Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1013071	02/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Arielle N B Kauvar Md Pc	1044 Fifth Avenue, New York, NY	

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 a lack of humidity records and an interview with the Moh's processor, the laboratory failed to follow the manufacturer's instructions to monitor and document the humidity. Findings Include: The Moh's processor confirmed on February 22, 2019, at approximately 10:00 AM that the laboratory failed to follow the manufacturer's directions to monitor and document the humidity of the room where Moh's processing occurs from July 2017 through the date of this survey.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor's observation of the reagents used for Moh's slide staining, and an interview with the Moh's processor, the laboratory failed to discontinue the use of the

	expired histological reagent. Findings Include: It was confirmed with the Moh's processor on February 22, 2019 at approximately 10:25 am, the laboratory failed to discard the expired reagents: Eosin Lot # 054145 - expired 11/2018. Approximately 13 patient specimens were tested and results released during that time.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 a review of procedures and an interview with the Moh's processor, the laboratory director failed to ensure that the laboratory's QA program was maintained as part of the laboratory's overall quality systems program. Refer to D5413 and D5417