Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1018979	06/14/2018
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 June 14, 2018 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:
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: Based on a review of the laboratory's hematology proficiency testing (PT) documentation, and interviews, the laboratory failed to retain attestation statements signed by the laboratory director (LD) for six (6) of six (6) events reviewed. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) hematology PT documentation, a total of six (6) events, revealed no LD signed attestation statements for: 2016 Event 3, 2017 Event 1, 2017 Event 2, 2017 Event 3, 2018 Event 1, 2018 Event 2. The inspector noted that a stamp pad signature was utilized for the PT reports and inquired if the LD was responsible for stamping to document his attestation that proficiency testing samples were tested in the same

	manner as patient specimens. The primary testing personnel stated: "No, the lab testing personnel can use the stamp in the lab and the lab director is to follow behind to initial and date the stamping. No documentation of the LD's written signature or initials with a date was available for review. 2. In an interview with the LD and technical consultant on 6/14/18 at approximately 4:30 PM , it was confirmed that the laboratory failed to retain copies of API attestation statements signed by the LD for six (6) of six (6) events reviewed.
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 the laboratory's hematology quality control (QC) Levey Jennings records from June 2016 through May 2018, and an interview, the laboratory failed to document lab director and technical consultant assessment and monitoring of the instrument's Complete Blood Count (CBC) testing according to their written quality assurance policy for sixteen (16) of twenty-four (24) months reviewed. See D5791 (**REPEAT DEFICIENCY)
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of policies and procedures, instrument validation records, manufacturer's Users Guide, and an interview, the laboratory director (LD) failed to document approval of a hematology Complete Blood Count (CBC) procedure in September 2017 when the laboratory installed a new Abbott Emerald analyzer. Findings include: 1. During a tour of the laboratory at approximately 2:00 PM on 6/14/18, the inspector noted an Abbott Emerald hematology analyzer in use for CBC patient testing. 2. Review of the laboratory's Protocols and Package Inserts Manual revealed a hematology procedure for the Cell Dyn 1800. Review of the Quality Assurance Manual revealed a calibration protocol for the Cell Dyn 1800. 3. Review of the Abbott Emerald instrument installation and validation documentation revealed that the laboratory replaced a Cell Dyn 1800 with the Emerald (Serial Number 030617-007156) on 9/6/17. The inspector requested to review the CBC testing and calibration procedures for the Emerald analyzer. The primary testing personnel stated "we have not updated the procedure manual but we do have a User's Guide in the lab cabinet". The inspector reviewed the User's Guide and noted that the procedures included in the guide had not been signed as approved by the LD. 4. In an

	interview with the TC at approximately 4:30 PM on 6/14/18, it was confirmed that the LD failed to document approval of an Abbott Emerald hematology CBC procedure after the analyzer's installation for patient testing in September 2017.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of the policies and procedures, Quality Control (QC) monthly reports, and an interview, the laboratory failed to document, according to their written policy, review of monthly hematology Complete Blood Count (CBC) QC statistics for sixteen (16) of twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's policies and procedures revealed a quality assurance (QA) plan that outlined that the lab director (LD) and technical consultant (TC) are to review the hematology analyzer's Levey Jennings reports on a monthly basis in order to assess and correct problems. 2. In review of the laboratory's monthly QC from June 2016 through May 2018, the inspector noted that a stamp pad LD signature was utilized on sixteen (16) monthly QC cover pages to indicate review of the reports. The inspector inquired if the LD was responsible for stamping to document his review of the QC. The primary testing personnel stated: "No, we stamp the cover pages in the lab and the lab director will initial and date beside the stamped signature when he visits the lab". No documentation of the LD's written signature or initials with a date was available for review on the sixteen (16) monthly QC reports dated January 2017 to the date of survey on 6/14/18. The TC signature was also not documented on the monthly QC reports. 3. In an interview with the LD and TC at approximately 4:30 PM, it was confirmed that the laboratory failed to follow a written QA policy to document LD and TC review of the hematology analyzer's CBC Levey Jennings QC statistics for sixteen (16) of twenty-four (24) months reviewed. **REPEAT DEFICIENCY