Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2043041	09/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
Vicki Rapaport, Md A Professional Corp	436 N Bedford Dr, Ste 306, Beverly Hills, CA	

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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on the survey on September 13, 2024, the surveyor's observations during the laboratory tour and interviews with the medical assistant (MA) and manager, it was determined that the laboratory failed to be in compliance with applicable Federal, State, and local laboratory requirements and guidelines. The findings include: 1. Based on the observations during the laboratory tour at approximately 1:25 p.m., only the diplomas of the laboratory director (LD) were found to be posted, and no State license was found. 2. Based on the interviews with the MA and manager on September 13, 2024, at approximately 1:45 p.m., no State license was found in all files, e-mails, and rooms at the facility. 3. Based on the desk review performed by the surveyor on September 16, 2024, it was determined that the State license of the facility had expired on June 24, 2017. 4. Based on the annual testing declaration submitted at the time of survey, the facility processed, performed, and reported approximately 1,010 patient test results for Mycology and Dermatopathology during the time when the State license was expired.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

	This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory tour and interview with the laboratory's medical assistant (MA), it was determined that the laboratory failed to follow established safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. The findings include: 1. Based on the surveyor's observations during the laboratory tour on September 13, 2024, no eye wash station or portable eye wash bottles were found. 2. Based on the observations of the surveyor during the laboratory tour, the fire extinguisher found was tied to the platform on the lower corner of the wall heading into the break room, which cannot be accessed due to a cabinet beside it. No check tag was also found, and when the MA was interviewed, no documentation for maintenance was available for review. 3. Based on the interview with the MA, the facility recently renovated the area that included the eye wash station and none replaced it. 4. The MA affirmed by interview on September 13, 2024, at approximately 1:25 p.m. that the laboratory lacked an eyewash, the fire extinguisher was inaccessible, and that no function check maintenance was performed located near the testing area. 5. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 09/11/2024, the laboratory processed and reported approximately 1,010 patient test samples.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the lack of documentation of testing personnel competency assessment records, a review of patient records, and an interview with the medical assistant (MA) on September 13, 2024, as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to establish a written policy and procedure to assess the testing personnel competency for the years 2022, 2023, and 2024. Findings include: 1. Based on the survey on September 13, 2024, it was determined that the laboratory lacked an established and approved policy and procedure for competency assessment, resulting in missed personnel competency assessment for all physician assistants (PAs) and MAs for the for the years 2022, 2023, and 2024. 2. The MA affirmed by interview at approximately 12:45 p.m. on September 13, 2024, that all personnel that collected and processed the samples for the KOH test had no competency assessment for the years 2022, 2023, and 2024. 3. Based on the review of patient records, the laboratory failed to provide documentation of training and competency assessment for all personnel performing KOH sample collection and processing for the years 2022, 2023, and 2024. 4. According to the laboratory's annual testing declaration submitted at the time of the survey, the laboratory performed 10 KOH tests for the subspecialty of Mycology, for which the competencies of the PAs were not performed.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue

	corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on the surveyor's review of five (5) patient records and an interview with the medical assistant (MA), two (2) out of 5 records were discrepant in their log sheet and final report. The findings include: 1. Based on the survey on September 13, 2024, at approximately 12:05 p.m., the surveyor reviewed a total of 5 randomly chosen patient records covering the period from June 23, 2022, to May 20, 2024 for KOH test. 2. Based on the records reviewed, 2 out of 5 KOH patient records were inconsistent as follows: a. Patient #2, DOB-4-18-55, was examined for two sites, namely, the neck and left hip. The assessment notes only stated left hip, while the final report stated neck as the source of the specimen. b. Patient #4 DOB-6-17-55, review of the patient log showed positive result but recorded negative in the reading report. 3. The MA affirmed by interview on September 13, 2024, that the inconsistentcies described in number 1 (a & b) above were recorded erroneously. Further investigation is needed to be performed. No corrective action was available at the time of the survey. 4. Based on the annual testing volume declaration submitted at the time of the survey, the laboratory reported approximately 10 patient test results for Mycology during the time when the inconsistent log and report occurred.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure, randomly chosen patient records, and an interview with the medical assistant (MA), it was determined the laboratory had failed to follow an established written policy and procedure for an ongoing process to monitor the quality assessment (QA). Findings include: 1. Based on the survey on September 13, 2024, at approximately 11:45 a.m., it was determined that the laboratory had a policy and procedure, including a plan for quality assessment, but no documentation was found to support that it was performed. 2. The MA affirmed by interview on September 13, 2024, at approximately 11:45 a.m. that the laboratory did not perform QA for the years 2022, 2023, and 2024. 3. Based on the submitted testing declaration at the time of the survey, the laboratory processed and performed 1,010 Mycology and Dermatopathology patient test samples during the time that no QA was performed.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

	This STANDARD is not met as evidenced by: Based on the interviews with the medical assistant, review of the laboratory's policies and procedures, observations during the tour of the facility, and review of five (5) randomly selected patient records on July 25, 2024, the laboratory director is herein cited for failure to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored. 1. Expired State license. See D3009. 2. Lack and inaccessible safety equipment. See D3011. 3. No Personnel Competency Assessment for 2022, 2023, and 2024. See D5209. 4. Inconsistent patient log and report records. See D5821. 5. No Quality Assessment documentation. See D5891.