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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 36D0332772 | (X3) Date Survey Completed 07/29/2025 |
| Name of Provider or Supplier Zanesville Family Practice Inc | Street Address, City, State 1215 Newark Road, Zanesville, 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 |
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| D5311 | <p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #3, the laboratory failed to establish and follow written policies and procedures for specimen acceptability and rejection of urine specimens collected for Uricult tests. This deficient practice had the potential to affect 1,973 out of 1,973 patients tested under the subspecialty of Bacteriology from 09/20/2023 through 07/29/2025. Findings Include: 1. Review of the laboratory's "Lab Procedure Manual" policies and procedures, approved by the Laboratory Director on 08/21/2023, and provided on the date of inspection, did not find any mention of policies or procedures for specimen acceptability and rejection of urine specimens collected for Uricult tests. 2. The inspector requested policies and procedures for specimen acceptability and rejection of urine specimens collected for Uricult tests from TP #3. TP #3 confirmed the laboratory did not include specimen acceptability and rejection in their policies and procedures and did not have any documentation to provide on the date of the inspection. The interview occurred on 07/29/2025 at 10:30 AM.</p> |