Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2181941	04/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Doctors Of Clinical Specialties Llc	801 West Oak Street Suite 202, Kissimmee, 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	An initial certification survey was conducted from April 8, 2021 to April 9, 2021. Doctors of Clinical Specialties LLC was not in compliance with 42 CFR 493, requirements for clinical laboratories. Based on the survey findings, an Immediate Jeopardy situation was identified. The laboratory failed to perform calibration on the Beckman Coulter DxH 520 hematology instrument at least once every 6 months from 04/09/2020 to 04/08/2021 (See D5439). The laboratory failed to perform liquid quality controls on days when patient specimens were tested on the Beckman Coulter DxH 520 hematology instrument from 04/09/2020 to 04/08/2021 (See D5447). The laboratory was notified of the Immediate Jeopardy at 3:30 PM on 04/09/2021. The following Conditions were cited: D2000 Enrollment and Testing of Samples 493.801 D5400 Analytic Systems 493.1250 D6000 Moderate Complexity Laboratory Director 493.1403 D6063 Laboratory Personnel 493.1421
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to enroll in proficiency testing with an approved proficiency testing (PT) program for the specialty of hematology from 04/09/2020 to 4/8/2021. Findings: Review of the laboratory records showed there was no documentation of proficiency testing performed. The laboratory

	was performing the following hematology tests: white blood cell count (WBC), red blood cell count, hematocrit, hemoglobin, platelet count and a WBC differential. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 03/26/2021, the laboratory had an estimated annual test volume of 6,000. On 04/08/2021 at 2:38 PM, the Director of Operations stated they were not enrolled in proficiency testing.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on interview and record review, the laboratory failed to establish and follow a written procedure to access the training and competency of 3 of 3 (A, B, C) Testing Personnel. Findings: Review of the laboratory's records showed the laboratory failed to have a procedure on training and competency. The laboratory failed to maintain documentation of the initial training on the Beckman Coulter DxH 520 hematology instrument and a competency evaluation after six months. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 03/26/2021, the laboratory had an estimated annual test volume of 6,000. On 04/08/2021 at 2:38 PM, the Director of Operation stated there was no procedure for training and competency and they did not have any training documentation on the current testing personnel. On 04/08/2021 at 3:00 PM, Testing Personnel C stated when the hematology instrument was installed, training documentation was filled out on the former testing personnel and that she did not know where the training documentation was located.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish a Quality Assessment (QA) procedure for monitoring, assessing and correcting identified problems from 04/09/2020 to 04/08/2021. Findings: Review of the laboratory records showed there was no procedure on QA. According to the Application for Certification signed and dated by the Laboratory Director on 03/26/2021, the laboratory had an estimated annual test volume of 6,000. On 04/08/2021 at 4:15 PM, the Director of Operations stated they did not have a laboratory procedure manual.
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 interview, the laboratory failed to have an effective Quality Assurance (QA) plan that identified issues during the analytic phase of testing from 04/09/2020 to 04/08/2021. Findings Cross Reference D5401: Based on record review and interview, the laboratory failed to have written procedure manual for hematology testing in the laboratory from 04/09/2020 to 04/08/2021. Cross Reference D5413: Based on observation, record review and interview, the laboratory failed to record the temperatures and humidity of the room where testing was performed from 04/09/2020 to 04/08/2021. Cross Reference D5439: Based on record review and interview, the laboratory failed to perform calibration on the Beckman Coulter DxH 520 hematology instrument at least once every 6 months from 04/09/2020 to 04/08 /2021. Cross Reference D5447: Based on record review and interview, the laboratory failed to run liquid quality controls at least daily on days when patient specimens were tested on the Beckman Coulter DxH 520 hematology instrument from 04/09/2020 to 04/08/2021.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain a written procedure manual for hematology testing in the laboratory from 04/09/2020 to 04/08 /2021. Findings: Review of laboratory records showed the laboratory failed to maintain a procedure manual for the hematology testing performed in the laboratory. According to the Application for Certification signed and dated by the Laboratory Director on 03/26/2021, the laboratory had an estimated annual test volume of 6,000. On 04/08/21 at 4:15 PM, the Director of Operations stated they did not have a laboratory procedure manual.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to record the temperatures and humidity of the room where the testing was performed from 04/09/2020 to 04/08 /2021. Findings: Review of quality control documents showed there were no logs recording the temperature and the humidity of the room where the testing was performed. Review of the Beckman Coulter DxH 520 hematology instrument "Instructions for Use" manual noted the room temp should be 18 to 32 degrees Celsius (64.4 - 89.6 degrees Fahrenheit) and humidity should be a maximum of 80 percent. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 03/26/2021, the laboratory had an estimated annual test volume of 6,000. On 04/07/21 at 2:11 PM, the Director of Operations stated they did not record the temperature and humidity of the room where the testing was performed.
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 record review and interview, the laboratory failed to perform calibration on the Beckman Coulter DxH 520 hematology instrument at least once every 6 months from 04/09/2020 to 04/08/2021. Findings: Review of the laboratory records showed there was no documentation of calibrations performed on the hematology instrument after the initial validation of the instrument on 03/30/2021. Review of the patient logs showed the first day of patient testing was 04/09/2020. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 03/26/2021, the laboratory had an estimated annual test volume of 6,000. On 04/08/2021 at 2:18 PM, Testing Personnel C stated they did not perform any calibrations on the instrument.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to run liquid quality controls on days when patient specimens were tested on the Beckman Coulter DxH 520 hematology instrument from 04/09/2020 to 04/08/2021. Findings: Review of the laboratory records showed there was no documentation of liquid quality controls run on days of patient testing. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 03/26/2021, the laboratory had an estimated annual test volume of 6,000. On 04/08/2021 at 2:17 PM, Testing Personnel C stated they did not run any liquid quality controls.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to provide overall management and direction of the laboratory. Findings: Cross Reference D6015 - Based on record review and interview, the Laboratory Director failed to ensure the laboratory was enrolled in proficiency testing with an approved proficiency testing (PT) program for the specialty of hematology from 04/09/2020 to 4/8/2021. Cross Reference D6020 - Based on record review and interview, the Laboratory Director failed to ensure a quality control program was established to assure the quality of laboratory services provided from 04/09/2020 to 04/08/2021. Cross Reference D6021 - Based on record review and interview, the Laboratory Director failed to ensure a quality assessment (QA) program was established to assure the quality of laboratory services provided. Cross Reference D6031 - Based on record review and interview, the Laboratory Director failed to ensure the laboratory had written procedure manual for hematology testing in the laboratory from 04/09/2020 to 04/08/2021.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

	This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure the laboratory was enrolled in proficiency testing with an approved proficiency testing (PT) program for the specialty of hematology from 04/09/2020 to 4/8/2021. Findings: Review of the laboratory records showed there was no documentation of proficiency testing performed. The laboratory was performing the following hematology tests: white blood cell count (WBC), red blood cell count, hematocrit, hemoglobin, platelet count and a WBC differential. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 03/26/2021, the laboratory had an estimated annual test volume of 6,000. On 04/08/2021 at 2:38 PM, the Director of Operations stated they were not enrolled in proficiency testing.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure a quality control program was established to assure the quality of laboratory services provided from 04/09/2020 to 04/08/2021 Findings: The Laboratory Director failed to ensure the calibration on the Beckman Coulter DxH 520 hematology instrument be performed at least once every 6 months from 04/09/2020 to 04/08/2021. (See D5439) The Laboratory Director failed to ensure that liquid quality controls were run on days when patient specimens were tested on the Beckman Coulter DxH 520 hematology instrument from 04/09/2020 to 04/08/2021. (See D5447)
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure a quality assessment (QA) program was established to assure the quality of laboratory services provided. Findings: The Laboratory Director failed to establish a Quality Assessment (QA) procedure for monitoring, assessing and correcting identified problems from 04/09/2020 to 04/08/2021. (See D5291)
D6031	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure the laboratory had a written procedure manual for hematology testing in the laboratory from 04/09/2020 to 04/08/2021. Findings: The Laboratory Director failed to ensure the laboratory had a written procedure manual for hematology testing in the laboratory from 04/09/2020 to 04/08/2021. (See D5401)
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to verify the educational qualifications (degrees) of 3 of 3 (A, B, C) Testing Personnel. Findings: Cross Reference D6065. Based on record review and interview, the laboratory failed to verify the educational qualifications (degrees) 3 of 3 (A, B, C) Testing Personnel.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify the educational qualifications (degrees) for 3 of 3 (A, B, C) Testing Personnel. Findings: Review of the CMS 209 Laboratory Personnel Report, signed by the Laboratory Director on 04 /08/2021, showed there were 3 employees listed as moderate complexity testing personnel. Review of the laboratory records showed there was no documentation of

	the degrees for the testing personnel available for review. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 03/26/2021, the laboratory had an estimated annual test volume of 6,000. On 04/09/2021 at 3:35 PM, Testing Personnel C stated she would have to get the degrees from Human Resources.