Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0978157	08/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
A Capital Womens Health Clinic	1511 Starling Drive, Richmond, 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 A Capital Women's Health Clinic on 08/25/22 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: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D5400 - 42 C.F. R. 493-1250 Condition: Analytic Systems.
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 the review of proficiency testing (PT) records, lack of documentation, and interview, the laboratory failed to maintain documentation of the attestation statement, event scores and review of final scores for one of five events reviewed at the date of survey on 08/25/22. Findings include: 1. Review of the available American Proficiency Institute (API) PT records revealed lack of documentation of the attestation statement, the ABO/RHO D (RHO) Type final results, and documentation of the review of the results for the 2022 API Immunology/Immunohematology 1st event. During an interview with the medical office staff on 08/25/22 at approximately

	10:30 AM the inspector requested the PT records. The records were not available for review. 2. An exit interview with the medical office staff on 08/25/22 at approximately 11:30 AM confirmed the findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the review of policy and procedures (P&P), quality assurance (QA) records, quality control (QC) records, temperature records, lack of documentation and interview, the lab failed to: 1) perform Rh blood typing QC each day from 05/25/22 up to 08/23/22 (Refer to D5403); 2) monitor and document the refrigerator and room temperatures from 05/25/22 up to 08/23/22 (Refer to D5411); and 3) ensure the QA monitors and checklists were performed on a quarterly basis from 06/01/21 up to the date of survey on 08/25/22 (Refer to D5791).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), daily quality control (QC) records, patient recovery logs, and interviews, the lab failed to follow the established P&P for performing the Rh blood typing QC materials each day from 05/25/22 up to 08/23/22. Findings include: 1. Review of the P&P revealed the following statements: "Quality Assurance Policies- Guidelines for Quality Control- 2. Each day a set of controls is tested and recorded on the daily log. Any control results not within

	acceptable results are repeated and longed in along with the values not acceptable and the reason for the poor results recorded and dated and signed by the person performing the testing." "Rh Typing- Control: Use a known patient control that is Rh positive to confirm tests." 2. Review of the daily QC records from 06/01/21 up to the date of survey on 08/25/22 revealed lack of documentation of the performance of a known Rh patient positive control for the following dates: 05/25 and 26/22, 06/02, 03, 04, 07, 09, 10, 14, 15, 16, 23, 24, 25, 28, 29 and 30/22, 07/07, 08, 14, 15, 19, 28, 29 and 30/22, and 08/02, 03, 09, 10, 16, and 23/22. Total 31 days. 3. Review of the patient recovery logs revealed approximately 127 patients seen during the timeframe outlined above. 4. An exit interview with the medical office staff on 08/25/22 at approximately 11:30 AM confirmed the findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on the review of manufacturer's package insert (PI), policy and procedures (P&P), daily quality control (QC) records, lack of documentation and interview, the lab failed to follow the manufacturer PI for monitoring and documenting the refrigerator and room temperatures for the Rh blood typing reagent storage and testing each day from 05/25/22 up to 08/23/22. Findings include: 1. Review of the PI for the Albaclone Anti-D blend blood-grouping reagent revealed the following statements: "Storage- the reagent should be stored at 2-8 degrees Celsius." "Slide Technique- 3. Mix by rocking the slide for approximately 30 seconds and incubate the test at 18-24 degrees Celsius for 5 minutes with occasional mixing." 2. Review of the P&P revealed the following statement: "Quality Assurance Policies- Guidelines for Quality Control- 4. All test materials are stored according the manufacturer's directions." 3. Review of the daily QC records from 06/01/21 up to the date of survey on 08/25/22 revealed lack of documentation of the refrigerator and room temperatures for the following dates: 05/25 and 26/22, 06/02, 03, 04, 07, 09, 10, 14, 15, 16, 23, 24, 25, 28, 29 and 30/22, 07/07, 08, 14, 15, 19, 28, 29 and 30/22, and 08/02, 03, 09, 10, 16, and 23/22. Total 31 days. The inspector requested to review the temperature documentation for the above-mentioned timeframe. The documentation was not available for review. 4. An exit interview with the medical office staff on 08/25/22 at approximately 11:30 AM confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), quality assurance (QA) records,

	proficiency testing (PT) records, quality control (QC) records, temperature records, lack of documentation and interview, the lab failed to follow the established P&P of performing and documenting the quarterly quality assurance monitors from 06/01/21 up to the date of survey on 08/25/22. Findings include: 1. Review of the laboratory's P&P, PT, QA and QC records, and temperature records revealed the following: - lack of maintenance of the PT attestation statement, the ABO/RHO D (RHO) Type final results, and documentation of the review of the results for the 2022 API Immunology /Immunohematology 1st event. Refer to D2015. - lack of the Rh blood typing QC each day from 05/25/22 up to 08/23/22. Refer to D5403. - lack of documentation of refrigerator and room temperatures from 05/25/22 up to 08/23/22. Refer to D5411. 2. Review of the P&P revealed the following statements: "Quality assurance program is overseen by the director for the identification of problem areas and ways to improve service to our patients. The over all plan is reviewed annually to determine if we are effective in achieving our goals. Monitoring of our QA markers are performed the office manager on a quarterly basis." 3. Review of available QA records revealed that the laboratory utilizes a quality assurance checklist that included the following statements: Write "Y" for Yes, "N" No or "NA" for not applicable to indicate the outcome of the assessed item. Items of assessment include but not limited: Orientation and training documentation; temperature requirements, quality control reviews; proficiency testing performance and documentation; tests have been properly ordered, recorded and reported; and the director has reviewed and associated remedial actions taken. In addition, the record review revealed QA checklists completed and signed by the lab director on 03/22/21 and 06/01/21. There were no other checklists available for review upon request at the date of survey on 08/25/22. 4. An exit interview with the medical office staff on 08/25/22 at approximately 11:30 AM confirmed the findings.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), quality assurance (QA) records, proficiency testing (PT) records, quality control (QC) records, temperature records, lack of documentation and interviews, the lab director failed to: 1) ensure the maintenance of PT records for the first event in 2022 (Refer to D2015); 2) ensure the performance of Rh blood typing QC each day from 05/25/22 up to 08/23/22 (Refer to D5403); 3) ensure monitoring and documentation of refrigerator and room temperatures from 05/25/22 up to 08/23/22 (Refer to D5411); and 4) ensure the QA monitors and checklists were performed on a quarterly basis from 06/01/21 up to the date of survey on 08/25/22 (Refer to D5791).