

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 36D1050330	<b>(X3) Date Survey Completed</b> 10/12/2022
<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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director (LD), the laboratory failed to blindly verify the accuracy of the slide interpretation procedures at least twice annually for 2021 and 2022. This deficient practice had the potential to affect 114,421 patients tested in the sub-specialty of histopathology. Findings Include: 1. A review of two documents titled "Weekly QA" for 2021 and 2022 found the original diagnosis was provided to the peer reviewer performing test accuracy verification. 2. A review of the policy and procedure document titled "Anatomical Pathology QIP and QA" found no mention of blind peer reviews for test accuracy verification. 3. An interview with the LD confirmed the laboratory provided initial diagnosis without verifying the accuracy of slide interpretations during 2021 and 2022. The interview occurred 10/12/2022 at 1:30 PM.</p>
<b>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on record reviews and an interview with the Laboratory Director (LD), the LD failed to ensure policies and procedures were approved, signed and dated before use. This deficient practice had the potential to affect 30,000 patients tested under the sub-</p>

specialty of histopathology from 01/04/2021 to 10/12/2022. Findings Include: 1. Review of the laboratory's policy and procedure manual provided on the date of the inspection titled, "Policies and procedures, GI Pathology Digestive Specialists", revealed no LD approval signature and date. 2. The inspector requested the policies and procedures approved, signed and dated from the LD. 3. The LD confirmed policies and procedures were not approved, signed and dated before use. The interview occurred 10/12/2022 at 2:00 PM.

**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 record review and an interview with the General Supervisor (GS), the Laboratory Director (LD), failed to ensure prior to testing patients' specimens, one out of two new Testing Personnel (TP)#13 had received the appropriate training, and had demonstrated they could perform all testing operations reliably to provide and report accurate results for the high complexity test procedures performed. This deficient practice had the potential to affect all patients tested under the sub-specialty of histopathology from 04/19/2021 to 04/18/2022. Findings Include: 1. Review of the form CMS 209 signed and dated by the LD on 09/12/2022, found 14 individuals listed as TP. 2. A document provided 10/03/2022 at 1:36 PM via electronic mail (email) from the GS titled "Testing Personnel" revealed a hire date of 04/19/2021 for TP#13. 3. Review of the laboratory's policy and procedure titled "Competency Training for Nonpathologist Grossing", provided on the date of inspection found the following statements: " 6.2.5 Initial training and competency must be documented for all newly hired grossing personnel." 4. The Inspector requested initial competency assessment records for TP#13. 5. The GS confirmed the laboratory did not perform an initial competency assessment for TP#13, and was unable to provide the requested documentation on the date of the inspection. The interview occurred 08/10/2022 at 10:00 AM.