

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0865013	(X3) Date Survey Completed 03/22/2022
Name of Provider or Supplier Valley Gastroenterology & Endoscopy	Street Address, City, State 68377 Stewart Drive, Suite 202, Saint Clairsville, OH	
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
D5217	<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 General Supervisor (GS), the laboratory failed to blindly verify the accuracy of the slide interpretation procedures at least twice annually for 2021. This deficient practice had the potential to affect 8462 patients tested in the sub-specialty of histopathology. Findings Include: 1. Review of three documents titled "Record of Peer Review 2021" for quarters 1, 2 and 4 found the original diagnosis provided to the peer reviewer. 2. Review of the policy and procedure document titled "Quality Assurance Pathologist Proficiency Testing" found no mention of blind peer reviews for test accuracy verification. 3. An interview with the GS confirmed the laboratory provided initial diagnosis with the slides sent for 2021 quarters 1, 2 and 4 and the test accuracy verification was not performed blindly in 2021. The interview occurred 03/22/2022 at 1:30 PM.</p>
D6107	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.</p>

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 specify in writing the duties and responsibilities of the General Supervisor (GS) and two out of two Testing Personnel (TP) listed on the form CMS-209. This deficient practice had the potential to affect 8462 patients tested under the sub-specialty of histopathology. Findings include: 1. Review of the laboratory's form CMS-209 Personnel Report (CLIA) found one individual listed as the GS and TP, and another individual listed as TP. 2. Review of the policy and procedure manual titled, "Histology Policy and Procedure Manual" approved by the LD on 01/08/2022 failed to find evidence of the written duties and responsibilities for the GS/TP#1 and TP#2 delegated by the LD. 3. An interview with the GS confirmed the LD failed to specify in writing the duties and responsibilities of the GS/TP#1 and TP#2. The interview occurred 03/22/2022 at 1:15 PM.