

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D1050330	<b>(X3) Date Survey Completed</b>  03/01/2021
<b>Name of Provider or Supplier</b>  Gi Pathology Of Dayton - Digestive	<b>Street Address, City, State</b>  5697 Shull Rd, Huber Heights, OH	
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>D6120</b>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)</p> <p>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #3, the Technical Supervisor (TS) failed to evaluate the competency of TP #1, TP #2 and TP #3 to assure they maintained their competency to perform high complexity test procedures and report test results promptly, accurately, and proficiently in 2019 and 2020. All patient testing performed by TP #1, TP #2 and TP #3 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's Form CMS-209 signed and dated by the Laboratory Director on 02/22/2021, revealed three out of three individuals listed as TP. 2. Review of the laboratory's "Pathology Quality Management Plan" policy and procedure found the following statements: "6.4 Competency Training and Education The Department has an internal program of continuing education and evaluation of competency (direct observation, worksheet review). In addition, the laboratory provides for competency training in laboratory safety. Initial and Annual competency assessments are documented Annual Validation Summary forms and are signed by the employee, manager and Laboratory Director. The competency validation forms become part of the employee's personnel record." 3. The inspector requested 2019 and 2020 competency assessment documentation from the General Supervisor via email on 01/19/2021. Annual competency assessment documents dated 02/23/2019 were received from the General Supervisor via email on 03/02/2021 for TP #3 only. 4. A phone interview with TP #3 on 03/02/2021 at 5:10</p>

PM confirmed an annual competency was not performed in 2020. The laboratory was unable to provide 2019 competency assessment documentation for TP #1 and TP #3, and 2020 competency assessment documentation for TP #1, TP #2 and TP #3.

**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 record review and interviews with the Laboratory Director (LD) and the General Supervisor (GS), the laboratory failed to ensure Testing Personnel (TP) #3 met the qualification requirements of 493.1489 for high complexity testing procedures. All high complexity patient testing performed by TP#3 had the potential to be affected by this deficient practice. Findings Include: 1. The laboratory failed to ensure TP#3 met the minimum qualification requirements of 493.1489 for high complexity testing procedures. (Refer to 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 record review and phone interviews with the Laboratory Director (LD) and General Supervisor (GS), the laboratory failed to ensure Testing Personnel (TP) #3 met the minimum qualification requirements of 493.1489 for high complexity testing procedures. All high complexity patient testing performed by TP#3 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 02/22/2021, found three individuals listed and certified by the Laboratory Director to perform high complexity testing procedures. 2. Review of education documentation revealed one out of three TP, TP#3, achieved a Bachelor of Science degree in Education which does not meet the minimum qualification requirements for high complexity TP. 3. The Inspector requested any additional education documentation for TP#3 that meets the high complexity TP qualification requirements from the GS. The GS confirmed no other education documentation was available and were unable to provide the requested documentation on the date of the inspection to prove high complexity TP qualification requirements were met for TP#3. The interview occurred on 03/01/2021 at 10:10 AM.