

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  53D2112143	<b>(X3) Date Survey Completed</b>  09/08/2020
<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>D5785</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by: Based on reagent refrigerator and room temperature records review, humidity percent records review, lack of documentation, and interview with staff, the laboratory failed to document corrective actions taken for out of range reagent storage temperatures for Schiff reagent used for Peroxidase Acid Schiff (PAS) stain, humidity ranges for staining, and room temperature ranges for processing paraffin blocks for embedding tissue. The laboratory performed approximately 1000 to 1600 tests per year. Findings include: 1. Reagent refrigerator temperature records review included temperatures of -1 degree C (30.2 F) from October 1, 2018 to October 31, 2018; November 1, 2018 to November 30, 2018; December 3, 2018 to December 31, 2018; February 1, 2019 to February 28, 2019, and April 1, 2019 to April 30, 2019. The acceptable range stated on the temperature chart was from 2 to 8 degrees C. 2. Room humidity records review included the humidity percent was below the 15 percent acceptable lower limit for performing hematoxylin and eosin, and PAS staining every test day in January 2020 except for January 27th and 29th and for every test day in February 2020. The laboratory performed testing Sunday through Friday. 3. The laboratory room temperature was above the acceptable upper limit of 29 degrees C (84.2F) January 2-6, 13-17, 20-24, and the 26th and 27th of January 2020 to provide for a stable platform for microtome cutting at the laboratory specified thickness. 4. In an interview with staff on 09/08/2020 at approximately 11:45 A.M., staff confirmed the room temperature and humidity conditions exceeded the stated ranges on the dates recorded. Staff stated the paraffin does not maintain its rigidity for cutting embedded histology specimens when the room temperature is above the acceptable range and that the</p>

refrigerator is used to store reagents that require a 2 to 8 degree storage temperature range and that the laboratory failed to document the corrective actions taken to resolve the out of range conditions for testing.

**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 patient test records review, lack of documentation, and interview with staff, the laboratory failed to maintain a record system that included the records and dates of all specimen testing and the identity of the personnel who performed the gross analysis tests. The laboratory performed approximately 10 to 20 endoscopy and colonoscopy specimens per day. Findings include: 1. Laboratory intermediate worksheet review failed to include a laboratory record for each specimen received and processed between March 2020 and June 2020. 2. Test records review failed to include the identity of the person performing the gross analysis for specimen block numbers: YP18-1616, YP18-1841, YP-2011, YP19-0695, YP19-1514, YP20-0109, YP20-0175, YP20-0320, YP20-0495, and YP20-0911. 3. In an interview conducted on 09/08/2020 at approximately 11:00 A.M., staff stated they currently maintained the record of specimen processed for 3 months then discarded the records older than 3 months; and confirmed the identity of the personnel who performed the gross analysis was not recorded.

**D6168**

**TESTING PERSONNEL**  
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:  
Based on lack of documentation and confirmation by staff, one of one high complexity test person lacked documentation to qualify for grossing histopathology specimens. (See D6171)

**D6171**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an

accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on lack of documentation, and interview with staff, 1 of 1 testing person lacked documentation to qualify as a high complexity testing person for histopathology grossing tests. The laboratory performed approximately 10 to 20 endoscopy and colonoscopy specimens per day. Findings include: 1. Test person 1 failed to have documentation of previous high complexity testing performance on or before

February 28, 1992. 2. In an interview conducted on 09/08/2020 at approximately 10:30 A.M., staff stated they have been performing gross analysis before 1992. Staff confirmed they did not have documentation of testing prior to February 1992 when the CLIA regulations were implemented.