Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	23D2289252	06/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
Msu Health Care Heart And Vascular Center	804 Service Road Suite 204, East Lansing, 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
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 observation, record review, and interviews, the laboratory failed to establish policies and procedures to include imminently life-threatening values (refer to D5403), the laboratory failed to ensure laboratory procedures were approved, signed, and dated prior to patient testing using the Hemochron Signature Elite Activated Clotting Time (ACT) analyzer (refer to D5407), failed to follow the Hemochron Signature Elite Activated Clotting Time (ACT) manufacturer's instructions (refer to D5411), Based on observation, record review, and interview with the Testing Personnel, the laboratory failed to monitor room and refrigerator temperatures to ensure proper storage of reagents, controls, and for reliable operation of test systems (refer to D5413), failed to verify performance specifications for its Hemochron Signature Elite Activated Clotting Time (ACT) testing prior to using the test system for patient testing (refer to D5421), failed to perform Activated Clotting Time (ACT) control procedures each day of patient testing (refer D5445), and failed to transmit patient test data to the final test report destination (refer D5801).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic

	examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on record review and interview with the Testing Personnel, Clinic Manager, and Director of Clinical Operations, the laboratory failed to establish policies and procedures to include imminently life-threatening values for 2 (April 2024 to June 2024) of 2 months since the laboratory started patient testing. Findings include: 1. A review of the laboratory's "Activated Clotting Time (ACT) Testing Policy" revealed a section titled "Result Reporting and Documentation" stating, "Critical or panic values (as defined by the laboratory) shall be reported immediately to the requiring physician or healthcare provider." 2. An interview on 6/4/24 at 3:20 pm with the Testing Personnel, Clinic Manager, and Director of Clinical Operations revealed the laboratory had not established critical or panic values for its Activated Clotting Time (ACT) patient testing.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: . Based on record review and interview with the Testing Personnel, Clinic Manager, and Director of Operations, the laboratory failed to ensure laboratory procedures were approved, signed, and dated prior to patient testing using the Hemochron Signature Elite Activated Clotting Time (ACT) analyzer for one (Patient 4/8/24) of one patient test performed. Findings include: 1. A review of the laboratory's procedure manual revealed procedures were not approved, signed, and dated by the Laboratory Director for the laboratory's Hemochron Signature Elite analyzer used for Activated Clotting Time (ACT) testing prior to testing one patient on 4/8/24. 2. An interview with the Testing Personnel, Clinic Manager, and Director of Operations on 06/04/2024 at 3:20 pm confirmed the laboratory failed to ensure procedure manuals were approved, signed, and dated prior to testing patients.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results

	within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: . Based on record review and interview with the Testing Personnel, the laboratory failed to follow the Hemochron Signature Elite Activated Clotting Time (ACT) manufacturer's instructions for one (Patient 4/8/24) of one patient test performed. Findings include: 1. A review of the laboratory's "Activated Clotting Time (ACT) Testing Policy" revealed a section titled "Instrument Operation and Maintenance" stating, "The Hemochron Signature Elite shall be operated according to the manufacturer's instructions" and "Calibration and quality control testing shall be performed every 8 hours of testing and with each new lot of cartridges, or as per manufacturer's recommendations." 2. The surveyor requested the manufacturer's instructions referenced by the laboratory's policy on 6/4/24 at 1:52 pm and an electronic copy was retrieved online and printed for review. 3. An interview on 6/4/24 at 1:52 pm with the Testing Personnel confirmed the manufacturer instructions retrieved and printed had not been used by the laboratory.
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 observation, record review, and interview with the Testing Personnel, the laboratory failed to monitor room and refrigerator temperatures to ensure proper storage of reagents, controls, and for reliable operation of test systems for 2 (April 2024 to June 2024) of 2 months since the laboratory started patient testing. Findings include: 1. The surveyor observed the laboratory storing the Hemochron Signature Elite analyzer at room temperature and the control materials in the refrigerator on 6/4/24 at 1:37 pm. 2. A review of the manufacturer's instructions for the Hemochron Signature Elite analyzer revealed a section titled, "Specifications" stating, "Operating Environment: 15 degrees C to 30 degrees C." 3. A review of the laboratory's "DirectCheck Whole Blood Control" package insert revealed a section titled "Handling and Storage" stating, "When refrigerated (2-8 degrees C) the vials are stable until the marked expiration date." 4. Based on interview with the Testing Personnel on 06/04/2024 at 3:10 pm confirmed laboratory room and refrigerator temperatures had not been monitored and recorded.
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: . Based on record review and interview with the Testing Personnel, the laboratory failed to verify performance specifications for its Hemochron Signature Elite Activated Clotting Time (ACT) testing prior to using the test system for patient testing for one patient test performed. Findings include: 1. The surveyor requested the laboratory's verification of performance specification documentation for its Activated Clotting Time (ACT) testing using the Hemochron Signature Elite on 6/4/24 at 1:52 pm and it was not made available. 2. A review of patient test records revealed one patient had ACT testing performed on 4/8/24 during a Cath Lab procedure. 3. An interview on 6/4/24 at 3:20 pm with the Testing Personnel confirmed the laboratory had not verified performance specifications of its Hemochron Signature Elite Activated Clotting Time (ACT) test system prior to initiating patient testing.
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 record review and interview with the Testing Personnel, the laboratory failed to perform Activated Clotting Time (ACT) control procedures each day of patient testing for one (Patient 4/8/24) of one patient with testing performed. Findings include: 1. A review of the laboratory's "Activated Clotting Time (ACT) Testing Policy" revealed a section titled "Quality Control Materials and Procedures" stating, "Quality control testing shall be performed at least every 30 days or as directed by the manufacturer." 2. A review of the laboratory's "HEMOCHRON Activated Clotting Time Low Range Procedure for CathLab" revealed a section titled "Maintenance and QC Schedule for Hemochron Signature Elite" stating, "Liquid QC Abnormal and Normal Every day of patient testing or every 30 days if no patient testing performed in the past 30 days." 3. A review of the laboratory's quality control records revealed a lack of control procedures performed on 4/8/24 when patient testing was performed. 4. An interview with Testing Personnel on 06/04/2024 at 3:20 pm revealed the laboratory had not established an Individualized Quality Control Plan (IQCP) and the laboratory failed to run controls each date of patient testing and document results.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to

	ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on record review and interview with the Clinic Manager, the laboratory failed to transmit patient test data to the final test report destination for one (Patient 4/8/24) of one patient test performed. Findings include: 1. The surveyor requested the patient test report on 06/04/24 at 3:20 pm for one patient receiving Activated Clotting Time testing on 4/8/24 and it was not made available. 2. An interview with the Testing Personnel and Clinic Manager on 6/4/24 at 3:20 pm confirmed the patient test result was verbally communicated to the ordering physician and a test report including the results was not available.
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 laboratory verified the performance of its Hemochron Signature Elite Activated Clotting Time (ACT) test system prior to using it for patient testing (refer to D6012), failed to ensure quality assessment programs were established (refer to D6021), failed to ensure the Technical Consultant was qualified (refer to D6028 A), failed to ensure the Clinical Consultant was qualified (refer to D6028 B), failed to ensure testing personnel were qualified (refer to D6065), failed to ensure the procedure manual included imminently life-threatening test results, panic, or alert values (refer to D6031 A), failed to ensure laboratory procedures were approved, signed, and dated prior to patient testing for Hemochron Signature Elite Activated Clotting Time (ACT) analyzer (refer to D6031 B), and failed to ensure manufacturer's instructions for the Hemochron Signature Elite Activated Clotting Time test system were available for laboratory staff (refer to D6031 C).
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: . Based on record review and interview, the Laboratory Director failed to ensure the laboratory verified the performance of its Hemochron Signature Elite Activated Clotting Time (ACT) test system prior to using it for patient testing. Refer to D5421.
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 record review and interview with the Testing Personnel, Clinic Manager, and Director of Clinical Operations, the Laboratory Director failed to ensure quality assessment programs were established for two (April 2024 to June 2024) of two months since the laboratory started patient testing. Findings include: 1. A review of the laboratory's "Activated Clotting Time (ACT) Testing Policy" revealed a section titled "Quality Assurance and Improvement" stating, "The laboratory shall establish and maintain a quality assurance program to monitor and ensure the accuracy and reliability of ACT testing. Quality control data, corrective actions, and any other relevant information shall be reviewed periodically by the laboratory supervisor and the medical director." 2. The surveyor requested the laboratory's quality assurance program on 6/4/24 3:20 pm and it was not made available. 3. An interview on 6/4/24 at 3/20 pm with the Testing Personnel, Clinic Manager, and Director of Clinical Operations confirmed a quality assessment program had not been established.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: . A. Based on record review and lack of documentation, the Laboratory Director failed to ensure the Technical Consultant was qualified. Refer to D6035. B. Based on record review and a lack of documentation, the Laboratory Director failed to ensure the Clinical Consultant was qualified. Refer to D6057. C. Based on record review and lack of documentation, the Laboratory Director failed to ensure testing personnel were qualified. Refer to D6065.
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: . A. Based on record review and interview, the Laboratory Director failed to ensure the procedure manual included imminently life-threatening test results, panic, or alert values. Refer to D5403. B. Based on record review and interview, the Laboratory Director failed to ensure laboratory procedures were approved, signed, and dated prior to patient testing for Hemochron Signature Elite Activated Clotting Time (ACT) analyzer. Refer to D5407. C. Based on record review and interview, the Laboratory Director failed to ensure manufacturer's instructions for the Hemochron Signature Elite Activated Clotting Time test system were available for laboratory staff. Refer to D5411.
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 lack of documentation, the Technical Consultant was unqualified. Refer to 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 record review and lack of documentation, the Technical Consultant was unqualified for two (April 2024 to June 2024) of two months since the laboratory started patient testing. Findings include: 1. A review of the laboratory's personnel records revealed a lack of the Technical Consultant's qualifications to include at least one year of laboratory training or experience or both in non-waived hematology testing. 2 .The surveyor requested the Technical Consultant's hematology testing training or experience on 6/4/24 at 1:55 pm and it was not made available. 3. The laboratory was given an additional seven days after the survey to provide the missing documentation and it was not received.
D6056	CLINICAL CONSULTANT CFR(s): 493.1415 The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: . Based on record review and a lack of documentation, the Clinical Consultant was unqualified. Refer to D6057.
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: . Based on record review and lack of documentation, the Clinical Consultant was unqualified for two (April 2024 to June 2024) of two months since the laboratory

	started patient testing. Findings include: 1. A review of the laboratory's personnel records revealed a lack of the Clinical Consultant's qualifications. 2. The surveyor requested the Clinical Consultant's qualifications on 6/4/24 at 1:55 pm and they were not made available. 3. The laboratory was given an additional seven days after the survey to provide the missing documentation and it was not received.
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: . Based on record review and lack of documentation, testing personnel were unqualified. Refer to D6065.
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: . Based on record review and lack of documentation, testing personnel were unqualified for two (Testing Personnel #1 and #2) of two testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's personnel records revealed a lack of qualifications for Testing Personnel #1 and #2. 2. The surveyor requested Testing Personnel #1 and #2's qualifications on 6/4/24 at 1:55 pm and they were not made available. 3. The laboratory was given an additional seven days after the survey to provide the missing documentation and it was not received.