

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0920591	(X3) Date Survey Completed 05/19/2023
Name of Provider or Supplier Duong Christopher Bui, Md	Street Address, City, State 202 N Euclid St Ste 201, Santa Ana, 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
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 review of the laboratory's evaluation of proficiency testing performance by peer review, and interview with the laboratory testing personnel and staff, it was determined that the laboratory failed to, at least twice annually, perform peer review to verify the accuracy of histopathology testing. The findings included: a. The laboratory failed to perform evaluation of proficiency testing performance peer review at least twice annually for the years of 2021 and 2022. b. The laboratory staff provided (5/19/2023 @ 11:10 am) and showed two copies of QUALITY (QA) ASSESSMENT EVALUATION CHART. c. The first QUALITY (QA) ASSESSMENT EVALUATION CHART was QA dated on 5/16/23 with signature for a total randomly picked 10 histology slides ALL from 2021 with Accession #, Patient Name, Initial Date of Diagnosis, Initial Pathologist, QA Date, QA Pathologist, and Diagnosis (Agree, Minor Discre., Major Discre) and Comments. d. The second QUALITY (QA) ASSESSMENT EVALUATION CHART was QA dated on 5/9/23 with signature for a total randomly picked 12 histology slides total, 10 from 2022 and 2 from 2023 with Accession #, Patient Name, Initial Date of Diagnosis, Initial Pathologist, QA Date, QA Pathologist, and Diagnosis (Agree, Minor Discre., Major Discre) and Comments.</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</p>

identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's evaluation of proficiency testing performance by peer review records, and interview with the laboratory testing personnel and staff, it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and ensure the accuracy of testing procedure. The findings included: a. The laboratory failed to establish and follow written policies and procedure for evaluation of proficiency testing performance to ensure the accuracy of the histopathology diagnosis testing, see D-5217. b. At the time of survey (5/19/2023 @ 11:20 am), the laboratory failed to provide and show the written policies and procedures for evaluation of proficiency testing performance quality assessment.

D6095

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(6)

The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's evaluation of proficiency testing performance by peer review, lack of written policies and procedures for quality assessment of the proficiency testing performance, and interview with the laboratory testing personnel and staff, it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. The findings included: a. The laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system see D-5217 and D-5291.