Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D1004425	04/12/2024
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
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 lack of accuracy verification documentation for Frozen Biopsy testing and interview with the laboratory director (LD), the laboratory failed to verify the accuracy of testing performed under the subspecialty of Histopathology at least twice annually during 2022 and 2023. Findings include: 1. No documentation was presented for review to indicate the laboratory verified the accuracy of Frozen Biopsy testing at least twice annually during 2022 and 2023. 2. The LD interviewed on 4/12/2024 at 10: 15 AM confirmed the laboratory failed to verify the accuracy of Frozen Biopsy testing at least twice annually during 2022 and 2023. 3. The laboratory's reported annual test volume is 1500 in the subspecialty of Histopathology.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on lack of established quality assessment (QA) policies and procedures and interview with the laboratory director (LD), the laboratory failed to establish policies and procedures to monitor, assess and correct problems identified in the general

	laboratory systems requirements specified at 493.1231 through 493.1236. Findings include: 1. No QA documentation was provided for review during the survey conducted on 4/12/2024 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the general laboratory system requirements specified at 493.1231 through 493.1236, including but not limited to, Proficiency Testing and/or accuracy verification policies and procedures. 2. The LD interviewed on 4/12/2024 at 10:35 AM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the general laboratory systems requirements.
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 humidity records for review from 2022, 2023 and 2024, review of the manufacturer's specifications for the Leica CM1510 Cryostat, and interview with the laboratory director (LD), the laboratory failed to monitor and document the humidity of the room where the above instrumentation is utilized. Findings include: 1. The laboratory utilizes the Leica CM1510 Cryostat in conjunction with Mohs testing under the subspecialty of Histopathology with a reported annual test volume of 1500. 2. The manufacturer's specifications for the Leica CM1510 Cryostat reviewed during the survey listed an operating relative humidity range of 10%-60%. 3. On the survey date of 4/12/2024, no documentation was provided for review to indicate the laboratory monitored and documented the humidity of the room where the above instrumentation is utilized on each day of patient testing during 2022, 2023 and 2024 through the date of the survey. 4. The LD interviewed on 4/12/2024 at 10:25 AM confirmed the laboratory failed to monitor and document the ambient humidity 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 lack of quality assessment (QA) policies and procedures and interview with the laboratory director (LD), the laboratory failed to establish QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. Findings include: 1. No QA

	documentation was provided for review during the survey conducted on 4/12/2024 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the analytic systems specified at 493. 1231 through 493.1236. 2. The LD interviewed on 4/12/2024 at 10:35 AM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the analytic systems. **This is a repeat deficiency from the previous survey conducted on 10/21/2021.**