Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2179455	12/16/2020
Name of Provider or Supplier	**Street Address, City, State**	
Metairie Total Health Llp	3829 Veterans Memorial Blvd, Suite 101-B, 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 December 16, 2020 at Metairie Total Health LLP, CLIA ID # 19D2179455. 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: I. Based on review of the laboratory's policies, personnel records, and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for the Technical Consultant were complete. Findings: 1. Review of the laboratory's "Personnel Competency Evaluation" policy revealed written procedures for competency assessment including frequency of performance for the Technical Consultant were not included. 2. Review of the personnel records for the Technical Consultant revealed a competency assessment for the duties of the Technical Consultant was not performed. 3. In interview on December 16, 2020 at 11:42 am, the laboratory's Co-Owner confirmed the Laboratory Director did not perform a competency assessment for the Technical Consultant. II. Based on review of the laboratory's policies and procedures, personnel competency form, and interview with personnel, the laboratory failed to ensure procedures to assess testing personnel competency were complete. Findings: 1. Review of the laboratory's "Personnel Competency Evaluation" policy revealed "Ongoing personnel competency is assessed by visual observation, adherence to written procedures, and proficiency testing performance. The laboratory director evaluates the competency of testing personnel when a new method has begun by using the Fast Pack Training Checklist. For annual

	evaluations, use the Personnel Evaluation Checklist." 2. Review of the "Personnel Evaluation Checklist" revealed the following: "Evaluate those individuals who operate the Fast Pack IP System after the first 6 months of operation; then, personnel should be evaluated annually." 3. Further review of the "Personnel Evaluation Checklist" revealed the laboratory included five (5) of the six (6) procedures as a minimal requirement for assessing the competency of personnel. 4. Further review of the "Personnel Evaluation Checklist" revealed the laboratory did not include "direct observation of performance of instrument maintenance and function checks" as a procedure to assess competency as part of the minimal requirement. 5. In interview on December 16, 2020 at 11:09 am, the laboratory's Co-Owner confirmed the laboratory's testing personnel competency assessment did not include the identified procedure.
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 policies and procedures and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not include the following: a) Comparison of test results for analytes tested on multiple instruments to include frequency and acceptability criteria 2. In interview on December 16, 2020 at 10:07 am, the laboratory's Co-Owner confirmed the laboratory did not include the identified procedure in their policy and procedure manual.
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 review of the laboratory's policies and procedures and interview with personnel, the laboratory failed to have complete policies and procedures for quality control (QC). Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not include the following written procedures: a) Quality Control: to include but not limited to corrective action to take when results do not meet acceptability criteria 2. In interview on December 16, 2020 at 11:20 am, the laboratory's Co-Owner stated he did not find a policy related to corrective actions for unacceptable QC.
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 during laboratory tour, review of the laboratory's validation records, and interview with personnel, the laboratory failed to perform complete reference range studies. Findings: 1. Observation by surveyor during the laboratory tour on December 16, 2020 at 8:59 am revealed the laboratory utilizes two (2) Qualigen Fast Pack IP Systems (0182 and 0662) for Testosterone testing. 2. Review of the laboratory's validation records revealed the following from Qualigen under "Identify the Reference Range for your Practice" section "Each laboratory should determine their own reference range appropriate for their population." 3. Further review of the laboratory's validation records for the two (2) Qualigen analyzers revealed the laboratory's documented reference range as "350 ng/dL-1000 ng /dL." The laboratory did not have documentation of testing normal donors. Validations were approved by Laboratory Director on "8/1/2020." 4. In interview on December 16, 2020 at 11:09 am, the laboratory's Co-Owner stated the laboratory's reference range came from a clinical reference. The Co-Owner stated the laboratory did not have enough patients to do a reference range study. 5. Further review of the laboratory's validation records revealed the laboratory did not have documentation of clinical reference used for reference range and verification of reference range.
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: I. Based on review of patient final reports, test menu, and interview with personnel, the laboratory failed to include the laboratory's address on patient final reports. Findings: 1. Review of patient final reports revealed the address of the laboratory performing the testing was not included. 2. In interview on December 16, 2020 at 10: 17 am, the laboratory's Medical Assistant confirmed the laboratory did not include the address on patient final reports. 3. Review of the laboratory's test menu revealed the laboratory performs 360 Testosterone tests annually. II. Based on review of patient final reports, test menu, and interview with personnel, the laboratory failed to include a second patient identifier on final reports. Findings: 1. Review of patient final reports revealed the laboratory did not include a second patient identifier. The patient reports included the patient's name. 2. In interview on December 16, 2020 at 11:09 am, the laboratory's Co-Owner confirmed the patient final reports did not include a second patient identifier. 3. Review of the laboratory's test menu revealed the laboratory performs 360 Testosterone 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.
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 review of the laboratory's test menu, patient final test reports and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Findings: 1. The laboratory failed to include the laboratory's address on patient final reports. Refer to D5805 I. 2. The laboratory failed to include a second patient identifier on final reports. Refer to D5805 II.

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 review of personnel training records, validation records, and interview with personnel, the Laboratory Director failed to ensure one (1) of One (1) Testing Personnel had training for Testosterone test prior to patient testing. Findings: 1. Review of validation records revealed the Qualigen analyzers for Testosterone testing were approved by the Laboratory Director on "8/1/2020." 2. In interview on December 16, 2020 at 10:17 am, the Medical Assistant stated the first day of patient testing was September 28, 2020. 3. Review of personnel records for the laboratory's Testing Personnel revealed the following training documents: "FastPack IP Training Checklist" and "Personnel Evaluation Checklist" dated "12-14-2020." 4. In interview on December 16, 2020 at 10:07 am, the Co-Owner stated he was unsure of why the training document was dated as being performed in December. The Co-Owner confirmed the training documents for the laboratory's Testing Personnel were not performed prior to patient testing.
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 policies and procedures for assessing personnel competency were established and maintained. Findings: 1. The laboratory failed to ensure written policies and procedures to assess competency for the Technical Consultant were complete. Refer to D5209 I. 2. The laboratory failed to ensure procedures to assess testing personnel competency were complete. Refer to D5209 II.
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 responsible for any aspect of the testing process. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to have complete policies and procedures for quality control (QC). Refer to D5403.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to have complete policies and procedures for quality control (QC). Refer to D5403. 3. The laboratory failed to include the laboratory's address on patient final reports. Refer to D5805 I. 4. The laboratory failed to include a second patient identifier on final reports. Refer to D5805 II.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to ensure performance verification studies were complete. Refer to D5421.