Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2320450	12/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Gabriel Domenech Md Pa	201 Nw 82 Avenue Suite 201, Plantation, 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 announced CLIA initial survey was conducted from 12/09/2025 to 12/12/2025 at GABRIEL DOMENECH MD PA. The laboratory was not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D2000 493.801 -Condition: Enrollment and Testing of Samples D6000 493.1403 - Condition: Moderate Complexity Laboratory Director
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 lack of records and staff interview, the laboratory failed to enroll in a Proficiency Testing (PT) program approved by the Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) for Hematology Specialty since April 2025. Findings included: 1-Review of test menu listed on Form CMS-116 signed by Laboratory Director on 12/08/2025, the laboratory performed the following tests: White Blood Cell count (WBC), Red Blood Cell count (RBC), Hematocrit, Hemoglobin (HG), Platelet (PLT), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC) and Red Cell Distribution Width (RDW-SD) with an annual estimated test volume of 1,200 tests. 2-The laboratory had no PT records for 2025. 3-During an interview on 12/09/2025 at 12:30 PM, Testing Personnel (TP) #1 stated that

	the laboratory did not have any records and asked for more time to verify with the Laboratory Director that was not available. On 12/12/2025 via email TP#1 confirmed that the laboratory failed to enroll in PT during 2025.
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 lack of procedure manual and staff interview, the laboratory failed to establish written policies and procedures to assess Testing Personnel during 2025. Findings included: 1-Review of the Form CMS-209 signed by the Laboratory Director (LD) in 12/08/2025, revealed that the LD was also the Clinical Consultant (CC) and Technical Consultant (TC) and the laboratory had two Testing Personnel (TP#1 and TP#2). 2-The laboratory did not have a Personnel Policy to assess Testing Personnel during 2025. 3-Review of personnel records revealed the following: a) Laboratory Orientation Checklist for TP#1 and TP#2 had a completion date of 02/26/2025 and was not signed. b) Employee Performance Evaluation (EPE) form for TP#1 with date 08/14/2025 and signed by TP#2 and EPE for TP#2 with date 08/14/2025 signed by TP#1 c).EPE for TP#1 and TP#2, did not include the six required procedures and failed to list the CLIA related tasks and Technical Consultant failed to sign them. 4-During an interview on 12/09/2025 at 10:45 AM, TP#1 confirmed that the laboratory failed to establish written policies to assess Testing Personnel and that the TC failed to sign the Orientation Checklist and the EPE.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 staff interview, the laboratory failed to develop a procedure manual that addresses the required procedures for the Hematology Specialty testing during 2025. Findings included: 1-The laboratory documentation available for the Hematology specialty was the Sysmex XN-330 user manual. 2-Review of laboratory records, showed there was no procedure manual for the hematology testing doing a Complete Blood Count. 3-Review of Form CMS-116 signed by the Laboratory Director on 12/08/2025, revealed that the laboratory had an estimate annual test 1,200 tests. 4-During an interview on 12/09/2025 at 11:A5 PM, Testing Personnel #1 confirmed that the laboratory failed to develop a procedure manual for the hematology testing.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 staff interview, the laboratory failed to monitor room humidity and temperature to ensure optimal operation for the Sysmex XN-330 Analyzer during 2025. Findings included: 1-Review of Sysmex XN-330 Hematology Analyzer manual revealed a requirement for optimal operation a range of room temperature of 15 to 35 C and Humidity between 20 to 85 %. 2-Review of temperature log for 2025 revealed that the laboratory failed to monitor daily the room temperature and humidity during 2025. 3-During an interview on 12/09/2025 at 11:30 AM, Testing Personnel #1 confirmed that there was no documentation of the room temperature and humidity for the period of reference.
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. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have an effective Quality Assessment (QA) policy to monitor the laboratory performance and implement corrective actions during 2025. Findings included: 1-Review of laboratory records revealed that the laboratory failed to establish and follow a Quality Assessment Policy. 2- Review of Laboratory Quality Assurance form with date 08/14 /2025 and signed by testing Personnel #1, revealed that the laboratory failed to record if there was any incidence in the laboratory, at that time the laboratory was not enrolled in proficiency testing (See D6015) and was not monitoring room temperature and Humidity (See D5413). 3-Review of Monthly Quality Assurance form with date September 2025 and with no signature, revealed that the laboratory failed to record if the laboratory followed the personnel policies or not, if proficiency testing policies were followed or not, and if the pre analytic and analytic policies were followed or not. 4-During an interview on 12/09/2025 at 11:55 AM, the Testing Personnel #1 confirmed that the laboratory failed to have an effective QA policy.
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 staff interview, the laboratory director (LD) failed to effectively oversee the laboratory since April 2025. Findings included: -Failed to ensure the laboratory enrolled in proficiency testing during 2025. (See D6015). -Failed to ensure the laboratory established and followed a Quality Assessment policy. (See D6020) -Failed to ensure the laboratory the laboratory had a policy to assess personnel competencies and failed to ensure the laboratory testing personnel had a competency evaluation. (See D6028) -Failed to ensure the laboratory the personnel had access to an approved procedure manual. (See D6031).
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on lack of records and staff interview, the Laboratory Director (LD) failed to ensure that the laboratory enrolled and participated in Proficiency Testing (PT) for the hematology specialty since April 2025. Findings included: 1-Review of Form CMS-116, signed by the Laboratory Director on 12/08/2025, revealed that the laboratory was doing the following tests: White Blood Cells, Red Blood Cells, Hemoglobin, Hematocrit, Mean Corpuscular Volume, Mean Corpuscular Hemoglobin, Mean Corpuscular Hemoglobin Concentration, Red Cell Distribution Width-Standard Deviation, Red Cell Distribution Width - Coefficient Variation, Platelets, Mean Platelet Volume and White Blood Cell Differential. The annual estimated volume was 1,200 tests. 2-The laboratory had no proficiency testing records for 2025. 3- Via email on 12/12/2025, Testing Personnel #1 confirmed that the LD failed to ensure the laboratory was enrolled in PT since April 2025.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and 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 staff interview, the Laboratory Director (LD) failed to ensure Quality Assessment (QA) policy was established and followed since April 2025 (See D5791).
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) (e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to ensure the laboratory had a personnel policy to assess competency of testing personnel since April 2025. (See D5209)
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to ensure the laboratory had an approved procedure manual available to all personnel. (See D5403)