Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2241653	10/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Hpm Vieques	Calle Benitez Guzman # 47, Vieques, 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
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 endocrinology quality control records review (august 2, 2022 to october 13, 2022) and interview with the laboratory director, it was determined that the laboratory failed to include a negative and positive control material when performed hCG (Human Chrorionic Gonadotropin) tests. The finding include : 1. Endocrinology quality control logs were reviewed from August 2, 2022 to October 13, 2022. 2. Review of records on October 13, 2022 at 11:20 a.m. showed that the laboratory did not include a positive nor a negative control material when patient's test were performed on: September 22, 2022 - patient number 549523 October 11, 2022 - patient numbers: 5689636, 569113 3. The laboratory director confirmed on october 13, 2022 at 11:30 a.m. that the laboratory failed to include a negative and positive control material when performed hCG (Human Chrorionic Gonadotropin) tests.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units

	of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on laboratory test reports records review (August - October 2022) and laboratory director interview on October 13, 2022, it was determined that the laboratory failed to indicate the name and address of the laboratory location where the test was performed in the 100 per cent of the tests results reported by the laboratory information system from August 2, 2022 to October 11, 2022: hematology, endocrinology, urinalysis, syphilis serology and general immunology. The findings include: 1. The laboratory names is HPM Vieques, Clia number is 40D2241653, address: Calle Benitez Guzmn # 47, Vieques, P.R. and state license number is 1414. (review on 10/13/22 at 10:50 a.m.) 2. On October 13, 2022 at 10:55 A.M., the 100 per cent of the laboratory tests results (hematology, endocrinology, urinalysis, syphilis serology and general immunology) reported by the laboratory information system showed as the laboratory name the following laboratory information in those results reports : laboratory name: Health Promed address : Ave Borinquen 20220, San Juan, P.R. 00915 Clia number : 40D2117678 License : 1347 3. The laboratory performed and reported the following patients samples since the laboratory began to performed patient samples on August 2, 2022 syphilis serology-12 general immunology-6 urinalysis-49 endocrinology-3 hematology-65 3. The laboratory director confirmed on October 13, 2022 at 11:30 A.M., that those patient samples were performed in HPM Vieques, however, the laboratory information system had not been updated yet.
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 endocrinology quality control records review (august to october 2022) and laboratory director interview on october 13, 2022 at 11:30 AM, it was determined that laboratory failed to ensure compliance with the requirements for analytic systems. Refer to D5449.