

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658071	(X3) Date Survey Completed 08/30/2021
Name of Provider or Supplier Laboratorio Clinico Soram	Street Address, City, State 1 Mario Braschi, Coamo, 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 manufacturer's instructions, lack of Freezer temperature monitoring chart and laboratory general supervisor interview on August 30, 2021 at 10:15 AM, it was determined that the laboratory failed to follow manufacturer's instructions when 2,445 out of 2,445 patients specimens were tested for Thyroid Stimulating Hormone (TSH) by the Dimension EXL system from January 2, 2021 to August 24, 2021. The findings include: 1. The laboratory uses the LOCI THYR calibrator to perform the TSH tests by the Dimension EXL system . 2. The manufacturer requires to store the LOCI THYR calibrator at -25 to -15 C. 3. The laboratory did not monitor nor document the temperature of the Freezer where the LOCI THYR calibrator was stored from January 2, 2021 to August 24, 2021. 4. The laboratory general supervisor confirmed on August 30, 2021 at 10:15 AM, that the laboratory did not monitor nor document the temperature of the freezer during this period. 5. The laboratory processed and reported 2,445 out of 2,445 patients specimens TSH by the Dimension EXL system from January 2, 2021 to August 24, 2021.</p>
D6042	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)</p> <p>(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</p>

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 manufacturer's instructions, lack of Freezer temperature monitoring chart and laboratory general supervisor interview on August 30, 2021 at 10:15 AM, it was determined that the technical consultant failed to ensure compliance with the manufacturer's instruction for the TSH tests. Refer to D 5405 (The laboratory did not follow manufacturer's instructions when 2,445 out of 2,445 patients specimens were tested for TSH by the Dimension EXL system from January 2, 2021 to August 24, 2021).

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 manufacturer's instructions, lack of Freezer temperature monitoring chart and laboratory general supervisor interview on August 30, 2021 at 10:15 AM, it was determined that the laboratory director failed to ensure compliance with the requirements for the TSH tests. Refer to D 5405 (The laboratory did not follow manufacturer's instructions when 2,445 out of 2,445 patients specimens were tested for TSH by the Dimension EXL system from January 2, 2021 to August 24, 2021).