Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1007256	05/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Novant Health Cancer Institute - Mount Airy	1908 Caudle Dr, Mount Airy, NC	

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
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of policies and procedures, review of personnel records, and interview with the TS (technical supervisor) 5/23/23, the laboratory director failed to ensure that competency evaluation policies were followed for evaluation of the GS (general supervisor). Review of the laboratory's "Quality Assessment Plan" revealed "... IX. DOCUMENTATION The following will be maintained electronically, on site, or in individual testing personnel files for Moderate and High Complexity laboratories: ... 2. Initial, semi-annual (non-waived testing), and Annual Training /Competency Documentation. ..." Review of personnel records revealed no documentation of annual competency evaluations for the GS during 2021, 2022, or 2023. During interview at approximately 10:15 a.m., the TS confirmed there were no annual competency evaluations available for the GS.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether

	supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of policies and procedures, review of personnel records, and interview with the TS (technical supervisor) 5/23/23, the laboratory director failed to specify in writing the duties and responsibilities for the GS (general supervisor). Review of the laboratory's "Quality Assessment Plan" revealed "... IX. DOCUMENTATION The following will be maintained electronically, on site, or in individual testing personnel files for Moderate and High Complexity laboratories: ... 3. Job descriptions ...". Review of personnel records revealed the laboratory did not have a list of authorized duties and responsibilities for the GS. During interview at approximately 10:15 a.m., the TS confirmed the laboratory did not have a list of authorized duties and responsibilities for the GS.