Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2221312	(X3) Date Survey Completed 08/16/2022
Name of Provider or Supplier West Jefferson Medical Center-Ridgelake Imaging	**Street Address, City, State** 2121 Ridgelake Dr, 1st Floor, Metairie, LA	
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 Initial survey was performed on August 16, 2022 at West Jefferson Medical Center-Ridgelake Imaging, CLIA ID # 19D2221312. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 review of the laboratory's policies, personnel records, and interview with personnel, the laboratory failed to establish written policies and procedures to assess competency of the Clinical Consultant. Findings: 1. Review of the laboratory's "Point-of-Care General Policy" under the "Education and Competency In POCT" section revealed the laboratory did not include performance of competency assessment for the Clinical Consultant, to include, but not limited to the frequency. 2. Review of personnel records for the Clinical Consultant revealed a competency assessment for his duties as Clinical Consultant was not performed. 3. In interview on August 16, 2022 at 9:57 am, the Laboratory Director confirmed the laboratory's policies did not include competency assessment for the Clinical Consultant. The Laboratory Director confirmed she did not perform a competency assessment for the Clinical Consultant.
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 review of the laboratory's procedure manual and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's procedure manual revealed the laboratory did not have written policies and procedures that included the monthly laboratory information system (LIS) check. 2. In interview on August 16, 2022 at 11:40 am the Laboratory Director stated the laboratory performs a "Calculated Patient Data Verification" monthly. The Laboratory Director confirmed the laboratory did not include a written procedure in their policy/procedure manual.
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 review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to have the policy and procedure manual approved and signed by the Laboratory Director. Findings: 1. Review of the laboratory's policies revealed the policies were maintained electronically and did not include the Laboratory Director's approval/signature. 2. In interview on August 16, 2022 at 9:30 am, the Laboratory Director confirmed she did not sign the laboratory's policies.
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 by surveyor, review of validation records, policies, and interview with personnel, the laboratory failed to include complete performance verification studies for reportable and reference ranges for creatinine testing on the EPOC analyzer. Findings: 1. Observation by surveyor during the laboratory tour on August 16, 2022 at 9:19 am revealed the laboratory utilizes the EPOC analyzer for creatinine testing. 2. Review of the laboratory's "Method Performance Specifications" policy revealed: a) "Reportable Range: The laboratory is responsible for verifying the reportable range of patient test results for each test system. The reportable range includes all results that may be reliably reported and is also called the ANALYTICAL MEASUREMENT RANGE (AMR). The AMR is the range of analyte values that a method can directly measure on the specimen without any dilution, concentration, or

	other pretreatment not part of the usual assay process." b) "Reference Range (Normal Values): The laboratory must verify that the manufacturer's reference intervals (reference range or normal values) are appropriate for the laboratory's patient population. This may be accomplished by testing an appropriate number of 'normal' donor specimens to verify the manufacturer's claims for normal values; however, a minimum of 20 donors is required. Note: If a formal reference interval study is not possible or practical, as decided by the medical director the laboratory should evaluate the use of published data for its own reference intervals and retain documentation of this evaluation." 3. Review of the laboratory's "Verification of Reportable Range /Linearity" procedure revealed "validate that verified reportable ranges are edited in the instrument, on the report and in the LIS to match the range proven by in-house testing. Place all raw data, graphs and interpretation in binder." 4. Review of the laboratory's validation records revealed the laboratory did not include the following: a) Reportable range to include the actual ranges measured by the laboratory, not the manufacturer's ranges b) Reference range studies 5. In interview on August 16, 2022 at 11:00 am, the Laboratory Director stated the laboratory utilized the manufacturer's reportable range, not the ranges achieved by the laboratory. 6. In further interview on August 16, 2022 at 11:20 am, the Laboratory Director stated the creatinine reference ranges from main campus were adopted by their laboratory. The Laboratory Director confirmed reference range studies or a clinical reference for the reference ranges utilized by laboratory were not included.
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 observation by surveyor, review of the laboratory's Individualized Quality Control Plan (IQCP), and interview with personnel, the laboratory failed to have a complete IQCP to support the reduction in frequency of quality control for creatinine testing on the EPOC analyzer. Findings: 1. Observation by surveyor during the laboratory tour on August 16, 2022 at 9:19 am revealed the laboratory utilizes the EPOC analyzer for creatinine testing. 2. Review of the laboratory's IQCP documents revealed the laboratory did not include the frequency of performance of the Quality Assessment (QA) monitoring to include, but not limited to " CAP AQ2 proficiency testing, review of quality control, evaluation or errors relating to all phases of testing, evaluation of corrective actions taken if problems identified, and review of complaints." 3. In interview on August 16, 2022 at 9:36 am the Laboratory Director confirmed the frequency of performance of QA monitoring was not included in the laboratory's IQCP for creatinine testing.
D5805	TEST REPORT CFR(s): 493.1291(c)

	The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of random selection of patient final test reports, test menu, and interview with personnel, the laboratory failed to include the name and address of the laboratory where testing was performed for five (5) of five (5) patients reviewed. Findings: 1. Review of the following laboratory's patient final test reports revealed the name and address of the laboratory that performed the testing was not included: Patient 1003895376 Patient 1001345214 Patient 1003893856 Patient 1003282495 Patient 1003864121 2. In interview on August 16, 2022 at 12:03 pm, the Laboratory Director confirmed the patient final test reports did not include the name and address of the laboratory that performed the testing. 3. Review of the laboratory's test menu revealed the laboratory performs 250 creatinine tests annually.
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 observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Refer to D5421.
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 observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a complete quality control program was established to assure the quality of laboratory testing. Refer to D5445.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5805.
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 record review and interview with personnel, the Laboratory Director failed to ensure complete policies and procedures for assessing personnel competency 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 record review and interview with personnel, the Laboratory Director failed

	to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to have the policy and procedure manual approved and signed by the Laboratory Director. Refer to D5407.
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: Based on review of personnel records and interview with personnel, the Laboratory Director failed to delegate, in writing, the responsibilities of Clinical Consultant. Findings: 1. Review of personnel records for the Clinical Consultant revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities to the Clinical Consultant. 2. In interview on August 16, 2022 at 10:06 am, the Laboratory Director confirmed she did not have written documentation of delegation of responsibilities to the Clinical Consultant.