

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  53D2112143	<b>(X3) Date Survey Completed</b>  04/02/2018
<b>Name of Provider or Supplier</b>  Digestive Health Associates Pathology Laboratory	<b>Street Address, City, State</b>  7220 Commons Circle, Cheyenne, WY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5291</b>	<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 procedure manual review, competency evaluations review, lack of specific documentation of twice annual documentation of gross analysis accuracy, and interview with staff, the laboratory failed to establish the laboratory procedure to monitor twice annual accuracy verification for gross analysis testing. Findings include: 1. The laboratory procedure manual review failed to include the laboratory's quality assessment procedure for twice annual gross analysis testing accuracy. 2. Testing personnel competency review included gross analysis test accuracy evaluation. 3. In an interview conducted on 04/02/2018 at approximately 1:15 P.M. staff stated testing personnel competency evaluation included testing accuracy as one of the criteria and was performed twice annually. Staff confirmed the laboratory did not establish a quality assessment policy for twice annual test accuracy. The laboratory staff stated the laboratory current quality assessment policy did not specify they monitored twice annual testing verification through personnel competency performance.</p>
<b>D5313</b>	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)</p> <p>The laboratory must document the date and time it receives a specimen.</p>

This STANDARD is not met as evidenced by:  
Based on laboratory record review, lack of documentation, direct observation and interview with staff, the laboratory failed to record the date and time of receipt for 13 of 13 histopathology specimen records reviewed. Findings include: 1. Patient test records review for patient PX 43-212, PX43-312, YP 17-0059, YP17-0223, YP17-0573, YP17-0827, YP17-0944, YP17-1012, YP18-0045, YP18-0347, YP18-0347, YP18-0223, YP18-0424, and YP18-0121, lacked documentation of the date and time specimens were received. 2. During direct observation of the specimen grossing and processing the specimen to the point of paraffin embedding, the testing staff was asked about recording the date and time specimens were received from the endoscopy surgical center. Staff stated, at the time of observation on 04/02/2018 at approximately 9:20 A.M., the laboratory did not have a policy to record the date and time of specimen receipt.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

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 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 test report review, direct observation, and interview with staff, the laboratory test report failed to include the location of the laboratory performing gross analysis testing. The laboratory performed approximately 10 to 15 gross analysis per day. Findings include: 1. The laboratory test report included a gross analysis test result. 2. Gross analysis testing was observed being performed at the location of the laboratory surveyed (7220 Commons Circle, Cheyenne, WY) on 04/02/2018 at approximately 9:20 A.M. 3. The laboratory report did not include the test location for gross analysis testing. 4. In an interview conducted on 04/02/2018 at approximately 10:45 A.M., laboratory staff confirmed the final test report did not state the gross analysis test location.