Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0332772	07/31/2019
Name of Provider or Supplier	**Street Address, City, State**	
Zanesville Family Practice Inc	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
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on record review and an interview with testing personnel (TP), the laboratory failed to have written or electronic test requests/orders from an authorized person for three out of three patient medical records reviewed. All patient urine cultures tested from 09/06/2017 to 07/31/2019 had the potential to be affected by this deficient practice. Findings were as follows: 1. Review of three patient medical records, provided on the date of inspection, revealed urine culture results for each patient, however did not find any written or electronic test request/order for the urine culture tests performed, as indicated below: Patient Initials Date(s) of visit MM 01/29/2019, 02/18/2019 MK 06/18/2018, 07/02/2019, 07/30/2019 BW 03/04/2019 2. The inspector requested the laboratory's test requisition and accessioning policy and procedure and the corresponding test requisitions for the above mentioned patients from the TP#5. 3. TP#5 stated the Laboratory Director provided verbal orders for the urine culture testing and confirmed the laboratory did not have any written or electronic test requests/orders available, did not have a test requisition and accessioning policy and procedure established and were unable to provided the requested documentation on the date of the inspection. The interview on 07/31/2019 at 10:35 AM.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) 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. This STANDARD is not met as evidenced by: Based on record review and an interview with testing personnel (TP), the laboratory failed to follow their established policy and procedure for the Uricult urine culture incubation time for fifteen out of sixty three patient urine cultures tested, of which had the potential to be affected by this deficient practice. Findings Include: 1 Review of the laboratory's "Urine Culture Procedure, 1215 Newark Road Zanesville, OH 43701" policy and procedure, approved, signed and dated by the Laboratory Director on 04/01 /2014, 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 Uricult urine cultures that exceeded 24 hours of incubation as listed below: Chart Number Date/Time Set Up Date/Time Read 4044 02/07/19 7:45 AM 02/08/19 8:30 AM 5653 02/07/19 8:25 AM 02/08/19 8:30 AM 8161 02/12/19 8: 20 AM 02/13/19 9:00 AM 10092 02/13/19 9:30 AM 02/14/19 11:00 AM 10092 03/20 /19 9:35 AM 03/21/19 1:00 PM 5201 06/20/19 11:58 AM 6/21/19 12:55 AM No # 06 /26/19 9:50 AM 06/27/19 1:10 PM No # 07/05/19 7:35* 07/06/19 8:30* No # 07/08 /19 1:20 PM 07/09/19 2:50 PM No # 07/08/19 8:20 AM 07/09/19 2:50 PM No # 07/09 /19 8:05 AM 07/10/19 10:55 AM No # 07/09/19 7:30 AM 07/10/19 10:55 AM No # 07/10/19 8:15* 07/11/19 11:30 AM No # 07/11/19 10:15 AM 07/12/19 10:55 AM No # 07/11/19 9:35 AM 07/12/19 10:56 AM 3. TP#5 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 07/31/2019 at 10:21 AM. * no AM /PM noted on the log
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on record review and an interview with testing personnel (TP), the laboratory failed to document the date and time in which urine culture specimens were collected. All patients tested under the sub-specialty of bacteriology from 09/06/2017 to 07/31 /2019 had the potential to be affected by this deficient practice. Findings were as follows: 1. Review of the Uricult manufacturer's instructions revealed the following statement under the specimen collection and preparation procedure for urine culture paddles: "Specimens should be inoculated onto Uricult Urine Culture-Paddles immediately following collection." 2. Review of three out of three of the laboratory's "Uricult Results" patient logs revealed columns titled "Chart Number", "Patient Name", "Date & Time Set Up", "Initials Set Up", "Date & Time Read", "Initials Read", "Results" and "Charted Initials" and were completed for each patient test, however specimen collection date and time was not recorded. 3. The Inspector requested the laboratory's documentation of urine specimen collection date and time between 09/06/2017 to 07/31/2019 from TP#5. TP#5 confirmed the laboratory did not

	document urine culture specimen collection date and time and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 07/31/2019 at 10:21 AM.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and an interview with testing personnel (TP), the laboratory failed to include an identification number or unique patient identifier on six out of six patient Uricult urine culture final test reports reviewed. All patients tested in this laboratory from 09/06/2017 to 07/31/2019 had the potential to be affected by this deficient practice. Findings Include: 1. Review of six out of six patient Uricult urine culture final test reports, provided on the date of the inspection, found only the patient name listed with no other patient identifiers. 2. TP#5 confirmed the patient's name was the only identifier used on the test reports. The interview occurred on 07/31/2019 at 11:35 AM.