9/16/18. 3. Review of the patient MOHS test logs revealed that the laboratory reported the following number of cases on the dates outlined above: 2/20/17- Case numbers 007, 008, 009, 010, 011, 012, 013, 014, 015; 8 /19/18- Case numbers 056, 057, 058, 059, 060, 061, 062; 9/16/18- Case numbers 063, 064, 065, 066, 067, 068, 069, 070, 071; a total of twenty-five (25) MOHS patient cases. 4. In an interview with the nurse manager at approximately 3:30 PM, it was

	confirmed that the laboratory failed to document the crytostat temperature, according to their policy, as outlined above in calendar year 2017 and 2018.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a review of policies, instrument maintenance logs, patient logs, and an interview, the laboratory failed to perform and document equipment maintenance on three (3) dates of patient testing in the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's policy manual revealed a "Cryostat Maintenance" policy that stated: "all required maintenance procedures will be documented on the cryostat maintenance record chart". 2. Review of the laboratory's Tanner Cryostat instrument maintenance charts from August 2016 to the date of the survey on July 25, 2018, revealed the following required daily maintenance procedures: clean debris, insert clean blade in blade holder, return clean check holders to cryostat cup, oil cryostat, manually defrost and/or decontaminate cryostat, clean work areas with 10 percent bleach, and complete biohazard clean procedures. The charts indicated that MOHS patient testing was performed once monthly. The chart review revealed that the laboratory failed to document performance of the maintenance listed above on: 2/20/17, 8/19/18, and 9/16/18. 3. Review of the patient MOHS test logs revealed that the laboratory reported the following number of cases on the dates outlined above: 2/20/17- Case numbers 007, 008, 009, 010, 011, 012, 013, 014, 015; 8/19/18- Case numbers 056, 057, 058, 059, 060, 061, 062; 9/16/18- Case numbers 063, 064, 065, 066, 067, 068, 069, 070, 071; a total of twenty-five (25) MOHS patient cases. 4. In an interview with the nurse manager at approximately 3:30 PM, it was confirmed that the laboratory failed to document required cryostat equipment maintenance, according to their policy, as outlined above in calendar year 2017 and 2018.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of temperature logs, instrument maintenance logs, quality assurance (QA) records, patient logs, and an interviews, the laboratory failed to identify and document problems in cryostat equipment maintenance and temperature documentation for three (3) days and twenty five (25) patients in calendar years 2017

	and 2018. Findings include: 1. Review of the laboratory's Cryostat Temperature and Maintenance charts from August 2016 to the date of the survey on July 25, 2018, revealed that the laboratory failed to document temperatures and maintenance on: 2/20 /17, 8/19/18, and 9/16/18 (Cross Reference D 5413 and D 5433). 2. Review of the patient MOHS test logs revealed that the laboratory reported the following number of cases on the dates outlined above: 2/20/17- Case numbers 007, 008, 009, 010, 011, 012, 013, 014, 015; 8/19/18- Case numbers 056, 057, 058, 059, 060, 061, 062; 9/16 /18- Case numbers 063, 064, 065, 066, 067, 068, 069, 070, 071; a total of twenty-five (25) MOHS patient cases. 3. Review of the laboratory's QA log revealed no documentation of corrective action regarding the missing maintenance and temperatures listed above. The inspector inquired during an interview with nurse manager at approximately 2:30 PM if the laboratory's QA included review of the required cryostat maintenance procedures. The nurse manager stated: "We will start monitoring the maintenance documentation more closely going forward. We have been in a rush at the end of our MOHS test dates to complete logs and we need to slow down." 4. In an interview with the nurse manager at approximately 3:30 PM, it was confirmed that the laboratory failed to to document or identify the QA problems with cryostat equipment maintenance and temperature documentation as outlined above in calendar year 2017 and 2018: