

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1013071	(X3) Date Survey Completed 02/14/2023
Name of Provider or Supplier Arielle N B Kauvar Md Pc	Street Address, City, State 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation of the Tissue Tek Embedding O.C.T., Rapid Differential bottles, Gills Hematoxylin stain, Bluing Solution, and confirmed via phone with the Moh's technician, the laboratory failed to ensure that stains and embedding material used for Moh's slides did not exceed the expiration dates. FINDINGS: The surveyor confirmed on February 14, 2023, at 11:00 A.M. through direct observation that the following materials were used in Moh's processing after the expiration dates: 1. Gills Hematoxylin stain (1/2 gallon), Lot #122924, Expiration date 12/31/22. 2. Bluing Solution (1/2 gallon), Lot # 113536, Expiration date 12/21/22. 3. Tissue Tek Embedding O.C.T. medium, Lot #1170-00, Expiration date 7/31/22 including eleven 4 oz bottles located under the sink and one 4 oz bottle located on top of the cryostat. 4. Approximately fifteen patient samples were processed and Moh's slide results were reported from 12/31/22 through 1/30/23.</p>
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by:</p>

Based on direct observation, the plan of correction from the previous survey 2/22/2019, and confirmed via phone interview with the Moh's technician, the laboratory director failed to provide overall management for all phases of histology testing. Refer to D6094 FINDINGS: The laboratory director failed to ensure: 1. That the plan of correction from the survey conducted on February 22, 2019, was maintained. 2. That the QA policy was maintained,. Refer to D6094.

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 the POC from the 2/22/2019 survey, direct observation of staining and embedding materials, and the Quality Assessment (QA) policy, the laboratory director failed to maintain the written QA policy to include overtime and monitoring the corrective action from the 2/22/2019 POC to ensure that the corrective action prevented recurrence of the original problem. Refer to D5417 THIS IS A RECITED STANDARD DEFICIENCY FROM THE SURVEY CONDUCTED ON February 22, 2019.