Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0952483	04/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Central Ii	Ave Font Martelo # 350, Humacao, 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
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 observation, patient's final tests results records (years 2017-2019), CLIA Certificate of Compliance review, reference laboratory patient's tests review and laboratory director interview on April 10, 2019 at 11:00 AM, it was found that the laboratory processed and reported a patient sample for HA1C (glycosylate haemoglobin) although the laboratory was not certified for routine chemistry subspecialty. The findings include: 1.Review of patient's results records from May 2017 to February 2019, showed a patient result JMNG (Id #002237-000) with HA1C in 6.00% on September 10, 2018 at 10:08 AM. This sample was taken on September 10, 2018 at 6:52 AM. 2.Review of the CLIA Certificate of Compliance showed that the laboratory was not certified to perform routine chemistry tests. 3.The laboratory director stated during interview on April 10, 2019 at 11:00 AM that the laboratory reported a patient sample for HA1C (JMNG Id #002237-000) on September 11, 2018 at 10:08 AM for Dimension Xpand Plus chemistry instrument. 4.The instrument Dimension Xpand Plus was observed at the facility, the laboratory director stated on April 10, 2019 at 11:00 AM that the laboratory did not perform routine chemistry patient's samples tests since August 2016. 5.This laboratory refers patient's samples from tests that do not perform in their laboratory to Laboratorio Clnico de Referencia

	M. Landrn, Inc. 6.Review the lists of samples referred to the reference laboratory on September 10, 2018, the laboratory no evidence was found that this test was referred to the Laboratorio Clnico de Referencia M. Landrn, Inc. For that patient JMNG on September 10, 2018 only the following tests were reported CMP (Comprehensive Metabolic Panel), Lipid panel, Microalbumin y TSH (Thyroid Stimulating Hormone). 7.The laboratory did not perform the daily preventive maintenance of the Dimension Xpand Plus routine chemistry instrument. 8.The laboratory did not perform the daily quality control of the Dimension Xpand Plus routine chemistry instrument. (HA1C) 9. The laboratory did not participate in a Puerto Rico Proficiency Testing Program for this test. (HA1C)
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 (QA) records review (years 2017-2019) and laboratory director interview on April 10, 2019 at 11:00 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for post-analytic systems. (test report) The findings include: 1. Review of the laboratory quality assessment manual showed that the laboratory establishes twice a year assessment for each post-analytic system process to keep track the laboratory performance. 2. From May 2017 to March 2018, showed that the laboratory processed and reported a patient sample for HA1C (glycosylate haemoglobin) although the laboratory was not certified for routine chemistry subspecialty. Refer to D5805.
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 (years 2017-2019) and laboratory director interview at 11:00AM on April 10, 2019, it was determined that laboratory director failed to ensure compliance with quality assessment (QA) requirements. Refer to DD5891.