Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2006076	08/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Cibuco Inc	Road 159 Km 7 Hm 5, Corozal, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on Access 2 system validation records(years 2017 and 2018), annual volume records(years 2017 and 2018) review and technical consultant interview on August 16, 2018 at 9:15 AM, it was determined that the laboratory failed to verify the reference interval (normal values) are appropriate for the laboratory population before reporting the following patient test results by the Access 2 system from September 1, 2017 to August 15, 2018: thyroid stimulation hormone (TSH), thyroxin (T4), triiodothyroxine (T3), free thyroxin (free T4), prostatic specific antigen (PSA) and vitamin D (vit D). The findings include: 1. The laboratory performed the validation of the following tests by Access 2 system: T4, T 3, free T4, PSA and vitamin D on August 15, 2017 and TSH on May 5, 2018. 2. On August 16, 2018 at 9:15 AM, the Access 2 system validation records showed that the laboratory did not verify that the reference interval (normal values) of the following tests T4, T 3, free T4, PSA, vit D and TSH are appropriate for the laboratory population. 3. The technical consultant confirmed on on August 16, 2018 at 9:25 AM, that the laboratory did not verify the reference range of those tests before reporting. 4. The laboratory processed and reported the following tests by the Access 2 system: a. From June 1, 2018 to August

	15, 2018: 528 patients TSH specimens. b. From September 1, 2017 to August 15, 2018: 250 patients T4 specimens, 326 patients T4 free specimens, 153 patients T 3 specimens, 536 patients PSA specimens and 592 patients vit D specimens.
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 Access 2 system validation records(years 2017 and 2018), annual volume records(years 2017 and 2018) review and technical consultant interview on August 16, 2018 at 9:15 AM, it was determined that the technical consultant failed to ensure compliance with the analytic system requirements. Refer to D 5421 (The laboratory did not verify the reference interval (normal values) are appropriate for the laboratory population before reporting the following patient test results by the Access 2 system from September 1, 2017 to August 15, 2018).
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 Access 2 system validation records(years 2017 and 2018), annual volume records(years 2017 and 2018) review and technical consultant interview on August 16, 2018 at 9:15 AM, it was determined that the laboratory director failed to comply with the analytic system requirement. Refer to D 5421 (The laboratory did not verify the reference interval (normal values) are appropriate for the laboratory population before reporting the following patient test results by the Access 2 system from September 1, 2017 to August 15, 2018).