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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 34D1007254 | (X3) Date Survey Completed 01/19/2023 |
| Name of Provider or Supplier Novant Health Cancer Institute - | Street Address, City, State 1213 Lexington Avenue, Suite B, Thomasville, 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 |
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| D6103 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of policies and procedures, review of personnel records, and interview with TS (technical supervisor) #2 on 1/19/23, the laboratory director failed to ensure that competency evaluation policies were followed for 1 of 2 technical supervisors (TS #1). 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 competency evaluations for TS #1 during 2020, 2021, or 2022. During interview at approximately 10:30 a.m., TS #2 confirmed there were no competency evaluations available for TS #1.</p> |
| D6107 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>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</p> |

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 TS (technical supervisor) #2 on 1/19/23, the laboratory director failed to specify in writing the duties and responsibilities for 1 of 2 technical supervisors (TS #1). 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 TS #1 who serves as an off-site technical and general supervisor for the laboratory. During interview at approximately 10:30 a.m., TS #2 stated that TS #1's duties would not be exactly the same as hers.