

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D0332772	<b>(X3) Date Survey Completed</b>  09/19/2023
<b>Name of Provider or Supplier</b>  Zanesville Family Practice Inc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by:                      ITEM 1 Based on document review, and an interview with Testing Personnel (TP) #3, the laboratory failed to establish and follow a written procedure for the transport conditions of specimens to be tested at an off-site laboratory. This deficient practice had the potential to affect 53 Bacteriology, 3306 Chemistry, 13 Cytology and 2492 Hematology specimens transported and tested to off-site laboratories from 01/04/2022 through 09/19/2023. Findings Include: 1. Review of the laboratory's policy and procedure titled, "Miscellaneous Specimen Handling", signed and dated by the Laboratory Director on 11/16/2021, provided on the date of inspection, did not find any mention of specimen handling and transport conditions for specimens sent off-site. 2. Review of the "NextGen Lab E-Requisition" sheets provided with the specimens sent off-site for testing, did not find any mention of specimen handling and transport conditions. 3. The Inspector requested a policy and procedure for the specimens transported from the laboratory to an off-site location which includes specimen handling and transport conditions, from TP #3. TP #3 confirmed there was no policy and procedure which included the specimen handling and transport conditions and was unable to provide the requested information. The interview occurred on 09/19/2023 at 11:30 AM. ITEM 2 REPEAT DEFICIENCY Based on record review and an interview with testing personnel (TP) #3, the laboratory failed to follow their established policy and procedure for the Uricult urine culture incubation</p>

time of 18-24 hours. This deficient practice had the potential to affect 11 out of 95 patients tested under the subspecialty of Bacteriology from 02/27/2023 to 08/17/2023. Findings Include: 1. Review of the laboratory's policy and procedure titled "Urine Culture Procedure", signed and dated by the Laboratory Director on 11/16/2021 and provided on the date of inspection, found the following statements: "Test Procedure: ... 5). Place vial in an incubator in an upright position for 18-24 hours." 2. Review of the laboratory's "Uricult Results" log, provided on the date of the inspection, revealed 11 out of 95 Uricult urine cultures that exceeded 24 hours of incubation time as listed below: DoB Set Up Read 05/15/60 02/27/23 02/28/23 11:45 AM 12:00 PM 12/24/33 05/25/23 05/26/23 9:35 AM 10:00 AM 02/28/60 05/31/23 06/01/23 9:55 AM 10:00 AM 01/08/57 06/07/23 06/08/23 11:00 AM 12:00 PM 11/29/71 06/19/23 06/20/23 8:33 AM 10:50 AM 04/09/73 06/20/23 06/21/23 8:50 AM 9:55 AM 03/05/51 06/22/23 06/23/23 11:55 AM 12:00 PM 12/24/33 06/22/23 06/23/23 11:55 AM 12:00 PM 10/26/86 08/02/23 08/03/23 8:00 AM 9:00 AM 05/13/83 08/14/23 08/15/23 7:35 AM 11:25 AM 08/14/42 08/16/23 08/17/23 8:55 AM 9:00 AM 3. TP#3 confirmed the Uricult urine cultures listed above had exceeded the maximum incubation time of 24 hours as stated in the policy and procedure. The interview occurred on 09/19/2023 at 12:20 PM. DoB: Date of birth

**D6019**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(iv)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:  
 Based on review of the laboratory's proficiency testing (PT) documentation, quality assessment documentation and an interview with Testing Personnel (TP) #3, the Laboratory Director failed to ensure that an approved corrective action plan is followed when any PT results are below 80%, unacceptable or unsatisfactory. This deficient practice had the potential to affect 230 out of 230 patients tested under the subspecialty of Bacteriology from 01/04/2022 through 09/19/2023. Findings Include: 1. Review of the laboratory's 2022 and 2023 PT documentation, provided on the date of survey, did not find records of any evaluation for the following subspecialties: AAFP 2022-C, Bacteriology, current score 0% WSLH 2023 Module 5270, Bacteriology, current score 80% 2. Review of the policy and procedure titled "Proficiency Testing" signed and dated by the Laboratory Director on 11/16/2021 and provided on the date of inspection, found the following statements: "10) In case of unsatisfactory results, investigate the cause and correct. document the corrective action taken." 3. Review of quality assessment documentation did not find any corrective action plan for the 2022 and 2023 Bacteriology PT results that were below 80%, unacceptable or unsatisfactory. 4. The Inspector requested the corrective action plan for the laboratory's PT scores that were below 80%, unacceptable or unsatisfactory from TP #3. TP#3 confirmed the laboratory did not follow the laboratory's corrective action plan for PT scores less than 80%, unacceptable or unsatisfactory and was unable to provide the requested documentation on the date of survey. The interview occurred on 09/19/2023 at 10:45 AM. AAFP: American Academy of Family Physicians WSLH: Wisconsin State Laboratory of Hygiene