Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 49D1018979	**(X3) Date Survey Completed** 10/25/2022
Name of Provider or Supplier Nowcare Medical Associates	**Street Address, City, State** 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 October 25, 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 is in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and includes one Condition under 42 CFR part 493 CLIA Regulation: D6000 -42 CFR. 493.1403 Laboratory Director
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, lack of documentation, and an interview, the laboratory failed to document a review/evaluation of three (3) of 3 hematology PT modules in calendar year 2021. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) hematology 2021 PT records (Events A-C) revealed no API retained results or documentation of review/evaluation for: 2021 API Hematology Module Complete Blood Count and Auto Differential Events 1, 2, 3. 2. The inspector requested to review the API results and evaluation documentation for the 3 hematology module events outlined above. The clinical coordinator stated on 10/25/22 at approximately 11:30 AM, "I can print the results from API web site." No documentation of review/evaluation was available for review. 3. An exit interview with the clinical coordinator on 10/25/22 at approximately 12:00 PM confirmed the above findings.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of procedures, and interviews, the laboratory failed to ensure that five (5) of 5 Abbott iSTAT boxed control reagents stored in the laboratory for use was within the manufacturer's expiration dates as observed on October 25, 2022. Findings include: 1. During a laboratory tour at approximately 10: 00 AM, the inspector noted the following 5 boxes of Abbott iSTAT control reagents (labeled as received and opened 5/19/22) stored in the lab refrigerator: TriControl Level 1 Lot #301141 one (1) box, expiration date of 9/30/2022; TriControl Level 2 Lot #311141 two (2) boxes, expiration date of 9/30/2022; TriControl Level 3 Lot #321141 2 boxes, expiration date of 9/30/2022; a total of 5 boxes were expired, observed on 10/25/22. The laboratory inspector inquired regarding the storage and use of the expired control reagents stored above. The clinical coordinator indicated that the laboratory had used the controls for accuracy determination of iSTAT chemistry Chem8 testing but was unable to confirm when the observed controls were last utilized. The clinical coordinator stated on 10/25/22 at approximately 10:15 AM, "I am going to dispose of these right now." 2. Review of the laboratory's procedure manual revealed an iSTAT Chem8 Procedure (review date 10/8/22) that stated, "Reagent: follow reagent package instructions for storage and stability". 3. An exit interview with the clinical coordinator on 10/25/22 at approximately 12:00 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-three (23) months reviewed (review timeframe: December 2020 - October 25, 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 December 2020 to the date of the inspection on 10/25/22, 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 2021 and year to date 2022. No records were available. 3. An exit interview with the clinical coordinator on 10/25/22 at approximately 12:00 PM confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR

	CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the laboratory's policies, quality assessment (QA), proficiency testing (PT), analyzer maintenance, Centers for Medicare and Medicaid Services Laboratory Personnel Report form, laboratory personnel files, lack of documentation, and interviews, the laboratory director failed to: 1. ensure that the policy for monthly QA review was maintained during the twenty-three (23) month review timeframe (December 2020 through the date of the survey on October 25, 2022). Cross Reference D6021. 2. identify the QA failures for lack of retention of PT review /evaluation records in calendar year 2021, documentation of twice annual hematology instrument preventative maintenance, initial training/competency for four (4) of 4 new testing personnel (TP), semiannual competency assessment documentation for three (3) of 4 new TP, annual hematology competency evaluation documentation for (5) of 5 TP in the 23 months reviewed (December 2020 to date of inspection 10/25/22). Cross Reference D6022.
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 a review of the laboratory's policy and procedure manual, quality assessment (QA) records, lack of documentation, and interviews, the laboratory director (LD) failed to ensure that the QA policies were maintained during the twenty-three (23) month review timeframe (December 2020 through the date of the survey on October 25, 2022). Findings include: 1. Review of the laboratory's policy and procedure manual revealed a QA policy that outlined a monthly QA meeting with the lab director to evaluate testing personnel, procedure manual updates, quality control, maintenance, proficiency testing documentation, communication, and remedial actions. 2. Review of the laboratory's available QA documentation from December 2020 through the date of the survey on 10/25/22 revealed no monthly QA documentation. The inspector requested to review the QA documentation for the 23 months of review. No records were available for review. The clinical coordinator stated on 10/25/22 at approximately 11:00 AM, "We have all of the QA checklists up through 2020. Our technical consultant laboratory technologist retired in 2021 and was very good to keep those QA records up to date. We have restarted our monthly QA meetings as of this month for all of our office laboratories." 3. An exit interview with the clinical coordinator on 10/25/22 at approximately 12:00 PM confirmed the above findings.

D6022	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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, manufacturer's operations manual, hematology analyzer maintenance records, Centers for Medicare and Medicaid Services Laboratory Personnel Report form, laboratory personnel files, procedures, lack of documentation, and interviews, the laboratory director failed to identify the following quality assessment (QA) failures as they occurred: 1. lack of retention of PT review/evaluation records for three (3) of 3 hematology PT modules in calendar year 2021. Cross Reference: D5211. 2. lack of documentation for required twice annual hematology instrument preventative maintenance during the twenty-three (23) months reviewed (review timeframe: December 2020 - October 25, 2022). Cross Reference: D5429. 3. lack of retention of initial training/competency for four (4) of 4 new testing personnel (TP) from March 9, 2021 to the date of the inspection on 10/25/22. Cross Reference: D6029. 4. lack of retention of semiannual competency assessment documentation for three (3) of 4 new TP from 03/09/21 to the date of the inspection 10/25/22. Cross Reference: D6053. 5. lack of retention of annual hematology competency evaluation documentation for five (5) of 5 TP in calendar year 2021. Cross Reference: D6054.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. 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 laboratory director (LD) failed to document initial training/competency for four (4) of 4 new testing personnel (TP) from March 9, 2021 to the date of the inspection on October 25, 2022. Findings include: 1. Review of the CMS 209 personnel form revealed that the LD identified nine (9) TP as responsible for performing non-waived hematology Abbott Emerald Complete Blood Count (CBC) and SARS-CoV-2 (COVID-19) patient testing under Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA) during the review timeframe (December 2020 to 10/25/22). During the entrance interview on 10/25/22

	at approximately 9:00 AM, the clinical coordinator identified 4 of the 9 listed TP as new testing personnel. 2. Review of the personnel records revealed that the following TP files lacked hematology and Quidel Sofia COVID-19 initial training/competency assessments: TP #1 start date of 03/09/21; TP #2 start date of 11/29/21; TP #3 start date of 08/30/21; TP #4 start date of 09/12/22. (*See Personnel Code Sheet.) 3. The inspector requested to review the initial training/competency documentation for the 4 TP outlined above. No documentation was available. The clinical coordinator stated on 10/25/22 at approximately 11:00 AM: "Our former technical consultant used to complete the competencies but has since retired. We cannot locate the competency assessments for last year and the lab director is working to get them completed." 4. Review of the laboratory's procedure manual revealed: Policy (titled: Miscellaneous Laboratory Protocol) statement - "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." Procedure: Quidel Sofia COVID-19 manufacturer's package insert and FDA's issued EUA - "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." 5. An exit interview with the clinical coordinator on 10/25/22 at approximately 12:00 PM confirmed the above findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. 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 interview, the technical consultant (TC) failed to document semiannual competency assessments for three (3) of 4 new testing personnel (TP) from March 9, 2021 to the date of the inspection on October 25, 2022. Findings include: 1. Review of the CMS 209 personnel form revealed that the laboratory director (LD) also serves in the role of TC. The LD identified nine (9) TP as responsible for performing non-waived hematology Abbott Emerald Complete Blood Count (CBC) during the review timeframe (December 2020 to 10/25/22). 2. Review of the personnel records revealed that the following 3 TP files lacked semiannual hematology competency assessments as of the date of the inspection on 10/25/22: TP #1 start date of 03/09/21; TP #2 start date of 11/29/21; TP #3 start date of 08/30/21. (*See Personnel Code Sheet) 3. The inspector requested to review semiannual competency documentation for the 3 TP outlined above. No documentation was available. 4. Review of the laboratory's procedure manual revealed the following protocol: 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." 5. An exit interview with the clinical coordinator on 10/25/22 at approximately 12:00 PM confirmed the above findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. 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 interviews, the technical consultant (TC) failed to document annual competency assessments for (5) of 5 testing personnel (TP) in calendar year 2021. Findings include: 1. Review of the CMS 209 personnel form revealed that the laboratory director (LD) also serves in the role of TC. The LD identified nine (9) TP as responsible for performing non-waived patient hematology Abbott Emerald Complete Blood Count (CBC). 2. Review of the personnel records revealed that the files of TP #5 - #9 lacked hematology competency assessments for calendar year 2021. (*See Personnel Code Sheet) 3. The inspector requested to review the 2021 annual competency documentation for the 5 TP outlined above. No documentation was available. The clinical coordinator stated on 10/25/22 at approximately 11:00 AM: "Our former technical consultant used to complete the competencies but has since retired. We cannot locate the competency assessments for last year and the director is working to get them completed." 4. Review of the laboratory's procedure manual revealed the following policies: 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." 5. An exit interview with the clinical coordinator on 10/25/22 at approximately 12:00 PM confirmed the above findings.