Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658231	04/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hospital Pavia Yauco	Road 128 Po Box 68, Yauco, 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
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on test requisition records review and laboratory director interview on April 23, 2019 at 1:45 PM, it was determined that the laboratory failed to ensure that 25 out of 25 test requisitions have the date and time of specimen collection from April 18, 2019 to April 23, 2019. The findings include: 1. On April 23, 2019 at 1:45 PM, the tests requisition records showed that the laboratory did not include the date nor time of specimen collection in 25 out of 25 test requisitions from April 18, 2019 to April 23, 2019: #159669, #102876, #163775, #102056, #116126, #55674, #52932, #52932, #45796, #98069, #19511, #174986, #6330, #83258, #30021, #55211, #54693, #5318819, #21040, #70227, #101745, #190194, #T000054693, #19511, #20889, 2. The laboratory director confirmed on April 23, 2019 at 1:45 PM, that those tests requisitions did not include the date nor time of specimen collection in the laboratory test requisitions.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the Rapidlab 1200 Operator's Guide, preventive maintenance records (years 2018 and 2019) review and interview with the laboratory director on April 23, 2019 at 2:15 PM, it was determined that the laboratory failed to follow manufacturer's instruction for the preventive maintenance of the Rapidlab 12000 system from August 1, 2018 to April 23, 2019. The findings include: 1. The laboratory processed and reported the patients blood gases specimens by the Rapidlab 12000 system. 2. On April 23, 2019 at 2:15 PM, the Rapidlab 1200 Operator's Guide was reviewed, the manufacturer instructed the laboratory to check every day the barometer calibration of the Rapidlab 1200 system. 3. The preventive maintenance records of the Rapidlab 12000 system showed that the laboratory did not check every day the the barometer calibration from August 1, 2018 to April 23, 2019. 4. The laboratory processed and reported 2, 710 out of 2,710 patients blood gases specimens by the Rapidlab 1200 system from August 1, 2018 to April 23, 2019.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on syphilis serology and general serology testing records(years 2017, 2018 and 2019) review and interview with the testing personnel in charge of the syphilis serology and general serology tests on April 23, 2019 at 11:40 AM, it was determined that the laboratory failed to include at least once a day, a control material with tittered reactivity when 4 out 4 patients specimens were tested and reported for syphilis serology by rapid plasma reagin (RPR) and Rheumatoid Factor (RA) quantitative tests from January 8, 2019 to February 7, 2019. The findings include: 1. On April 23, 2019 at 11:40 AM, the syphilis serology and general serology testing records showed that the laboratory did not include at least once a day, the control material with tittered reactivity when 4 out 4 patients specimens were tested and reported for RPR and RA quantitative tests from January 8, 2019 to February 7, 2019: Date patients Quantitative processed specimens tests 01/08/2019 6300094 RPR 01/22/2019 207655 RA 01/22 /2019 T5312 RA 02/07/2019 227396 RPR 2. The testing personnel stated on April 23, 2019 at 11:40 AM, that the quality control procedures were performed but not recorded.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)

	(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on the Rapidlab 1200 Operator's Guide, preventive maintenance records (years 2018 and 2019), syphilis serology and general serology testing records(years 2017, 2018 and 2019) review, interview with laboratory director and testing personnel on April 23, 2019 at 2:15 PM, it was determined that the technical consultant failed to comply with the requirements for analytic systems. The findings include: 1. Refer to D 5429 (The laboratory failed to follow manufacturer's instruction for the preventive maintenance of the Rapidlab 12000 system from August 1, 2018 to April 23, 2019) 2. Refer to D 5451 (The laboratory failed to include at least once a day, a control material with tittered reactivity when 4 out 4 patients specimens were tested and reported for RPR and RA quantitative tests from January 8, 2019 to February 7, 2019).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on test requisition records review and laboratory director interview on April 23, 2019 at 1:45 PM, it was determined that the laboratory director failed to ensure that the laboratory include the date and time of specimen collection in 25 out of 25 laboratory test requisition from April 18, 2019 to April 23, 2019. Refer to D 5305 (The laboratory did include the date nor time of specimen collection in 25 out of 25 test requisition from April 18, 2019 to April 23, 2019: #159669, #102876, #163775, #102056, #116126, #55674, #52932, #52932, #45796, #98069, #19511, #174986, #6330, #83258, #30021, #55211, #54693, #5318819, #21040, #70227, #101745, #190194, #T000054693, #19511, #20889).
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 the Rapidlab 1200 Operator's Guide, preventive maintenance records (years 2018 and 2019), syphilis serology and general serology testing records(years 2017, 2018 and 2019) review, interview with laboratory director and testing personnel on April 23, 2019 at 2:15 PM, it was determined that the laboratory director failed to comply with the requirements for analytic systems. The findings include: 1. Refer to D 5429 (The laboratory failed to follow manufacturer's instruction for the preventive maintenance of the Rapidlab 12000 system from August 1, 2018 to April 23, 2019) 2. Refer to D 5451 (The laboratory failed to include at least once a day, a control material with tittered reactivity when 4 out 4 patients specimens were tested and reported for RPR and RA quantitative tests from January 8, 2019 to February 7, 2019).
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on the Rapidlab 1200 Operator's Guide, preventive maintenance records (years 2018 and 2019), syphilis serology and general serology testing records(years 2017, 2018 and 2019) review, interview with laboratory director and testing personnel on April 23, 2019 at 2:15 PM, it was determined that the testing personnel failed to follow quality control procedures. The findings include: 1. Refer to D 5429 (The laboratory failed to follow manufacturer's instruction for the preventive maintenance of the Rapidlab 12000 system from August 1, 2018 to April 23, 2019) 2. Refer to D 5451 (The laboratory failed to include at least once a day, a control material with tittered reactivity when 4 out 4 patients specimens were tested and reported for RPR and RA quantitative tests from January 8, 2019 to February 7, 2019).