Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2000903	04/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Nowcare - First Colonial	1168 First Colonial Road-Suite 100, 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-First Colonial on April 10, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows and include the following Condition under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel form (CMS 209), available proficiency testing (PT) records, and interviews, the laboratory failed to rotate PT among testing personnel (TP) performing Complete Blood Count (CBC) patient testing for four (4) of the 4 PT events reviewed. Findings include: 1. Review of the CMS Form 209 revealed the laboratory director identified three (3) testing personnel qualified/responsible for performing patient CBC testing during the review timeframe of 7/19/22 to 4/10/24. 2. Review of the laboratory's American Proficiency Institute (API) PT documentation, a total of 4 events (2023 Events 1-3, 2024 Event 1), revealed that TP #1 signed into the analyzer as operator and performed the following CBC PT: 2023 API Hematology Event 1; 2023 API Hematology Event 2; 2023 API Hematology Event 3; 2024 API Hematology Event 1. TP #1 performed 4 of 4 PT events outlined above. (See Personnel Code Sheet.) 3. An exit interview with the quality manager and assistant on 4/10/24 at 12 noon confirmed the above findings.

D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: A. Based on a review of proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to retain attestation statements signed by the laboratory director (LD) and testing personnel (TP) for five (5) of 5 PT events as reviewed on the date of the inspection, April 10, 2024. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) hematology PT documentation, a total of 5 events (2022 Event 3, 2023 Events 1-3, 2024 Event 1), revealed that the laboratory failed to retain attestations signed by LD and TP for the following: 2022 API Event 3; 2023 API Event 1; 2023 API Event 2; 2023 API Event 3; 2024 API Event 1. The inspector requested to review the attestation documentation for the 5 events outlined above. The records were not available for review. 2. An exit interview with the quality manager and assistant on 4/10/24 at 12 noon confirmed the above findings. B. Based on a review of proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to retain the hematology analyzer printed results for one (1) of five (5) PT events reviewed on the date of the inspection, April 10, 2024. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) hematology PT documentation, a total of 5 events (2022 Event 3, 2023 Events 1-3, 2024 Event 1), revealed that the laboratory failed to retain the Abbott Emerald analyzer printed results for the PT challenges assayed for 2022 API Event 3. 2. The inspector requested to review the analyzer printed records for the API 2022 event outlined above. The records were not available for review. 3. An exit interview with the quality manager and assistant on 4/10/24 at 12 noon 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 review of Centers for Medicare and Medicaid Services Statement of Deficiencies Plan of Correction protocol/procedure, calibration records, lack of

	documentation, and interviews, the laboratory failed to: 1. follow an approved corrective action procedure established to post and denote every six month CBC calibration schedule during the twenty-one (21) months reviewed (timeframe July 2022 to the date of the inspection on April 10, 2024) - CROSS REFERENCE D5401; 2. document instrument calibration procedures for CBC patient testing every six months during the 21 months reviewed -CROSS REFERENCE D5437 (*REPEAT DEFICIENCY).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services Statement of Deficiencies Plan of Correction (CMS-2567 POC), calibration records, lack of documentation, and interviews, the laboratory failed to follow a laboratory director (LD) approved corrective action procedure established to denote/post/alert every six month Complete Blood Count (CBC) calibration schedule for the testing personnel staff during twenty-one (21) months reviewed (timeframe July 2022 to the date of the inspection on April 10, 2024). Findings include: 1. Review of the laboratory's procedures revealed the following protocol: CMS-2567 POC (LD signed/approved 8/8 /22) which outlined a corrective action plan for retention/documentation of every six month CBC analyzer calibrations that stated "We have added the every six month calibration dates to the laboratory calendar placed in the lab in plain view so that all lab personnel are aware of calibration due dates. Going forward the technical consultant will be responsible to ensure that all calibrations are completed with the LD providing backup to confirm completion and documentation". 2. Review of the laboratory's Abbott Emerald calibration documentation from July 2022 to 04/10/24 revealed documentation of one calibration (dated 4/4/23). No additional records were available for review. The inspector noted no calibration calendar/schedule posted in the laboratory. 3. An exit interview with the quality manager and assistant on 4/10/24 at 12 noon 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, calibration records, lack of documentation, and an interview, the laboratory failed to perform hematology calibration procedures every six months for Complete Blood Count (CBC) according to their procedure during the twenty-one months reviewed (timeframe: July 2022 to the date of the inspection on April 10, 2024). *REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's procedures revealed a policy that outlined to calibrate CBC testing every six 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 calibration documentation from July 2022 to 04/10/24 revealed documentation of one calibration (dated 4/4/23).The inspector requested to review additional calibration records for the Abbott Emerald analyzer. No additional records were available for review. 3. An exit interview with the quality manager and assistant on 4/10/24 at 12 noon confirmed the above findings.