

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2158023	(X3) Date Survey Completed 02/09/2022
Name of Provider or Supplier David Saperstein, Md	Street Address, City, State 6051 E Cortez St, 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	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of accuracy verification documentation for review and interview with the laboratory director, the laboratory failed to verify the accuracy of testing performed under the sub-specialty of Histopathology at least twice annually during 2020 and 2021. Findings include: 1. No documentation was presented for review during the survey conducted on February 9, 2022 to indicate the laboratory verified the accuracy of the microscopic interpretation (reading) of histopathology specimens at least twice annually during 2020 and 2021. 2. The laboratory director confirmed that the laboratory failed to verify the accuracy of histopathology testing at least twice annually during 2020 and 2021. 3. The laboratory's approximate annual test volume under the sub-specialty of Histopathology is 350.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on lack of written Quality Assessment policies and procedures and interview with the laboratory director, the laboratory failed to establish policies and procedures</p>

related to accuracy verification for histopathology testing performed by the laboratory. Findings include: 1. The laboratory performs testing under the subspecialty of Histopathology, with an approximate annual test volume of 350. 2. No documentation was presented during the survey to indicate the laboratory had established policies and procedures related to the verification of accuracy process for the testing indicated above, including but not limited to, information specific to the frequency of the review, number of cases reviewed, individual or laboratory performing the review and a remedial action plan in the event of a noted discrepancy. 3. The laboratory director confirmed that the laboratory failed to have an established written policy in place at the time of the survey conducted on February 9, 2022, specific to the verification of accuracy process for histopathology testing performed by the laboratory.