

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0723691	(X3) Date Survey Completed 12/06/2018
Name of Provider or Supplier Laboratorio Clinico Del Este	Street Address, City, State Calle Jesus T Pineiro #8 1er Piso, Las Piedras, 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
D5405	<p>PROCEDURE MANUAL CFR(s): 493.1251(c)</p> <p>Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on review of Instant view - H. pylori test manufacturer's instruction, H. pylori testing records review (years 2017 to 2018) and laboratory director interview on December 6, 2018 at 12:15 PM, it was determined that the laboratory failed to follow the manufacturer's instructions when two out of two patients specimens with less than 19 years of age were tested and reported for H. pylori by Instant view method from December 12, 2017 to August 30, 2018. The findings include: 1. The laboratory used the Instant view - H. pylori test method from December 12, 2017 to August 30, 2018. 2. The Instant view- H. pylori manufacturer's instructions showed that this assay has not been established for patients less than 19 years of age. 3. On December 6, 2018 at 12:15 PM, the H. pylori testing records showed that the laboratory tested and reported two out of two patients specimens with less than 19 years of age from December 12, 2017 to August 30, 2018: date patient's ID patient's age 12/12/ 2017 #22822 11 years old 08/30/2018 #26566 17 years old 4. The laboratory director interview confirmed on December 6, 2018 at 12:15 PM, that the laboratory tested and reported two out of two patients specimens with less than 19 years of age with the Instant view - H. pylori test method.</p>
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</p>

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 review of validation records of the Immola Randox system for comprehensive metabolic panel (CMP) tests and laboratory director interview on December 6, 2018 at 9:50 AM, it was determined that the laboratory failed to verify that the manufacturer's CMP reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 763 out of 763 patient CMP results from August 1, 2018 to December 5, 2018. The findings include: 1. On December 6, 2018 at 9:50 AM, the Immola Randox validation records showed that the laboratory performed the validation procedures in June 2018 and it did not verify that the manufacturer's CMP reference intervals (normal values) are appropriate for the laboratory's patient population. 2. The laboratory director confirmed on December 6, 2018 at 9:50 AM, that the laboratory did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting CMP patient results. 3. The laboratory processed and reported 763 out of 763 patient CMP results from August 1, 2018 to December 5, 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 validation records of the Immola Randox system for comprehensive metabolic panel (CMP), Instant view - H. pylori test manufacturer's instruction, H. pylori testing records review (years 2017 to 2018) and laboratory director interview on December 6, 2018 at 12:15 PM, it was found that the laboratory director failed to ensure compliance with the analytic system requirements. The finding includes: 1. The laboratory director failed to ensure compliance with the analytic system requirements for general serology and routine chemistry specialties. Refer to D 5405 (The laboratory failed to follow the manufacturer's instructions when two out of two patients specimens with less than 19 years of age were tested and reported for H. pylori by Instant view method from December 12, 2017 to August 30, 2018). Refer to D 5421 (The laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 763 out of 763 patient CMP results from August 1, 2018 to December 5, 2018).