Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0864999	09/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Woods Cardiology Internal Medicine	27550 Schoenherr Rd Suite 200, Warren, 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 purpose of this unannounced survey was for complaint #MI00122664. The Department of Licensing and Regulatory Affairs has evaluated this facility and determined that it is not in compliance with CLIA regulations (42 CFR Part 93, effective April 24, 2003) and Immediate Jeopardy was identified for the following Condition: 493.1240 Condition: Preanalytic systems
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: . Based on a lack of documentation and interview with the Technical Consultant, the laboratory failed to retain quality control and test system maintenance records for 17 (September 2019 to March 2021) of 24 months reviewed. Findings include: 1. The surveyor requested quality control and test system maintenance records from the previous two years of testing on 9/23/21 at 10:14 am and records from September 2019 to March 2021 were not available. 2. An interview on 9/23/21 at 10:14 am with the Technical Consultant confirmed quality control and test system maintenance records were not retained for at least two years.
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.

	This STANDARD is not met as evidenced by: . Based on a lack of documentation and an interview with the Technical Consultant, the laboratory failed to retain quality assessment records for 17 (September 2019 to March 2021) of 24 months reviewed. Findings include: 1. The surveyor requested quality assessment documentation from the previous two years on 9/23/21 at 10:14 am and records from September 2019 to March 2021 were not made available. 2. An interview on 9/23/21 at 10:14 am with the Technical Consultant revealed the laboratory did not retain documentation of quality assessments for at least 2 years.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to meet applicable preanalytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to follow their specimen labeling procedure. Refer to D5311 A. 2. The laboratory failed to establish policies and procedures for the acceptable conditions for specimen transportation. Refer to D5311 B.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: . A. Based on observation, record review, and interviews, the laboratory failed to follow their specimen labeling procedure for 4 (3 blood tubes and 1 urine cup) of 4 unlabeled specimens observed. Findings include: 1. The surveyor observed 3 unlabeled blood tubes in the draw station area across from the laboratory during a tour of the facility on 9/23/21 at 10:31 am. 2. An interview with Testing Personnel #1 (TP1) and Testing Personnel #2 (TP2) on 9/23/21 at 10:31 am confirmed the 3 blood tubes were in the draw station unlabeled. 3. The surveyor asked TP1 and TP2 how the laboratory would verify which patient these tubes came from on 9/23/21 at 10:31 am and was not given a response. 4. The surveyor observed a conversation between TP1, TP2, and a staff member in the clinic reception area on 9/23/21 at 10:31 am which revealed the staff member in the clinic reception area had drawn the tubes, did not label them, and left the draw station area to perform other tasks. 5. The surveyor observed the staff member identified as leaving the tubes in the draw station label the three tubes with a first and last name prior to placing them in the test tube rack near

	the centrifuge in the laboratory on 9/23/21 at 10:33 am. 6. A review of the laboratory's "Specimen Collection by Venipuncture" policy revealed a section stating, "A. Specimen Identification: the following three things must be on each specimen patients full name, patients date of birth, date and time of specimen collection" and a section titled "Tube Selection" stating, "Specimen collection tubes are not to be labeled until after the collection of the specimen and before the patient is allowed to leave the collection area. Specimens must be properly labeled before proceeding on to any other task. A tube should not be allowed to sit unlabeled at anytime." 7. The surveyor observed an unlabeled urine cup in the laboratory sink on 9/23/21 at 10:55 am. 8. An interview on 9/23/21 at 10:55 am with TP2 confirmed the urine cup in the laboratory sink was unlabeled and had an aliquot sent for send out testing at the reference laboratory. B. Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to establish policies and procedures for the acceptable conditions for specimen transportation for 2 (September 2019 to September 2021) of 2 years reviewed. Findings include: 1. An interview on 9/23/21 at 10:53 am with TP1 revealed specimens from another clinic are transported to their facility for laboratory testing. 2. The surveyor requested a policy or procedure for the conditions for specimen transportation on 9/23/21 at 3:36 pm and one was not made available. 3. An interview on 9/23/21 at 3:36 pm with TP1 confirmed the laboratory did not establish a policy or procedure for the conditions of specimen transportation.
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 record review and interviews, the laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1.The laboratory failed to verify the manufacturer-established performance specifications prior to reporting patient test results. Refer to D5421. 2. The laboratory failed to perform controls each day of patient testing and follow control procedures for the NanoEnTek Frend immunoassay analyzer. Refer to D5445. 3. The laboratory failed to perform and document corrective actions taken when quality control testing results did not meet the laboratory's requirements. Refer to D5783.
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 observation, lack of documentation, and an interview with the Technical Consultant, the laboratory failed to verify the performance specifications prior to reporting patient test results for 13,660 patient tests performed on the Horiba Pentra 400 chemistry analyzer since it was put into use in June 2021. Findings include: 1. The surveyor observed a Horiba Pentra 400 chemistry analyzer during a tour of the facility on 9/23/21 at 10:39 am. 2. A review of the laboratory's verification of performance specification records revealed a lack of records for the Horiba Pentra 400 chemistry analyzer. 3. The surveyor requested the verification of performance specification records for the Horiba Pentra 400 chemistry analyzer on 9/23/21 at 3:13 pm and they were not made available. 4. An interview on 9/23/21 at 3:21 pm with the Technical Consultant confirmed the verification of performance specification records for the Horiba Pentra 400 chemistry analyzer were not available. 5. The surveyor requested a total number of patient tests performed using the Horiba Pentra 400 chemistry analyzer on 9/23/21 at 4:18 pm and was provided with daily usage summaries, revealing 13,660 patient tests had been performed using this test system since it was put into use in June 2021.
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 interviews, the laboratory failed to perform controls each day of patient testing and follow control procedures for the NanoEnTek Frend immunoassay analyzer for 1,000 of 1,044 tests performed by the laboratory. Findings include: 1. An interview on 9/23/21 at 10:40 am with Testing Personnel #1 (TP1) revealed the laboratory had not been performing controls each day of patient testing on the NanoEnTek Frend analyzer. 2. The surveyor requested the laboratory's Individualized Quality Control Program (IQCP) at 10:40 am. 3. A review of the laboratory's IQCP revealed an incomplete Risk Assessment, no documentation of a Quality Control Program, no documentation of a Quality Assessment Program, and no supporting data for the IQCP. 4. A review of the laboratory's "Free T4 by NanoEnTek FREND", "Total Testosterone by NanoEnTek FREND", "PSA by NanoEnTek FREND", "Vitamin D25 Total by NanoEnTek FREND", and the "TSH by NanoEnTek FREND" procedures all revealed sections titled "External Quality Control" stating, "It is recommended a minimum of 2 levels of external quality control with CLINIQA liquid QC Immunoassay control be tested at a minimum of 1. With each new lot number of reagents received 2. With each shipment of reagent of the same lot number 3. With each newly trained operator 4. Once every 30 days a lot number has been in service 5. Whenever reagent performance is in question 6. When any major service or repair is done on the instrument" 5. A review of the laboratory's quality control documentation for the Free Thyroxine (Free T4) assay on the Frend

	analyzer revealed the following: a. Quality control testing was not performed each date of patient testing. b. Quality control failed for level 1 on 6/3/21 and were not reran and in range until 6/10/21. Patients were tested on 6/4/21, 6/7/21, 6/8/21, and 6/9 /21 (total of 17 tests performed). c. Quality control was not performed for the month of August 2021, which had 13 patient testing dates. 6. A review of the laboratory's quality control documentation for the Total Testosterone assay on the Frend analyzer revealed the following: a. Quality control testing was not performed each date of patient testing. b. Quality control was not performed every 30 days for the months of June, July, and August 2021, which had 17 total patient testing dates. 7. A review of the laboratory's quality control documentation for the Prostate Specific Antigen (PSA) assay on the Frend analyzer revealed the following: a. Quality control testing was not performed each date of patient testing. b. Quality control was not performed every 30 days in the months of June, July, and August 2021, which had a total of 20 patient testing dates. 8. A review of the laboratory's quality control documentation for the Vitamin D assay on the Frend analyzer revealed the following: a. Quality control testing was not performed each date of patient testing. b. Quality control was not performed once every 30 days for the months of July and August 2021, which had a total of 27 patient testing dates. 9. A review of the laboratory's quality control documentation for the Thyroid Stimulating Hormone (TSH) assay on the Frend analyzer revealed the following: a. Quality control testing was not performed each date of patient testing b. Quality control was not performed every 30 days in the month of June 2021, which had a total of 20 patient testing dates. 10. An interview on 9/23/21 at 3:29 pm with TP1 confirmed the IQCP had been implemented prior to being completed and quality control had not been performed each date of patient testing. 11. The surveyor reviewed the laboratory's daily usage summaries for the NanoEnTek Frend Analyzer that revealed the laboratory had performed 1,044 tests and 1,000 of those were performed on dates when quality control was not performed.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: . A. Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to perform and document corrective actions taken when quality control testing results did not meet the laboratory's requirements for 3 (7/6/21, 7/20 /21, and 7/27/21) of 21 dates reviewed. Findings include: 1. A review of the Horiba Pentra 400 chemistry analyzer's quality control data revealed the following dates when one level of quality control was outside of 2 standard deviations without rerunning the control: a. 7/6/21 Sodium. b. 7/20/21 Potassium, calcium, and Alkaline Phosphatase. c. 7/27/21 Creatinine and uric acid. 2. A review of the laboratory's "Resolving Out of Range Controls" policy revealed a section stating, "Resolving out of range controls: The following steps should be followed to determine the type of error and how to resolve it. A. All control levels should be run initially to check the performance of the system. Repeat testing and investigation should be held until all

	control results are completed. B. Once all control levels are complete and results have been compared to the acceptability charts then any out of range control can be assessed. C. One analyte of one level out of range: 1. Based on the control chart, if this is the first time the control has been out in the last 10 to 15 points, the control can be accepted as a random error. This requires Manager or designee approval." 3. An interview on 9/23/21 at 4:18 pm with TP1 revealed the laboratory considers quality control to be in range when it is within 2 standard deviations from the mean, confirmed the quality control on the dates listed above were out of range, and confirmed corrective action was not performed for the dates when quality control fell outside 2 standard deviations.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the Laboratory Director failed to ensure corrective action was performed when proficiency testing results were unacceptable for 1 (2nd event Chemistry) of 1 proficiency testing event reviewed. Findings include: 1. A review of the CASPER 0096 CMS report revealed the laboratory obtained a 0% for uric acid testing. 2. A review of the laboratory's proficiency testing records revealed a lack of documentation of corrective action as a result of the uric acid testing score. 3. A review of the laboratory's "Quality Management Plan Including QC/QA Protocols" revealed a section titled, "Proficiency Testing Assessment" stating, "External proficiency test results (when received) are reviewed and evaluated. Unacceptable results are documented with an explanation of the corrective action taken. After the next completed proficiency test event, the results are evaluated for the effectiveness of the previous corrective action plan." 4. An interview on 9/23/21 at 3:36 pm with TP1 confirmed the Laboratory Director did not ensure corrective action was performed when the uric acid proficiency testing results were unacceptable.
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, record review, and interview with the Technical Consultant, the Laboratory Director failed to ensure the quality assessment program

	was maintained for 6 (March 2021 to September 2021) of 6 months. Findings include: 1. A review of the laboratory's records revealed a lack of documentation of quality assessments performed from March 2021 to September 2021. 2. A review of the laboratory's "Quality Management Plan Including QC/QA protocols" policy revealed a section stating, "Data collection - Monthly. Data is collected using departmental records and monitor sheets. Data is summarized in a quarterly report by the Laboratory Manager or designee. The quarterly report is then reviewed by the Facility Director/Physician as well as the general staff." and "All quality assurance documents and reports will be maintained for two years." 3. An interview on 9/23/21 at 10:14 am with the Technical Consultant revealed the laboratory did not have documentation of quality assessments since March 2021.