Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 49D2038942	**(X3) Date Survey Completed** 04/03/2018
Name of Provider or Supplier Whole Woman's Health Of Charlottesville	**Street Address, City, State** 2321 Commonwealth Drive, Charlottesville, VA	
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 CLIA recertification survey was conducted at Whole Women's Health of Charlottesville on April 3, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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 a review of the laboratory's proficiency testing (PT) documentation, and an interview, the laboratory failed to retain attestation statements signed by the laboratory director and testing personnel for three (3) of six (6) events reviewed. Findings include: 1. Review of the laboratory's 2016 American Academy of Family Physicians (AAFP) Blood Bank Testing Rh Factor PT documentation, and 2017 American Association of Bioanalysts (AAB), a total of six (6) events, revealed no signed attestation statements for: 2016 AAFP Event A, 2016 AAFP Event B, 2016 AAFP Event C. The inspector requested to review the attestation documentation. No documentation was available for review. 2. During the exit interview with the Laboratory Director, Clinic Manager, and Director of Special Projects at

	approximately 4:30 PM, it was confirmed that the laboratory failed to retain copies of the AAFP attestation statements for the PT events outlined above in 2016.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records and interviews, the laboratory failed to evaluate non-graded PT results for three (3) of fifteen (15) Blood Bank Testing Rh Factor challenges reviewed for calendar year 2016. Findings include: 1. Review of the laboratory's American Academy of Family Physicians (AAFP) PT documentation for 2016, a total of three (3) events and fifteen (15) challenges, revealed no evaluation or verification of accuracy for the non-graded responses for: 2016 Event C Blood Bank Testing Rh Factor - BB 11, BB 12, BB 13. The inspector requested to review evaluation documentation for the three (3) non-graded challenges listed above. No additional documentation was available for review. 2. In an interview with the Laboratory Director, Clinic Manager, and Director of Special Projects at approximately 4:30 PM, it was confirmed that the laboratory failed to evaluate the non-graded PT results for the event listed above.
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 a tour, review of the laboratory's test logs, quality assurance (QA) policy, and interviews, the laboratory failed to document quality control (QC) for Anti-D Rh tests on twenty (20) days of patient testing in the fifteen (15) months reviewed. Findings include: 1. During a tour of the laboratory testing area, the inspector noted the moderate complexity qualitative Eldoncard Rhesus Factor kits in use for RhD antigen detection. The inspector requested to see the quality control media used for the kits. The lab director stated "the QC is on order. We do not have any vials at this time". 2. Review of the laboratory's patient test logs from January 2016 to the date of the survey, April 3, 2018 revealed the following twenty (20) days with no QC documentation: 11/16/17, 12/13/17, 12/14/17, 12/20/17, 12/21/17, 01/03/18, 01/04/18, 01/10/18, 01/11/18, 01/18/18, 01/22/18, 01/23/18, 01/25/18, 01/30/18, 01/31/18, 02/01/18, 02/05/18, 02/06/18, 02/07/18, and 02/12/18. The inspector requested to review the QC documentation on the dates of patient testing listed above. No documentation was available for review. 3. Review of the laboratory's QA policies revealed a QC protocol that stated: "Rh controls are to be documented daily. Results of all tests are

	recorded on the daily log sheet with proper laboratory testing protocol that QC is verified". 4. During the exit interview with the Laboratory Director, Clinic Manager, and Director of Special Projects at approximately 4:30 PM, it was confirmed that the laboratory failed to document quality control (QC) for Anti-D Rh on twenty (20) days of patient testing in the fifteen (15) months reviewed.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records, and an interview, the laboratory director failed to document evaluation of three (3) of six (6) Blood Bank Rh Factor PT modules reviewed. Findings include: 1. The inspector reviewed three (3) American Academy of Family Medicine (AAFP) PT events documents for 2016 and three (3) American Association of Bioanalysts (AAB) PT events for 2017. The PT review, a total of six (6) events, revealed no documentation of result evaluation for the following: 2016 AAFP Event B, 2016 AAFP Event C, 2017 AAB 1st Event. The inspector requested to review documentation of laboratory director review for the events. No documentation was available for review. 2. During the exit interview with the Laboratory Director, Clinic Manager, and Director of Special Projects at approximately 4:30 PM, it was confirmed that the laboratory director failed document review for the proficiency testing events listed above.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of patient test logs, procedure and policy manuals, and interview, the laboratory director failed to ensure that the QC policies were maintained for Anti-D Rh on twenty (20) days of patient testing in the fifteen (15) months reviewed. Findings include: 1. Review of the laboratory's patient test logs from January 2016 to the date of the survey, April 3, 2018 revealed the following twenty (20) days with no QC documentation: 11/16/17, 12/13/17, 12/14/17, 12/20/17, 12/21/17, 01/03/18, 01/04/18, 01/10/18, 01/11/18, 01/18/18, 01/22/18, 01/23/18, 01/25/18, 01/30/18, 01/31/18, 02/01/18, 02/05/18, 02/06/18, 02/07/18, and 02/12/18. The inspector requested to review the QC documentation on the dates of patient testing listed above. No

	documentation was available for review. 2. Review of the laboratory's QA policies revealed a QC protocol that stated "Rh controls are to be documented daily. Results of all tests are recorded on the daily log sheet with proper laboratory testing protocol that QC is verified". 3. During the exit interview with the Laboratory Director, Clinic Manager, and Director of Special Projects at approximately 4:30 PM, it was confirmed that the laboratory director failed to ensure that the QC policies were maintained for Anti-D Rh on the twenty (20) days of patient testing listed above.