Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1032132	(X3) Date Survey Completed 09/26/2018
Name of Provider or Supplier Novant Health Lakeside Family Physicians	**Street Address, City, State** 10816 Blackdog Lane, Suite 160, Charlotte, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of review of technical consultant (TC) quality assessment records, and technical consultant (TC) interview 09 /26/18, testing personnel (TP) #3 failed to follow manufacturer's instructions for calibrating the Free Style Precision H Glucometer. The laboratory performs glucose testing on the Free Style Precision H Glucometer. Review of manufacturer's instructions revealed ".....Calibration....IMPORTANT: Always calibrate the meter with each new box of test strips. Failure to calibrate properly will cause incorrect results." Review of TC quality assessment records dated 07/14/17 and 10/25/17 revealed TP #3 failed to calibrate the Free Style Precision H Glucometer as required by manufacturer. 1. 07/14/17, the glucometer was documented by TC as not calibrated to the current lot number of test strips in use. 2. 10/25/17, the glucometer was documented by TC as not calibrated to the current lot number of test strips in use. Review of TC quality assessment records revealed the TC had retrained and consulted TP #3 on both occasions. Interview with TC at approximately 1:00 p.m. confirmed TP#3 was not calibrating the glucometer as required, she stated she has retrained and consulted TP #3, but there are still some problems with performing and/or documenting all quality control procedures as required by the laboratory's policies and procedures.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1)

	Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manual, review of technical consultant (TC) quality assessment records, and technical consultant (TC) interview 09/26/18, testing personnel (TP) #3 failed to follow established laboratory critical result reporting procedures. Review of laboratory procedure, "Critical Laboratory Results Communication", revealed 1. Once initial results have been obtained and confirmed as critical, repeat the test to verify the result.....2. Report the verified critical value to the ordering physician or designee....3. Document in Epic in the Enter/Edit results activity by doing the following:.....in the flags field, click the selection button....select ....Low Panic or High Panic....document the critical value notification in the comment field..... the documentation should include first and last name of the person notified, date and time the critical value was reported, and the name of the personnel reporting the result, as well as documentation that the test was repeated/confirmed.....Document the notification of the test report on the NHmg Laboratory Critical Values Log along with the repeated/confirmed value. Review of TC quality assessment records revealed TP #3 failed to follow laboratory critical results reporting procedures on the following dates: 1. 09/11/17, Medical Record Number (MRN) 50057746, critical low HGB not documented correctly; "MD aware" comment instead of first and last name of the person notified, no documentation of test repeated or confirmed, and repeat value not entered on Critical Values Log. 2. 11/30/17, MRN 72087799, critical high white blood cell (WBC) not documented correctly; Flag not changed to high panic, repeat result comment not entered, and repeat result not documented on Critical Values Log. 3. 12/04/17, MRN 5018680, critical hemoglobin (HGB) not documented correctly; Flag not changed to low panic, repeat result comment not entered, and repeat result not documented on Critical Values Log. 4. Quality Assessment dated 08/01/18, noted by TC that critical values were not being documented on the Critical Values Log. 5. 08/20/18, MRN 51339863, critical HGB repeat value not documented on the Critical Values Log. Review of TC quality assessment records revealed the TC had retrained and consulted TP #3 on multiple occasions on the required documentation for critical results. Interview with TC at approximately 1:00 p.m. confirmed TP#3 was not following the laboratories critical result reporting procedures as required she stated she has retrained and consulted TP #3, but TP #3 is still having some errors in her documentation of critical results.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) 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. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manual, review of technical consultant (TC) quality assessment records, and technical consultant (TC) interview 09/26/18, testing personnel (TP) #3 failed to follow laboratory quality control policies, failed to document laboratory quality control activities and failed to perform and/or document required maintenance. 1. Review of laboratory policies and quality

assessment records revealed TP #3 failed to perform and/or document the validation of 6 sets of new lots of control material for the Coulter Act Diff 2 analyzer from approximately 03/17 until 06/18. Findings: Review of laboratory policy "Quality Control" revealed "General QC Information....3. Testing personnel will perform and record QC as indicated in each technical procedure." Review of laboratory policy "Coulter AcT Diff 2" revealed "Validation of New Lot of Control material"..."The following actions are take 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 of controls will be tested a minimum of one time prior to use for CLIA labs. 3. The new lot number will be tested as a patient sample....6. The manufacturer's package insert, all instrument printout from the validation study, and any other information regarding the study, will be secured together....and maintained for 2 years." Review of "Quality Assessment /Incident Management Form" dated 03/28/17, 05/23/17 and 06/06/18 revealed TP#3 failed to correctly perform and/or document the validation of the following 6 sets of control materials for the Coulter AcT Diff 2 analyzer. a. Lot Number (#) 066200/ 074000/ 085800 - no validation documentation b. Lot # 066100/ 073900/ 085700 - no validation documentation c. Lot # 066800/ 074500/ 086300 - no validation documentation d. Lot # 066600/ 074300/ 086100 - no validation documentation e. Lot # 061800/ 077000/ 081300 - documentation included in incorrect data set (validation study) f. Lot # 062100/ 077300/ 081600 - validation samples not run as patient samples. 2. Review of laboratory policies and quality assessment records revealed TP #3 failed to perform and/or document the weekly maintenance of printing Levy-Jennings (L-J) graphs and quality control (QC) logs (Control Summary) for the Coulter AcT Diff 2 analyzer. Findings: Review of laboratory policy "Coulter AcT Diff 2" revealed ....."Maintenance....Weekly.....Print and review Levy-Jennings Graphs and QC Logs." Review of "Quality Assessment/Incident Management Form" dated 05/23/17, 03/13/18, 06/06/18, and 08/01/18 revealed TP #3 failed to print and/or review L-J Graphs and/or QC Logs weekly as required for the Coulter Act Diff 2 analyzer. The following weeks and/or lot # sets were not printed and/or documented as reviewed. a. 03/31/17, Lot # 066600/074300/086100, L-J graphs were not printed or reviewed. b. QC logs (Control Summary) for Lot # 066100/ 073900/ 085700 were not printed or reviewed. c. QC logs (Control Summary) for 12/26/17 to 12/29/17 were not printed or reviewed for the Normal and High QC levels. d. 2/16/18, L-J graphs were not printed or reviewed. e. Lot # 062100/773000/081600, L-J graphs were not reviewed. f. Lot # 061800/077000/081300, L-J graphs were not printed or reviewed. g. 6/22/18, Lot #062300/070000/081500, L-J graphs were not reviewed. 3. Review of laboratory policies and quality assessment records revealed TP #3 failed to perform and/or document quality control for the Alere Afinion ACR analyzer. Findings: The laboratory performs urine albumin and creatinine testing on the Alere Afinion ACR analyzer. Review of laboratory policy "Urine Albumin/Creatinine Afinion AS 100" revealed ".....External.....External controls must be run each day of patient testing, with each new lot number or shipment of test cassettes, each new untrained operator,..." Review of "Quality Assessment/Incident Management Form" dated 7/14 /17 revealed TP #3 had failed to perform and/or document the quality control for the current lot number of cassettes in use for urine albumin and creatinine testing on the Alere Afinion ACR analyzer. 4. Review of TC quality assessment records revealed the TC had retrained and consulted TP #3 on multiple occasions in regards to the failures to perform and/or document quality control for the Coulter AcT Diff 2 and the Alere Afinion ACR analyzers and for failure to perform weekly maintenance procedures for the Coulter AcT Diff 2 analyzer. 5. Interview with TC at approximately 1:00 p.m. confirmed TP#3 failed to follow laboratory quality control policies, failed to document all quality control activities and failed to perform weekly

	maintenance procedures. She stated she has retrained and consulted TP #3, but there are still some problems with performing and/or documenting all quality control procedures and maintenance procedures as required by the laboratory's policies and procedures.
D6073	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(4) Each individual performing moderate complexity testing must follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manual, review of technical consultant (TC) quality assessment records, and technical consultant (TC) interview 09 /26/18, testing personnel (TP) #3 failed to follow corrective action procedures when laboratory temperatures were out of range. Review of laboratory procedure, "Lab General Maintenance" revealed "....Temperatures/Humidity.....Temperatures /humidity must be recorded each day of patient testing. Any temperatures out of range should have corrective action performed and should be documented on the temperature /general maintenance log or corrective action form." Review of TC quality assessment records revealed TP #3 failed to follow corrective action procedures when laboratory temperatures were not within acceptable range of 20-25 degrees Celsius. 1. 12/12/17; room temperature was recorded as 19.6 degrees Celsius, no corrective action documented. 2. 04/06/18; room temperature was recorded as 19.6 degrees Celsius, no corrective action documented. 3. 06/06/18; room temperature was recorded as 25.2 degrees Celsius, no corrective action documented. Review of TC quality assessment records revealed the TC had retrained and consulted TP #3 on multiple occasions in regards to the failures to perform and document corrective actions when the laboratory temperatures were not within acceptable range. Interview with TC at approximately 1: 00 p.m. confirmed TP#3 failed to follow laboratory corrective action procedures. She stated she has retrained and consulted TP #3, but there are still some problems with performing and documenting corrective actions.