

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2179455	(X3) Date Survey Completed 06/29/2022
Name of Provider or Supplier Metairie Total Health Llp	Street Address, City, State 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	A Recertification survey was performed on June 29, 2022 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.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records and interview with personnel, the laboratory failed to ensure attestation statements were signed by the appropriate personnel as required for four (4) of four (4) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's 2021 and 2022 American Proficiency Institute (API) proficiency testing records revealed the laboratory's testing personnel did not sign the attestation statements for the following four (4) events: a) 2021 Chemistry Core 1st event b) 2021 Chemistry Core 2nd event c) 2021 Chemistry Core 3rd event d) 2022 Chemistry Core 1st event 2. In interview on June 29, 2022 at 12:25 pm, the owner confirmed the laboratory's testing personnel did not sign the identified attestation statements.</p>

<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>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 establish written policies for reporting SARS COV-2 results. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not have written procedures for reporting SARS COV-2 results, to include, but not limited to who is responsible, and frequency of reporting. 2. In interview on June 29, 2022 at 9:39 am, the owner confirmed the laboratory did not have a written policy for reporting SARS COV-2 results to the state.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with personnel, the laboratory failed to ensure supplies did not exceed expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on June 29, 2022 at 9:21 am revealed the following expired items: a) Hemocue Microcuvettes, Lot 2004205, Expiration date: 2022-03-28, Quantity: two (2) bottles b) Aptima Urine Specimen Collection Kit, Lot 295122, Expiration date: 2022-03-31, Quantity: one (1) kit c) Aptima Urine Specimen Collection Kit, Lot 299764, Expiration date: 2022-04-30, Quantity: three (3) kits d) BD Vacutainer C&S Transfer Straw Kit, Lot 0301561, Expiration date: 2022-04, Quantity: fourteen (14) tubes e) Hologic Aptima Swab Specimen Transfer Tube, Lot 2838112, Expiration date: 2021-10-31, Quantity: one (1) tube f) Hologic Aptima Unisex Swab Specimen Collection Kit, Lot 281228HA, Expiration date: 2021-10-31, Quantity: twelve (12) packs g) Hologic Aptima Unisex Swab Specimen Collection Kit, Lot 286751HA, Expiration date: 2022-03-31, Quantity: one (1) pack 2. In interview on June 29, 2022 at 9:33 am, Testing Personnel 2 owner confirmed the Hemocue Microcuvettes were expired. 3. In further interview on June 29, 2022 at 9:53 am, the owner stated the remaining identified items were supplies from a reference laboratory. The owner confirmed the remaining identified items were expired.</p>
<p>D5421</p>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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)</p>

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 review of the laboratory's validation records and interview with personnel, the laboratory failed to ensure the Laboratory Director documented the acceptability of the performance verification studies for the Qualigen Fast Pak Instrument (serial number 0862). Findings: 1. In interview on June 29, 2022 at 9:21 am the owner stated the laboratory received a new Qualigen Fast Pak instrument (serial number 0862) in April 2022. 2. Review of the laboratory's validation studies for the Qualigen Fast Pak Instrument (serial number 0862) revealed the Laboratory Director signed on "4/15 /2022;" however did not document if the instrument's performance was acceptable. The check box was not marked for "OK to begin testing" or "NOT OK to begin testing." 3. In interview on June 29, 2022 at 12:12 pm, the owner confirmed the acceptability of the validation studies for the new Qualigen Fast Pak instrument (serial number 0862) was not documented.

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 review of the laboratory's Individualized Quality Control Plan (IQCP) and interview with personnel, the laboratory failed to maintain a complete IQCP to support the reduction in frequency of quality control (QC) for testosterone testing. Findings: 1. The surveyor was given an email document (one page) on June 29, 2022 with the subject header "IQCP Risk Assessment and Quality Control Plan for Fastpack" which included the Laboratory Director's signature approving the plan. 2. Further review of the one page email document revealed the following parts of the IQCP were not maintained: a) Risk Assessment Plan: that included assessment of the specimen, test system, reagent, environment, and testing personnel b) Quality Control Plan c) Quality Assessment Plan 3. In interview on June 29, 2022 at 12:12 pm, the owner confirmed the laboratory did not provide the identified components for the IQCP document.

D5809

TEST REPORT

CFR(s): 493.1291(e)

The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to

clients whenever changes occur that affect the test results or interpretation of test results.

This STANDARD is not met as evidenced by:

Based on review of the United States Food and Drug Administration (FDA) Emergency Use Authorization (EUA) instructions, test menu, and interview with personnel, the laboratory failed to include "Fact Sheets" to patients for EUA SARS COV-2 tests. Findings: 1. In interview on June 29, 2022 at 9:21 am the owner stated the laboratory utilized the following SARS COV-2 test kits: a) Abbott Binax Now COVID Ag (Antigen) Card: started in June 2022 b) Quidel Quickvue SARS Ag: utilized September 2021 through April 2022 2. Review of the manufacturers' instructions revealed "Authorized laboratories * using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media." 3. In interview on June 29, 2022 at 9:33 am, Testing Personnel 1 stated the FAQ (Frequently Asked Questions) from the CDC (Center for Disease Control and Prevention) are given to patients. Testing Personnel 1 further stated if the patient does not want the printout they are told to go to the CDC's website. 4. In further interview on June 29, 2022 at 12:12 pm, Testing Personnel 1 stated she found the "Fact Sheets" for the COVID test kits in use and confirmed they were not provided to patients. 5. Review of the laboratory's test menu revealed the laboratory performs fifty (50) SARS COV-2 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 record review and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Refer to D5421.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(iii)

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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on observation by surveyor and interview with personnel, the Laboratory

	<p>Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5417.</p>
D6016	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Refer to D2015.</p>
D6020	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Refer to D5445.</p>
D6026	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8)</p> <p>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.</p> <p>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 D5809.</p>
D6031	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</p>

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 laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5401.