

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2142802	(X3) Date Survey Completed 08/25/2020
Name of Provider or Supplier Solaris Diagnostics	Street Address, City, State 110 Dewey Drive, Ste A, Nicholasville, KY	
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
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 staff interview and record review on 08/24/2020, the laboratory failed to provide documentation the laboratory reported all SARS-CoV-2 non-waived tests results to the appropriate agencies. (See D5403 and D5805)</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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</p>

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 staff interview and procedure review on 08/24/2020, the laboratory failed to ensure all Novel Coronavirus results were reported to the appropriate health department from 03/18/2020 through 08/24/2020. The findings include: 1. Patient test results were reported from 03/18/2020 through 08/24/2020. The laboratory failed to provide documentation that the results were reported to the appropriate agency. 2. Interview with the laboratory staff on 8/24/2020 at 5:08 PM confirmed that the laboratory did not have a system in place to ensure that all Novel Coronavirus (COVID-19) results were reported to the appropriate health department as required by the CARES Act Section 18115.

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 staff interview and record review on 8/24/2020, the laboratory failed to ensure the test report include the name and address of the testing facility on three (3) of three (3) patient reports from 03/18/2020 through 07/27/2020. Findings include: 1. Patient #1 report on 03/18/2020 failed to reveal the reference laboratory's name and address. 2. Patient #2 report on 07/25/2020 failed to reveal the reference laboratory's name and address. 3. Patient #3 report on 07/27/2020 failed to reveal the reference laboratory's name and address. 4. Interview with the testing staff on 8/24/2020 at 5:08 PM revealed the laboratory did not have a mechanism to ensure the reference laboratory's name and address were included in the final report from 03/18/2020 through 07/27/2020.