Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 36D1040740	**(X3) Date Survey Completed** 10/18/2023
Name of Provider or Supplier Associates In Women's Health	**Street Address, City, State** 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**
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and an interview with the sole Testing Personnel (TP), the laboratory failed to perform and document a negative quality control (QC) for the Neisseria Gonorrhea (NG) and Chlamydia Trachomatis (CT) tests on the Cepheid GeneXpert after the manufacturer performed a preventive maintenance (PM) procedure on 03/25/2022. This deficient practice had the potential to affect 1861 out of 1861 patient tests performed between 03/25/2022 through 04/20/2023. Findings Include: 1. Review of the laboratory's "Associates in Women's Health of the Mahoning Valley, Inc. Policy and Procedure Manual", provided on the date of the inspection and approved via signature and date by the Laboratory Director on 03/29 /2018, did not find any instructions for conducting QC after Cepheid GeneXpert analyzer preventive maintenance (PM) procedures conducted by the manufacturer. 2. Review of the laboratory's 2021, 2022 and 2023 QC records and manufacturer's preventative maintenance records did not find any documentation that the laboratory conducted a negative QC on 03/25/2022 for NG and CT after the Cepheid GeneXpert manufacturer returned the Cepheid GeneXpert analyzer back to the laboratory for patient testing. 3. The Inspector requested the laboratory's QC documentation conducted post manufacturer's services and preventative maintenance procedures from the sole TP. The sole TP confirmed on 10/27/2023 via electronic mail at 12:07 PM

	that the laboratory failed to conduct a negative QC for NG and CT after the manufacturer's service and preventative maintenance procedure on 03/25/2022 and was unable to provide the requested documentation.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review and an interview with the sole Testing Personnel (TP), the TC failed to evaluate and document the first semi-annual competency of the sole TP who were responsible for moderate complexity Neisseria Gonorrhea (NG) and Chlamydia Trachomatis (CT) testing procedures during the first year the individual tested patient specimens. This deficient practice had the potential to affect 2931 out of 2931 patient tests performed by the sole TP between 10/07/2021 through 10/07/2022. Findings Include: 1. Review of the laboratory's Form CMS-209, provided on the date of the inspection, approved, signed and dated by the Laboratory Director on 10/02/2023, revealed one individual qualified and listed as TP. 2. Review of the laboratory's "Testing Employee Competency Assessment" policy and procedure, provided on the date of the inspection, approved, signed and dated by the Laboratory Director on 03/29 /2018, found the following statement: "The testing employee competency assessment is required at least semi-annually in the first year and annually thereafter." 3. Review of the laboratory's 2021, 2022 and 2023 competency assessment records, provided for the inspection, did not find any record of the first semi-annual competency assessment during the sole TP's first year of NG and CT testing on patient specimens. The sole TP's initial training and demonstration of competency was completed on 10/07/2021 and their second semiannual assessment was completed on 10/07/2022. 4. The Inspector requested the laboratory's first semiannual competency assessment records for the sole TP from the sole TP. The sole TP confirmed the TC did not assess their first semiannual competency during their first year of testing patient specimens according to the laboratory's policy and procedure and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 10 /18/2023 at 8:26 AM.