Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0234323	10/03/2019
Name of Provider or Supplier	**Street Address, City, State**	
Women's Health Center Of West Virginia	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
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on a review of laboratory proficiency testing (PT) records and an interview with Technical Consultant 1 (TC1), the laboratory received an unsatisfactory score of 0% for Vaginal Wet Preparation in 2 of 5 American Proficiency Institute testing events in 2018 and 2019. Findings: 1. A review of 2018 API records identified an unsatisfactory performance of 0% for Vaginal Wet Preparation in the 2018 Hematology 2nd testing event. For sample VA-02 the laboratory reported "clue cells seen", when the correct answer was "no yeast, Trich, or clue cells". This resulted in an unsatisfactory score of 0%. 2. A review of 2019 API PT records identified an unsatisfactory performance of 0% for Vaginal Wet Preparation in the 2019 Hematology 1st testing event. For sample VA-01 the laboratory reported "yeast seen", when the correct answer was "clue cells seen". This resulted in an unsatisfactory score of 0%. 3. An interview with TC1, on 10/3/19 at approximately 8:40 AM, confirmed the findings. 4. The laboratory took remedial action for both unsatisfactory performances and documented the action taken.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by:

	Based on a review of laboratory policies and procedures and an interview with the Technical Supervisor 1 (TS1), the laboratory failed to have the procedure manuals for the Anti-D testing procedure signed by the current Laboratory Director (LD). Findings: 1. A review of the laboratory policies and procedures identified that manufacturer directions/product inserts are utilized as the procedure for the Anti-D testing performed. 2. The manufacturer directions/product inserts used as the procedure manual for Anti-D testing, Quotient Anti-D Delta Albaclone and Reagent Control for Anti-D Albacheck, were not signed by the current LD. 3. An interview with TS1, on 10/3/19 at approximately 8:32 AM, confirmed that those manufacture direction/product inserts for Quotient Anti-D Delta Albaclone and Reagent Control for Anti-D Albacheck are the current procedures for Anti-D testing and that the current LD had not signed them.