Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D2311338	**(X3) Date Survey Completed** 02/10/2025
Name of Provider or Supplier Hesham Fakhri Md Pllc Dba Vein, Heart And	**Street Address, City, State** 1810 S Macdill Ave Suite 2, Tampa, FL	
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 announced CLIA initial survey was conducted at Hesham Fakhri MD PLLC DBA Vein, Heart and Vascular Institute on 02/10/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D2000 - 493.801 Enrollment and Testing of Samples. D6000 - 493.1403 Moderate Complexity Laboratory Director. D6033- 493.1409 Technical Consultant Moderate Complexity.
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 record review and interview the laboratory failed to be enrolled in a proficiency testing (PT) program for speciality of Hematology testing performed by the laboratory from 10/22/24 to 02/10/25. Findings include: 1. Review of the CMS-116 form signed by the Laboratory Director 02/4/2025 listed the nonwaived testing performed by the laboratory was Activated Clotting Time (ACT). 2. Installation records for the ACT test system GEM Hemochron documented performance verification performed 10/22/2024. 3. No documentation was presented when proof of proficiency enrollment for the Hematology ACT testing performed by the laboratory

	was requested. The Operations Manager on 02/10/25 at 10:45 AM confirmed the laboratory was not enrolled with a PT program for the ACT testing performed by the laboratory.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to perform two control materials of different concentrations for seven of seven days of patient testing (10/31/24, 11/11/24, 12/5/24, 12/9/24, 12/12/24, 01/23/25, and 01/30/25) for hematology Activated Clotting Time (ACT). Findings include: 1. Patient records documented patient ACT testing was performed 10/31/24, 11/11/24, 12/5/24, 12/9/24, 12/12/24, 01/23/25, and 01/30/25. There was no documentation two level of control material was tested on the listed days of patient testing. 2. On 02/10/25 at 10:20 AM, the Operations Manager confirmed two level of control material was not tested on the seven days patient ACT testing was performed.
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, the Laboratory Director failed to ensure the quality control and quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occurred (See D6020), and the Laboratory Director failed to ensure that prior to testing patients' specimens, the Technical Consultant had the appropriate experience and one of two Testing Personnel (TP B) had appropriate training, and two of two Testing Personnel had demonstrated that they could perform testing operations reliably to provide and report accurate results for moderate complexity testing of hematology Activated Clotting Time (ACT) from 10/2024-2/2025 (See D6029).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure that the quality control (QC) and quality assessment (QA) programs were established to assure the quality of laboratory services and to identify failures in quality for the

	hematology Activated Clotting Time (ACT) testing performed from 10/2024 to 2 /2025. Findings include: 1. The Laboratory Director did not ensure two control materials of different concentrations were performed on seven of seven days of patient testing (10/31/24, 11/11/24, 12/5/24, 12/9/24, 12/12/24, 1/23/25, and 1/30/25) for hematology Activated Clotting Time (ACT). (See D5447) 2. The Lab Director did not ensure the laboratory was enrolled in a proficiency testing (PT) program for speciality of Hematology testing performed by the laboratory from 10/22/24 to 2/10/25. (See D2000) 3. The Quality Assurance (QA) Protocol and Documentation Checklist indicated regular internal audits would be conducted and documented, and QC and proficiency testing results would be included in QA review. 4. No documentation of QA audits were available for review. On 2/10/25 at 10:50 AM, the Operation Manager confirmed there was no documented proof of QA audits being performed.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (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 record review and interview, the Laboratory Director failed to ensure that prior to testing patients' specimens the Technical Consultant had the appropriate experience and one of two Testing Personnel (TP B) had appropriate training, and two of two Testing Personnel (TP-A and TP-B) had demonstrated that they could perform testing operations reliably to provide and report accurate results for the hematology Activated Clotting Time (ACT) from 10/2024-02/2025. Findings include: 1. The Laboratory Personnel Report signed by the Laboratory Director 02/04/2025 listed himself as the one technical consultant (TC). The personnel records for the Laboratory Director failed to include proof of at least one year of laboratory training or experience in the speciality of hematology testing performed by the laboratory. (See D6033) 2. The Laboratory Personnel Report signed by the Laboratory Director 02/04 /2025 listed two Testing Personnel (TP-A and TP-B). TP-B personnel record failed to include documentation of training for the ACT testing performed. TP-A and TP-B personnel folders failed to include documentation of ability to perform testing operations reliably to provide and report accurate results. 3. On 02/10/25 at 10:37 AM, the Operation Manager confirmed the listed TC did not have appropriate experience, TP-A and TP-B did not have documentation of ability to perform testing operations reliably to provide and report accurate results, and TP-B did not have documentation of training for the ACT testing.
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY 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 record review and interview, the laboratory failed to have a Technical

	Consultant (TC) who meets the qualification requirements from 10/21/2024 to 02/10 /2025 for the speciality of Hematology testing performed by the laboratory (See D6034).
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have a Technical Consultant (TC) who meets the qualification requirements from 10/21/2024 to 2/10 /2025 for the speciality of Hematology testing performed by the laboratory. Findings include: 1. The Laboratory Personnel Report signed by the Laboratory Director 2/4 /2025 listed himself as the one TC. 2. The personnel records for the Laboratory Director failed to include proof of at least one year of laboratory training or experience in the speciality of hematology testing performed by the laboratory. 3. On 02/10/2025 at 9:50 AM, the Vice President and Operations Manager, and on 02/10/25 at 10:30 AM, the Lab Director confirmed the listed Technical Consultant did not have proof of at least one year of laboratory training or experience in the speciality of hematology testing performed by the laboratory to qualify for the position of Technical Consultant.