Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0697355	06/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
G Alexander Carden Md Pa & David W Dodson Md Pa	1411 N Flagler Dr Ste 7900, West Palm Beach, 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 conducted on 06/06/2023 to 06/28/2023 at G Alexander Carden MD PA and David W Dodson MD PA. The laboratory was not in compliance with 42 CFR 493, Requirements for Clinical Laboratories. Based on the survey findings, an Immediate Jeopardy situation was identified and the laboratory was notified at 1:00 PM on 06/14/2023. The following Condition was not met: D5200 - General Laboratory System 493.1230 D5400 - Analytic System 493.1250 D6000 - Moderate Complexity Laboratory Director 493.1403
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the Laboratory Personnel Report, proficiency testing (PT) records and interview, the laboratory failed to have all testing personnel rotate through performance of proficiency testing (PT) in the specialty of Hematology for six of six (2021 2nd, 3rd, 2022 1st, 2nd, 3rd and 2023 1st) events. Findings Included: Review of the Laboratory Personnel Report, signed and dated by the Laboratory Director on 06 /03/2023, listed two testing personnel (Testing Person A [TP-A] and Testing Person B [TP-B]). Review of the PT records from American Proficiency Institute (API) showed all the PT attestation forms were signed by Testing Person A (TP-A) as the "Person Performing Test" for the hematology PT for 2021 2nd, and 3rd event, 2022 1st, 2nd, 3rd event, and 2023 1st event. On 06/06/2023 at 11:49 AM, TP-A confirmed that TP-B performed patient testing on the hematology analyzer and did not participate in any PT testing.

D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of competency evaluation records, the procedure manual, the laboratory's plan of correction from the 2021 recertification survey, and interview, the laboratory failed to monitor and evaluate the overall quality of the general laboratory system and correct identified problems as evidenced by a lack of competency assessment documentation for two of two Testing Personnel (A, B) for one (2022) out of two years (2022 -2023) reviewed (See D5209).
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 review of the Laboratory Personnel Report, the procedure manual, competency evaluation records, the previous recertification survey plan of correction and interview, the laboratory failed to document the competency assessment for two of two Testing Personnel (A, B) for one (2022) out of two years (2022 - 2023) reviewed. This is a repeat deficiency from the recertification survey conducted 06/03 /2021. Findings Included: Review of the Laboratory Personnel Report, signed and dated on 06/03/2023 by the Laboratory Director, showed there were two Testing Personnel (A, B) listed on the report. Review of the procedure titled "Performance /Competency Testing" noted, "The purpose of the testing is to assess the qualifications and performance of the laboratory testing staff on an annual basis." Review of competency evaluations showed evaluations were performed in 2021 and 2023. On 06 /06/2023 at 2:57 PM, Testing Person A confirmed no competency evaluations were conducted in 2022. Review of the laboratory's accepted plan of correction from the recertification survey conducted on 06/03/2021 (signed by the Laboratory Director on 06/28/2021) revealed "5) We [the laboratory] will continue to perform these evaluations and competencies every year from this point forward. 6) The testing personnel and Lab Director will closely review, and monitor all personnel qualifications, and make sure the personnel evaluations and competencies are done on an annual basis. As a reminder this will be added as an item on our Maintenance log with the date of the next evaluations due." The completion date for D5209 was 06/21 /2021.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)

	At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory test menu, lack of documentation of twice annual verification of accuracy, and interview, the laboratory failed to verify the accuracy of twenty-one pathogens at least twice annually from 07/03/2021 to 12/31/2022. Findings Included: Review of the test menu provided with Clinical Laboratory Improvement Amendment (CLIA) Application for Certification indicated the following pathogens were tested on the QIAstat DX analyzer: Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus A & B, Influenza A, Influenza A H1, Influenza A H1N1 pdm09, Influenza A H3, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus A & B, Rhinovirus/Enterovirus, SARS-CoV-2 (Severe acute respiratory syndrome coronavirus 2), Bordetella pertussis, Chlamydia pneumoniae, and Mycoplasma pneumoniae. On 06/06/2023 at 11:46 AM, Testing Person A confirmed the laboratory had not participated in proficiency testing or verified the accuracy of their test method twice annually.
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 review of the Clinical Laboratory Improvement Amendment (CLIA) Application (Form-CMS 116), instrument verification, quality control (QC) records, Instructions for Use of the QIAstat-DX Respiratory SARS-CoV-2 Panel, and interview, the laboratory failed to run two levels of controls for the analytes Apolipoprotein (APO) A and APO B on each day of patient testing from 08/09/2021 to 06/06/2023 (See D5447), and failed to document and perform external positive and negative controls for the QIAstat-DX Respiratory SARS-CoV-2 Panel performed on the QIAstat DX analyzer for 299 patients from 07/31/2021 to 06/07/2023 (See D5449).
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 review of instrument verification, quality control (QC) records, usage report, and interview, the laboratory failed to run two levels of controls for the analytes Apolipoprotein (APO) A and APO B on each day of patient testing from 08/09/2021 to 06/06/2023. Findings Included: Review of the Ortho Clinical Diagnostic Vitros 5600 analyzer showed the instrument verification was completed on 08/09/2021. Review of the daily QC for November 2021, July 2022 and May 2023 showed only one level of controls were run for the analytes APO A and APO B. Review of the laboratory's usage report revealed 1089 patients were reported for APO A and 1246 patients for APO B between 08/09/2021 and 06/06/2023. On 06/06/2023 at 5:30 PM, Testing Person A confirmed only one level of controls were run for the analytes APO A and APO B.
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 review of the Clinical Laboratory Improvement Amendment (CLIA) Application (Form-CMS 116), the QIAstat-DX Respiratory SARS-CoV-2 Panel Instructions for Use, lack of quality control records, and interview, the laboratory failed to document and perform external positive and negative controls for the QIAstat-DX Respiratory SARS-CoV-2 Panel performed on the QIAstat DX analyzer for 299 patients from 07/31/2021 to 06/07/2023. Findings Included: Review of the Form-CMS 116 dated and signed by the Laboratory Director on 06/03/23 revealed the following pathogens were tested on the QIAstat DX analyzer: Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus A & B, Influenza A, Influenza A H1, Influenza A H1N1 pdm09, Influenza A H3, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus A & B, Rhinovirus/Enterovirus, SARS-CoV-2, Bordetella pertussis, Chlamydia pneumoniae, and Mycoplasma pneumoniae. Review of the QIAstat-DX Respiratory SARS-CoV-2 Panel Instructons for Use noted "External controls are not provided with the QIAstat-DX Respiratory SARS-CoV-2 Panel. Quality control requirements should be performed in conformance with local, state and/or federal regulations . . . ." Review of the quality control records for the laboratory revealed there were no records of external controls being performed on the QIAstat DX analyzer. On 06/06/2023 at 4:40 PM, Testing Person A stated she did not run external controls. On 06/07/2023 at 10:50 AM, Testing Person A stated they did not have an IQCP (Individualized Quality Control Plan).
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 review of the Clinical Laboratory Improvement Amendment (CLIA) Application (Form-CMS 116), quality control (QC) records, Instructions for Use of the QIAstat-DX Respiratory SARS-CoV-2 Panel, and interview, the Laboratory Director failed to ensure a quality control program was established and maintained to ensure the quality of laboratory services provided for 299 patients from 07/31/2021 to 06/07/2023 (See D6020).
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 review of the Clinical Laboratory Improvement Amendment (CLIA) Application (Form-CMS 116), quality control (QC) records, Instructions for Use of the QIAstat-DX Respiratory SARS-CoV-2 Panel, and interview, the Laboratory Director failed to ensure a quality control program was established and maintained to ensure the quality of laboratory services provided from 07/31/2021 to 06/07/2023. Findings Included: The Laboratory Director failed to identify that the laboratory did not run two levels of controls for the analytes Apolipoprotein (APO) A and APO B on each day of patient testing from 08/09/2021 to 06/06/2023 (See D5447). The Laboratory Director failed to identify that the laboratory did not document and perform external positive and negative controls for the QIAstat-DX Respiratory SARS-CoV-2 Panel performed on the QIAstat DX analyzer for 299 patients from 07 /31/2021 to 06/07/2023 (See D5449).