

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2043041	(X3) Date Survey Completed 02/08/2022
Name of Provider or Supplier Vicki Rapaport, Md A Professional Corp	Street Address, City, State 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
D3043	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7)</p> <p>The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of an up-to-date policies and procedures manual, policy for documents, reports, and biopsy slides retention, review of six (6) randomly chosen dermatopathology test records, and interview with the laboratory's testing personnel (TP), the laboratory failed to have a policy for documents and biopsy slides retention. The findings included: 1. On the day of survey, February 8, 2022, at approximately 11:40 a.m. based on review of the policies and procedures (P&P) manual, the laboratory failed to provide an up-to-date P&P on the current practice including a policy for length of retention of documents, patient reports, and biopsy slides. 2. The laboratory TP confirmed by interview on February 8, 2022, at approximately 12:00 p.m. that the laboratory did not have an updated P&P for document and biopsy slide preparations retention policy. 3. The laboratory reports performing approximately 590 dermatopathology patients' tests annually.</p>
D5391	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)</p> <p>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 preanalytic systems specified at 493.1241 through 493.1242.</p>

This STANDARD is not met as evidenced by:
 Based on the surveyors' interviews with the laboratory director (LD) and laboratory testing personnel (TP) and record review of pre-analytic remedial action records on February 8, 2022; the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the laboratory's preanalytic systems when received patient biopsy slides did not meet the laboratory's criteria for acceptability. Findings included: 1. According to laboratory TP, during preanalytic review of patients' processed biopsy slides, if a patient specimen was received that did not meet the laboratory's criteria for acceptability, a description as to why the specimen did not meet the laboratory's criteria for acceptability would be documented, appropriate corrective actions would be taken and noted, and the incident would be captured for quality assessment review. 2. Based on surveyor review of policies and procedures on 02/07/2022 at approximately 11:30 a.m., it was determined that the laboratory failed to maintain written policies and procedures detailing the quality assessment process described. 3. According to the LD declaration statement, the laboratory performed approximately 590 patient tests annually

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 observation on the lack of temperature recording logs for the refrigerator and room temperature and interview with the technical testing personnel (TP); it was determined that the laboratory failed to monitor the temperature of equipment essential for proper storage of reagents and specimens that adversely affect patient test results. The findings included: 1. On the day of the survey, February 8, 2022, based on observation and interview with the TP the laboratory failed to provide daily temperature recording logs for the refrigerator; where fungal culture media are stored and room temperature that verify accurate temperature which affect Mycology testing of patients' samples. 2. The TS confirmed on 02/08/2022, at approximately 11:00 a.m. that the laboratory has failed to record temperature for the years 2020 and 2021 of the refrigerator and room temperature. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tested and reported approximately 70 Mycology samples annually.

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 review of the laboratory's records of policies and procedures, lack of temperature logs documentation and corrective action reports, and interview with the laboratory personnel on February 8, 2022; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic and analytic phases of laboratory testing were monitored. See D3043, D5391, and D5413.