Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0911305	11/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Novant Health Walkertown Family Medicine	2800 Darrow Road, Walkertown, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of 2019 and 2020 API (American Proficiency Institute) proficiency testing records and interview with the TC (technical consultant) 11/16/21, the laboratory failed to ensure the attestation statements for 9 of 22 test events were signed by the TP (testing personnel) and the LD (laboratory director). Findings: Review of 2019 and 2020 API proficiency testing records revealed: 1. 2019 a. attestation statements for the 1st and 3rd hematology events not signed by the LD and TP; b. attestation statement for the 3rd immunology event not signed by the LD and TP; c. attestation statement for the 2nd chemistry miscellaneous event not signed by the LD. 2. 2020 a. attestation statement for the 2nd hematology event not signed by the LD and TP; b. attestation statements for the 1st and 2nd immunology events not signed by the LD and TP; c. attestation for the 3rd immunology event not signed by the LD; d. attestation statement for the 2nd chemistry miscellaneous event not signed by the LD and TP. During interview at approximately 10:40 a.m., the TC verified that the attestation statements had not been signed by the TP and LD as required.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of the laboratory's policies and procedures, and review of 2019, 2020, and 2021 hematology maintenance logs 11/16 /21, the laboratory failed to perform and document monthly maintenance for 28 of 34 months as specified by the manufacturer for the Medonic M-series hematology analyzer. Findings: Review of the Medonic M-series User's Manual revealed "Section 8: Cleaning, Maintenance & Transport" specifies maintenance procedures to be performed daily, monthly, and every six months. On page 65, it states "8.2 Monthly Cleaning This section describes the cleaning procedure to be used to secure the correct function of the instrument on a monthly basis. ..." The section includes instructions for cleaning the analyzer with hypochlorite and instructions for performing the clot prevention procedure using enzymatic cleaner. The laboratory's "Medonic M-Series Hematology Analyzer" procedure states on page 11 "... MAINTENANCE ... Monthly Cleaning ... 7. Document on the Medonic M-Series Maintenance Log. ... Clot Prevention ... 8. Document on the Medonic M-Series Maintenance Log. ..." Review of 2019, 2020, and 2021 hematology maintenance logs revealed monthly maintenance was not performed and documented as required for the following months: 1. 2019 - no monthly maintenance documented for 10 of 12 months. Monthly maintenance was not documented in May, and logs for January, February, March, April, August, September, October, November, and December were not available for review. 2. 2020 - no monthly maintenance documented for 10 of 12 months (January, February, March, April, June, July, September, October, November, December). 3. 2021 - no monthly maintenance documented for 8 of 10 months (January, February, March, April, May, June, July, October).
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of the laboratory's policies and procedures, review of the laboratory's 2019 and 2021 calibration records, and interview with the TC (technical consultant) 11/16/21, the laboratory failed to calibrate the Medonic M-series hematology analyzer at least once every six months as required during 2020. The Medonic M-series User's Manual states on page 59 "Section 7: Calibration ... It is recommended to calibrate the instrument every six months. ..." The laboratory's Medonic M-Series Hematology Analyzer" procedure states on page 6 "... Calibration Calibration of the analyzer using Boule Calibrator I is required as follows: 1. Upon initial installation 2. At least every six (6) months ... " Review of the laboratory's calibration records revealed the Medonic M-series hematology analyzer was calibrated on the following dates: 2/14/19, 8/16/19, 2/16/21,

	and 8/11/21. There were no records available to indicate the analyzer was calibrated in 2020. During interview at approximately 12:15 p.m., the TC confirmed the laboratory failed to calibrate the analyzer during 2020.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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 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 the laboratory's policies and procedures, review of 2019, 2020 and 2021 Albumin Creatinine Ratio (ACR) quality control (QC) and patient records 11/16 /21, the laboratory failed to perform QC as required before reporting patient test results. Approximately 76 patients were tested from 12/17/19-1/6/21 when QC was not performed as specified in the laboratory's IQCP (Individualized Quality Control Plan). Findings: Review of laboratory procedure NMG-LB-158 "Abbott Afinion Urine Albumin/ Creatinine Ratio" revealed "QC-Internal, External... External controls must be tested: 1. On each day of patient testing... 7. OR according to your IQCP." Review of the laboratory's IQCP for the Urine Albumin/Creatinine Ratio performed on the Afinion AS 100 analyzer revealed "External controls will be tested with each new lot number or shipment of test materials and once weekly on Mondays due to large patient volume." Review of 2019, 2020, and 2021 ACR QC and patient records revealed 76 patients were tested when QC was not performed as specified in the laboratory's IQCP: a. QC performed on 12/17/19 and not again until 12/31/19 - 16 patients were tested during this time. b. QC performed on 5/20/20 and not again until 6 /4/20 - 20 patients were tested during this time. c. QC performed on 06/11/20 and not again until 6/22/20 - 11 patients were tested during this time. d. QC performed on 09 /10/20 and not again until 9/18/20 - 6 patients were tested during this time. e. QC performed on 11/24/20 and not again until 12/8/20 - 13 patients were tested during this time. f. QC performed on 12/24/20 and not again until 01/6/21 - 10 patients were tested during this time.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by:

	Based on review of 2019, 2020, and 2021 API (American Proficiency Institute) proficiency testing records and interview with the TC (technical consultant) 11/16/21, the LD (laboratory director) failed to ensure that 7 of 24 proficiency testing reports were reviewed to evaluate the laboratory's performance and identify any problems requiring corrective action. Review of 2019, 2020, and 2021 API proficiency testing graded results revealed: 1. 2019 a. 3rd hematology event results not signed by the LD. b. 2nd and 3rd immunology event results not signed by the LD. c. 1st and 2nd chemistry miscellaneous event results not signed by the LD. 2. 2020 a. 3rd immunology event results not signed by the LD. 3. 2021 a. 2nd hematology event results not signed by the LD. During interview at approximately 10:40 a.m., the TC verified that the results had not been signed by the LD to indicate review.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan, review of 2019, 2020, and 2021 laboratory records, and interview with TP (testing personnel) #1 and the TC (technical consultant) 11/16/21, the laboratory director failed to ensure that the quality assessment plan was followed to identify and correct problems and prevent their recurrence. The laboratory's "Quality Assessment Plan" states "... V. PROCESSES / PROGRAM COMPONENTS Quality Assessment Activities 1. Quality Assessment Activities, also known as monitors, will be completed by the testing personnel throughout each year in moderately and highly complex laboratories. 2. Each activity (monitor) will include instructions for completion and reporting. 3. All laboratory personnel must be familiar with and follow the written quality assessment plan and safety policies. ..." The plan includes monitors for each quarter (1st, 2nd, 3rd, 4th) and an "Annual General Laboratory Assessment". The monitors for each quarter include different items to monitor the preanalytic, analytic, and postanalytic portions of the testing process. Review of 2019, 2020, and 2021 laboratory records revealed: 1. There was no quality assessment activity documented by the laboratory from 8/23/19 - 5/12 /21. The laboratory performed the 2nd Quarter monitor for 2019 and there was no quality assessment activity documented again until the 1st Quarter monitor for 2021. During interview at approximately 12:35 p.m., TP #1 stated the laboratory was closed due to COVID for part of March, all of April, and part of May 2020. During interview at approximately 1:00 p.m., the TC confirmed that quality assessment monitors were not completed by testing personnel as required in the quality assessment plan. 2. The laboratory failed to identify that proficiency testing attestation statements were not signed as required by the laboratory director and testing personnel and failed to ensure graded results were reviewed by the laboratory director. See the deficiencies cited at D2009 and D6018. 3. The laboratory failed to identify that maintenance and calibration were not performed as required for the Medonic M-series hematology analyzer. See the deficiencies cited at D5429 and D5437. 4. The laboratory failed to identify that the IQCP (Individualized Quality Control Plan) for Albumin Creatinine Ratio (ACR) testing was not followed. Approximately 76 patients were tested from 12

	/17/19-1/6/21 when QC was not performed as specified in the laboratory's IQCP. See the deficiency cited at D5445.