

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1085492	(X3) Date Survey Completed 10/11/2018
Name of Provider or Supplier Laboratorio Clinico Central Naranjito Psc	Street Address, City, State Centro Comercial El Mercado Plaza 7, Naranjito, 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 EXL 200 manufacturer's instructions, Dimension EXL 200 temperature records (years 2017 and 2018) review and testing personnel interview on October 11, 2018 at 10:10 AM, it was determined that the laboratory did not follow manufacturer's specifications for reagent temperature when the following patients specimens for comprehensive metabolic panel (CMP) tests were processed and reported by the Dimension EXL 200 system: 484 out of 484 patients specimens from July 1, 2017 to September 19, 2017 and 110 out of 110 patients specimens from May 1, 2018 to October 10, 2018. The findings include: 1. Dimension EXL 200 manufacturer establish for the reagent temperature specification a range from 2 C to 8 C. 2. On October 11, 2018 at 10:10 AM, the daily temperature check showed temperatures over 8 C from July 1, 2017 to September 19, 2017 and form May 1, 2018 to October 10, 2018. 3. The testing personnel confirmed on October 11, 2018 at 10:10 AM, that the daily temperature check showed temperatures over 8 C from July 1, 2017 to September 19, 2017 and form May 1, 2018 to October 10, 2018. 4. The laboratory processed and reported 484 out of 484 reported CMP specimens from July 1, 2017 to September 19, 2017 and 110 out of 110 CMP patients specimens from May 1, 2018 to October 10, 2018 by the Dimension EXL 200 system.</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 EXL 200 manufacturer's instructions, Dimension EXL 200 temperature records (years 2017 and 2018) review and testing personnel interview on October 11, 2018 at 10:10 AM, it was determined that the laboratory director failed to ensure that the laboratory follow manufacturer's specifications for reagent temperature when the following patients specimens for comprehensive metabolic panel (CMP) tests were processed and reported by the Dimension EXL 200 system: 484 out of 484 patients specimens from July 1, 2017 to September 19, 2017 and 110 out of 110 patients specimens from May 1, 2018 to October 10, 2018. Refer to D 5405.

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 EXL 200 manufacturer's instructions, Dimension EXL 200 temperature records (years 2017 and 2018) review and testing personnel interview on October 11, 2018 at 10:10 AM, it was determined that the testing personnel did not follow manufacturer's specifications for reagent temperature when the following patients specimens for comprehensive metabolic panel (CMP) tests were processed and reported by the Dimension EXL 200 system: 484 out of 484 patients specimens from July 1, 2017 to September 19, 2017 and 110 out of 110 patients specimens from May 1, 2018 to October 10, 2018. Refer to D 5405.