

| | | |
|--|---|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 05D0874154 | (X3) Date Survey Completed 06/11/2021 |
| Name of Provider or Supplier Digestive Care Consultants | Street Address, City, State 23451 Madison St, Ste 290, Torrance, 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 |
|---------------------------|---|
| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of documentation and interview with the technical consultant (TC) on June 10, 2021, as specified in the personnel requirements in subpart M, the laboratory failed to establish and follow written policies and procedures to assess all testing personnel competency. Findings include: 1. The laboratory had two (2) testing personnel (TP). 2. One (1) out of two (2) of the (TP) listed on the CMS-209 Form, did not have any documentation of training or competency for the tests performed at the laboratory. The second TP had an incomplete competency for 2019 with missing signatures and no competency evaluation for 2020. 3. This deficient practice was affirmed by interview with the TC on June 10, 2021 at approximately 12:50 p.m. 4. The laboratory reportedly performs approximately 4,810 tests annually.</p> |
| D5293 | <p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by:</p> |

Based on review of the laboratory procedure manual and interview with the technical consultant (TC), the laboratory failed to perform a quality assessment that included a review of the effectiveness of corrective actions taken to resolve problems, and/or revision of policies and procedures necessary to prevent recurrence of problems, and failed to document all general laboratory systems quality assessment activities. The findings included: 1. The laboratory policy manual states that the laboratory would document on the incident log: rejected specimens, slide quality and staining, maintain a document control for all phases of testing, and incidents and actions taken that affected the quality of the patient testing. 2. The laboratory did not have any records of quality assessment or an incident log or other means of documentation of incidents. 3. The TC affirmed this deficiency by interview on June 10, 2021 at approximately 1:45 p.m.. 4. The laboratory records performing approximately 4,810 patient specimens annually.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures manual and interview with the technical consultant (TC), it was determined; that the laboratory failed to update protocols in place when changes occurred in the laboratory and the effective date and signature of approval by the laboratory director (LD) of such changes. The findings included: 1. On the day of the survey 06/10/2021 approximately 1:30 p.m. the procedure manual in place had not being updated to reflect current testing performed in the laboratory. 2. The existing protocols presented to the surveyor included testing no longer performed in the laboratory. 3. The TC affirmed on June 10, 2021 at approximately 2:00 p.m. that the laboratory failed to update protocols for the current testing performed in the laboratory and that the effective date and the laboratory director's signature were missing. 4. The laboratory's testing declaration form stated that the laboratory processes approximately 4,810 Histopathology samples annually.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on review of policies and procedures and the lack of documentation for quality assessment; it was determined that the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services it provides. (See D5293).

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review and the lack of documentation for competency assessments and interview with the technical consultant (TC), for two (2) out of two (2) testing personnel (TP) records reviewed for the years 2019 and 2020, it was determined that the laboratory's TC failed to perform and document the performance of individuals responsible for moderate complexity testing annually the individual tests patient specimens. (See D5209).