

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2114624	(X3) Date Survey Completed 02/16/2022
Name of Provider or Supplier Arizona Gastroenterology, Ltd	Street Address, City, State 7622 N La Cholla Blvd Ste 37, 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
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 review of the laboratory's established competency policies and procedures and interview with the facility personnel, the laboratory failed to follow established policies and procedures to assess employee competency. Findings include: 1. The laboratory performs the gross evaluation on patient specimens in the sub-specialty of Histopathology, with an approximate annual test volume of 15,909. 2. During the survey conducted on February 16, 2022, the laboratory's established policy titled, "Qualifications, Training and Competency Assessment" stated, "Training must be verified and documented. Competency of each employee must be assessed and documented. All laboratory staff will be evaluated within six months of hire and annually thereafter." 3. No documentation of initial training of two testing personnel who perform the gross description of patient specimens was presented for review during the survey. See D6102 for findings. 4. The facility personnel confirmed that the laboratory failed to follow their established policy to assess and document the training of testing personnel who perform the gross evaluation on histopathology specimens.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where</p>

the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of patient test reports and interview with the laboratory director, the laboratory failed to include on the test report the laboratory address where the testing was performed. Findings include: 1. The laboratory performs patient testing in the subspecialty of histopathology, with an approximate annual test volume of 15,909. 2. The test reports reviewed during the survey (AZG20-00011 and AZG21-06249) failed to include the correct laboratory address where the testing was performed. 3. At the time of the survey conducted on February 16, 2022, the laboratory address listed in the CLIA database for CLIA# 03D2114624 was 7622 N La Cholla Blvd. Ste 37, Tucson, AZ 85741. The laboratory address has remained unchanged in the CLIA database since the CLIA number was effective on 6/17/2016. 4. The test reports indicated above stated, "...the technical component has been performed at Arizona Gastroenterology Ltd, CLIA# 03D2114624, 7566 N. La Cholla Blvd, Tucson, AZ 85741." 5. The facility personnel confirmed that the laboratory address where the diagnosis was made was not indicated on the patient test reports issued by the laboratory.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on lack of training documentation for two out of two testing personnel who perform testing in the sub-specialty of Histopathology and interview with the facility personnel, the laboratory director failed to ensure that all testing personnel receive the appropriate training and demonstrate that they can perform all testing operations reliably and accurately prior to testing patients' specimens. Findings include: 1. No initial training documentation was presented for review for two out of two testing personnel hired in June 2021 and October 2021, who perform the gross evaluation on patient specimens in the sub-specialty of Histopathology. 2. The facility personnel confirmed that the laboratory failed to have documentation of initial training for the testing personnel indicated above.