Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0969326	05/23/2022
Name of Provider or Supplier	**Street Address, City, State**	
Women's Cancer & Wellness Institute	9101 Stony Point Dr Suite 3300, 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 the Women's Cancer & Wellness Institute on 05/23/22 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 is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a tour of the lab, review of quality control (QC) records, calibration verification records, lack of documentation and interviews, the lab failed to verify the accuracy, precision, and reportable range of the new Abaxis Piccolo chemistry analyzer installed on 07/27/21 prior to testing patients and reporting approximately 4,200 patients from 07/27/21 up to date of survey on 05/23/22. Findings include: 1. During a tour of the lab testing area on 05/23/22 at approximately 12:30 PM, the surveyor observed one Abaxis Piccolo chemistry analyzer, serial number P26743. In an interview with the technical consultant during the tour, they stated that the chemistry analyzer was replaced in July 2021. 2. A review of QC and calibration verification records, and an interview with the technical consultant on 05/23/22 at approximately 1500 revealed that the lab received the new Abaxis piccolo chemistry

	analyzer, serial number P26743, as a loaner instrument on 07/27/21 while the previous analyzer was returned to the manufacturer for repairs (Serial number P25744). The lab kept the loaner instrument as their primary instrument. The QC records revealed the lab assayed two levels of QC materials on 07/27/21 twice and three times on 07/28 /21. The lab performed a calibration verification procedure on 08/21/21. 3. The surveyor requested to review the initial performance specification documents for the loaner instrument introduced for patient testing on 07/21/21. The documents were not available for review. 4. Review of daily patient testing records revealed that approximately 4,200 patients assayed and reported from 07/27/21 up to the date of survey on 05/23/22. 5. An exit interview with the technical consultant at approximately 1600 on 05/23/22 confirmed the findings.
D6055	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 whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), initial performance specification records, testing personnel (TP) records, lack of documentation, and interview, the technical consultant failed to provide documentation of the training and evaluation of training of four of four TP for the new hematology analyzer initiated for patient testing on 01/13/22. Findings include: 1. Review of the CLIA CMS-209 Form revealed four TP performing patient testing. 2. Review of the initial performance specifications records for the New DxH 500 hematology analyzer (SN S460011041R78T) revealed initiation for patient testing on 01/13/22. 3. Review of four TP records revealed lack of documentation of training and evaluation of training for the new DxH 500 hematology analyzer prior to patient testing on 01/13/22. The surveyor requested the aforementioned documents. The documents were not available for review at the date of survey on 05/23/22. 4. An exit interview with the technical consultant at approximately 1600 on 05/23/22 confirmed the findings.