Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1018979	07/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Nowcare Medical Associates	6632 Indian River Road - Suite 103, Virginia Beach, VA	

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
D0000	An announced CLIA recertification survey was conducted at Nowcare Medical Associates on July 17, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and includes two Conditions under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems, D6063 -42 CFR. 493.1421 Condition Testing Personnel.
D2127	HEMATOLOGY CFR(s): 493.851(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on a review of hematology proficiency testing (PT) documentation, and an interview, the laboratory failed to ensure Complete Blood Count (CBC) PT testing results were returned to American Proficiency Institute (API) for one (1) of five (5) events reviewed from October 26, 2022 to the date of the survey on July 17, 2024. Findings include: 1. Review of the laboratory's API hematology PT documentation (2022 Event 3, 2023 Events 1-3, 2024 Event 1), a total of 5 events, revealed that the laboratory failed to submit and received failure to participate scores for the following CBC module: API 2022 Hematology Event 3 - 0% scores for Cell Identification, Red Blood Cell, White Blood Cell, Platelet, Hemoglobin, and Hematocrit. 2. An interview with the quality director on 7/17/24 at 1:30 PM confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250

	Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of manufacturer's operations manual, hematology analyzer maintenance records, procedures, instrument calibration records, lack of documentation, and interviews, the laboratory failed to: 1. document performance of required twice annual instrument preventative maintenance during the twenty (20) months reviewed (review timeframe: October 26, 2022 - July 17, 2024) **REPEAT DEFICIENCY, See D5429; 2. perform instrument calibration procedures for Complete Blood Count according to their procedure during the 20 months reviewed (timeframe: 10/26/22 to 7/17/24). See D5437.
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 a review of manufacturer's operations manual, hematology analyzer maintenance records, lack of documentation, and an interview, the laboratory failed to document performance of required twice annual instrument preventative maintenance during the twenty (20) months reviewed (review timeframe: November 2022 - July 17, 2024). **REPEAT DEFICIENCY Findings include: 1. Review of the Abbott Emerald Operations Manual revealed manufacturer's instructions to "perform Lubricating Syringe Pistons maintenance procedure twice annually" (under heading: Preventative Maintenance). 2. Review of the laboratory's available Emerald hematology maintenance logs from November 2022 to the date of the inspection on 7 /17/24 revealed no documentation of the required semi-annual maintenance outlined above. The inspector requested to review documentation of the piston syringe maintenance in calendar year 2023 and year to date 2024. No records were available. 3. An exit interview with the quality director on 7/17/24 at 1:30 PM confirmed the above findings.
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 procedures, instrument calibration records, lack of documentation, and an interview, the laboratory failed to perform instrument calibration procedures for Complete Blood Count (CBC) according to their procedure during the twenty (20) months reviewed (timeframe: 10/26/22 to 7/17/24). Findings include: 1. Review of the laboratory's procedure manual revealed a Hematology Calibration policy that outlined to calibrate CBC testing at a frequency of every 6 months. The policy stated: "Calibration is a procedure that confirms the accuracy and precision of the Emerald equipment. Calibration of the Emerald machine is performed every six months or more frequently as needed." 2. Review of the laboratory's Abbott Emerald instrument calibration documentation from 10/26/22 to the date of the inspection on 7/17/24, a total of 20 months, revealed the following 2 calibration records: 4/4/23, 4/30/24. The inspector requested to review hematology calibration recorded in October 2023. No additional calibration documentation was available for review. 3. An exit interview with quality director on 7/17/24 at 1:30 PM confirmed the above findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form, testing personnel records, lack of documentation, and interview, the laboratory failed to retain documentation of education qualifications for one of three testing personnel responsible for reporting moderate complexity patient test results during the review timeframe of October 26, 2022 to the date of the inspection on July 17, 2024. See D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by:

	Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), personnel records, lack of documentation, and an interview, the laboratory failed to retain documentation of education qualifications for one (1) of three (3) testing personnel (TP) responsible for hematology and chemistry testing during the review timeframe of October 26, 2022 to the date of the inspection on July 17, 2024. Findings include: 1. Review of the CMS 209 form revealed that the laboratory director identified 3 personnel as responsible and qualified to perform moderate complexity hematology Completed Blood Count and chemistry iSTAT Chem8 patient testing. 2. Review of the available laboratory personnel records for evaluation of education documentation revealed no record of education for TP A. (See Personnel Code Sheet.) The inspector requested to review an official transcript or diploma documentation of education for TP A. No documentation was available for review. 3. An exit interview with the quality director on 7/17/24 at 1:30 PM confirmed the above findings