

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1080070	(X3) Date Survey Completed 01/19/2024
Name of Provider or Supplier Novant Health Hillsdale Medical Associates	Street Address, City, State 121 Medical Drive, Advance, 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 2021, 2022, and 2023 HemoCue WBC quality control records 1/19/24, testing personnel failed to follow the laboratory's policy for validation of 7 of 9 lot numbers of control material used on the HemoCue WBC analyzer from 3/26/21-1/18/24. Findings: Review of the "HemoCue WBC Analyzer" procedure revealed on page 4 "... 6. Validation of new lots of control material a. The following actions are taken prior to implementation of a new lot number of quality control material: i. The new lot number of control material is to be tested in parallel with the existing control material for a minimum of one time prior to placing the new lot number into routine use. ii. 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. b. At the end of the validation study, if the controls have performed as expected, the validation has been completed and the material is ready for routine quality control testing. c. 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 a minimum of 2 years. ..." Review of 2021, 2022, and 2023 HemoCue WBC quality control records revealed there was no documentation the following lot numbers of control material were validated prior to use: a. HC03221, HC03222, HC03223, expiration date 6/5/22; b. HC06221, HC06222, HC06223, expiration date 9/5/22; c. HC09221, HC09222, HC09223, expiration date 12/5/22; d. HC12221, HC12222, HC12223, expiration date 3/5/23; e. HC03231, HC03232, HC03233, expiration date 6/5/23; f. HC06231,</p>

HC06232, HC06233, expiration date 9/5/23; g. HC09231, HC09232, HC09233,
expiration date 12/5/23.