| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>39D0932375 | (X3) Date Survey Completed<br>08/05/2025 |
|---|---|---|
| **Name of Provider or Supplier**<br>Zitelli And Brodland Pc South | **Street Address, City, State**<br>575 Coal Valley Road, Suite 360, Clairton, PA | |
| 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 |
|---|---|
| **D5415** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(c)<br><br>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the laboratory and interview with the Laboratory Manger (LM), the laboratory failed to label 20 of 20 aliquoted reagents with the pertinent information required for proper use when macroscopic histopathology examinations were performed from 07/12/2023 to 08/05/2025. Findings include: 1. On day of the survey 08/05/2025 at 12:15 pm, during the laboratory tour, observation of patient treatment room revealed 20 of 20 containers used to aliquot CDI tissue marking dye was not properly labeled with the following when macroscopic histopathology examinations were performed from 07/12/2023 to 08/05/2025: - identity of reagent - storage requirements - preparation and expiration dates 2. The laboratory performed 4507 histopathology examinations in 2024 (CMS 116, estimated annual volume, dated 07/08/2025) 3. The LM confirmed the findings above on 08/05/2025 at 12:15 pm. |