

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0894647	(X3) Date Survey Completed 12/14/2021
Name of Provider or Supplier Hubbell Dermatology & Aesthetics, Apmc	Street Address, City, State 309 Settlers Trace Blvd, Ste 100, Lafayette, 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 at Hubbell Dermatology and Aesthetics, APMC-CLIA ID 19D0894647 on December 14, 2021. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on observation by surveyor, review of test log, and interview with personnel, the laboratory failed to report eight (8) SARS COV-2 results to the state as required. Findings: 1. Observation by surveyor during the laboratory tour on December 14, 2021 at 9:17 am revealed the laboratory had Quidel Quickvue SARS Antigen and Sienna COVID-19 Antigen Rapid test kits. 2. Further observation by surveyor on December 14, 2021 at 9:28 am revealed a "COVID-19 Antigen Rapid Employee Test Log" taped inside the cabinet door where the SARS COV-2 test kits were stored. The "COVID-19 Antigen Rapid Employee Test Log" had eight (8) names that included date/time of test performance, test result, manufacturer of test kit utilized with lot number/expiration date, and the initials of person who read (interpreted) the result. 3. In interview on December 14, 2021 at 9:28 am, the Medical Supervisor confirmed the</p>

	<p>Sienna COVID-19 test kits were used for COVID testing of eight (8) employees. The Medical Supervisor stated she thought if the tests were not billed for it was not considered patient testing. The Medical Supervisor stated the laboratory does not report their in-house COVID test results to the state.</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 December 14, 2021 at 9:28 am, the Medical Supervisor stated the laboratory does not report their in-house COVID test results to the state. The Medical Supervisor confirmed the laboratory did not have a written policy for the reporting of positive and negative 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 and test kits did not exceed their expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on December 14, 2021 at 9:17 am revealed the following expired items: a) Quidel Quickvue SARS Antigen Test, Lot 706622, Expiration date: 2021-11-20, Quantity: one (1) kit b) Consult Diagnostics Influenza A & B Test Cassettes, Lot 449G41B, Expiration date: 2021-07-31, Quantity: one (1) kit c) Consult Diagnostics Strep A Dipstick, Lot STA905009, Expiration date: 2021-04-30, Quantity: one (1) kit d) BD Vacutainer SST blood collection tubes, Lot 030367, Expiration date: 2021-10-31, Quantity: ninety five (95) tubes 2. In interview on December 14, 2021 at 9:32 am, the Medical Supervisor confirmed the identified items were expired.</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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)</p>

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:

Review of patient final reports, test menu, and interview with personnel, the laboratory failed to include the address on patient final reports for KOH prep testing. Findings: 1. Review of the following random selection of patient final reports for KOH prep testing revealed the laboratory's address was not included: Patient 67686 Patient 65934 Patient 67876 Patient 65583 2. In interview on December 14, 2021 at 10:49 am, the Medical Supervisor confirmed the KOH prep patient final reports did not include the laboratory's address. 3. Review of the laboratory's test menu revealed the laboratory performs 100 KOH prep tests annually.

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.

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on observation by surveyor, review of test log, and interview with personnel, the Laboratory Director failed to provide overall management and direction. Refer to D6082.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

	<p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of test log, and interview with personnel, the Laboratory Director failed to ensure the laboratory reported SARS COV-2 results as required. Refer to D3000.</p>
<p>D6087</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii)</p> <p>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D5417.</p>
<p>D6106</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies 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. Refer to D5401.</p>