

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1094392	(X3) Date Survey Completed 04/14/2021
Name of Provider or Supplier Skin And Cancer Associates Llp	Street Address, City, State 17170 Royal Palm Blvd, Weston, FL	
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 completed on 4/12/2021 to 4/14/2021 at Skin and Cancer Associates LLP. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 record review and interview, the laboratory failed to report 10 Coronavirus disease 2019 (COVID-19) negative results for BD Veritor System for Rapid Detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) from 3/25/2021 to 4/8/2021. Findings Included: Review of Patient log revealed the laboratory started performing patient testing on 3/25/2021 with the BD Veritor System for Rapid Detection of SARS-CoV-2. The laboratory failed to report to the Florida Department of Health (FDOH) 10 negative COVID-19 results from 3/25/2021 to 4/8/2021. During an interview on 02/04/2021 at 1:30 pm, the laboratory director confirmed the laboratory failed to report to the FDOH 10 negative Covid-19 results from 3/25/2021 to 4/8/2021.</p>
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 record review and interview, the laboratory failed to have a step-by-step procedure for BD Veritor for Rapid Detection of SARS-COV-2 (Severe Acute Respiratory Syndrome Coronavirus 2). Findings Included: Review of the procedure manual revealed that there was no documentation of a step-by-step procedure for BD Veritor for Rapid Detection of SARS-COV-2. During an interview on 4/12/2021 at 11:00 am, the laboratory director confirmed COVID-19 testing was performed from 3/25/2021 to 4/8/2021. During an interview on 4/12/2021 at 12:24 pm, the laboratory director and laboratory manager confirmed a procedure was not created for BD Veritor for Rapid Detection of SARS-COV-2.