

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658240	(X3) Date Survey Completed 08/22/2019
Name of Provider or Supplier Laboratorio Clinico Magdalena	Street Address, City, State Ashford Ave 1452 Oficina 309, 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
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 Dimension EX manufacturer's instructions, Cuvette temperature records (years 2018 and 2019) review, laboratory director and testing personnel interview on August 22, 2019 at 9:05 AM, it was determined that the laboratory failed to follow manufacturer's instruction for the Cuvette temperature requirement when 123 patients specimens were processed and reported for comprehensive metabolic panel (CMP) tests from April 22, 2019 to August 22, 2019. The findings include: 1. The Dimension EX manufacturer's requires the Cuvette temperature range from 36.8 C to 37.2 C. 2. On August 22, 2019 at 9:05 AM, the Cuvette temperature records showed that the laboratory processed and reported patients specimens at Cuvette temperatures below the lower temperature limits that the manufacturer required from April 22, 2019 to August 22, 2019: Month days at temperature below the lower limit April 2019 7 out of 20 days May 2019 22 out of 22 days June 2019 19 out of 19 days July 2019 14 out of 14 days August 2019 16 out of 16 days 3. The laboratory director and testing personnel confirmed on August 22, 2019 at 9:05 AM, that the Cuvette temperature records showed temperatures bellow the lower limits those days. 4. The laboratory processed and reported 123 out of 123 patients specimens for CMP tests from April 22, 2019 to August 22, 2019.</p>
D6020	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p>

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on Dimension EX manufacturer's instructions, Cuvette temperature records (years 2018 and 2019) review, laboratory director and testing personnel interview on August 22, 2019 at 9:05 AM, it was determined that the laboratory director failed to ensure compliance with the analytic system requirements for the CMP tests. Refer to D 5405. (The laboratory did not follow manufacturer's instruction for the Cuvette temperature requirement when 123 patients specimens were processed and reported for CMP tests from April 22, 2019 to August 22, 2019).

D6072

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:
Based on Dimension EX manufacturer's instructions, Cuvette temperature records (years 2018 and 2019) review, laboratory director and testing personnel interview on August 22, 2019 at 9:05 AM, it was determined that testing personnel failed to follow quality control procedures for the CMP tests. Refer to D 5405. (The laboratory did not follow manufacturer's instruction for the Cuvette temperature requirement when 123 patients specimens were processed and reported for CMP tests from April 22, 2019 to August 22, 2019).