Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2032923	11/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Doctors Clinical Laboratory Services	8280 Nw 27th St Ste 501, Doral, 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 conducted from 11/09/2021 to 11/12/2021 found that DOCTORS CLINICAL LABORATORY SERVICES clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following conditions were cited: -D5300. Preanalytic Systems. -D5400. Analytic Systems.
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 lack of records and interview, the laboratory failed to report 14,302 test results to Florida Department of Health (FDOH) from 06/24/2020 to 11/12/2021. The laboratory performed 2804 with rapid tests to detect Immunoglobulin G (IgG) /Immunoglobulin M (IgM) for SARS-COV-2 using Healgen and Ecotest; 10628 tests using Roche Elecsys to detect Anti-SARS-CoV-2 antibodies and 880 tests with Elecsys to detect Anti SARS CoV 2 S antibodies to the spike protein. Findings include: -The laboratory performed 14,312 tests to detect SARS-CoV-2 antibodies from 06/24/2020 to 11/12/2021: a) 10628 tests using Elecsys Anti-SARS-CoV-2 from 06/24/2020 to 11/12/2021. b) 880 tests using Elecsys to detect Anti SARS CoV 2 S from 03/30/2021 to 11/12/2021. c) 2804 tests using the rapid tests for IgG /IgM to SARS-COV-2 using Healgen and Ecotest from 07/01/2020 to 11/12/2021. -The

	laboratory had no records of reports to the FDOH for 14302 tests performed from 06/24/2020 to 11/12/2021. During an interview on 11/12/2021 at 5:00 PM, the General Supervisor explained that the laboratory reported 10 tests in July 2020, but they received a phone call from Dr JM from Department of Health on 07/23/2020, where they were told not to report the antibodies and they stopped reporting.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and interview with Laboratory Supervisor (LS), the laboratory failed to retain quality control records for the following tests: Hema Screen, ASI Mono II, AIMSTEP, Erythrocytes Sedimentation Rate (ESR), ASI Sickle Cell and ASI Rapid Plasma Reagin (RPR) Card for year 2020. Findings include: Review of Daily Quality Control (QC) records for Hema Screen occult blood, ASI Mononucleosis antibodies, AIMSTEP Pregnancy, ESR, Sickle Cell and RPR tests revealed that there were not records for 2020. During an interview on 11/12/2021 at 4:30 PM, the LS explained that the laboratory moved the records of reference to an outside storage space that the laboratory rented, they tried to locate the records of reference during the inspection, but they were not able to find them.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review, and interview, the laboratory failed to follow Qiagen QuantiFERON- Tuberculosis (TB) Gold Plus (QFT-Plus) manufacturer's instructions to ensure the quality of blood specimens prior to testing by documenting the time and date of blood specimens received and incubated from 01/01/2020 to 11/12/2021. (see D5311)
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

	This STANDARD is not met as evidenced by: Based on record review, and interview, the laboratory failed to follow Qiagen QuantiFERON- Tuberculosis (TB) Gold Plus (QFT-Plus) manufacturer's instructions to ensure the quality of blood specimens prior to testing by documenting the time and date of blood specimens received and incubated 01/01/2020 to 11/12/2021. Findings include: Review of QFT-Plus Instructions for Use stated "Tubes must be transferred to a 37 Celsius (C) 1C incubator within 2 hours. If QFT-Plus Blood Collection Tubes are not incubated at 37 C directly after blood collection and shaking, invert the tubes to mix 10 times (10x) prior to incubator at 37 C. Incubate the QFT-Plus Blood collection tubes upright at 371 C for 16 to 24 hours. In order to obtain valid results from the QFT-Plus assay, the operator needs to perform specific tasks within set times. Prior to harvesting plasma, samples in QFT-Plus Blood Collection Tubes must have been incubated at 37 C for 16-24 hours." QFT-Plus Blood Collection Tubes also contain the following controls: Nil (the negative control) and mitogen (the positive control). Review of QuantiFERON Incubator logs revealed the laboratory was not documenting the collection time and incubation in and out time for QFT blood specimens from 01/01/2020 to 11/12/2021. Review of CMS-116 Laboratory Application revealed 14,865 patients had been tested from 01/01/2021 to 11/12/2021. During an interview on 11/12/2021 at 1:00 PM, the office manager confirmed laboratory failed to follow manufacturer's instructions to ensure the quality of blood specimens prior to testing by documenting the time and date of specimen received and incubated.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory did not meet the condition for analytic systems. Findings include: -Based on observation and interview, the laboratory failed to validate the ASI Rapid Plasma Reagin (RPR) Card Test for Syphilis testing without humidifying covers during rotation time from 01/01/2020 to 11/12/2021. Refer to D5423. -Based on lack of documentation and staff interview, the laboratory failed to document and perform external positive and negative controls for Healgen Scientific LLC COVID-19 IgG/IgM Rapid Test Cassette from 07/01/2020 to 11/12/2021 and for Ecotest COVID-19 IgG/IgM Rapid Test Device from 04/08/2021 to 11/12/2021. Refer to D5449.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test

	system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to validate the ASI Rapid Plasma Reagin (RPR) Card Test test for Syphilis testing with no humidifying covers use during rotation time from 01/01/2020 to 11/12/2021. Findings include: Review of the ASI RPR Card Test Syphilis package insert approved by the Food and Drug Administration (FDA)stated that RPR cards are rotated for 8 minutes at 100 rpm on mechanical rotator with humidifying cover. During laboratory tour on 11/12/2021 at 1: 20 PM, the surveyor noticed that no humidifying cover for the RPR rotator were available in the laboratory. During an interview on 11/12/2021 at 01:50 PM, testing personnel B confirmed that the laboratory failed to validate the ASI RPR Card Test Syphilis without use of humidifyng covers as per FDA approved manufacturer guidelines for Syphilis testing from 01/01/2020 to 11/12/2021 and that the laboratory performed 8,834 RPR tests during this period of time.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory failed to document and perform external positive and negative controls for Healgen Scientific LLC COVID-19 IgG/IgM Rapid Test Cassette from 07/01/2020 to 11/12/2021 and for Ecotest COVID-19 IgG/IgM Rapid Test Device from 04/08/2021 to 11/12/2021. Findings include: Review of Manufacturer Instructions (MI) for Healgen Scientific LLC COVID-19 IgG/IgM Rapid Test Cassette and Ecotest COVID-19 IgG/IgM Rapid Test Device Quality Control for qualitative serology tests revealed that both MI recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. The laboratory performed 2804 tests from 07/01/2020 till 11/12/2021. During an interview on 11/12/2021 at 2:00 PM, with Laboratory Manager, she confirmed that the laboratory failed to follow MI to test a positive and negative control for the tests of references for the period of 07/01/2020 to 11/12/2021.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems

	identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory Quality Assessment (QA) failed to identify and correct the following deficiencies: failure to follow Qiagen QuantiFERON- Tuberculosis (TB) Gold Plus (QFT-Plus) manufacturer's instructions to ensure the quality of blood specimens prior to testing by documenting the time and date of blood specimens received and incubated from 01/01/2020 to 11/12/2021, failure to validate the ASI Rapid Plasma Reagin (RPR) Card Test for use without humidifying covers outside of the Food and Drug Administration (FDA) approved manufacturer guidelines for Syphilis testing from 01/01/2020 to 11/12/2021 and failed to document and perform external positive and negative controls for Healgen Scientific LLC COVID-19 IgG/IgM Rapid Test Cassette from 07/01/2020 to 11/12 /2021 and for Ecotest COVID-19 IgG/IgM Rapid Test Device from 04/08/2021 to 11 /12/2021. Findings include: Refer to D5311, D5421 and D5449.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director (LD) failed to ensure the Quality Assessment (QA) identified and corrected problems in analytic systems for 2 (2020 and 2021) out of 2 years reviewed. Refer to D5791.