

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1078227	(X3) Date Survey Completed 09/22/2022
Name of Provider or Supplier Novant Health West Forsyth	Street Address, City, State 105 Stadium Oaks Drive, Clemmons, 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
D6072	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3)</p> <p>Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2020, 2021, and 2022 HemoCue WBC quality control records 9/22/22, testing personnel failed to follow the laboratory's policy for validation of each new lot number of control material used on the HemoCue WBC analyzer. Findings: Review of the "HemoCue WBC Analyzer" procedure revealed on page 3 "... Validation of New Lot of Control material The following actions are taken prior to implementation of a new lot number of quality control material: 1. The new lot number of control material is to be tested in parallel with the existing control material. 2. The new lot number of control material will be tested a minimum of 1 time prior to use. ... 4. The results must be compared to the manufacturer's assay ranges and confirmed that the values are within acceptable limits. Document results on the HemoCue WBC QC Lot Validation Study log. ... 6. The manufacturer's package insert, all instrument correlation documentation from the validation study, and any other information regarding the study, will be secured together (stapled or paper clipped) and maintained for 2 years. ..." Review of 2020, 2021, and 2022 HemoCue WBC quality control records revealed there was no documentation the following lot numbers of control material were validated prior to use: a. HC12201, HC12202, HC12203 in use 12/4/20; b. HC03211, HC03212, HC03213 in use 3/3/21; c. HC0621, HC06212, HC06213 in use 6/1/21; d. HC09211, HC09212, HC09213 in use 9/7/21; e. HC12211, HC12212, HC12213 in use 11/3/21; f. HC03221, HC03222, HC03223 in use 3/9/22; g. HC06221, HC06222, HC06223 in use 6/1/22; h. HC09221, HC09222, HC09223 in use 8/22/22.</p>