Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2162437	08/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Modern Vascular Of Tucson	2171 W Orange Grove Road, Tucson, AZ	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the laboratory's test menu, review of the Centers for Medicare and Medicaid services (CMS) CASPER report 96D, and interview with the laboratory program director (PD) testing personnel-1 (PD-TP1) on August 10, 2022, the laboratory failed to enroll in an HHS approved proficiency testing (PT) program for the specialty of Chemistry and Hematology. Findings include: 1. The laboratory utilizes the Abbott i-STAT point of care (POC) testing with the Chem8+ cartridge for basic chemistry panel and hemoglobin/Hematocrit, and the Abbott i-STAT Activated clotting time (Act) Kaolin cartridge for coagulation testing. a. The laboratory initiated testing in May of 2020 for sodium, potassium, calcium, Chloride, creatinine, Albumin, Urea (BUN), glucose, Hemoglobin and Hematocrit which are regulated analytes requiring PT enrollment. b. The laboratory program manager PD-TP1 confirmed by interview on August 10, 2022 at 0900 am, the lack of enrollment for PT testing for the Chem8 plus as required in 42 CFR part 493 subpart I for regulated analytes. c. The laboratory recorded performing approximately 850 Chem8+ patient samples annually on initial application. 2. The laboratory performs Activated clotting time (Act) Kaolin on the Abbott i-STAT POC analyzer. a. The laboratory failed to perform twice annual verification of testing quality as required for non-regulated

	analytes, b. The laboratory PD-TP1 confirmed by interview on August 10, 2022 at 10: 00 am, the failure to perform twice annual verification of testing for the ACT Kaolin testing. c. The laboratory initially reported performing approximately 15,000 i-STAT tests annually.
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 the Laboratory procedure manual, review of the laboratory quality control (QC) logs and interview with the laboratory Program Manager, Testing personnel-1 (PD-TP1) on August 10, 2022, the laboratory personnel failed to follow the performance of QC as written procedures for point of care testing (POC) tests, assays, performed by the laboratory personnel. Findings Include: 1. The laboratory utilizes the Abbott i-STAT point of care (POC) testing with the Chem8+ cartridge for basic chemistry panel and hemoglobin/Hematocrit, and the Abbott i-STAT Activated clotting time (Act) Kaolin cartridge for coagulation testing. a. The laboratory's procedure Lab#01 states that the for i-STAT Kaolin ACT testing "Liquid Quality Control, Two levels of liquid quality control are run every day of use." b. The laboratory procedure Lab#02 for the Chem8 plus i-STAT analyzer Section F. Liquid Quality Control: "Two levels of QC are run each day of patient testing." 3. A random selection of 12 patient records and review of the laboratory's QC log revealed that for the ACT Kaolin testing dates, no Liquid external QC was performed for three (3) of four (4) patient days of testing, and for the Chem8 plus cartridge, revealed eleven (11) of twelve (12) patient test dates, the laboratory did not perform or document two external liquid QC controls performed . Act Kaolin Patient: Patient Test Date External Liquid QC Performed 69359 07/08/2020 Not performed 77922 07/13/2020 Not performed 78297 07/16/2020 Not performed 77922 07/27/2020 Performed Chem8 plus Patient: Patient Test Date QC Performed 01314 07/01/2020 Not performed 77300 07/07/2020 Not performed 77890 07/09/2020 Not performed 75207 07/09 /2020 Not performed 77922 07/13/2020 Not performed 81314 07/15/2020 Not performed 78297 07/16/2020 Not performed 77922 07/27/2020 Performed 77922 09 /05/2020 Not performed 75995 10/28/2020 Not performed 79181 02/15/2021 Not performed 78189 03/05/2021 Not performed 4. The laboratory PD-TP1 confirmed by interview on August 10, 2022 at 11:00 am, the laboratory did not performing external liquid QC as instructed in the laboratory procedure manual, but performs liquid external QC monthly and with each new lot. 5. The laboratory does not have an Individualized Quality Control plan (IQCP) documented for Act Kaolin or Chem8 plus testing. 6. The laboratory initially reported performing approximately 15,000 patient tests annually.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

	This STANDARD is not met as evidenced by: Based on a random sampling of patient test records and interview with the Program Manager Testing Personnel 1 (PM-TP!) the laboratory failed to ensure that pertinent "reference intervals" or "normal" values were included in the patient test report. Findings Include: 1. The laboratory utilizes the Abbott i-STAT point of care (POC) testing with the Chem8+ cartridge for basic chemistry panel and hemoglobin /Hematocrit, and the Abbott i-STAT Activated clotting time (Act) Kaolin cartridge for coagulation testing. The laboratory tapes the i-STAT results onto the patient result print out onto a blank paper and stamps the patient identification and the laboratory information onto the paper. The i-STAT tape prints the reference values below the patient results. 2. Review of twelve (12) patient test reports/records revealed that 10 of the 12 patient test report records did not include the normal or refence ranges. 3. The Laboratory PM-TP1 confirmed by interview on August 10, 2022 at 11:30 am, that lack of testing reference values included with the patient report when taped onto the blank paper. 4. The laboratory initial reports record the laboratory performing approximately 15,000 patient chem8 and ACT Kaolin tests annually.
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 record review and interview with the laboratory Program Manager (PM-TP2) on August 10, 2022, the laboratory failed to have a director who meets the qualification requirements of 493.1405 as a LD for Moderate complexity Point of care testing (See D6003); the laboratory director failed to ensure that the QC program as established, is maintained to assure the quality of laboratory services provided (see D6020); the laboratory director failed to ensure that quality assessment program as established in the "Scope of Program" portion of the policy and that they are maintained to assure the quality of laboratory services provided (See D6021); the laboratory director failed to ensure that the quality control (See D5401) and quality assessment programs (See D6022) are established and maintained to identify failures in quality as they occur.
D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such

certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the Laboratory is located; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years

	were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications. This STANDARD is not met as evidenced by: Based on review of the laboratory's Centers for Medicare and Medicaid services (CMS) 209 personnel record, review of the laboratory director's (LD) license and resume, and interview with the Program Manager Testing personnel- 1 (PM-TP1) on August 10, 2022, the laboratory failed to have a director who meets the qualification requirements for a moderate complexity laboratory. Findings include; 1. The laboratory had a LD change in 2021, in which a new laboratory director (LD-2) was assigned. The LD-2 did not have the training or experience in laboratory testing as required by CMS. 2. Review of the LD-2 License, resume and education documents, the LD-2 does not possess the requisite laboratory training or experience of one year directing or supervising a non-waived laboratory. 3.The PM-TP-1 confirmed by interview on August 10, 2022 at 0930 am, the LD-2 lacked required experience of oversight of a non-waived laboratory for one year or the 20 hour CME course education course, 4. The laboratory recorded performing approximately 15,000 chemistry/Hematology patient tests annually.
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review of the laboratory policy and procedure manual, review of the laboratory quality control (QC) logs and interview with the laboratory program

	manager-testing personnel-1 (PM-TP1) on August 10, 2022, the laboratory director failed to ensure that the QC program as established, is maintained to assure the quality of laboratory services provided. Findings Include: 1. The laboratory went from performing external liquid QC on each day of patient testing as stated in the laboratory procedure manual to performing external liquid QC with each new lot of cartridges and Monthly thereafter. See D5401. 2. The laboratory PM-TP1 confirmed by interview on August 10, 2022 at 11:30 am, the laboratory does not have an individualized quality control plan (IQCP) and that they were following manufacturers recommendations for performing external liquid QC. 3. The laboratory initially reported performing approximately 15,000 patient tests annually.
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 review of the laboratory Policy and procedure manual, and interview with the Program Manager-testing personnel #1, (PM-TP1) on August 10, 2022, the laboratory director failed to ensure that quality assessment program as established in the "Scope of Program" portion of the policy and that they are maintained to assure the quality of laboratory services provided. Findings include: 1. Under the laboratory Policy/Procedure manual Lab#04 "Quality Assessment Plan (QAP) for lab draws (iSTAT)", the laboratory lacked documentation of performing assessments as outline in the "Scope of Program" for General laboratory procedures, Pre-Analytic, Analytic and Post-Analytic phases of testing. 2. Page 25 of the laboratory' QAP requires review of testing personnel training and competency, the laboratory lacked documentation and review of training and competency for four (4) of four (4) testing personnel: Testing Personnel: Start Date Training 6 month Annual PM-TP1 Not Recorded Self-generated NA NA RN-TP-2 Not Recorded No Documentation No Documentation 7/20 /2021-No LD RN-TP-3 Not Recorded No Documentation No Documentation None RN-TP-4 Not recorded No Documentation No Documentation 7/20/2021 3. The laboratory PM-TP1 confirmed by interview on August 10, 2022 at 11:50 am, the lack of documentation and review of testing personnel training and competency as established by the laboratory. 4. The laboratory's initial testing volume was listed as approximately 15,000 patient tests annually.
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 review of the laboratory policies and procedures, review of the laboratory's quality control logs and interview with the Program Manager Testing Personnel-1 (PM-TP1), on August 10, 2022, the laboratory director failed to ensure that the quality control and quality assessment programs are maintained to identify failures in quality as they occur.(See D5401)
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's Centers for Medicare and Medicaid services (CMS) 209 personnel record, review of the laboratory director's (LF) license and resume and interview with the Program Manager Testing personnel- 1 (PM-TP1) on August 10, 2022, the laboratory failed to have a Technical Consultant (TC) who meets the qualification requirements for a moderate complexity laboratory performing Chemistry and Hematology patient testing.. Findings include: See D6035
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service,

	excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of the laboratory's Centers for Medicare and Medicaid services (CMS) 209 personnel record, review of the laboratory director's (LF) license and resume and interview with the Program Manager Testing personnel- 1 (PM-TP1) on August 10, 2022, the laboratory failed to have a Technical Consultant (TC) who meets the qualification requirements for a moderate complexity laboratory performing Chemistry and Hematology patient testing.. Findings include: 1. The laboratory had a LD and TC change on November 2021, in which a new laboratory director (LD-2) was assigned. 2. Review of the LD-2 License, Resume and education documents, the LD-2 does not possess the requisite laboratory training or experience of one year training in the specialty/subspecialty of Chemistry, and Hematology. 3.The PM-TP-1 confirmed by interview on August 10, 2022 at 0930 am, the LD-2 lacked oversight of a non-waived laboratory for one year in Chemistry and Hematology, 4. The laboratory recorded performing approximately 850 Chemistry/Hematology patient tests annually.