Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D1004425	10/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Kevin A Fuciarelli Md Pc	10615 N Hayden Rd C-102, Scottsdale, AZ	

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 lack of temperature records for review and interview with the facility personnel, the laboratory failed to monitor and document the room temperature where dermatopathology reagents are utilized and stored and failed to monitor and document the temperature of the cryostat used in conjunction with Mohs testing during February 2021. Findings include: 1. The laboratory processes and interprets dermatopathology slides in conjunction with Mohs surgery, with an approximate annual test volume of 2,356. 2. No room temperature documentation was presented for review from February 2021 to indicate the laboratory monitored and documented the temperature of the room each day of patient testing, where dermatopathology reagents are utilized and stored. 3. No documentation was presented for review to indicate the laboratory monitored and documented the cryostat temperature each day of patient testing during February 2021. 4. The laboratory performed testing on approximately 67 patients during February 2021. 5. The facility personnel confirmed that the laboratory failed to monitor and document the cryostat temperature and the room temperature of the laboratory where reagents are stored and used for patient testing during February 2021.
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 review of microscope maintenance logs and interview with the facility personnel, the laboratory failed to perform and document the microscope maintenance as defined by policy during February 2021. Findings include: 1. The laboratory log titled, "Lab Maintenance" indicates the Microscope is cleaned once a month and evidence of the cleaning is documented on each monthly log. 2. No documentation was presented for review to indicate the laboratory performed the microscope maintenance as indicated above during February 2021. Approximately 67 patients were tested during that time period. 3. The facility personnel confirmed that the laboratory failed to perform and document maintenance on the microscope as indicated in policy during the timeframe indicated above.
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: Based on lack of Quality Control (QC) documentation and interview with the facility personnel, the laboratory failed to document the acceptability of staining materials used for patient testing performed in the sub-specialty of histopathology. Findings include: 1. The laboratory performs testing in the sub-specialty of Histopathology, with an approximate annual test volume of 2,356. 2. No documentation of the Hematoxylin & Eosin (H & E) stain acceptability was presented for review for testing that occurred during February 2021. Approximately 67 patients were tested during that time period. 3. The facility personnel confirmed that the laboratory failed to document the stain acceptability during February 2021, as indicated above.
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 the laboratory's established quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to establish a mechanism in their QA processes to monitor the analytic portion of histopathology testing that is performed by the laboratory. Findings include: 1. The laboratory processes and interprets histopathology slides from patient specimens during the Mohs process. The laboratory's approximate annual test volume is 2,356. 2. No documentation was submitted for review during the survey to indicate the laboratory established QA policies and procedures to monitor, assess, and when inicated, correct problems identified in the analytic systems. See D5413, D5433 and D5473 for specific findings. 3. The facility personnel confirmed that the laboratory's established QA process did not monitor the analytic systems for errors or missing records.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on lack of Quality Control records for review, the laboratory director failed to ensure that quality control programs are maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5473 for findings.