Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1085740	04/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
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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 interview with lab staff, the histology lab did not record the temperature reading of the thermometer in the cryostat. Findings: 1. The lab uses a cryostat to process tissue samples. The temperature of the cryostat is important to its function and the laboratory observes and records the temperature of the cryostat each day of use. The temperature readings may assist the lab in identifying trends in temperature requiring attention; and 2. From January thru April of 2018 lab staff recorded a checkmark to indicate that the temperature of the cryostat was observed and that it was within an allowable range, and did not document the temperature that was observed.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The

	laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on observation and interview with lab staff, the lab did not have quality control policies to document the staining characteristics for the hematoxylin and eosin (H&E) stain each day of use to show that the stain reacted in an accurate and reliable manner. The lab did not have records showing that it observed the first slide stained on each day of testing and that the stain characteristics were acceptable. B. Based on review of the written procedure for the Mart-1 stain and interview with lab staff, the written lab procedure to test a known positive and negative tissue sample each day the Mart -1 stain is used was not the control procedure the lab used. Findings 1. The labs written procedure for immunohistochemistry stains states that a positive and negative control slide are to be tested to confirm the reactivity of the Mart-1 stain; and 2. The MOHS surgeon states that the Mart-1 stain will stain the patient tissue in a manner that can be evaluated and interpreted as a control. The control procedures for the Mart-1 stain the lab used were not described in the written procedure.