Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D2240331	04/05/2023
Name of Provider or Supplier	**Street Address, City, State**	
Modern Vascular Of St Louis Llc	641 N New Ballas Rd, Creve Coeur, MO	

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
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 review of chemistry - core proficiency testing (PT) results reported to the CLIA database by the PT provider for 2022/2023 and email from laboratory manager on March 30, 2023, the laboratory failed to successfully participate in PT. Refer to D2096, the laboratory failed to achieve satisfactory performance for the analytes ionized Calcium, Chloride, Creatinine, Glucose, Potassium, Sodium, Total Carbon Dioxide, and Urea Nitrogen (BUN) in two consecutive testing events; D2097 the laboratory failed to attain an overall testing event score of satisfactory performance for two out of three consecutive testing events; D2130 the laboratory failed to achieve satisfactory performance for the hemoglobin and hematocrit in two consecutive PT

	events; and D2131 the laboratory failed to achieve an overall testing event score of satisfactory performance for the specialty of hematology in two out of three consecutive PT events.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of chemistry - core proficiency testing (PT) results reported to the CLIA database by the PT provider for 2022/2023 and email from the laboratory manager, the laboratory failed to achieve satisfactory performance for the analytes ionized Calcium, Chloride, Creatinine, Glucose, Potassium, Sodium, Total Carbon Dioxide, and Urea Nitrogen (BUN) in two consecutive testing events. Findings: 1. Review of the chemistry- core PT results for the third event of 2022 showed the laboratory obtained an unsatisfactory score of zero percent for the analytes ionized Calcium, Chloride, Creatinine, Glucose, Potassium, Sodium, Total Carbon Dioxide, and Urea Nitrogen (BUN). 2. Review of the chemistry- core PT results for the first event of 2023 showed the laboratory obtained an unsatisfactory score of zero percent for the analytes ionized Calcium and Glucose. 3. Review of the chemistry- core PT results for the first event of 2023 showed the laboratory obtained an unsatisfactory score of 20 percent for the analytes Creatinine, Sodium, Total Carbon Dioxide, and BUN 4. Review of the chemistry- core PT results for the first event of 2023 showed the laboratory obtained an unsatisfactory score of 40 percent for the analytes Chloride and Potassium. 5. Email from the laboratory manager on March 30, 2023 confirmed the laboratory failed to achieve satisfactory performance two consecutive testing events.
D2097	ROUTINE CHEMISTRY CFR(s): 493.841(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of chemistry - core proficiency testing (PT) results reported to the CLIA database by the PT provider for 2022/2023 and email from the laboratory manager, the laboratory failed to attain an overall testing event score of satisfactory performance for two out of three consecutive testing events. Findings: 1. Review of chemistry - core PT results for 2022 event three showed the laboratory obtained an overall testing score of zero percent. 2. Review of chemistry - core PT results for 2023 event one showed the laboratory obtained an overall testing score of 20 percent. 3. Email from the laboratory manager on March 30, 2023 confirmed the laboratory failed to attain an overall testing event score of satisfactory performance for two out of three consecutive testing events.
D2130	HEMATOLOGY

	CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of hematology results from the chemistry - core proficiency testing (PT) records reported to the CLIA database by the PT provider for 2022/2023 and email from the laboratory manager, the laboratory failed to achieve satisfactory performance for the hemoglobin and hematocrit in two consecutive PT events. Findings: 1. Review of hematology results from the chemistry - core PT results for the third event of 2022 revealed the laboratory obtained an unacceptable score of zero percent for the analytes hemoglobin and hematocrit. 2. Review of hematology results from the chemistry - core PT results for the first event of 2023 revealed the laboratory obtained an unacceptable score of 20 percent for the analyte hemoglobin and hematocrit. 3. Email from the laboratory manager on March 30, 2023 confirmed the laboratory failed to achieve satisfactory performance for the analytes hemoglobin and hematocrit in two consecutive PT events.
D2131	HEMATOLOGY CFR(s): 493.851(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of hematology results from the chemistry - core proficiency testing (PT) records reported to the CLIA database by the PT provider for 2022/2023 and email from the laboratory manager, the laboratory failed to achieve an overall testing event score of satisfactory performance for the specialty of hematology in two out of three consecutive PT events. Findings: 1. Review of hematology PT results for the third event of 2022 revealed the laboratory obtained an unacceptable score of zero percent for the specialty of hematology. 2. Review of hematology PT results for the first event of 2023 revealed the laboratory obtained an unacceptable score of 20 percent for the specialty of hematology. 3. Email from the laboratory manager on March 30, 2023 confirmed the laboratory failed to achieve satisfactory performance for specialty of hematology in two out of three consecutive PT events.