

| | | |
|--|---|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 05D0689131 | (X3) Date Survey Completed 08/14/2023 |
| Name of Provider or Supplier Richard G Bennett, Md | Street Address, City, State 1301 20th St, Ste 570, Santa Monica, 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 |
|---------------------------|--|
| 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> <p>This STANDARD is not met as evidenced by: Based on the surveyors' interviews with the laboratory's staff and record review of pre-analytic, analytic, and postanalytic phases of testing on August 14, 2023, the laboratory failed to establish written policies and procedures for an ongoing quality assessment mechanism to monitor, assess, and when indicated, correct problems identified in the laboratory's systems. Findings included: 1. Based on interview with the laboratory's sample processing staff, and review of seven (7) randomly chosen test reports; the staff affirmed that the laboratory does not have written quality assessment procedure to monitor, assess and correct patients' issues identified. 2. Based on surveyor review of policies and procedures on 8/14/2023 at 3:00 p.m.; it was determined that the laboratory failed to maintain written policies and procedures detailing the quality assessment process described for all phases of laboratory testing performed. 3. According to the laboratory testing declaration of tests volume, the laboratory performed approximately 7000 Histopathology patient tests annually.</p> |
| D5415 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> |

This STANDARD is not met as evidenced by:
Based on observation of the laboratory's reagent materials used for Histology staining and interview with the laboratory staff; it was determined that the laboratory failed to label various reagents to indicate date of use and expiration dates when such reagents are used in the laboratory. The findings included: 1. Based on the surveyor's observation during the laboratory's tour on August 14 ,2023, at 12:30 pm.; no opening, preparation, or expiration date labels were used or documented for various reagents and stains used. 2. The laboratory's staff affirmed in an interview conducted 8 /14/2023, at approximately 12:15 p.m. that the reagents mentioned in statement 1 were not labeled with the opening, preparation, and expiration dates or documented. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 700 test samples.

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 the surveyor's observation, lack of maintenance protocol and documentation, and interview with the laboratory's staff; it was determined that the laboratory failed to establish and document a maintenance protocol for the venting fume hood and function check protocols provided by the manufacturer. The laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance. The findings included: 1. The laboratory used a venting fume hood during Histology sample staining. 2. At the time of the laboratory tour on August 14, 2023, at approximately 11:45 a.m. the surveyor observed that the venting fume hood had not being serviced for maintenance since about 2014. There were no maintenance records found or a recent service tag on the fume hood. 3. The staff affirmed on August 14, 2023, that the laboratory failed to establish a maintenance and service protocol for the fume hood. 4. Based on the laboratory's testing declaration submitted at the time of the survey, the laboratory processed and stained approximately 700 samples.

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 for policies and procedures, seven (7) randomly chosen patients' test records, interviews with the laboratory staff, and direct observation by the surveyors during the lab tour, on August 14, 2023; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of laboratory testing were monitored. See D5391, D5415, and 5433.