

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2169343	(X3) Date Survey Completed 08/20/2021
Name of Provider or Supplier Peak Diagnostic Services, Llc	Street Address, City, State 4045 E Bell Rd #139a, Phoenix, 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	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on lack of accuracy verification documentation for review and interview with the facility personnel, the laboratory failed to verify the accuracy of testing performed under the sub-specialty of Histopathology at least twice annually during 2020. Findings include: 1. No documentation was presented for review during the survey conducted on August 20, 2021 to indicate the laboratory verified the accuracy of the microscopic interpretation (reading) of histopathology specimens at least twice annually during 2020. 2. The laboratory's established policy regarding accuracy verification states, "For each quarterly QA review, a minimum of 8-10 pathology cases will be selected, with all slides and final report. These cases will then be reviewed by a pathologist for quality assessment". 3. The facility personnel confirmed that the laboratory failed to verify the accuracy of histopathology testing at least twice annually during 2020 and failed to follow their established policy as indicated above. 4. The laboratory's approximate annual test volume under the sub-specialty of Histopathology is 8,000. The laboratory began patient testing on October 8, 2019.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result

reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on lack of microscope maintenance records and interview with the facility personnel, the laboratory failed to perform and document the microscope maintenance as defined by policy during 2020. Findings include: 1. The laboratory's established microscope maintenance policy states, "Microscopes are cleaned, aligned, and serviced annually. The microscope is maintained at a temperature and relative humidity in accordance with the user manual. Annual servicing sheets are logged appropriately." 2. No documentation was presented for review to indicate the laboratory performed the microscope maintenance as indicated above during 2020. 3. The facility personnel confirmed that the laboratory failed to perform maintenance on the microscope as indicated in policy during the timeframe indicated above.