Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0969326	02/11/2026
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 unannounced, off-site CLIA proficiency testing (PT) desk review was conducted for Women's Cancer & Wellness Institute on February 11, 2026 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 and includes the Conditions under 42 CFR part 493 CLIA Regulation: D2016 - 42 CFR. 493.803 Condition: Successful Participation, D6000 - 42 CFR. 493.1403 Condition: Laboratories performing moderate complexity testing-Laboratory Director.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by:

	Based on a review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report, the laboratory's proficiency testing records and interview, the laboratory failed to successfully participate within the Chemistry specialty for Potassium (K) analyte. The laboratory had unsatisfactory K scores for the second and third events of calendar year 2025. Refer to D2088.
D2088	ROUTINE CHEMISTRY CFR(s): 493.841(b) (b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on a pre-survey review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report, Proficiency Testing (PT) records, and interview, the laboratory failed to attain a score of at least 80% for the analyte Potassium (K) on two (2) consecutive chemistry module testing events resulting in an initial unsuccessful PT performance. The findings include: 1. A pre-survey review of the CMS 0155 report revealed the laboratory received unsatisfactory scores for the regulated analyte #0465, K, of 0% in the 2025 Chemistry-2nd Event and a score of 60% in the 2025 Chemistry-3rd Event. 2. Review of the laboratory's American Proficiency Institute (API) PT evaluations revealed K scores of less than 80% for the following 2 consecutive chemistry PT events: API 2025 Chemistry Event 2: K scored 0% ; API 2025 Chemistry Event 3: K scored 60%; resulting in an initial unsuccessful PT performance. 3. In an email interview with the Technical Consultant on February 11, 2026 at 12:56 PM, the above findings were confirmed.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report, proficiency testing records, and interview, the laboratory director failed to provide overall direction and management of the laboratory services. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report, proficiency testing (PT) records, and interview, the laboratory director (LD) failed to ensure the overall quality of the laboratory services provided.

	The LD failed to ensure successful participation in the laboratory's Health and Human Services (HHS) approved PT program. Refer to D2088.