Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2000903	07/19/2022
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 July 19, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows and include two Conditions under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems, D6063 -42 CFR. 493.1421 Condition Testing Personnel.
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 a review of the Centers for Medicare and Medicaid Services CLIA Certification form (CMS 116), review of procedures, maintenance logs, lack of documentation, and an interview, the laboratory failed to document performance of required monthly calibration checks for the Sofia 2 analyzer utilized for COVID-19 testing for nineteen (19) of 19 months reviewed (January 2021 to the date of the inspection on July 19, 2022). Findings include: 1. During a pre-survey review on 07/18 /21, the inspector noted that the laboratory director (LD) indicated on the submitted CMS 116 form that patient COVID-19 testing was performed by utilizing Quidel Sofia SARS Antigen test cassettes. 2. During a laboratory tour on 07/19/22 at approximately 2:00 PM, the inspector noted that one (1) Sofia analyzer (Serial Number 29043224) was in use for COVID-19 testing in the urgent care facility laboratory. 3. During a review of the laboratory procedures, the inspector noted a

	Sofia 2 Flu + SARS Antigen, Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA) package insert in use as the procedure dated January 2021. The review revealed manufacturer's instructions: "The Calibration Check is a required function that checks the Sofia 2 optics and calculations systems using a specific calibration cassette. The Calibration Check is to be performed every 30 days." 4. Review of the available maintenance logs revealed no documentation of the calibration function checks as outlined above. The inspector requested to review calibration checks performed from January 2021 to July 2022. No records were available for review. 5. An exit interview with the primary testing personnel and clinical coordinator on 7/19/22 at approximately 4:30 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 review of the laboratory's procedures, Centers for Medicare and Medicaid Services Statement of Deficiencies Plan of Correction (CMS-2567 POC), testing personnel records, manufacturer's operations manual, hematology analyzer maintenance records, instrument calibration records, lack of documentation, and an interview, the laboratory failed to: 1. follow an established laboratory director approved POC procedure to ensure documentation/retention of annual competency assessments for four (4) of 4 testing personnel in calendar years 2020, 2021, and year to date 2022 resulting in a repeated deficiency citation. See D5401; 2. document performance of required twice annual instrument maintenance for twenty-eight (28) of 28 months reviewed (review timeframe: March 2020 - July 19, 2022) See D5429; 3. document instrument calibration procedures for Complete Blood Count patient testing according to their written procedure during the 28 months reviewed resulting in two lapsed periods greater than the required every six months schedule. See D5437.
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 procedures, 2020 Centers for Medicare and Medicaid Services Statement of Deficiencies Plan of Correction (CMS-2567 POC), testing personnel records, lack of documentation, and an interview, the laboratory failed to follow an established laboratory director (LD) approved corrective action procedure to ensure documentation/retention of annual competency assessments for four (4) of 4 Testing

	Personnel (TP A, B, C, and D) during twenty-eight (28) of the 28 months reviewed. (See Personnel Code Sheet.) Findings include: 1. Review of the laboratory's procedures revealed the following two protocols: Miscellaneous Laboratory Protocol that stated: "As part of the quality assessment program the following protocols have been developed. Records of qualifications, training, and continuing education will be maintained on all laboratory personnel. The laboratory personnel performance and knowledge will periodically be reviewed by the lab director or technical consultant through direct observation as part of initial and ongoing training and competency. The laboratory staff will be trained on new procedures and test kits and proof of training will be kept on file. A review and re-evaluation of competency will be performed six months after hire and annually thereafter." CMS-2567 POC (LD signed/approved 3/26 /20) which outlined a corrective action plan for retention/documentation of competency assessments that stated "all pertinent testing personnel competency assessment files will be updated annually and retained onsite going forward". 2. Review of personnel records for calendar years 2020, 2021, and year to date 2022 revealed no Abbott Emerald hematology, Abbott iSTAT chemistry, or Quidel Sofia COVID-19 competency/training assessments for TP A, TP B, TP C, TP D (Cross reference D6046). 3. An exit interview with the clinical coordinator on 7/19/22 at approximately 4:30 PM confirmed the above findings
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-eight (28) months reviewed (review timeframe: March 2020 - July 19, 2022). 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 March 2020 to the date of the inspection on 07/19/22, 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 2020, 2021, and year to date 2022. No records were available. 3. An exit interview with the primary testing personnel and clinical coordinator on 7/19/22 at approximately 4:30 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) patient testing according to their procedure during the twenty-eight (28) months reviewed resulting in two (2) lapsed periods greater than the required every six (6) month of schedule (review timeframe: March 2020 to July, 19, 2022). 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 March 2020 to the date of the inspection on 07/19/22, a total of 28 months, revealed the following 2 lapses in CBC calibration: The inspector noted in calendar year 2020 a calibration dated 07/12/20 by the technical consultant (TC) with the next calibration performed on 03/21/21 eight (8) months later. The inspector noted no calibration documented for calendar year 2022 year to date. The inspector noted as of 07/19/22, the most recent calibration was dated 12/23/21 by the TC. 3. The inspector requested to review additional calibration records for the Abbott Emerald analyzer during the 2 calibration lapses outlined above: 8 month timeframe (07/12/20 to 03/21/21); 7 month timeframe (12/23/21 to 07/19/22). No additional calibration documentation was available for review. 4. An exit interview with the primary testing personnel and clinical coordinator on 7/19/22 at approximately 4:30 PM confirmed the above findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, policies/procedures, and an interview, the technical consultant (TC) failed to document annual competency assessments for four (4) of 4 testing personnel (TP) during the twenty-eight (28) months reviewed (review timeframe: March 2020 - July 19, 2022). **REPEAT DEFICIENCY** Findings include: 1. Review of the CMS 209 personnel form revealed that the laboratory director (LD) identified a TC and 4 TP as responsible for performing non-waived hematology Complete Blood Count (CBC) and iSTAT Chem8 testing. The LD also identified SARS-CoV-2 (COVID-19) patient testing under Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA) during the 28 months reviewed. 2. Review of personnel records revealed no Abbott Emerald hematology, Abbott iSTAT chemistry, or Quidel Sofia COVID-19 competency/training assessments for TP A, B, C, or D in calendar years 2020, 2021, and year to date 2022. (*See Personnel Code Sheet.) The inspector requested to

	review the competency documentation outlined above. The clinical coordinator stated on 7/19/22 at approximately 3:30 PM: "Our technical consultant is no longer working with the company. The competency records are in the white testing personnel binder if we have them." The inspector reviewed all available competency assessment records in the provided binder. Competency assessments beyond calendar 2019 were not available for review. 3. Review of the laboratory's procedure manual revealed the following protocols: Miscellaneous Laboratory Protocol: that stated: "As part of the quality assessment program the following protocols have been developed. Records of qualifications, training, and continuing education will be maintained on all laboratory personnel. The laboratory personnel performance and knowledge will periodically be reviewed by the lab director or technical consultant through direct observation as part of initial and ongoing training and competency. The laboratory staff will be trained on new procedures and test kits and proof of training will be kept on file. A review and re-evaluation of competency will be performed six months after hire and annually thereafter." Quidel Sofia COVID-19 FDA's issued EUA stated: "Conditions of Authorization for Laboratory and Patient Care Setting: All operators using the product must be trained in performing and interpreting the results of the product, use appropriate personal protective equipment when handling this kit, and use the product in accordance with the authorized labeling." 4. An exit interview with the primary testing personnel and clinical coordinator on 7/19/22 at approximately 4:30 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 three of four testing personnel responsible for reporting moderate complexity hematology patient test results during the review timeframe of March 2020 to the date of the inspection on July 19, 2022. 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 director (LD) failed to retain documentation of education qualifications for three (3) of four (4) hematology and chemistry testing personnel (TP) from March 2020 to the date of the inspection on July 19, 2022. Findings include: 1. Review of the CMS 209 form revealed the LD identified 4 personnel (TP A, B, C, D) as qualified to perform moderate complexity patient hematology Completed Blood Count (CBC) and chemistry iSTAT Chem8 testing. (See Personnel Code Sheet.) 2. Review of the available laboratory personnel records for evaluation of education documentation revealed no records of education for TP B, C, and D. 3. The inspector requested to review the documentation of education for the 3 TP outlined above. The records were not available for review. 4. An exit interview with the primary testing personnel and clinical coordinator on 7/19/22 at approximately 4:30 PM confirmed the above findings.