Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2264288	(X3) Date Survey Completed 01/19/2023
Name of Provider or Supplier Jackson Cardiology Consultants, Pllc	**Street Address, City, State** 205 Page Ave Suite B, Jackson, MI	
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	The Department of Licensing and Regulatory Affairs has evaluated this facility during an announced recertification survey. It was determined laboratory is not in compliance with CLIA regulations (42 CFR Part 93, effective April 24, 2003) and Immediate Jeopardy was identified. The following Conditions were not met: 493.801 Condition: Enrollment and testing of samples 493.1215 Condition: Hematology 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant
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 observation and interviews, the laboratory failed to enroll in proficiency testing for its Complete Blood Count (CBC) testing since testing was initiated on 11 /17/22. Findings include: 1. The surveyor observed a Sysmex pocH-100i hematology analyzer performing CBC testing while touring the laboratory on 1/18/23 at 12:58 pm and noted patient testing had started 11/17/22. 2. An interview on 1/18/23 at 1:19 pm with TP1 revealed the laboratory had not performed proficiency testing since the

	laboratory had began patient testing. 3. An interview on 1/19/23 at 11:14 am with the Practice Manager revealed the laboratory had not enrolled in a proficiency testing program for its CBC testing.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on observations, record review, and interviews, the laboratory failed to establish procedures to assess personnel competency (refer to D5209), failed to verify the accuracy of its Activated Clotting Time (ACT) testing at least twice annually (refer to D5217), failed to monitor and document room temperature, refrigerator temperature, and the actuator heat block temperature as required by the manufacturer (refer to D5413), failed to verify performance specifications for its Activated Clotting Time (ACT) testing using the Medtronic ACT Plus analyzer (refer to D5421 A), failed to verify performance specifications for its Complete Blood Count (CBC) testing using the Sysmex pocH-100i analyzer (refer to D5421 B), failed to perform and document maintenance for the Medtronic ACT Plus analyzer (refer to D5429), and failed to perform quality control testing at least every 8 hours of patient testing (refer to D5545).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on a lack of documentation and interview with Testing Personnel #1, the laboratory failed establish procedures to assess personnel competency of 4 (Clinical Consultant and Testing Personnel #1-#3) of 4 personnel listed on Form CMS-209. Findings include: 1. The surveyor requested laboratory personnel competency assessment documentation on 1/18/23 at 1:12 pm and it was not made available. 2. An interview on 1/18/23 at 1:20 pm with Testing Personnel #1 revealed the laboratory had not established a competency assessment policy and documentation of competency assessments for laboratory personnel were not available.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on a lack of documentation and interview with Testing Personnel #1, the

	laboratory failed to verify the accuracy of its Activated Clotting Time (ACT) testing at least twice annually for 1 (January 2022 to January 2023) of 1 year reviewed. Findings include: 1. A review of the laboratory's records revealed a lack of verification of accuracy testing for its ACT testing from January 2022 to January 2023. 2. An interview on 1/18/23 at 1:19 pm with Testing Personnel #1 confirmed the laboratory had not performed verification of accuracy testing from January 2022 to January 2023.
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 observation, lack of documentation, and interview with Testing Personnel #1, the laboratory failed to establish written policies and procedures for its laboratory testing for 2 (Activated Clotting Time and Complete Blood Count testing) of 2 test systems used by the laboratory. Findings include: 1. The surveyor observed the laboratory's Medtronic ACT Plus analyzer performing Activated Clotting Time testing and Sysmex pocH-100i analyzer performing Complete Blood Count testing during a tour of the laboratory on 1/18/23 at 12:58 pm. 2. The surveyor requested the laboratory's test procedures on 1/18/23 at 1:09 pm and they were now made available. 3. An interview on 1/18/23 at 1:09 pm with Testing Personnel #1 revealed the laboratory had not established written test procedures.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: . Based on record review, observation, and interview with Testing Personnel #1, the laboratory failed to monitor and document room temperature, refrigerator temperature, and the actuator heat block temperature as required by the manufacturer for 1 (January 2022 to January) of 1 year since the laboratory started performing Activated Clotting Time (ACT) patient testing. Findings include: 1. A review of the Medtronic ACT Plus manufacturer's instructions revealed a section stating. "The actuator heat block temperature should be checked once a month to verify that it is 37C 0.5C. The ACT Plus (Trademark) instrument records all temperature adjustments into its temperature log" and "Operating temperature: 14C to 32C (57F to 90F)." 2. The surveyor observed the laboratory's Medtronic CLOTtrac quality control materials kept in the refrigerator on 1/18/23 at 12:58 pm and the box indicated a

	storage temperature range of 2 degrees C to 10 degrees C. 3. The surveyor requested the laboratory's temperature monitoring documentation on 1/18/23 at 1:15 pm and it was not made available. 4. An interview on 1/18/23 at 1:15 pm with Testing Personnel #1 confirmed documentation of temperature monitoring was not available.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . A. Based on record review and interviews, the laboratory failed to verify performance specifications for its Activated Clotting Time (ACT) testing using the Medtronic ACT Plus analyzer since testing initiated on 1/18/22. Findings include: 1. A review of the laboratory's "ACT Machine Control Log" revealed the first testing date was 1/18/22. 2. The surveyor requested verification of performance specifications for the Medtronic ACT Plus analyzer on 1/18/23 at 2:14 pm and it was not made available 3. An interview on 1/19/23 at 11:14 am with the Practice Manager confirmed verification of performance specifications were not available. B. Based on a lack of documentation and interviews, the laboratory failed to verify performance specifications for its Complete Blood Count (CBC) testing using the Sysmex pocH-100i analyzer since testing initiated on 11/17/22. Findings include: 1. A review of the laboratory's Sysemx pocH-100i analyzer saved data revealed the first patient had been tested on 11/17/22. 2. The surveyor requested verification of performance specifications for the Sysmex pocH-100i analyzer on 1/18/23 at 2:14 pm and it was not made available. 3. An interview on 1/19/23 at 11:14 am with the Practice Manager confirmed verification of performance specifications were not available.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1, the laboratory failed to perform and document maintenance for the Medtronic ACT Plus analyzer for 1 (January 2022 to January 2023) of 1 year reviewed. Findings include: 1. A review of the Medtronic ACT Plus manufacturer's instructions revealed a section titled "Maintenance" stating, "To ensure proper performance of the ACT Plus instrument, it is important to clean the actuator assembly a minimum of every 30 days, or more frequently if required. If blood should get into the actuator assembly, it is critical that

	the instrument is cleaned as soon as possible." 2. An interview on 1/18/23 at 1:17 pm with Testing Personnel #1 revealed the laboratory had not performed and documented maintenance for the Medtronic ACT Plus analyzer.
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: . Based on record review and interview with Testing Personnel #1, the laboratory failed to perform quality control testing at least every 8 hours of patient testing for 76 of 128 patient testing dates performed between 1/18/22 and 1/18/23. Findings include: 1. A review of the laboratory's "ACT Machine Control Log" revealed a lack of quality control testing for the following dates when patient testing was performed: a. 1/20/22 b. 2/1/22 c. 2/9/22 d. 2/10/22 e. 2/16/22 f 2/23/22 g. 3/2/22 h. 3/3/22 i. 3/9/22 j. 3/16 /22 k. 3/17/22 l. 4/6/22 m. 4/7/22 n. 4/13/22 o. 4/14/22 p. 4/20/22 q. 4/21/22 r. 5/4/22 s. 5/5/22 t. 5/11/22 u. 5/12/22 v. 5/18/22 w. 5/25/22 x. 6/1/22 y. 6/8/22 z. 6/9/22 aa. 6 /15/22 bb. 6/22/22 cc. 6/29/22 dd. 6/30/22 ee. 7/6/22 ff. 7/7/22 gg. 7/13/22 hh. 7/14/22 ii. 7/20/22 jj. 7/28/22 kk. 8/3/22 ll. 8/4/22 mm. 8/10/22 nn. 8/25/22 oo. 8/31/22 pp. 9/1 /22 qq. 9/2/22 rr. 9/7/22 ss. 9/8/22 tt. 9/9/22 uu. 9/14/22 vv. 9/15/22 ww. 9/16/22 xx. 9 /21/22 yy. 9/22/22 zz. 9/23/22 aaa. 9/29/22 bbb. 9/30/22 ccc. 10/5/22 ddd. 10/6/22 eee. 10/7/22 fff. 10/12/22 ggg. 10/13/22 hhh. 10/14/22 iii. 10/19/22 jjj. 10/21/22 kkk. 10/26/22 lll. 11/3/22 mmm. 11/9/22 nnn. 11/10/22 ooo. 11/16/22 ppp. 11/23/22 qqq. 11/29/22 rrr. 11/30/22 sss. 12/1/22 ttt. 12/8/22 uuu. 12/15/22 vvv. 12/22/22 www. 1/5 /23 xxx. 1/18/23 2. A review of the Medtronic ACT Plus manufacturer instructions revealed a section titled "Quality Assurance" stating, "Liquid coagulation controls are used to verify instrument cartridge performance and end-user technique. When only liquid controls are used, minimum requirements are two levels of control for every 8 hours of patient testing." 3. An interview on 1/18/23 at 2:14 pm with Testing Personnel #1 revealed liquid controls were performed once weekly and dates on the log with "N/A" listed in the CLOTtrac columns had patients testing performed. The laboratory had not established an Individualized Quality Control Plan.
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 verification of performance specifications was performed for Activated Clotting Time (ACT) testing using the Medtronic ACT Plus analyzer (refer to D6012 A), failed to ensure the verification of performance specifications was performed for Complete Blood Count (CBC) testing using the Sysmex pocH-100i analyzer (refer to D6012 B), failed to ensure verification of accuracy of its Activated Clotting Time (ACT) testing

	was performed at least twice annually (refer to D6013), failed to ensure the laboratory was enrolled in proficiency testing for its complete blood count (CBC) testing (refer to D6015), failed to ensure a quality control program was established for its Activated Clotting Time testing using its Medtronic ACT Plus analyzer (refer to D6020), failed to establish quality assessment programs for its moderate complexity hematology testing (refer to D6021), failed to ensure room temperature, refrigerator temperature, and the actuator heat block temperatures were monitored and documented (refer to D6023 A), failed to ensure maintenance for the Medtronic ACT Plus analyzer was performed and documented (refer to D6023 B), failed to ensure personnel performing Activated Clotting Time (ACT) testing using the Medtronic ACT Plus analyzer received training (refer to D6029), failed to ensure procedures to assess competency of laboratory personnel were established (refer to D6030), and failed to ensure written policies and procedures for its laboratory testing were established (refer to D6031).
D6012	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(i) 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)(3) Ensure that-- (e)(3)(ii) The test methodologies selected have the capability of providing the quality of results required for patient care; This STANDARD is not met as evidenced by: . A. Based on record review and interview, the Laboratory Director failed to ensure the verification of performance specifications was performed for Activated Clotting Time (ACT) testing using the Medtronic ACT Plus analyzer. Refer to D5421 A. B. Based on record review and interview, the Laboratory Director failed to ensure the verification of performance specifications was performed for Complete Blood Count (CBC) testing using the Sysmex pocH-100i analyzer. Refer to D5421 A.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: . Based on a lack of documentation and interview with Testing Personnel #1, the Laboratory Director failed to ensure verification of accuracy of its Activated Clotting Time (ACT) testing was performed at least twice annually. Refer to D5217.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)

	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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: . Based on observation and interviews, the Laboratory Director failed to ensure the laboratory was enrolled in proficiency testing for its complete blood count (CBC) testing. Refer to D2000.
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 and interview with Testing Personnel #1, the Laboratory Director failed to ensure a quality control program was established for its Activated Clotting Time testing using its Medtronic ACT Plus analyzer. Refer to D5455.
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 documentation and interview with Testing Personnel #1, the Laboratory Director failed to establish quality assessment programs for its moderate complexity hematology testing for 1 (January 2022 to January 2023) of 1 year reviewed. Findings include: 1. The surveyor requested the laboratory's quality assessment documentation on 1/18/23 at 1:22 pm and it was not made available. 2. An interview on 1/18/23 at 1:22 pm with Testing Personnel #1 revealed the laboratory had not established a quality assessment program for monitoring its moderate complexity hematology testing.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6)

	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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: . A. Based on record review, observation, and interview with Testing Personnel #1, the Laboratory Director failed to ensure room temperature, refrigerator temperature, and the actuator heat block temperatures were monitored and documented. Refer to D5413. B. Based on record review and interview with Testing Personnel #1, the Laboratory Director failed to ensure maintenance for the Medtronic ACT Plus analyzer was performed and documented. Refer to D5429.
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 a lack of documentation and interview with Testing Personnel #1, the Laboratory Director failed to ensure personnel performing Activated Clotting Time (ACT) testing using the Medtronic ACT Plus analyzer received training for 2 (Testing Personnel #1 and #3) of 2 personnel performing ACT patient testing. Findings include: 1. The surveyor requested training and competency documentation for personnel performing ACT testing using the Medtronic ACT Plus analyzer on 1/18/23 at 1:12 pm and it was not made available. 2. An interview on 1/18/23 at 1:20 pm with Testing Personnel #1 revealed training and competency documentation for testing personnel performing ACT testing was not available. The personnel that had performed ACT testing were Testing Personnel #1 and #3.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or

	continuing education to improve skills; This STANDARD is not met as evidenced by: . Based on a lack of documentation and interview with Testing Personnel #1, the Laboratory Director failed to ensure procedures to assess competency of laboratory personnel were established. Refer to D5209.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: . Based on observation, lack of documentation, and interview with Testing Personnel #1, the Laboratory Director failed to ensure written policies and procedures for its laboratory testing were established. Refer to 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 record review and interview with the Technical Consultant, the laboratory failed to employ an individual to perform the duties of a Technical Consultant (refer to 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 with the Practice Manager, the laboratory failed to employ an individual to perform the duties of a Technical Consultant for 1 (January 2022 to Janaury 2023) of 1 year reviewed. Findings include: 1. The surveyor requested a completed Laboratory Personnel Report CMS-209 on 1/18/23 at 12:55

	pm. 2. A review of the laboratory's Laboratory Personnel Report CMS-209 revealed a lack of a Technical Consultant. 3. An interview on 1/19/23 at 11:14 am with the Practice Manager revealed the laboratory did not have an individual to perform the duties of a Technical Consultant.