Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D1040740	08/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Associates In Women's Health	1350 Fifth Avenue, Suite 324, Youngstown, 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 interviews with the Technical Consultant (TC) and testing personnel (TP) #1, the laboratory failed to have written or electronic test requests /orders from an authorized person for one out of 10 Chlamydia Trachomatis (CT) and Neisseria Gonorrhoeae (NG) tests run on the Cepheid Gene Xpert instrument and one out of 10 Trichomonas Vaginalis (trichomonas), Gardnerella Vaginalis (Gardnerella) and Candida tests run on the BD Affirm VPIII instrument. All patient testing for the above mentioned analytes had the potential to be affected by this deficient practice. Findings Include: 1. Review of 10 patient test records and test reports, provided on the date of the inspection, revealed one patient report with a CT/NG result, however did not find any written or electronic test request/order for the CT/NG tests performed, as indicated below: Date/Time Specimen Collected 03/08/2018 at 3:50 PM 2. Review of 10 patient test records and test reports, provided on the date of the inspection, revealed one patient report with Trichomonas, Gardnerella and Candida results, however did not find any written or electronic test request/order for the Trichomonas, Gardnerella and Candida tests performed, as indicated below: Date/Time Specimen Collected 10 /08/2018 at 2 PM 3. The inspector requested the laboratory's test requisition/order from an authorized individual for the patient CT/NG tests performed on 03/08/2018 at 3:50 PM and for the patient Trichomonas, Gardnerella and Candida tests performed on 10/08/2018 at 2 PM from the TC and TP#1. The TC and TP#1 confirmed the progress notes in the paper charts for the patients indicated above did not include orders for the corresponding tests performed and were unable to provide the requested documentation on the date of the inspection at 12:55 PM.

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 interviews with the Technical Consultant (TC) and testing personnel (TP) #1, the laboratory failed to document the date and time in which the Trichomonas Vaginalis (Trichomonas), Gardnerella Vaginalis (Gardnerella) and Candida specimens were received in the laboratory, specimens prepared, tested and reported. All patients tested on the BD Affirm instruments from 09/18/2017 to 08/21/2019 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the BD Affirm manufacturer's instructions revealed the following statement under "Specimen Storage and Transport": "When using the Affirm VPIII Ambient Temperature Transport System (ATTS): The total time between sample collection and proceeding with sample preparation should be no longer than 72 h when the sample is stored at ambient conditions (15-30C). When using either the Affirm VPIII Sample Collection Set or the swabs contained in the Affirm VPIII Microbial Identification Test Kit: The total time between placing the swab into the sample collection tube and proceeding with the sample preparation should be no more than 1 h if the sample is stored at room temperature, or 4 h if the sample is stored at 2-8C." 2. Review of 10 out of 10 of the laboratory's patient test records and final "Laboratory Report" for the BD Affirm testing, as listed below, did not find the time the laboratory received the specimens or the time the specimens were prepared, tested and reported. Collection Dates as indicated on the "Laboratory Report" 03/08/18 4/19/19 09/20/18 5/28/19 10/08/18 6/11/19 10/08/18 6/13/19 11/03/18 12/04/18 3. The Inspector requested the laboratory's documentation of the above listed 10 patient BD Affirm specimens for the time they were received in the laboratory, time prepared, time tested and time reported from the TC and TP#1. The TC and TP#1 stated the laboratory did not document specimen receipt time in the laboratory, preparation time, time tested and time reported and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 08/21/2019 at 11:30 AM.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interviews with the Technical Consultant (TC) and testing personnel (TP) #1, the laboratory failed to meet the criteria of acceptability for the Trichomonas Vaginalis (Trichomonas), Gardnerella Vaginalis (Gardnerella) and Candida quality control (QC) results run on the BD Affirm VPIII instruments "A" and "B" before reporting patient test results. 77 out of 77 patients tested on instrument "A" and 40 out of 40 patients tested on instrument "B" for Trichomonas, Gardnerella and Candida between 05/08/2019 and 06/05/2019 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's Individualized Quality Control Plan (IQCP) revealed the laboratory performed external positive and negative controls on each of the BD Affirm analyzers each week, each newly opened

	kit, each new lot number, each shipment, each new untrained operator and if any test results are questionable. 2. Review of the laboratory's "Associates in Women's Health of the Mahoning Valley, Inc. Policy & Procedure Manual", approved, signed/dated by the Laboratory Director on 03/21/18 and provided on the date of the inspection, found a section titled "Quality Control (QC)" on pages 47 and 48 of the manual that included the following: "QC Corrective Actions (for Out-of-Control" situations) ...6. Re-run the control ...9. Document corrective actions and repeat controls 10...If controls are still unacceptable, contact the manufacturer of the instrument/test kit for technical assistance..." 3. Review of the laboratory's 2019 "BD Affirm VPIII Microbial Identification Test QC Log" results, provided on the date of the inspection, revealed QC logs only for instrument "B" (no QC documentation for instrument "A" was provided) with the following dates of QC results, no corrective action documented for unacceptable QC, no indication that QC was re-run and found to be acceptable prior to testing and reporting patient specimens. Dates QC/Patients Tested Instrument "A" No QC documentation available *05/09/19; 4 patient specimens tested /reported *05/10/19; 7 patient specimens tested/reported *05/12/19; 2 patient specimens tested/reported *05/14/19; 4 patient specimens tested/reported *05/17/19; 6 patient specimens tested/reported *05/18/19; 4 patient specimens tested/reported *05 /20/19; 5 patient specimens tested/reported *05/21/19; 8 patient specimens tested /reported *05/24/19; 4 patient specimens tested/reported *05/28/19; 6 patient specimens tested/reported *05/30/19; 8 patient specimens tested/reported *05/31/19; 5 patient specimens tested/reported *06/01/19; 4 patient specimens tested/reported *06 /03/19; 6 patient specimens tested/reported *06/04/19; 4 patient specimens tested /reported == 77 patient specimens tested/reported Instrument "B" 05/08/19 QC acceptable *05/09/19; 13 patient specimens tested/reported with no indication of instrument "A" or "B" *05/14/19; 4 patient specimens tested/reported with no indication of instrument "A" or "B" 05/15/19 QC unacceptable negative QC resulted positive *05/16/19; 6 patient specimens tested/reported with no indication of instrument "A" or "B" 05/22/19 QC acceptable *05/23/19; 13 patient specimens tested /reported on instrument "B" *05/24/19; 4 patient specimens tested/reported on instrument "B" 05/29/19 QC unacceptable positive QC resulted negative negative QC resulted positive 06/05/19 QC acceptable == 40 patient specimens tested/reported 4. The Inspector requested the laboratory's QC logs for instrument "A" and corrective action documentation for the unacceptable QC results as listed above for instrument "B" from the TC and TP#1. The TC and TP#1 confirmed the laboratory could not locate the QC logs for instrument "A", the QC documentation for instrument "B" indicated unacceptable BD Affirm QC results as listed above, there was no record that QC was re-run or that any corrective action was documented, they were unable to provide the requested documentation on the date of the inspection and patient testing continued to be tested/reported. The interviews occurred on 08/21/2019 at 10:30 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 interviews with the Technical Consultant (TC) and testing personnel (TP) #1, the laboratory failed to include the specimen source for six out of 10 Chlamydia Trachomatis (CT) and Neisseria Gonorrhoeae (NG) on the final test reports. Findings Include: 1. Review of the laboratory's "CLIA Annual Test Volume Log", provided on the date of the inspection, revealed CT/NG testing was performed. 2. Review of 10 of the laboratory's CT/NG final test reports revealed a list of potential specimen sources to be circled (Endocervical, Patient Collected Vaginal or First Catch Urine), however did not find the specimen source indicated for six out of 10 patients who had CT/NG testing performed. 3. The TC and TP#1 confirmed that the laboratory did not consistently indicate the specimen source for the CT/NG testing performed. The interviews occurred on 08/21/2019 at 12:55 PM.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interviews with the Technical Consultant (TC) and testing personnel (TP) #1, the Laboratory Director failed to ensure the laboratory's quality assessment program was maintained effectively to assure the quality of the Chlamydia Trachomatis (CT) and Neisseria Gonorrhoeae (NG) tests run on the Cepheid Gene Xpert instrument and the Trichomonas Vaginalis (trichomonas), Gardnerella Vaginalis (Gardnerella) and Candida testing procedures performed on the BD Affirm instruments. All patient testing performed in this laboratory from 09/18/2017 to the date of the inspection had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Quarterly Chart Audit Worksheet" for 2018 and 2019, provided on the date of the inspection, did not find the laboratory identified that there were missing patient test orders, no quality control (QC) records for the BD Affirm instrument "A", unacceptable QC for the BD Affirm instrument "B" with no corrective actions prior to patient testing and required components were missing in the patient test records and on the final test reports. 2. The TC and TP#1 confirmed that the laboratory's quality assessment activities did not effectively identify the above mentioned deficiencies. The interviews occurred on 08/21/2019 at 1:15 PM.