

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2048941	(X3) Date Survey Completed 07/22/2019
Name of Provider or Supplier Adobe Gastroenterology	Street Address, City, State 2585 N Wyatt Dr, Tucson, 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
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 review of the laboratory's established Quality Assessment policies, review of QA records and interview with the facility personnel, the laboratory failed to identify and correct errors found within the accuracy verification process. Findings include: 1. The laboratory performs a microscopic examination on biopsy specimens and issues a diagnosis under the sub-specialty of Histopathology, with an approximate annual test volume of 5,201. 2. It is the practice of the laboratory to randomly select cases for review each month for each physician (5 total) who perform testing. The review is documented on a "Monthly Slide Professional Review (QA)" form, including an area to note if there is a discrepancy and the action taken. 3. Review of the Monthly Slide Professional Review (QA) form from April 2019 indicated a noted discrepancy for case# AG19-568. The action taken indicated that the report was amended. 4. No amended report for case# AG19-568 was presented for review during the survey. The original pathology report was reviewed by the surveyor but no amendment was documented. 5. During the survey the facility personnel contacted the reviewing physician who stated that the QA form was incorrect.</p>
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</p>

identified in the preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's 'Specimen Error/Issues Log' and interview with the facility personnel, the laboratory failed to correct ongoing, repetitive issues identified with specimen collection. Findings include: 1. The laboratory performs testing in the specialty of Pathology with an approximate annual test volume of 5,201. The biopsy specimens are collected and transported to the pathology lab from the adjacent surgery center. 2. Review of the laboratory's "Specimen Error/Issues Log" revealed the laboratory identified the following number of errors associated with the collection and/or transportation of the specimen: 17 errors identified in 2017 from the date of the last survey conducted on July 20, 2017 through December 31, 2017; 19 errors identified in 2018; and 18 errors identified in 2019 through the date of the survey conducted on July 22, 2019. 3. The repetitive errors identified on the log indicated above included specimen missing from the container, pathology requisition discrepancies to the number of specimens actually received by laboratory, patients Date of Birth missing or incorrect on pathology requisition, incorrect or missing site /source, patient name misspelled and/or incorrect on pathology requisition or container, and specimen container mislabeled. 4. The facility personnel confirmed that the majority of the errors were made by one individual responsible for the documentation of pathology requisitions, labeling of specimen containers and transportation of the specimen to the pathology laboratory. 5. No documentation was presented for review to indicate the laboratory corrected the ongoing, repetitive errors and issues stated above. 6. The facility personnel stated that verbal discussions took place with the surgery center personnel regarding the ongoing, repetitive issues but no evidence was presented for review to indicate the laboratory documented corrective action to correct the issues and prevent the errors from recurring.

D5787

TEST RECORDS

CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on review of patient slides processed and interpreted by the laboratory for testing performed in the sub-specialty of histopathology and interview with the facility personnel, the laboratory failed to list the correct name of the laboratory on the slide label. Findings include: 1. The laboratory performs testing in the specialty of Pathology with an approximate annual test volume of 5,201. It is the practice of the laboratory to process pathology specimens to create slides for microscopic interpretation. The laboratory labels each slide with a computer generated, barcode slide label that contains a unique accession number, patient name, description of the cut, the date the slide was made, and name of the laboratory where the slide was processed. 2. Patient slides reviewed during the survey for four out of four cases (AG17-01200, AG18-00987, AG18-01808 and AG19-00568) listed the name of the laboratory as "TPA Lab". 3. The facility personnel confirmed that the slide labels

contained the incorrect name of the laboratory and stated that they were sharing slide labeling software with another CLIA-certified laboratory. The correct laboratory name for CLIA# 03D2048941 listed in the CLIA Federal Database at the time of the survey was Adobe Gastroenterology.