Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0327623	(X3) Date Survey Completed 03/19/2019
Name of Provider or Supplier Dermatology & Skin Surgery Center	**Street Address, City, State** 71 South Terrace Avenue, Newark, OH	

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
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 an interview with the Laboratory Director (LD), the laboratory failed to define criteria consistent with manufacturer's instructions and document temperature conditions for reliable tissue biopsy procedures and test result reporting. This deficient practice had the potential to affect 409 patients tested in the specialty of histopathology. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "CLIA LABORATORY MANUAL, Dermatology and Skin Surgery Center, Larry J. Little, M.D., 71 S. Terrace Ave Newark, Ohio", provided on the date of the inspection, did not find any instructions to monitor and document temperature conditions consistent with manufacturer's operating and storage specifications. 2. The Surveyor requested the laboratory's policy and procedure for temperature criteria consistent with all manufacturer's instructions and storage conditions from the LD. The LD confirmed the laboratory did not establish a policy and procedure for the temperature criteria consistent with any manufacturer's instructions and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 03/19/2019 at 9:565 AM.
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 record review and an interview with the Laboratory Director (LD), the laboratory failed to establish, perform and document a maintenance protocol that ensured accurate and reliable microscope performance which was necessary for microscopic tissue biopsy grossing and slide interpretation test results and test result reporting. This deficient practice had the potential to affect 409 patients tested in the specialty of histopathology. Findings Include: 1. Review of the laboratory's policy and procedure manuals titled "CLIA LABORATORY MANUAL Dermatology and Skin Surgery Center, Larry J. Little, M.D., 71 S. Terrace Ave Newark, Ohio", provided on the date of the inspection, did not find any mention of a microscope maintenance policy and procedure. 2. Direct observation of the histopathology laboratory for tissue biopsy grossing and processing on 03/19/2019 at 11:15 AM found a Leica DM 1000 microscope which was utilized to assess the acceptability of hematoxylin and eosin intended stain reactivity, and slide interpretations and reporting. 3. The Surveyor requested the laboratory's microscope maintenance policy and procedure and all microscope maintenance documentation from 2017 to current from the LD. The LD confirmed the laboratory did not establish a policy and procedure, perform and document any microscope maintenance and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 03/19/2019 at 11:20 AM.