

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2157736	(X3) Date Survey Completed 12/01/2020
Name of Provider or Supplier Laboratorio Clinico Inter Metro	Street Address, City, State Ave Las Cumbres Int Calle Santa Rosa #1, San Juan, 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	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p> <ol style="list-style-type: none"> Based on review of validation records of the Architect C4000 system and laboratory director interview on December 01 2020 at 1:00 PM, it was determined that the laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting the following patients results from July 01, 2020 to October 31, 2020: 8 out of 8 Basic Metabolic Panel(BMP), 128 out of 128 Comprehensive Metabolic Panel (CMP) and 94 out of 94 Lipid Panel. The findings include: a. The Architect C4000 system system validation records showed that the laboratory performed the validation procedures for BMP, CMP and Lipid panel tests on January 18, 2020. However, the laboratory did not verify for those tests that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting patients results from July 01, 2020 to October 31, 2020. b. The laboratory director confirmed on December 01 2020 at 1:00 PM, that the laboratory did not verify that the manufacturer's reference intervals (normal values) for BMP, CMP and lipid profile tests before reporting patients results. Also stated that the laboratory did not establish a protocol to perform the require performance characteristic verification. c. The laboratory processed and reported the following patients results from July 01, 2020 to

October 31, 2020: 8 BMP, 128 CMP and 94 Lipid Panel tests. 2. Based on review of validation records of the Architect i1000 system and laboratory director interview on December 01 2020 at 1:00 PM, it was determined that the laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting the following patients results from July 01, 2020 to October 31, 2020: 30 out of 30 carcinoembryonic antigen (CEA), 27 out of 27 Vitamin D Hydroxy, 51 out of 51 thyroxine (T4) total, 15 out of 15 T4 Free, 86 out of 86 thyroid stimulating hormone (TSH) and 46 out of 46 triiodothyronine (T3) uptake. The findings include: a. The Architect i1000 system system validation records showed that the laboratory performed the validation procedures for CEA, Vitamin D 25 Hydroxy, T4 total, T4 Free, TSH and T3 uptake tests on January 18, 2020. However, the laboratory did not verify for those tests that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting patient results from July 01, 2020 to October 31, 2020. b. The laboratory director confirmed on December 01 2020 at 1:00 PM, that the laboratory did not verify that the manufacturer's reference intervals (normal values) for CEA, Vitamin D 25 Hydroxy, T4 total, T4 Free, TSH and T3 uptake tests tests before reporting patients results. Also stated that the laboratory did not establish a protocol to perform the require performance characteristic verification. c. The laboratory processed and reported the following patient results from July 01, 2020 to October 31, 2020: 30 CEA, 27 Vitamin D Hydroxy, 51 T4 total, 15 T4 Free, 86 TSH and 46 T3 uptake tests. 3. Based on review of validation records of the Cell Dyn Ruby system for complete cell count (CBC) test and laboratory director interview on December 01 2020 at 1:00 PM, it was determined that the laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 184 out of 184 patients specimens for CBC tests from July 01, 2020 to October 31, 2020. The findings include: a. The Cell Dyn Ruby system validation records showed that the laboratory performed the validation procedures for CBC tests on November 20, 2019. However, the laboratory did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 184 CBC's patients results from July 01, 2020 to October 31, 2020. b. The laboratory director confirmed on December 01 2020 at 1:00 PM, that the laboratory did not verify that the manufacturer's reference intervals (normal values) for the CBC tests before reporting patients results. Also stated that the laboratory did not establish a protocol to perform the require performance characteristic verification. c. The laboratory processed and reported 184 CBC's patients results from July 01, 2020 to October 31, 2020.

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 review of validation records and laboratory director interview on December 01 2020 at 1:00 PM, it was determined that the laboratory director failed to comply with the analytic system requirements for routine chemistry, endocrinology and hematology tests from July 1, 2020 to October 31, 2020. The finding includes: 1. The laboratory director did not ensure that the laboratory verified the manufacturer's reference intervals (normal values) before reporting the following patients results

when it validated the following systems: Architect C4000, Architect i1000 and Cell Dyn Ruby. Refer to D5421(1)(2)(3).