Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 51D0234323	**(X3) Date Survey Completed** 11/17/2021
Name of Provider or Supplier Women's Health Center Of West Virginia	**Street Address, City, State** 510 Washington Street West, Charleston, WV	
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**
D0000	An announced, on site, recertification survey was conducted at Womens Health Center of WV Inc. on November 17, 2021, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory failed to (5) document the testing of proficiency testing (PT) samples and retain the signed attestation statements for the American Proficiency Institute (API) proficiency testing program in 2020 and 2021. Findings: 1. Review of API records revealed a lack of documentation for the processing and examination of PT samples in 9 of 9 testing events for 2020 and 7 of 7 testing events for 2021. 2. Review of API records identified no attestation statement signed by testing personnel and the laboratory director for one of two 2021 Hematology/Coagulation testing events. 2. An interview with the laboratory consultant, 11/17/21 at approximately 9:00 AM, confirmed the findings.

D2127	HEMATOLOGY CFR(s): 493.851(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to submit proficiency testing (PT) results within the timeframe specified by the American Proficiency Institute (API) for one of two Hematology/Coagulation 2021 events. Findings: 1. Review of API PT records identified the following: 1st event 2021 Hematology /Coagulation- 0% failure to participate 2. An interview with the laboratory consultant, 11/17/21 at approximately 9:45 AM, confirmed the findings.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to attain a satisfactory score for Microscopy (Vaginal Wet Preparation) in two consecutive American Proficiency Institute (API) proficiency testing (PT) events, resulting in an unsuccessful performance for analyte. Findings: 1. Review of API records identified the following scores: 0% 2020 3rd event- Microscopy Vaginal Wet Preparation 0% 2021 1st event- Microscopy Vaginal Wet Preparation 2. An interview with the laboratory consultant, 11/17/21 at approximately 9:30 AM, confirmed the findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory failed to perform and document training and competency for 2 of 3 laboratory testing personnel (TP2 and TP3) as required by established policies and procedures. Findings: 1. Review of testing personnel records identified the following: TP2- 6 month competency for serum HCG testing was not completed TP3- Initial training was completed 10/14/21 for all test methods. Review of testing logs (January 2021 thru date of survey)identified TP3 performing quality control 8/23/21 and 2/15/21. 2. An interview with the laboratory consultant, 11/17/2021 at approximately 11:00 AM, confirmed the findings.