Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2025595	10/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Arizona Vein And Vascular	15571 N Reems Rd, Surprise, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records for testing performed in the specialty of Hematology and interview with the facility personnel, the laboratory director and the individual testing the samples failed to sign the PT attestation statement. Findings include: 1. The laboratory performs patient testing in the specialty of Hematology, with an approximate annual test volume of 30. 2. The PT attestation statement presented for review for the third event of 2016 for Hematology lacked the director's signature and the testing personnel's signature. 3. The PT attestation statement presented for review for the first event of 2018 for Hematology lacked the director's signature. 4. The facility personnel confirmed that the PT attestation statements indicated above were not signed by the laboratory director and testing personnel. **This is a repeat deficiency from the previous inspections conducted on 6 /13/2014 and 6/01/2016.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment (QA) records and interview with the facility personnel, it was determined that the laboratory (A) failed to perform and document a quality assessment review as indicated in laboratory policy and (B) failed to document corrective actions taken to resolve problems associated with unsatisfactory Proficiency Testing (PT) scores. Findings include: 1. The laboratory performs patient testing on the i-Stat analyzer in the specialty of hematology, with an approximate annual test volume of 30. A2. The laboratory's existing policy and procedure for Quality Assessment Review includes an annual review of the following areas: Patient Test Management, Quality Control, Proficiency Testing, Comparison of Test Results, Personnel, Complaint Investigation and Quality Assessment Reviews with staff. A3. No documentation of an annual QA Review was presented for review during the survey from 2016 and 2017. A4. The facility personnel confirmed that the lab failed to perform and document QA activities as outlined in laboratory policy. B2. The laboratory participates in PT for regulated analyte, PT/INR, and received an unsatisfactory score of 0% for the 3rd testing event of 2017. B3. The laboratory performs PT for the analyte, Activated Clotting Time (ACT), as a means to verify accuracy for this test which is not included in Subpart I and received an unsatisfactory score of 0% for the 3rd testing event of 2017. B4. No corrective action documentation was presented for review during the survey to indicate the laboratory resolved the problem of the unsatisfactory PT score as indicated above. B5. The facility personnel confirmed that the laboratory did not document corrective action for the unsatisfactory PT score indicated above.
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 the severity and number of recurring deficiencies cited for quality control practices identified during the survey conducted on October 11, 2018 and previous surveys conducted on June 13, 2014 and June 1, 2016, it was determined that the laboratory failed to monitor the overall quality of the analytic systems and correct problems as specified in 493.1289 for patient testing performed by the laboratory in the specialty of Hematology. See D5431 and D5445 for findings.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

	This STANDARD is not met as evidenced by: Based on review of hematology test records and interview with the facility personnel, the laboratory failed to perform and document the electronic simulator check performed on the I-stat analyzer each day of patient testing. Findings include: 1. The laboratory performs PT/INR and ACT testing on the I-stat analyzer, with an approximate annual test volume of 30. 2. No documentation was presented for review during the survey to indicate the laboratory performed and documented the electronic simulator check on the analyzer prior to testing patients on 03/14/2017 and 08/15 /2017. The number of patient samples tested on the I-stat analyzer on those dates could not be determined during the survey. 3. The facility personnel confirmed that the laboratory did not have documentation of the electronic simulator check for the dates indicated above.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of quality control (QC) documentation and interview with the facility personnel, the laboratory failed to perform and document control procedures using the number and frequency as required. Findings include: 1. The laboratory performs patient testing on the I-stat analyzer under the specialty of Hematology, with an approximate annual test volume of 30. On the date of the survey, October 11, 2018, the laboratory's quality control procedure for PT/INR testing consisted of performing two levels of liquid control material each day of patient testing. 2. No QC documentation was provided for review during the survey to indicate the laboratory performed two levels of control material of different concentrations each day of patient PT/INR testing during 2017 through the date of the survey. 3. The number of patient samples tested during 2017 through the date of the survey conducted on October 11, 2018 could not be determined at the time of the survey. 4. The facility personnel confirmed that the laboratory did not perform and document controls as required since January 1, 2016 and confirmed that the laboratory had not implemented an Individualized Quality Control Plan (IQCP) for testing performed on the I-stat analyzer. **This is a repeat deficiency from the previous surveys conducted on 06/13 /14 and 06/01/2016.
D5803	TEST REPORT CFR(s): 493.1291(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by:

	Based on review of patient test reports maintained in the electronic medical record (EMR) system and interview with the facility personnel, the laboratory failed to provide evidence of the test report maintained in the EMR for one out of one patient record reviewed during the survey. Findings include: 1. The laboratory performs testing in the specialty of Hematology, with an approximate annual test volume of 30. The laboratory utilizes an electronic medical record (EMR) system to maintain patient test reports. It is the practice of the laboratory to scan the test result into the EMR for each patient tested. 2. The laboratory's existing procedure for the "Annual Spot Check of Transcribed or Transmitted Results" states, "Each instrument needs to have its test result(s) checked against the result(s) scanned, transmitted or transcribed to the patient's medical record (electronic or hard copy)." 3. No evidence of the scanned test report was presented for review in the EMR for patient# 49177 tested on 06/06/2018. 4. The facility personnel confirmed that the laboratory failed to scan the test results to the EMR for the patient indicated above. **This is a repeat deficiency from the previous survey conducted on 06/01/2016.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of Quality Assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. Findings include: 1. The laboratory's existing procedure for the "Annual Spot Check of Transcribed or Transmitted Results" states, "Each instrument needs to have its test result(s) checked against the result(s) scanned, transmitted or transcribed to the patient's medical record (electronic or hard copy)." 2. No documentation was presented for review from 2017 to indicate the laboratory performed the annual spot check of transmitted results from testing performed on the I-stat analyzer. 3. The facility personnel confirmed that the laboratory did not perform the annual spot check of transmitted results in 2017.
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: Due to the number and severity of deficient practices identified during the survey and the number of repeat deficiencies from the previous surveys conducted on 6/13/14 and 06/01/16, the Condition of Laboratory Director was found to be not met as evidenced by: D6020 - failure to ensure the quality control program is maintained to assure the quality of laboratory services provided, D6021 - failure to ensure the quality assessment program is maintained to assure the quality of laboratory services provided and D6029 - failure to ensure that all personnel have the appropriate

	education and training for the type and complexity of services offered, prior to testing patient specimens. **This is a repeat deficiency from the previous survey conducted on 06/13/14 and 06/01/16.
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 lack of Quality Control documentation for review for PT/INR testing performed on the I-stat analyzer, the laboratory director failed to ensure that the quality control program is maintained to assure the quality of laboratory services provided. See D5445 for findings. **This is a repeat deficiency from the previous survey conducted on 06/01/16.
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 lack of quality assessment documentation, the laboratory director failed to ensure that quality assessment programs are maintained to assure the quality of laboratory services provided. See D5293 and D5891 for findings. **This is a repeat deficiency from the previous survey conducted on 06/01/16.
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 lack of training documentation and interview with the facility personnel, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate training for the type and complexity of services offered. Findings include: 1. The laboratory performs patient testing in the specialty of Hematology, with an approximate annual test volume of 30. 2. No initial training documentation was presented for review for one out of one testing personnel who began patient testing in December 2017. 3. The facility personnel confirmed that the testing personnel indicated above did not have documentation of initial training. **This is a repeat deficiency from the previous survey conducted on 06/01/16.