Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0895075	04/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Vega Alta Community Health	Carretera Numero 2, Km 31'9, Vega Alta, PR	

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
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on Mycoplasma pneumoniae quality control records patient records review (2019-2021) and interview with the laboratory general supervisor on April 14, 2021 at 11:20 AM, it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. The finding includes: 1. The laboratory did not include each day of testing a negative and a positive control materials when patients serum specimens were tested for qualitative Mycoplasma IgM by the Immuno Card Mycoplasma method. Refer to : 5449- The laboratory did not include positive and negative control material
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on quality assessment procedure manual and quality assessment records review (2019-2020) and laboratory general supervisor interview on April 14, 2021 at 10:10 A. M., it was determined that laboratory failed to monitor and evaluate the following QA activities: test request. The findings include: a. Review of the quality assessment

	procedure manual showed that evaluations to laboratory test request must be performed every three months. b. Review of the quality assessment records showed that the last evaluations to test requisitions was performed in December 2019. c. The laboratory general supervisor confirmed on April 14, 2021 at 10:15 A.M. that evaluations to test requisitions were not performed since December 2019.
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 Mycoplasma pneumoniae IgM quality control results (2019-2021) , patient test results records and interview with the laboratory supervisor on April 14, 2021 at 11:20 AM, it was found that the laboratory did not include a positive and a negative control material each day of patient testing. The findings include: 1. The laboratory began to perform patient's test for Mycoplasma pneumoniae on November 2019. 2. Review of the quality control and patient test results records showed that positive and negative controls were included when a new reagent box was opened. 3. The mycoplasma quality control records (2019-2021) and patient test results records showed that from November 2019 to April 2021 the laboratory processed and reported 468 mycoplasma IgM . 2019-28 patient 2020-380 patient 2021 -60 patient 4. The laboratory supervisor stated on April 14, 2021 at 11:30A.M., that they included a negative and a positive control material when a new reagent box was opened and documented the procedural control with each patient.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on quality assessment procedures manual, quality assessment records review (2019-2020) and laboratory general supervisor interview on April 14, 2021 at 10:10 A. M., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for post-analytic systems. The findings include: a. Review of the quality assessment program showed that evaluations to turn around time (TAT) must be evaluated every three months. b. Review of the quality assessment records showed that the last turn around time evaluation was performed in March 2019. c. The laboratory general supervisor confirmed on April 14, 2021 at 10:30 A.M. that turn around time evaluations were not performed since March 2019.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441

	The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on general immnunology quality control records review (2019-2021) and laboratory supervisor interview on April 14, 2021 at 11:30 A.M., it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control requirements. Refer to D6093
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 general immunology quality control record review from November 2019 to April 2021 and laboratory general supervisor interview on April 14, 2021 at 11:45 A. M. it was determined that the laboratory director failed to ensure compliance with the requirement for analytic systems. The finding includes: 1. The laboratory did not include a positive and a negative control material when performed Mycoplasma IgM each day of patient testing. Refer to 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 Quality Assessment (QA) records review (2019-2020) and laboratory general supervisor interview on April 14, 2021 at 10:00 A.M, it was determined that laboratory failed to ensure compliance with quality assessment (QA) requirements. The findings include: 1. Quality Assessment records showed that the laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the requirements for preanalytic and postanalytic systems. 2. The laboratory general supervisor confirmed on April 14, 2021 at 10:00 A.M, that the laboratory failed to evaluate the requirements for preanalytic and postanalytic systems. Refer to D5391 and D5891.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

	This STANDARD is not met as evidenced by: Based on general immunology quality control record review from November 2019 to April 2021 and laboratory general supervisor interview on April 14, 2021 at 11:45 A. M. it was determined that the laboratory general supervisor failed to ensure compliance with the requirement for analytic systems. The finding includes: 1. The laboratory did not include a positive and a negative control material when performed Mycoplasma IgM each day of patient testing. Refer to D5449.