

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1101243	(X3) Date Survey Completed 01/29/2020
Name of Provider or Supplier Novant Health Huntersville	Street Address, City, State 16525 Holly Crest Lane Suite 150, Huntersville, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2018 and 2019 Beckman Coulter Act Diff 2 hematology analyzer calibration records, review of General maintenance and temperature/humidity records, review of Quality Assessment(QA), and interview with Technical Consultant(TC) 1/29 /2020, the laboratory failed to retain all required calibration and maintenance/ temperature documentation for two years. Findings: a. Review of the 2018 Laboratory QC/QA Review Checklist revealed Act Diff 2 calibrations were performed 3/16/18 and 10/10/18. Review of the calibration records revealed documentation available for the 2019 calibrations only. The 2018 calibration records were not available at time of survey. b. The laboratory documents the room temperature, refrigerator temperature, freezer temperature, humidity, and Afinion cleaning on the General Maintenance and Temperature/humidity log. Review of the 2018 and 2019 logs revealed record of documentation for the "lab" maintenance and temperature/humidity was not available for January 2019 and February 2019. At approximately 12:30pm, the TC confirmed the 2018 calibrations and the general maintenance and temperature/humidity logs for January and February 2019 were not available.</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified</p>

in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of manufacturer's instructions, review of the laboratory's Individualized Quality Control plan(IQCP), review of laboratory quality control(QC) records, and interview with Technical Consultant(TC) 1/29/2020, the laboratory failed to perform and/or document QC as specified by the manufacturer and established by the laboratory for the Afinion Urine Albumin/Creatinine(ACR) testing performed. Findings: The manufacturer's instructions for ACR states, "Controls should be analyzed with each new shipment of Afinion ACR Test kits, each new lot of Afinion ACR test kits, at least every 30 days..." The laboratory's IQCP states, " External QC will be tested with each new lot or shipment of test materials and once monthly." Review of the laboratory QC records "microalbumin/creatinine Afinion AS100 QC log" revealed the laboratory failed to perform monthly QC as required in May 2019 and June 2019. QC was performed for test kit lot #10200628 on 4/5/2019. QC was not tested again on the kit lot #10200628 until 7/19/19. At approximately 1pm, the TC confirmed the laboratory failed to perform ACR QC monthly during May and June 2019.