Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2238416	09/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
Ozark Regional Vein Center	5433 W Walsh Lane, Rogers, AR	

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
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Through review of the laboratory's Quality Control (QC) Reports for Prothrombin Time assays (PT) , review of a documents titled IQCP Procedure", subsequent email documentation from the facility and interview it was determined that the laboratory failed to ensure two levels of quality control material are performed every eight hours of patient testing in calendar year 2022 . Findings follow: A) Review of the QC Reports for 2022 revealed that level 1 (lot 281141) and level 2 (lot 29142) quality control for PT assays was performed for PT Cartridge (lot # 521340) received date 3/5 /22 on one occasion without documenting the date or time of performance. B) Review of the QC Reports for 2022 revealed that level 1 (lot 281141) and level 2 (lot 29142) quality control for PT assays was performed for PT Cartridge (lot # 522129) received date 6/4/22 on one occasion without documenting the date or time of performance. C) During interview on 9/1/22 at 10:05 a.m., staff member (#1 on the CMS 209 form) was asked if the facility had developed an Individualized Quality Control Plan (IQCP) and he provided a procedure titled IQCP. D) Review of the IQCP procedure revealed that it was directions for developing an IQCP and lacked any data developed by the faciity regarding risk analysis or a specified QC plan. E) In an interview on 9/1/22 at 12:35 p.m. the staff member (# 1 on the CMS 209 form) confirmed that the occasions cited above were the only instances that PT QC had been performed and that PT assays have been performed every month since march 2022. F) When asked for the patients and dates that PT testing was performed, the staff member (#1 on the CMS 209 form) stated that there was no manual or computerized log of PT testing and the

	only way to determine that information would be to look at every individul patient's chart. G) On 9/7/22 facility staff member, identified on a separate staff identification chart, provided an email stating that PT assays were performed on 153 patients in 2022. H) In an interview on 9/1/22 at 12:35 p.m. the staff member (# 1 on the CMS 209 form) confirmed that QC for PT assays have not been performed within eight hours of every patient testing event.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Through a review of Personnel Records for three of three personnel listed on the form CMS-209, a lack of documentation and through interviews with laboratory staff, it was determined the laboratory director failed to give written authorization to perform moderately complex prothrombin time (PT) testing to three of three testing personnel who perform (PT) testing. Survey findings include: A) The surveyor reviewed staff laboratory personnel records for three testing personnel (listed as #2 through #4 on the form CMS-209) who perform moderate complexity PT testing B) Upon request, the laboratory was unable to provide a written authorization to perform testing for the three personnel, identified above, as none was provided in the personnel records reviewed. C) In an interview, at 10:05 on 9/1/22, laboratory employee #1 confirmed that written authorization by the laboratory director to perform testing was not present for any of the testing personnel and the personnel perform moderately complex PT testing.
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: Through a review of competency assessments for three of three laboratory testing personnel, a review of laboratory personnel documentation of education, and interviews with laboratory staff, it was determined the employee performing technical consultant duties did not have the required education/experience to meet the qualifications as evidenced by: D6035 - The employee performing the duties of technical consultant did not meet the education requirements for the position

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: Through a review of competency assessments for three of three laboratory testing personnel, a review of laboratory personnel documentation of education, and interviews with laboratory staff, it was determined the employee performing technical consultant duties did not have the required education and/or experience to meet the required qualifications. Survey findings include: A) A review of personnel records for three of three testing personnel listed on the form CMS-209 revealed that all competency assessments were signed by laboratory employee #1 (as listed on the CMS-209). B) Through a review of the unofficial transcript for laboratory employee #1, it was determined the highest level of education achieved was a Master's degree in "Nursing - Leadership and Management" . The minimum acceptable education is a bachelor's degree in a chemical, physical, or biological science or medical technology with subsequent experience in non-waived testing. C) During an interview, at 10:05a. m. on 9/1/22, laboratory employee #1 confirmed that his only lab experience has been the performance of waived category testing.
D6063	LABORATORY TESTING PERSONNEL

	CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Through a review of personnel files for three of three laboratory testing personnel listed on the CMS 209 form, through a lack of documentation, and through interviews with staff, it was determined that two of three laboratory testing personnel failed to meet qualification requirements as testing personnel as evidenced by: D6065 - two of three laboratory testing personnel lacked documentation of appropriate education to qualify as a testing personnel
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Through a review of laboratory personnel records for three testing personnel, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed document that two of three testing personnel (#3 and #4 as listed on the CMS 209 form) met educational requirements to perform moderate complexity testing. Survey findings follow: A) In an interview, at 08:55 a.m. on 9/1/22, employee #1 (as listed on the Personnel Identification Worksheet) confirmed employees #3 and #4 perform Prothrombin Time/International Normalized Ratio (PT/INR) tests using the moderate complexity I-Stat test system. B) The laboratory failed to have documentation of education that would qualify laboratory employees #3 and #4 to perform moderate complexity testing. C) In the interview, at 08:55 a.m. on 9/1/22 , laboratory employee #1 confirmed the lack of documentation of highest level of education, which would qualify employees #3 and #4 as a moderate complexity testing personnel.