Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2020801	11/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Desantis Family Practice	10 3rd Avenue Ne, Suite 500, Hickory, NC	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of manufacturer's IFU (instructions for use) and interview with TP (testing personnel #1) 11/9/21, the laboratory failed to follow manufacturer's instructions for the SARS-CoV-2 testing performed to ensure authorized Fact Sheets for patients and providers were included with SARS-CoV-2 test result reports. Findings: The laboratory began testing for SARS-CoV-2 using the Quidel Sofia 2 SARS Antigen FIA test system on 1/21/21 and the Flu and SARS Antigen FIA test system on 1/22/21. 1. The laboratory failed to ensure authorized Fact Sheets for Patients and providers were included with SARS CoV2 test result reports. Review of the IFU for Quidel Sofia Flu and SARS Antigen FIA and SARS Antigen FIA revealed on page 14 "Conditions of Authorization for the Laboratory and Patient Care Settings... Authorized laboratories using your product will include with test result reports, all authorized Fact Sheets." Interview with TP#1 at approximately 10 a.m confirmed the laboratory does not provide the authorized Fact Sheet with the SARS-CoV- 2 test result reports. She stated they distribute information to patients at time of testing regarding Infection Prevention Recommendations.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 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. This CONDITION is not met as evidenced by: Based on review of SARS-CoV-2 test records, SARS-CoV- 2 reporting procedures and documentation, interview with TP(testing personnel) 11/9/21 and electronic communication with the TC(technical consultant) 11/29/21, the laboratory failed to report SARS-CoV-2 negative test results from January 2021 to November 2021 and failed to retain documentation of positive reporting records from January 2021 to September 2021. Findings: 1. Review of SARS-Cov-2 test records revealed the laboratory began testing for SARS-Cov-2 on January 21, 2021. Review of test records also revealed the laboratory had approximately 964 patients that tested negative for SARS-CoV-2 from January 21, 2021 to November 9, 2021. Electronic communication with the TC on 11/29/21 confirmed the laboratory tested a total of 1024 patients for SARS-CoV-2 from January 21, 2021 to November 9, 2021. 2. Review of the laboratory's reporting procedure revealed the laboratory only reported positive SARS-CoV-2 test results by faxing the results daily to the local health department. At approximately 9:20am 11/9/21, TP #1 confirmed the laboratory is only sending positive SARS-CoV-2 test results to the local health department. Review of the reporting documentation revealed the laboratory only had fax confirmations for the reporting of positive SARS-CoV-2 test results available to review from September 2021 to time of survey. TP #1 confirmed at approximately 2:15p.m. that there was no documentation available to show of the positive test results that were reported prior to September 2021. 3. Interview with TP #3(office manager) at approximately 2:30pm confirmed the laboratory only reported the positive SARS-CoV-2 patient test results and failed to report the negative SARS-CoV-2 patient test results.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, and review of 2019, 2020, and 2021 Hematology calibration records 11/9/21, the laboratory failed to perform and document calibration procedures on the Beckman Coulter AcT Diff 2 analyzer as required. Findings: The laboratory's Act Diff 2 Hematology Analyzer procedure states, " Calibrations are done every 6 months." Review of the 2019, 2020, and 2021

	Act Diff 2 Hematology calibration records revealed the laboratory performed a calibration on 6/25/19 and not again until 2/19/20, a gap of almost 8 months and not again until 12/4/20, a gap of 9 months.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of the 2019, 2020, and 2021 chemistry calibration verification records, and interview with TP#1(testing personnel) and TC(technical consultant) 11/9/21, the laboratory failed to perform and document chemistry calibration verification procedures every 6 months as required. Findings: The Ace Axcel Chemistry Analyzer procedure stated, "Calibration verification on the instrument is done every 6 months." Review of the 2019, 2020, and 2021 calibration verification records revealed calibration verification was performed on 9/30/19 for all analytes and not again until 5/5/20, a gap of more than 7 months. Calibration verification was performed on 11/27/20 for all analytes and again on 3/31/21. The 3/31 /21 calibration verification did not include Cholesterol, HDL Cholesterol, or Triglycerides. The calibration verification was not performed again until 11/8/21- a gap of approximately 12 months for the Cholesterol, HDL Cholesterol, and Triglycerides and a gap of more than 7 months for all other analytes. At approximately 2:15 p.m., TP#1 confirmed the 3/31/21 calibration verification did not include the Lipid analytes. The TC confirmed the 6 month calibration verifications were performed late.