Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2169260	(X3) Date Survey Completed 10/14/2022
Name of Provider or Supplier Modern Vascular Fairfax	**Street Address, City, State** 2812 Old Lee Highway Bldg Suite 100-B, Fairfax, 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 unannounced off-site proficiency testing desk review of Modern Vascular of Fairfax was conducted on October 14, 2022 by a Medical Facilities Inspector of the Virginia Department of Health's Office of Licensure and Certification. The laboratory was inspected under 42 CFR Part 493 CLIA regulations. The laboratory was not in compliance with the following Conditions under 42 CFR part 493 CLIA Regulations: D2016 - 42 C.F.R. 493.803 (a)(b)(c) Condition- Successful Participation.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on an off-site desk review of the laboratory's American Proficiency Institute

	(API) proficiency testing (PT) records (API 2022 First Event, Second Event and Third Event) and interviews, the laboratory failed to participate in the two (2) of three (3) API Events in 2022 for Calcium-Ionized, Chloride, Creatinine, Glucose, Potassium, Sodium, Total Carbon Dioxide (TCO2), Urea Nitrogen, Hematocrit and Hemoglobin resulting in unsuccessful PT performance. Cross reference D2089 and 2123.
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on the review of the laboratory's American Proficiency Institute's proficiency testing (PT) records, and an interview, the laboratory failed to participate in two (2) of three (3) 2022 PT events for the analytes Calcium-Ionized, Chloride, Creatinine, Glucose, Potassium, Sodium, Total Carbon Dioxide (TCO2), Urea Nitrogen. Findings include: 1. Review of the laboratory's API PT records for 2022 Events 1, 2 and 3 revealed the following: 2022 API Chemistry Core Event 1 (Analytes--Calcium-Ionized, Chloride, Creatinine, Glucose, Potassium, Sodium, Total Carbon Dioxide (TCO2), Urea Nitrogen) = 0%, Failure to Participate. 2022 API Chemistry Core Event 2 (Analytes--Calcium-Ionized, Chloride, Creatinine, Glucose, Potassium, Sodium, Total Carbon Dioxide (TCO2), Urea Nitrogen) = 100%. 2022 API Chemistry Core Event 3 (Analytes--Calcium-Ionized, Chloride, Creatinine, Glucose, Potassium, Sodium, Total Carbon Dioxide (TCO2), Urea Nitrogen) = 0%, Failure to Participate. 2. An interview with the Chief Compliance Officer on October 14, 2022 at at approximately 12:15 PM confirmed the findings.
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on the review of the laboratory's American Proficiency Institute's proficiency testing (PT) records, and an interview, the laboratory failed to participate in two (2) of

	three (3) 2022 PT events for the analytes Hemoglobin and Hematocrit. Findings include: 1. Review of the laboratory's API PT records for 2022 Events 1, 2 and 3 revealed the following: 2022 API Chemistry Core Event 1 (Analytes-Hemoglobin and Hematocrit) = 0%, Failure to Participate. 2022 API Chemistry Core Event 2 (Analytes-Hemoglobin and Hematocrit) = 100%. 2022 API Hematology Event 3 (Analytes-Hemoglobin and Hematocrit) =0%, Failure to Participate. 2. An interview with the Chief Compliance Officer on October 14, 2022 at at approximately 12:15 PM confirmed the findings.